Efficacy of leeching (Ta‘līq al-‘Alaq) in patients with vitiligo (baras): a comprehensive case study

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ABSTRACT

Vitiligo is a hypomelanotic skin disorder in white patches appear on the skin surface and also involve the hair. The disease is idiopathic, acquired and affects 1-4 percent of the world population. It is belived that there is immunologic influence in the pathogenesis of vitiligo and there is evidence of early cell death in vitiligo melanocytes related to their increased sensitivity to oxidative stress. In Ayurveda the vitiation of three doshas results deraignement of rasa, rakta, mamsa and medadhuta which results in vitiligo patches on skin. In Unani System of Medicine (USM) the deraignment of body humours result in the Fasad-e-Ikhlat which results in the Baras (vitiligo). Since both in Ayurveda and USM leech has been used for various dermatologicalailments including vitiligo. In this study leeching (hirudotherapy) were done in vitiligo patients of both sexes with single and multiple patches and successful results were observed.

Keywords: Vitiligo, Unanai medicine, Melanocytes, Hirudotherapy, Leeching

INTRODUCTION

Vitiligo is not only medical problem but has a huge influence on patient’s psychology. This acquired and hypomelanotic skin disorder affects 1-4 percent of the world population.1,2 In India the incidence of vitiligo is found to be 0.25 to 2.5 percent. Gujarat and Rajasthan have the highest prevalence of 8.8 percent.4 It affect the both the sexes equally and is found in all the races. Various modalities of treatment like phototherapy with psoralens, steroids, heliotherapy, lser, vitamin-D analogues, skin grafts and other nature therapies are being advocated in vitiligo which has their own side effects and limitations. So, this study was undertaken for the treatment of vitiligo to find out the efficacy of leech therapy as already mentioned in the traditional classical books. Vitiligo affect about 0.5 percent to 2 percent of the world population.5 With familial incidence of 25 to 30 percent.6 In India its prevalence is about 0.25 percent to 2.5 percent and in few states like Gujarat and Rajasthan it is more prevalent i.e. 8 percent. The disease is psychologically devastating leading to depression is most of the patients because it is mostly seen in the prime phase of life i.e. in second or third decade. The etiology of vitiligo is still not fully known and various causes are put forward like neural abnormalities, melatonin receptor dysfunction, stress, depression impaired melanocyte migration, genetic susceptibility, biochemical defects, autoimmunity, oxidative stress, auto cytotoxicity.7 Since Unani classics are well illustrated for the treatment of vitiligo and the principles of treatment is based on psychotherapy, dietotherapy, drug therapy and regimenal therapy. In dietotherapy, the diet having hot properties is usually used. Cold and moist foods, fish, milk and all dairy products are advised to be avoided. In pharmacotherapy the treatment is specially based on Tanqiya-e-Badan and this tanqiya is performed in proper way by first administrating the Mundij-e-Balgam till the appearance of nuzj and this is then followed by three mushil (purges) alternated three tabrid (cooling).8 Hippocrates and Ibn-I-Sarabiyun suggested that after
tabreed in achieved the digestive system should be corrected by taking easily digestible diet.9 In treating vitiligo with regimental therapy Razi (850-925 AD) in his book Kitabul Hawi has mentioned vitiligo can be cured by different regimens like rubbing the affected part till it’s become erythematous or till blood perfusion is achieved on and around the vitiligo patch. He also mentioned that the patch may be given nick or prick and after that if some whitish fluid ooze out it means that the lesion can be well treated or recovered. Razi also mentioned that the vitiligious patches on the head and feet do not respond to treatment adequately. The concept of applying the topical application in the shape of ointment or oils and then exposing the lesion (vitiligo patch) to sunlight was given by Razi and was believed to activate and enhance the process of repigmentation. Razi also illustrated that vitiligo patches can be well treated by pricking over the patch and making it activate to regain its physiology.10 The other great Unani scholar Jalilus mentioned in Muqallajat-i Buqraṭiyāh, IbnSīnā Al-Qānānī’s “1-Tib, Jurjānīn his book DhakhiraKhwārizmShāhi, Hakīm Akbar Arzanīn his book Tībb-i Akbar, and Sādīd al-DīnGāzrūnīn the book Al-Sādīdī, described the cause of vitiligo as Duaf-iQwwat-i Mughayyira-i Badan (transformative faculty, the power that brings changes, and shapes the nutrients into tissues) and Mushabbihā-i Badan (power of resemblance).8,12 This Duaf (weakness) may be due to accumulation of Balgham-i Ghulż (viscous phlegm), Fasād al-Dam, or Barīdāt al-Dam, in the body.12,14 In Unani system of medicine (USM) it is believed that vitiligo is caused by the derangement in the body humours and in this study hirudotherapy is used for treating vitiligo with the belief that the deranged humours are taken out of the body and a wide number of bioactive enzymes are injected in human body which have a characteristic of reactivating the depigmented lesion and thus helps imparting the natural color.

