



Clinical Research

Clinical efficacy of *Apamarga Kshara Yoga* in the management of *Shvitra* (vitiligo)

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Abstract

Introduction: Vitiligo is a progressive, idiopathic, pigmentation disorder of the skin, characterized by hypopigmented patches. This condition is compared with *Shvitra* in Ayurveda. Many Ayurvedic drugs are beneficial in such cases and *Apamarga Kshara Yoga* is one among them. **Aim:** To evaluate the efficacy of *Apamarga Kshara Yoga* in *Lepa* and ointment forms in the management of *Shvitra*. **Materials and Methods:** Total 50 patients of *Shvitra* were randomly grouped into two. Patients registered in Group A ($n = 25$) were treated with *Apamarga Kshara Yoga Lepa* and Group B ($n = 25$) with *Apamarga Kshara Yoga* ointment for 2 months. *Rasayana Churna* (3g) along with Honey and Ghee was given twice daily internally in the both groups. **Results:** Significant improvement was found in the symptoms of *Shvitra* with treatment in both the groups. The difference in between the groups was statistically insignificant. **Conclusion:** Both forms of *Apamarga Kshara Yoga* are effective in cases of *Shvitra* and can be good alternatives for contemporary medicines.

Key words: *Apamarga Kshara*, *Lepa*, Leucoderma, *Manahshila*, *Shvitra*, Vitiligo

Introduction

There is a continuous search for better remedies to combat vitiligo (leucoderma) that is characterized by hypopigmented patches over the body. Though, it is not associated with any major systemic illness, such lesions will lead to social stigma, may affect the psychological status of the individual and has a major impact on self-esteem and perception of the self. Vitiligo is one of the oldest and commonest skin disorders affecting approximately 1–2% of the human population.^[1] Based on the dermatological outpatient's records, the incidence of vitiligo is found to be 0.25 to 2.5% in India.^[2]

All skin disorders in Ayurveda are placed under the name of *Kushtha*. In Ayurveda, *Shvitra* is considered as one of the varieties of *Kushtha*,^[3] that can be correlated with vitiligo based on the similarities of signs and symptoms. It is caused due to vitiation of *Tridosha* and *Dhatus* like *Rasa* (lymph), *Rakta* (blood), *Mamsa* (muscles) and *Meda* (fats).^[4] According to *Harita Samhita*, vitiated *Vata* along with *Pitta* affects the

Rakta Dhatu manifests *Pandura Varna* (whitish patches) on skin that is called as *Shvitra*.^[5] Depending upon chronicity and involvement of deeper tissue (*Dhatus*), disease becomes difficult to treat.

A number of topical formulations are mentioned for management of *Shvitra*. Modern science uses Psoralen + Ultra Violet-A exposure therapy and corticosteroids in the treatment of vitiligo. But they are associated with side effects like burning, itching, nausea, tanning, eye damage, skin aging and skin cancer.^[6] Hence, there is a need to develop an effective formulation with less adverse effects. Ayurveda has ample of formulations that can be used safely in *Shvitra*. *Apamarga Kshara Yoga*^[7] is one of such formulations. In the current study, it is planned to evaluate clinical efficacy of *Apamarga Kshara Yoga* in two different dosage forms i.e. *Lepa* and ointment.

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Materials and Methods

The study is a randomized single blind one involving 50 patients with vitiligo fulfilling the inclusion criteria. Each patient was examined in detail. Relevant pathological and biochemical investigations were done before and after treatment and informed consent was taken from all the patients before including into the trial [Chart 1]. The study was started after obtaining permission from Institutional Ethics Committee (PGT/7-A/2012-2013/1964/23 dated 21/09/2012) and was registered in Clinical Trial Registry of India (CTRI/2012/11/003157 dated 30/11/2012).

Inclusion criteria

- Patients having signs and symptoms of *Shvitra* (vitiligo)
- Patients having age between 16 and 60 years
- Patients with chronicity of <10 years
- Lesions with positive wood's lamp test.

