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Therapeutic Efficacy of *Majoon Atrilaal* and local application of *Sheetraj, Nila Tootiya* in the management of *Bars* (Vitiligo)

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ABSTRACT

Bars (Vitiligo) is the oldest and commonest skin disorders affecting approximately 0.1% to 2% of the world's population, and its prevalence is varying from 0.46% to 8.8 % in India. The disease shows no regard to the cultural, ethnic or socioeconomic background of the affected population. The cosmetic impact of this disease is huge and psychological impact is devastating, particularly in coloured races. In Unani system of medicine *Majoon Atrilaal* and local application of *Sheetraj* and *Nila Tootiya* have been used for the management of *Bars* since centuries, but the efficacy has yet to be proven on scientific parameters. Observational single blinded study was carried out on 20 clinically diagnosed patients of *Bars*. They were treated with 10 gm of *Majoon Atrilaal*, orally twice daily and *Sheetraj* with *Nila Tootiya* applied locally once in the morning, for a period of three months. The subjective parameter (hypo pigmented patches) and objective parameter (VASI) were statistically analyzed by applying Student 't' test (two tailed dependent) and paired proportion test. VASI (Vitiligo Area Scoring Index) showed significant difference $P<0.005$ and the hypo pigmented patches showed strongly significant difference $P<0.001$ when compared before and after treatment. The study revealed that the test drugs appeared to be effective in the management of *Bars*. No adverse effects or toxicity has been reported during or after the trial. Thus it can be concluded that the test drugs are safe and effective in the management of *Bars*.

Keywords: *Bars;* vitiligo*; Majoon Atrilaal; Sheetraj; Nila Tootiya*; Unani System of Medicine.

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INTRODUCTION

The skin is a complex organ; constitutes approximately one-twelfth of the body mass[1]. It provides an efficient barrier against physical assaults, chemical hazards and pathogens present in the external environment[2-3]. The skin colour of an individual depends on the thickness of the horny layer, circulation and the volume of reduced and oxygenated haemoglobin of the superficial vessels and on the presence of pigments in the skin and subcutaneous tissues. The most significant of which are melanin and the melanoid[4]. *Bars* (Vitiligo) is a common acquired chronic hypomelanotic skin disease characterized by the development of progressive depigmented macules (flat patches or lesions) resulting from the destruction or non-functioning of melanocytes (pigment cells) of the epidermis. Although several theories e.g. autoimmune, genetic, oxidative stress, neural or viral have been proposed to explain the loss of melanocytes in vitiligo, but the etiopathogenesis of the disease is still unclear[5]. The most common form of vitiligo is non-segmental one, which tends to appear as symmetric patches, sometimes over large areas of the body. Vitiligo occurs worldwide with an overall prevalence of 0.1% to 2%[6-8]. Its prevalence is varying from 0.46% to 8.8% in India[9]. Age at onset is variable and the average age of onset is about 20 years. About 50 percent of people with vitiligo have symptoms before the age of 20 years, and about 95 percent before the age of 40 years [10-14]. The aetiology of *Bars* has been discussed in detail in Unani classics. It is caused due to weakness of *Quwat-e Mughaiyirah wa Mushabbiha* (transformative faculty) of the skin and liver[15-24]. *Fasad-ud-Dam* (impairment of blood) and *Burudat-ud-Dam* (coldness of blood) are also aggravating factors for the infliction of *Bars*[16,17,25,26,27,28,29,30,31]. Various treatments are prescribed in the valuable literature of Unani Medicine.[25] In Unani system of medicine, the treatment of *Bars* is based on Psycho-therapy, Dieto-therapy and pharmaco-therapy. In pharmaco-therapy treatment should begin with the removal of *Balgham-e Ghaleez* from the body with *Munzij* and *Mus'hil* therapy. After completion of "*Munzij*" and *Mus'hil* treatment, drugs of hot temperament (*Haar Mizaj*) along with specific medicines such as *Babchi* (*Psoralea corylifolia* Linn), *Chaksu* (*Cassia absus* Linn), *Anjir* (*Ficus carica* Linn), *Panwar* (*Cleome brachycarpa Vahl ex* DC), *Atrilaal* (*Ammi majus* Linn), *Sudab* (*Ruta graveolence* Linn) and *Halela Siyah* (*Terminalia chebula*) for the treatment of *Bars* are advocated[15,25,32,33]. In India and elsewhere also, men, women and children with vitiligo face, severe psychological and social problems. There is a social stigma attached to vitiligo. Affected persons and their family, particularly girls are socially ostracized for marital purpose. Although, this disorder does not result in restriction of capacity to work or expectancy