Different modalities of treatment are in practice for the different forms of vitiligo.15 In allopathic system of medicine most of the preparation given topically are steroids i.e. glucocorticoids, clobetasol, betamethasone, tacrolimus, pimecrolimus either alone or in combination with ultraviolet light therapies.16 Since phototherapy has lot of adverse effectso it has been advised that phototherapy be used if primary treatments are in effective.17 In USM the treatment is much satisfactory by using formulation of certain drugs like Babchi (Psoralacorylifolia), Atrīlal (Ammimajuś) etc. USM founded by Hippocrate, is based on the concept of equilibrium of natural body humours. Hirudotherapy is one of the commonest and widely used treatment for evacuation of morbid humours and for this reason it has gained wide popularly for different diseases including vitiligo. Hirudotherapy was done in the patients of vitiligo as modality of regimental therapy. Owing to the hemual balance property and modern concept of bioactive molecules in the leech. Hirudotherapy has been done here for vitiligo with satisfactory results.

**CASE SERIES**

The present study is single group open case clinical study. Twenty patients were selected from general outpatient department (OPD) and screened before undergoing the scientific study. Our aim is to evaluate the safety and efficacy of a leeching (Irsal-e-Alaq) in the management of vitiligo. In addition to this our objective is to provide the safe, patient friendly and toxicity free alternative therapy for the patients of vitiligo. The present study has been carried out at Regional Research Institute of Unani Medicine for a period of one year. The duration of protocol therapy was 60 days.

**Table 1: Follow ups.**

| Visits        | Days |
|---------------|------|
| Base line     | 0th  |
| First visit   | 12th |
| Second visit  | 24th |
| Third visit   | 36th |
| Fourth visit  | 48th |
| Fifth visit/last visit | 60th |

Patients filling following features were randomly selected for the proposed case study: clinically diagnosed vitiligo; patients of both sexes including transgender; patients from 10 to 50 years of age; willingness to sign the informed consent, follow the protocol and participate in clinical trial voluntarily.

**Table 2: Distribution of patients.**

| Mizaj (temperament) | Number of patients | Percentage of patients |
|---------------------|--------------------|------------------------|
| Sanguineous (Damwi) | 2                  | 10                     |
| Bilious (Safrawi)   | 6                  | 30                     |
| Phlegmatic (Balghami)| 11                | 55                     |
| Black Bile (Saudawi)| 1                  | 5                      |

Patients reflecting following characteristics were excluded in the present study: patients below 10 years of age and above 50 years; pregnant and lactating ladies; diabetes mellitus, hypertension; renal dysfunction, liver diseases and gastrointestinal diseases (peptic ulcer disease); denial to sign informed consent; bleeding disorder; malignancy and autoimmune diseases; and white patches due to secondary cause.