Exclusion criteria

- Chronicity more than 10 years
- Patients suffering with chronic cardiac, renal, hepatic ailments, insulin-dependent diabetes mellitus (IDDM), non-IDDM and other serious systemic illness
- Patches due to burning, chemical explosion,
- Gravid and lactating women
- Lesions at *Guhyanga* (genital organ), *Panipadatala* (palms and soles), *Oshtha* (lips), *Ekanga* (involving an entire organ), *Sarvanga* (generalized lesions)^[8]

- Patches with *Raktaroma* (reddish hair) and *Samsakta* (coalescent).^[9]

Grouping and posology

Registered patients were grouped into two by using computer generated randomization plan.^[10] Patients of Group A were treated with *Apamarga Kshara Yoga Lepa*,^[7] while patients of Group B were treated with *Apamarga Kshara Yoga Ointment*^[11] [Table 1]. Patients in both the groups were advised to apply quantity sufficient drug locally on patches in the morning followed by 5–10 min. exposure to sunlight in the morning (before 9 AM) for 8 weeks. Besides, 3 g of *Rasayana Churna*^[12] along with *Madhu* and *Ghrita* was given twice a day as internal medication in both the groups. Patients were advised dietary restrictions during the treatment period.

Criteria for assessment

Scoring pattern was adopted for scrutinizing the symptomatology. The score was given on the basis of Size, Color and Number of patches, Percentage of body area involvement and chronicity of patches [Table 2]. For the assessment of involvement of body surface area, rule of nine was used to calculate the percentage of lesions with certain modifications. Whole body was scored but looking into the nature of the disease; score was further specified to the organs. Total score was obtained from calculation of Table 2. Maximum score was 25. Then obtained score was divided into mild, moderate and severe category.