of life, but it causes cosmetic disfigurement leading to psychological trauma to the patients[34]. Appearance of this disease can affect an individual's self-image, and any pathological variation can have psychological consequences. With the growing importance of the problem, and absence of convincing treatment in modern medicine, a preliminary single blinded trial was set to evaluate the efficacy of Unani formulation: *Majoon Atrilaal* and local application of *Sheetraj, Nila Tootiya* was intended to evolve an effective treatment of *Bars*, certainly without any side effects.

MATERIAL AND METHOD

An observational single blinded study, conducted at hospital of National Institute of Unani Medicine, Bangalore, from June 2013 - January 2014.Clinically diagnosed patient of *Bars* of either gender, between age group of 12-60 years were included in the study. Pregnant, lactating women and patients suffering from diabetes mellitus, thyroid dysfunction and other severe systemic diseases were excluded from the study. The investigations such as Hb%, TLC, DLC, ESR, RFT, LFT, FBS/PPBS were carried out in every patient before and after treatment in order to exclude the patients with pathological conditions mentioned under the exclusion criteria as well as to assess the safety parameters of the drugs. Before embarking upon the study, a comprehensive protocol was chalked out and put forth for ethical clearance. The study was approved by Institutional Ethical Committee of NIUM on 18th April 2012. After getting ethical clearance, the clinical study was started by enrolling eligible patients into the trial after taking written informed consent.

Trial formulation

Majoon Atrilaal

The ingredients of *Majoon Atrilaal* are *Atrilaal, Aaqarqarha, Turbud safaid, Sonth* and *Shehad*[35-38]. The ingredients local application are *Sheetraj* and *Nila Tootiya*[39-41]

Method of preparation of trial formulation

Majoon Atrilaal

The chief ingredient of *Majoon Atrilaal* i.e. *Atrilaal* was procured from the Agricultural University GKVK, Horticulture division Herbal, Bangalore, and the other ingredients of *Majoon Atrilaal* were procured from the local market of Bangalore. Proper identification of the drug was done by chief pharmacist, National Institute of Unani Medicine, to ensure their originality and authenticity. The drugs were cleaned by weeding out unwanted materials and impurities then powdered to make *Majoon*. For the preparation of *Majoon, qiwam* (base) of three *Tar* is

generally made. *Qiwam* was made by using honey as the base. After that, all the ingredients were mixed in *qiwam* to prepare *Majoon* of desired *qiwam.*

Local application

Sheetraj and *Nila Tootiya* were also procured from the local market of Bangalore and were powdered separately and then mixed in 4:1 ratio. After that, the patient was advised to mix the needed quantity of powdered drug with water and apply over the lesions.

Administration of trial formulation

***Majoon Atrilaal*:**

10 gm orally twice daily and local application of *Sheetraj* with *Nila Tootiya*,[38] over the lesions daily in the morning and exposure to sunlight for 5-15 minutes after application for three month.[39,41]

Subjective Parameter

Hypo pigmented/white macular patch

For the assessment of subjective parameter i.e. hypo pigmented/white macular patches, an arbitrary scale was framed and graded as 0, 1, 2 and 3 in which:

- Grade 0:suggests normal pigmentation (no de pigmentation)
- Grade 1: suggests mild hypopigmentation
- Grade 2: suggests moderate hypopigmentation
- Grade 3: suggests severe hypopigmentation

Follow up: fortnightly

Objective Parameter: Vitiligo area scoring index (VASI) [42]

VASI Assessment Factors

Composite Estimation of body surface area

The VASI is an assessment scale originally developed by Hamzavi I.*et al*,[42] for the calculation of affected area and improvement of therapy. It has a great reliability and validity

In vitiligo management the extent of the person's body surface area that is affected by vitiligo can also be estimated in the same way as for burns The 'Rule of Nines'

Arm — 9%, Head — 9%, Neck — 1%,Leg — 18% ,Anterior trunk — 18% ,Posterior trunk — 18%(The Lund and Browder chart).