We made investigation of several parameters (before and after treatment): complete blood count and erythrocytic sedimentation rate; bleeding time and clotting time; c reactive protein; liver function test – serum glutamic-oxalacetic transaminase (SGOT), serum glutamic-pyruvic transaminase (SGPT) and serum bilirubin; kidney function test (blood urea and serum creatinine); blood sugar random or fasting.
Table 3: Distribution of patients according to age group.

| Age group (in year) | Number of patients | Percentage of patients |
|---------------------|--------------------|------------------------|
| 10-20               | 1                  | 5                      |
| 21-30               | 9                  | 45                     |
| 31-40               | 6                  | 30                     |
| 41-50               | 4                  | 20                     |

Table 4: Distribution of patients according to gender.

| Gender     | Number of patients | Percentage of patients |
|------------|--------------------|------------------------|
| Male       | 12                 | 60                     |
| Female     | 8                  | 40                     |
| Transgender| 0                  | 0                      |

The treatment efficacy were measured with help of improvement in clinical parameters and vitiligo area scoring index (VASI) score. The part where the leech is to be applied was cleaned with non-chlorinated water and then leeches were applied on the vitiligous patches. The number of leeches to be applied was decided as per the area involved by vitiligo which ranges from minimum of two leeches and maximum of ten leeches. In case the leeches do not suck the blood, a small prick was given to ooze out some blood to facilitate the blood sucking to leech. The leeches were allowed to suck the blood till they are belly filled and fell down spontaneously. In case leech does not detach of its own, betadin swabs is touched to the leech. The part is left open for about one hour and allowed to bleed if it. Then a sterile dressing is applied and advised to keep for twelve hours. In Kashmir the leeches are procured from authorized local traditional leech vendors.

Table 5: Distribution of patients according to gender.

| Gender       | Number of patients | Percentage of patients |
|--------------|--------------------|------------------------|
| Male         | 12                 | 60                     |
| Female       | 8                  | 40                     |
| Transgender  | 0                  | 0                      |

Vitiligo is usually found associated with autoimmune and some inflammatory diseases like rheumatoid arthritis, diabetes mellitus, psoriasis, Hashimoto’s, thyroiditis, scleroderma, Addison’s disease, systemic lupus erythematosus (SLE), pernicious anemia and alopecia areata. Interleukin-18 and interleukin-18 are expressed at high levels in patients with vitiligo. Addisos’s disease has also been seen in patients with vitiligo.

**Statistical analysis**

In this section different parameters are analysed.

Table 5: Family history of vitiligo.

| Family history of vitiligo | Number of patients | Percentage of patients |
|----------------------------|--------------------|------------------------|
| Positive                   | 4                  | 80                     |
| Negative                   | 16                 | 20                     |

Table 6: According to BMI.

| BMI            | Number of patients | Percentage of patients |
|----------------|--------------------|------------------------|
| Normal weight  | 13                 | 65                     |
| Over weight    | 2                  | 10                     |
| Obese          | 5                  | 25                     |

Table 7: According to marital status.

| Marital status | Number of patients | Percentage of patients |
|----------------|--------------------|------------------------|
| Married        | 12                 | 60                     |
| Unmarried      | 8                  | 40                     |

Table 8: Analyzing VASI score among subjects.

| Base line (0th day) | 1st (12th day) | 2nd (24th day) | 3rd (36th day) | 4th (48th day) | 5th (60th day/last) | Status |
|---------------------|---------------|---------------|---------------|---------------|-------------------|--------|
| 2                   | 2             | 1.75          | 1.25          | 0.5           | 0                 | Cured  |
| 1                   | 1             | 1             | 0.75          | 0.4           | 0.02              |        |
| 2                   | 2             | 1             | 0.5           | 0             | 0.1               |        |
| 3                   | 3             | 2             | 1             | 0.5           | 0                 | Cured  |
| 3                   | 2             | 2             | 1             | 0.25          | 0                 | Cured  |
| 2                   | 1             | 0.75          | 0.5           | 0.2           | 0                 | Cured  |
| 2                   | 2             | 1             | 0.5           | 0.5           | 0.25              |        |
| 1                   | 1             | 0.75          | 0.4           | 0.15          | 0                 | Cured  |
| 2                   | 1             | 0.5           | 0.4           | 0.3           | 0.02              |        |
| 2                   | 1             | 0.4           | 0.3           | 0.1           | 0                 | Cured  |
| 1                   | 1             | 0.5           | 0.3           | 0.1           | 0                 | Cured  |
| 2                   | 1             | 1             | 0.5           | 0.5           | 0.5               |        |
| 3                   | 3             | 2             | 2             | 3             | 3                 | Not relived |
| 2                   | 1             | 0.75          | 0.6           | 0.3           | 0                 | Cured  |
| 2                   | 1.25          | 0.85          | 0.35          | 0.05          | 0                 | Cured  |
| 1                   | 0.6           | 0.3           | 0.05          | 0.05          | 0                 | Cured  |
| 2                   | 1             | 0.6           | 0.3           | 0.2           | 0                 | Cured  |
| 1                   | 0.6           | 0.45          | 0.2           | 0.05          | 0                 | Cured  |
| 1                   | 0.6           | 0.45          | 0.2           | 0.05          | 0                 | Cured  |