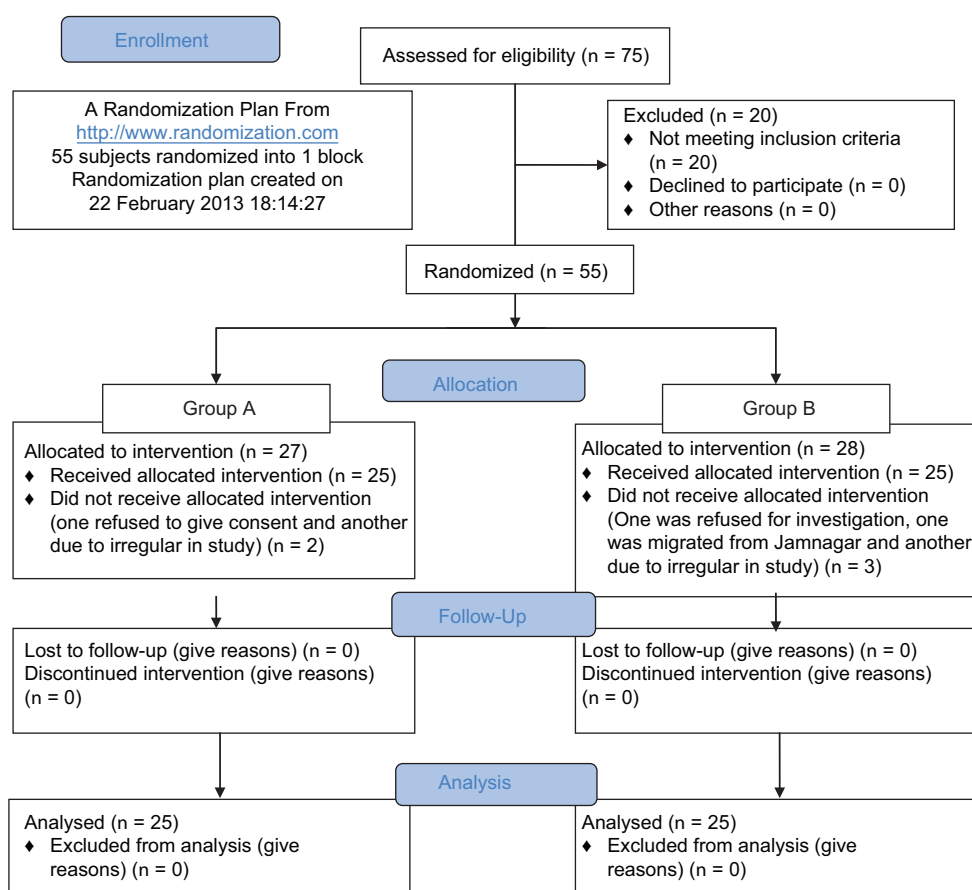


Chart 1: Consort flow diagram

Severity of disease

Category	Total Score
Mild	1-8
Moderate	9-16
Severe	17-25

Criteria for assessment of total effect

Effect of therapy	Percentage
No Change	0-25
Mild improvement	26-50
Moderate improvement	51-75
Marked improvement	76-99
Cured	100

Observations

Of the registered patients, 26 were in the age group of 16–30 years with chronicity of 1–2 years. Majority of the registered patients (30) were males, 11 had positive family history. Totally, 44 patients had white colored patches while 5 patients had red to white and only one patient had red colored patch. A total of 30 patients had number of patches more than 4; while 12 patients had 4 patches, 2 and 3 patches were found in 6 patients each while only one patient had a single patch. Totally, 12 patients had more than 4 cm size of patches, 4 patients had 4 cm, while 3 patients had 3 cm size of patches, 9 patients had 2 cm and only 2 patients had 1 cm size of patches. *Vata-Kaphaja Prakriti* was predominant in the majority of the patients. Hematological and biochemical investigations after the treatment were within normal limits.

Results

Effect of therapy shows that in Group A, 57.26% reduction was found in color of patches, in number of patches 43.80%

reduction was found while in percentage area of patches 40.58% reduction was found and 42.42% reduction was found in size of patches [Figures 1 and 2]. All these changes were statistically highly significant ($P < 0.001$) [Table 3].

In Group B, 55.46% reduction was found in color of patches and 40.42% in number of patches was found. In area of patches 35.53% reduction and 42.45% reduction was found in size of

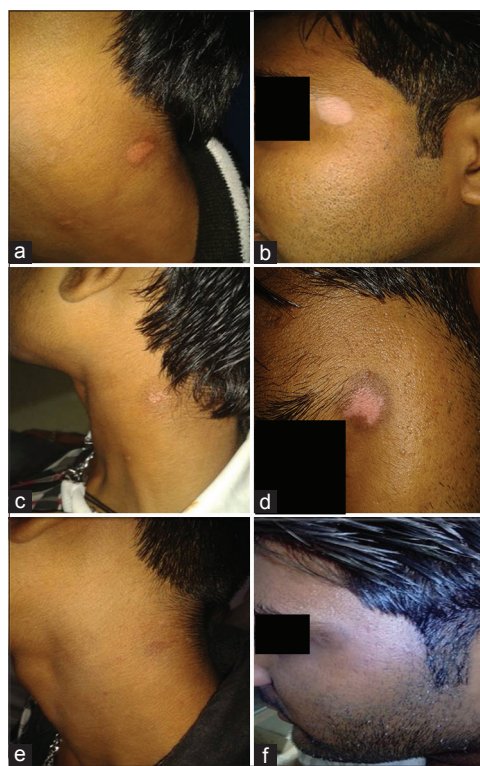


Figure 1: Before treatment (BT) and after treatment (AT) of both Groups; (a) Group B – BT, (b) Group A – BT, (c) Group B – during treatment, (d) Group A – during treatment, (e) Group B – AT, (f) Group A – AT

Table 1: Formulation composition of both dosage forms

<i>Apamarga Kshara Yoga Lepa</i>			<i>Apamarga Kshara Yoga ointment</i>		
<i>Apamarga Kshara</i>	Water soluble ash of <i>Achyranthes aspera</i> Linn.	1 part	<i>Apamarga Kshara</i>	Water soluble ash of <i>Achyranthes aspera</i> Linn.	½ part
<i>Ashuddha Manahshila</i>	Arsenic Disulphide	1 part	<i>Ashuddha Manahshila</i>	Arsenic Disulphide	½ part
<i>Gomutra</i>	Cow's Urine	Quantity sufficient	<i>Tila Taila</i>	Sesame Oil	4 parts
			<i>Gomutra</i>	Cow's Urine	16 parts
			<i>Siktha</i>	Bee wax	1:6 of prepared <i>Taila</i>