Formula by considering the contributions of all body regions:

The total body VASI is then calculated using the following formula by considering the contributions of all body regions

VASI = ∑ (All body parts) [Hand Units] X [Residual De-pigmentation]

Estimation of degree of pigmentation

The second parameter is Standardized assessment for estimating the degree of pigmentation to derive the Vitiligo Area Scoring Index. At 100% de- pigmentation, no pigment is present; at 90%, specks of pigment are present; at 75%, the de-pigmented area exceeds the pigmented area; at 50%, the de- pigmented and pigmented areas are equal; at 25%, the pigmented area exceeds the de-pigmented area; and at 10%, only specks of de-pigmentation are present.

Statistical Analysis

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Student *'t'* test (two tailed, dependent) and Paired proportion test used to find the significance between before and after treatment.

RESULTS AND DISCUSSION

In this study, a total of 30 patients having *Bars* (Vitiligo) were assessed by clinical examination. During assessment, out of 30 patients, 23 patients of *Bars* (Vitiligo) fulfilled the inclusion criteria and remaining 7 patients were excluded from the study. Thereafter 23 patients were enrolled into the study, 4 patients were dropped out due to unknown cause and remaining 19 patients completed the study. It was observed that out of 19 (100%) patients, the highest number of patients i.e. 6 (31.6%) were from the age group of 41-50 years and the male female ratio was 13:6. 12 out of 19 belongs to *Balghami Mizaj*. Out of 19 (100%) patients, 12 (63.2%) patients were having symmetrical patches and out of 19 (100%) patients, 15 (78.9%) patients have shown redness on rubbing. The analysis of subjective parameter (severity of hypo pigmented patches)revealed that, before treatment 19 (100%) were having severe hypopigmentation and after treatment 8 patients (42%) were presented with severe, 4 (21.1%) patients were presented with moderate, 6 (31.6%) patients were presented with mild hypopigmentation and in 1 (5.3%) patient there was complete disappearance of hypo pigmented patches (Table.1).

Table 1: Hypo pigmented patches

Hypo pigmented patches	BT	AT	% change
Non of Pigmentation	0	1(5.3%)	+5.3
Mild Hypopigmentation	0	6(31.6%)	+31.6
Moderate Hypopigmentation	0	4(21.1%)	+21.1%
Severe Hypopigmentation	19(100.0%)	8(42.1%)	57.9%
Total	19(100.0%)	19(100.0%)	-

Hypopigmentation is significantly reduced after treatment with **P<0.001****

Overall the hypopigmentation is significantly reduced after treatment with P<0.001**. The analysis of objective parameter (VASI Score) revealed that the mean ± SD of VASI Score before treatment was 4.37 ±8.24 and after treatment it was 2.79 ±5.48 with a P value of <0.005, indicating suggestive significant difference (Table.2).

Table 2: An Evaluation of VASI score-B before and after treatment

VASI score	BT	AT	difference	t value	P value
Min-Max	0.09-36.00	0.00-22.50	-	-	-
Mean ± SD	4.37±8.24	2.79±5.48	1.574	2.231	0.039*

On the paired proportion analysis of VASI; 26.4% improvement was observed (Table.3).

Table 3: VASI score-A

VASI score	BT	AT	% change
<1	7(36.8%)	12(63.2%)	+26.4
1-5	9(47.4%)	5(26.3%)	-21.1
5-10	1(5.3%)	0	-5.3%
10-15	1(5.3%)	1(5.3%)	0.0
15-20	0	0	0.0
>20	1(5.3%)	1(5.3%)	0.0
Total	19(100.0%)	19(100.0%)	-