Continued.
| Base line (0th day) | 1st (12th day) | 2nd (24th day) | 3rd (36th day) | 4th (48th day) | 5th (60th day/last) | Status       |
|---------------------|----------------|----------------|----------------|----------------|---------------------|-------------|
| 4                   | 3              | 3              | 2              | 2              | 2                   | Partially relived |
| 2                   | 2              | 1              | 1              | 2              | 2                   | Not relived   |

### Table 9: VASI score descriptive analysis.

| Parameter                        | Values                      | Number of values | Minimum | 25% percentile | Median | 75% percentile | Maximum | Mean | Standard deviation | Standard error | Lower 95% CI of mean | Upper 95% CI of mean |
|----------------------------------|-----------------------------|------------------|---------|----------------|--------|----------------|---------|------|--------------------|-------------------|---------------------|----------------------|
| Number of values                 | 20                          | 20               | 0.6     | 0.525          | 0.5    | 1.563          | 2       | 1.078 | 0.7947             | 0.1777            | -0.6281 to 0.0087   | 0.6281 to 0.2087   |
| Minimum                          | 1                           | 1                | 0.3     | 0.3125         | 0.3    | 0.925          | 2       | 0.725 | 0.7921             | 0.1771            | -0.7168 to 0.01026 | 0.7168 to 0.18026 |
| 25% percentile                   | 1.25                        | 1                | 0.525   | 0.8125         | 0.5    | 1.563          | 2       | 1.078 | 0.7947             | 0.1777            | -0.6281 to 0.0087   | 0.6281 to 0.2087   |
| Median                           | 2                           | 1                | 0.925   | 0.925          | 0.5    | 1.563          | 2       | 1.078 | 0.7947             | 0.1771            | -0.6281 to 0.0087   | 0.6281 to 0.2087   |
| 75% percentile                   | 2                           | 2                | 1.563   | 1.563          | 1.5    | 3.125          | 4       | 2.125 | 1.125              | 0.2125            | -0.01026 to 0.00026 | 0.01026 to 0.02026 |
| Maximum                          | 4                           | 3                | 3       | 3              | 2      | 3              | 3       | 3     | 3                  | 3                 | -0.01026 to 0.00026 | 0.01026 to 0.02026 |
| Mean                             | 2                           | 1.523            | 1.078   | 0.725          | 0.5    | 0.2125         | 3       | 0.3945 | 0.8648             | 0.1934            | -0.2106 to 0.001026 | 0.2106 to 0.02026 |
| Standard deviation               | 0.7947                      | 0.7921           | 0.7068  | 0.544          | 0.7946 | 0.8648         | 20      | 2.125 | 0.5825             | 0.3945            | -0.2106 to 0.001026 | 0.2106 to 0.02026 |
| Standard error                   | 0.1777                      | 0.1771           | 0.1581  | 0.1216         | 0.1777 | 0.1934         | 20      | 2.125 | 0.5825             | 0.3945            | -0.2106 to 0.001026 | 0.2106 to 0.02026 |
| Lower 95% CI of mean             | 1.628                       | 1.152            | 0.7467  | 0.4654         | 0.2106 | -0.01026       | 20      | 2.125 | 0.5825             | 0.3945            | -0.2106 to 0.001026 | 0.2106 to 0.02026 |
| Upper 95% CI of mean             | 2.372                       | 1.893            | 1.408   | 0.9746         | 0.9544 | 0.7993         | 20      | 2.125 | 0.5825             | 0.3945            | -0.2106 to 0.001026 | 0.2106 to 0.02026 |
| Sum                              | 40                          | 30.45            | 21.55   | 14.4           | 11.65  | 7.89           | 20      | 2.125 | 0.5825             | 0.3945            | -0.2106 to 0.001026 | 0.2106 to 0.02026 |