Table 2: Criteria for assessment

Score	Percentage of area (rule nine) (%)	Size of patches (cm)	Color of patches	Number of patches	Chronicity of patches (years)
1	1	1	Normal skin color	1	1
2	2	2	Red color	2	2
3	3	3	White to reddish	3	3
4	4	4	Red to whitish	4	4
5	>4	>4	White	>4	>4

patches that all changes were statistically highly significant ($P < 0.001$) [Table 4 and Figure 1].

In comparison of both groups, statistically insignificant difference ($P < 0.05$) was found in the effect of therapies on size, color, number of patches and area of body. Based on this, it can be said that both the dosage forms have similar effect on Shvitra (Vitiligo) [Table 5].

Discussion

Incompatible diet is emphasized to be an important etiological factor in manifestation of Shvitra. Charaka also stated that *Papakarma* (Sinful acts), *Guruninda* (Insult of the preceptors)^[13] Such psychological factors may induce stress in the patients and become *Vyanjaka Hetu* (triggering factor) that triggers disease manifestation mechanism. Sudden emotional trauma and depression have been noted to be responsible for sudden onset or rapid spread of lesion.^[14]



Figure 2: Before treatment (BT) and after treatment (AT) of both Groups (a) Group A – BT, (b) Group A – BT, (c) Group A – AT, (d) Group A – AT

In the present study, 47.27% of patients are from the age group of 16–30 years. Though, there is no significance of age with Shvitra, but, younger age individuals are more prone to psychological stress and consumption of *Virudhdha Ahara*. According to modern science, it may appear at any age.^[15] As Shvitra is *Pittapradhana Tridoshaja Vyadhi*, hence, may be prevalent in the age group of 16-30 years, which is *Pittapradhana*.^[5] 54.55% of patients were males and 45.45% of patients were females. Gender has no role in manifestation of disease.^[15] It is observed that, 80% patients were having negative family history while remaining 20% were having positive family history. It has been mentioned that hereditary diseases (*Sahaja Vyadhi*) are difficult to cure. Modern science says that the occurrence of vitiligo is in ratio of 1:3 when it comes to inheritance.^[15]

Apamarga Kshara Yoga has *Apamarga Kshara*, *Ashuddha Manahshila* and *Gomutra* as ingredients. *Ksharas* have qualities like *Ushna* (hot), *Tikshna* (irritant), *Pachana* (digestive), *Vilayana* (corrosive), *Shodhana* (purification), *Roṇana* (closure of wound), *Shoshana* (absorbing), *Sthambhana* (restrain), and *Lekhana* (scarificant) etc.^[16] *Apamarga Kshara* has *Tikshna Guna*^[17] so it can remove *Kleda*, *Ama* and *Kapha* and also can clear *Srotodushti* especially *Sanga*. *Manahshila* has *Katu* (pungent), *Tikta Rasa* (bitter taste), *Ushna Virya* and *Singdha* (unctuous), *Guru Guna* (heaviness), *Vata-Kapha Shamana Karma* and also has *Rasayana* and *Varnya Karma*.^[18] It acts on *Bhrajaka Pitta* and helps in restoring normal color of skin. So, may be helpful in vitiligo. Hematological and biochemical parameters of both groups were not affected with the treatment.

Both trial drugs have shown highly significant results in symptoms of Shvitra. Comparison in between the groups is statistically insignificant. As complete remission was not found; the duration was increased to 4–6 months in few cases, where the patients were responded significantly. This infers that, there is a need to increase the study period.