Despite advancement in technology and drug development, the figures in terms of *Bars* (Vitiligo) suggested the limitation of mainstream medicine in the management of vitiligo. In the study out of 19 (100%) patients, the highest number of patients i.e. 6 (31.6%) were from the age group of 41-50 years, 5 (26.3) patients were in the age group of less than 20 years, 3 (15.8%) patients were in the age group of 21-30 years, 3 (15.8%) patients were also in the age group of more than 50 years and 2 (10.5%) patients were in the age group of 31-40 years of age. Though the age prevalence of disease in this study is not according to prior ones but up to some extent it is in accordance with the findings described by Dutta AK[43]who suggested that 34.5% of patients develop Vitiligo between 11-20 years of age. Out of 19 (100%) patients, 13 (68.4%) were males and 6(31%) were females. As the data suggests that males are more affected than females, but there is no predilection for any gender in vitiligo as reported by Reghu Remya and Emmanuael James.[44]The maximum prevalence of *Bars* (vitiligo) according to *mizaj* was, 12 (63.2%) patients out of 19 (100%) were having *Balghami Mizaj* and 7 (36.8%) patients were having *Damvi Mizaj*. These findings were in accordance with the description of Buqrat, Ibn-e Sarafiyoon and other Unani physicians, that the disease is associated the with *Balgham-e Ghaleez*[28,29,33,45,46]. Out of 19 (100%) patients, 15 (78.9%) patients were consuming mixed diet and 4 (21.1%) patients were vegetarian. According to Vitiligo Support International there is no vitiligo diet. A healthy diet

with balanced nutrition from a variety of sources is good way to support the immune system.[41] However Ibn-e Sarafiyoon and other Unani physicians have mentioned that cold and moist foods, fish, milk, moist vegetables, and fruits can cause *Bars* (Vitiligo) and they suggested eating such food which produces hot and dry temperament [15,26,29,47]. Regarding family history, out of 19 (100%) patients, 2 (10.5%) patients were having positive family history of *Bars* indicating that there is a curvilinear relation between heredity and *Bars* (vitiligo*)* and is in accordance with the statement reported by Birgani GA and Masoodi R.[48] Ibn-e Sina had also mentioned that the *Bars* can be transmitted from parents to their offsprings[15]. Regarding the site involved, hands in 7 (26.4%) patients, face in 5 (26.4%) patients were the most common sites involved which is in conformity with the study of Babaie Nejad *et al.* and Talsania *et al* [49,50]. Regarding symmetry, out of 19 (100%) patients, 12 (63.2%) patients were having symmetrical patches and 7 (36.8%) patients were having asymmetrical patches. Both Allopathic and Unani physicians have described that most of the patients presents with symmetrical patches[27, 45]. This observation is in accordance with the description of Freedberg and Braun Falco[51, 52]. Regarding the number of patches, out of 19 (100%) patients, 15 (78.9%) patients were having multiple patches and 4 (21.1%) patients were having single patch, which is in conformity with the statement of Behl P.N and Murphy GF.[53,54] Regarding redness on rubbing, 15 (78.9%) patients have shown redness on rubbing, while 4 (21.1%) patients have not shown redness on rubbing, which is considered as a prognostic factor in *Bars* (vitiligo) reported by Hakeem Akbar Arzani.[27]

Effect of Test Drugs on Subjective/ Objective Parameters

The observed effect on subjective parameter was highly significant (P <0.001).Before treatment, VASI score (objective parameter) was 4.37 ± 8.24 (Mean ±SD) and after treatment it was reduced to 2.79± 5.48, which suggests highly significant difference (P <0.005). The improvement in subjective and objective parameters might be due to *Jali*, *Muhallil*, *Mukhrij-e Balgham* properties possessed by *Atrilaal*,[34,55] *Jali* and *Muqarreh* properties possessed by *Sheetraj* and *Mujaffif-e Qurooh* possessed by *Nila Tootiya*.[56,57]

CONCLUSION

The observations and findings are evident that the disease is due to *balgham-e ghair tabai 0*and *munzij-e balgham* drugs are effective. In the light of above findings and discussion it can be concluded that the test drugs are safe and effective in reducing the severity of *Bars* without producing any adverse effects. Therefore the test drugs can be used safely and effectively in the management of *Bars*. No adverse effects were observed during the trial and the patient

compliance to the treatment was good. The results of the study also suggest that the test formulation consistently have the effects in the improvement of *Bars*. Hence the present study supports the mode of action of drugs, the properties of drugs and its claim to be used in *Bars* (vitiligo). The limitations inherent in this study include small sample size, short duration of study. Hence it is recommended that further studies are needed with modified methodology to overcome these limitations for wider reliability and acceptability.

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