### Table 10: ANOVA.

| ANOVA                  | SS   | df | MS  |
|------------------------|------|----|-----|
| Treatment (between columns) | 37.67 | 5  | 7.535 |
| Individual (between rows)    | 50.46 | 19 | 2.656 |
| Residual (random)         | 14.78 | 95 | 0.1556 |
| Total                   | 102.9 | 119|     |

**Repeated measures ANOVA**

- P value: <0.0001
- P value summary: ***
- Are means significantly different? (p<0.05): Yes
- Number of groups: 6
- F: 48.43
- R squared: 0.7182

**Was the pairing significantly effective?**

- R squared: 0.4903
- F: 17.07
- P value: <0.0001
- P value summary: ***
- Is there significant matching? (p<0.05): Yes

### Table 11: Post hoc analysis.

| Tukey’s multiple comparison test | Mean difference | Significant? p<0.05? | Summary | 95% CI of diff |
|----------------------------------|-----------------|----------------------|---------|----------------|
| Base line (0th day) versus 1st (12th day) | 0.4775 | Yes                     | **      | 0.1138 to 0.8412  |
| Base line (0th day) versus 2nd (24th day) | 0.9225 | Yes                     | ***     | 0.5588 to 1.286   |
| Base line (0th day) versus 3rd (36th day) | 1.28  | Yes                     | ***     | 0.9163 to 1.644   |
| Base line (0th day) versus 4th (48th day) | 1.418 | Yes                     | ***     | 1.054 to 1.781    |
| Base line (0th day) versus 5th (60th day/last) | 1.606 | Yes                     | ***     | 1.242 to 1.969    |
| 1st (12th day) versus 2nd (24th day) | 0.445  | Yes                     | **      | 0.08126 to 0.8087  |
| 1st (12th day) versus 3rd (36th day) | 0.8025 | Yes                     | ***     | 0.4388 to 1.164    |
| 1st (12th day) versus 4th (48th day) | 0.94   | Yes                     | ***     | 0.5763 to 1.304    |
| 1st (12th day) versus 5th (60th day/last) | 1.128 | Yes                     | ***     | 0.7643 to 1.492    |
| 2nd (24th day) versus 3rd (36th day) | 0.3575 | Ns                       |        | -0.006238 to 0.7212 |
| 2nd (24th day) versus 4th (48th day) | 0.495  | Yes                     | **      | 0.1313 to 0.8587   |
| 2nd (24th day) versus 5th (60th day/last) | 0.683  | Yes                     | ***     | 0.3193 to 1.047    |
From the above analysis, it is quite evident and clear that there is strong statistical significant difference in terms of VASI score which in turn means that the treatment is very effective.

DISCUSSION

Leukoderma meaning white skin is caused by destruction of melanocytes. This idioopathic acquired disorder is characterized by circumscribed depigmented macules due to loss of functional melanocytes from the epidermis. Since vitiligo can develop at any age but certain studies reveal that in 50 percent of patients it appears before the age of twenty and about one third of causes report with family history. It has been observed that parts of the body which are exposed to sunlight show more predispositions to vitiligo. Vitiligo has two types: segmental; and non-segmental. In non-segmental cases, both side of the body are affected and the affected area of the skin typically expands with time. While as only ten percent of cases are segmental and they mostly involve one side of the body. Vitiligo with pale patchy areas of depigmented skin which usually occurs on extremities. These patches are initially small however with time they grow and change their shape. In certain cases itching has been noticed before a new patch occurs. The appearance of vitiligo lesions are initially noted around the body orifices like mouth, nostrils, perianal area, umbilicus, eyes, genital area.

CONCLUSION

From this study it has been concluded that hirudotherapy has a marked influence in correction of the deranged humours by way of natural Istifrag. Since leech saliva is very rich in vast number of bioactive substances like hyaluronidase, orgalse, calin, hirustasin, bdellins, endorphins, trypase inhibitor, hirudin, fibrinases, caligenases, deastabilase, etc. It has been observed that these substances also have marked effect on the repigmentation of the vitiligo patch.

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