Conclusion

Both the trial drugs provided significant results against size, color and number of patches. The difference in between the groups is

Table 3: Effect of therapy of patches on Group A (n=25)

Signs and symptoms of patches	Mean		Mean difference	Percentage change	S.D.	‘t’	P
	Before treatment	After treatment					
Color	4.68	2.00	2.68	57.26↓	0.99	13.56	<0.001
Number	4.20	2.36	1.84	43.80↓	0.90	10.24	<0.001
Area	2.76	1.64	1.12	40.58↓	0.73	7.72	<0.001
Size	3.96	2.28	1.68	42.42↓	1.09	8.57	<0.001

S.D: Standard deviation

Table 4: Effect of therapy on Group B (n=25)

Sign and symptoms of patches	Mean		Mean difference	Percentage change	S.D.	‘t’	P
	Before treatment	After treatment					
Color	4.76	2.12	2.64	55.46↓	0.64	20.70	<0.001
Number	4.08	2.44	1.64	40.20↓	0.91	9.04	<0.001
Area	3.04	1.96	1.08	35.53↓	0.76	7.11	<0.001
Size	4.24	2.44	1.80	42.45↓	1.00	9.00	<0.001

S.D: Standard deviation

Table 5: Comparative effect of therapies on chief complaints

Sign and symptoms of patches	Mean difference Group A (n=25)	Mean difference Group B (n=25)	S.D.	't'	P
Color	2.68	2.64	1.10	0.18	>0.05
Number	1.84	1.64	1.12	0.89	>0.05
Area	1.12	1.08	1.17	0.17	>0.05
Size	1.68	1.80	1.39	-0.43	>0.05

S.D: Standard deviation

statistically insignificant. Considering the encouraging results, it can be said that both the drugs can be successfully used in cases of *Shvitra*. However, the observations can be revalidated through well-designed clinical trials involving larger sample size. Experiments also can be made to identify responsible factors of the efficacy.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

श्वित्र चिकित्सा में अपामार्ग क्षार योग के प्रभाव का मूल्यांकन

हसमुख आर. जाधव, गालिब आर., प्रदीपकुमार प्रजापति

वितिलिगो एक विकासशील, अज्ञात कारणों से उत्पन्न, त्वक रंजन सम्बन्धित व्याधि है, जो कि अल्प रंजित धब्बों द्वारा परिलक्षित होती है। आयुर्वेद में इस अवस्था की तुलना श्वित्र के साथ की जाती है। अनेक आयुर्वेदिक औषधियाँ इस प्रकार के प्रकरण में लाभप्रद हैं, 'अपामार्ग क्षार योग' उनमें से एक है। प्रस्तुत अध्ययन अपामार्ग क्षार योग की लेप कल्पना एवं मलहर कल्पना के चिकित्सकीय प्रभाव का मूल्यांकन करने के हेतु किया गया है। कच्ची औषधियाँ फार्मसी, गुजरात आयुर्वेद विश्वविद्यालय, जामनगर से संग्रहित की गयी। लेप कल्पना एवं मलहर कल्पना का निर्माण प्राचीन शास्त्र नियमों का अनुसरण कर किया गया। श्वित्र व्याधि के कुल ५० रोगी यादृच्छिक रूप से दो समूहों में विभाजित किये गए। समूह ए में २५ पंजीकृत रोगियों का उपचार अपामार्ग क्षारयोग लेप द्वारा एवं समूह बी में २५ पंजीकृत रोगियों का उपचार अपामार्ग क्षारयोग मलहर द्वारा दो माह की अवधि के लिए किया गया। दोनों समूहों में रसायन चूर्ण ३ ग्राम की मात्रा में मधु एवं घृत के साथ दिन में दो बार अभ्यंतर सेवनार्थ दिया गया। दोनों ही समूहों में चिकित्सकीय उपचार द्वारा श्वित्र व्याधि के लक्षणों में प्राप्त परिणाम सकारात्मक एवं सांख्यकीय रूप से सार्थक रहे। दोनों समूहों में प्राप्त परिणाम में अंतर सांख्यकीय रूप से निरर्थक था, जबकि मध्यम सुधार दोनों ही समूहों में देखा गया। अध्ययन से प्राप्त परिणाम एवं अवलोकन के आधार पर हम यह कह सकते हैं कि, श्वित्र व्याधि में अपामार्ग क्षार योग की दोनों ही कल्पनायें प्रभावी हैं एवं एक बेहतर वैकल्पिक औषधि है।