

A randomized clinical trial of Shaman chikitsa versus Shaman chikitsa with vamana in vitiligo (Shwitra)

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ARTICLE INFO	ABSTRACT
<p>Received : 04 April 2023 Revised : 25 June 2023 Accepted : 13 July 2023</p> <p>Available online: 12 November 2023</p> <p>Key Words: Ayurveda Panchakarma Suvarnakar Lepa Swayambhu Guggul Vamana Vitiligo</p>	<p>Vitiligo is a chronic skin disorder due to melanocyte destruction in the epidermis. It is a social stigma. Therefore, it affects the patient psychologically as well. Various therapies have been evaluated in the management of vitiligo. Vamana is a helpful panchakarma to treat skin diseases, but it has still not been studied. To study the efficacy of Vamana, we randomly selected 30 patients with vitiligo and divided them into two groups of 15 patients in each group. For Group A, Vamana was administered, and oral Swayambhu Guggul was administered at 500 mg/day with cow urine and Savarnakar Lepa for local application. This treatment was given for six weeks. In Group -B, the same treatment was given without Vamana. The Vitiligo Area Severity Index (VASI) and overall assessment were used to assess the results. Group A decreased the score from 59.67 to 27.20 ± 18.28, and Group B decreased the score from 42.6 to 36.2 ± 7.58. The P value was statistically significant in Group A and nonsignificant in Group B. In the overall assessment, Group A showed statistically significant results. We concluded that Vamana with Shaman Chikitsa is more efficacious than Shaman Chikitsa alone, but more studies are required to ascertain whether vitiligo can be reversed completely by the combined treatment of Vamana and Shaman Chikitsa.</p>

Introduction

Vitiligo has been known to humanity since ancient times. 'Celsus' first introduced the term 'vitiligo'. Kaposi demonstrated pigment granules in the epidermis of patients suffering from vitiligo. Brocq and Izzedine also contributed to understanding the pathogenesis of vitiligo (Bergqvist and Ezzedine, 2020). It is a disorder affecting melanocyte pigments in the skin. It appears as a dilution in the pigment of the affected skin areas. Vitiligo can be seen as a chalky white macule (Arora and Kumaran, 2017). The etiopathogenesis of this disorder is not entirely understood, but the autoimmune factor has been accepted as the cause. Other causes, such as genetic factors, melanocyte self-destruction, and oxidative stress, also play an essential role in the causation. Melanin pigment is

found in the epidermis and is responsible for skin color. In this condition, the melanin pigment is absent, which causes white patches over the skin. In addition, CD8⁺ T cells produce interferon-gamma (IFN γ), which destroys melanocytes (Rodrigues *et al.*, 2017). Social stigma has been reported with vitiligo across the world. In India, most vitiligo patients suffer from discrimination in their social life, leading to frustration, lack of confidence, and depression (Bergqvist and Ezzedine, 2020). Vitiligo is classified as segmental (SV) or nonsegmental vitiligo (NSV). The prevalence rate of vitiligo is 0.5 – 2% worldwide (4), but it is 8.8% in India. (Sarma *et al.*, 2020). A few studies have been carried out on managing vitiligo with Ayurvedic drugs. Sr. Donata, (Donata *et al.*, 1990) performed trials of

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Ayurvedic drugs in oral medication and external application for six months. The study claims that four out of ten patients had good relief. Another study (Narahari *et al.*, 2011) tried Virechana and local applications for vitiligo. Bharad S K *et al.* (Barad *et al.*, 2021) prepared Marichyadi Lepa in two different ways and tried it in vitiligo.

Bakuchi (*Psoralea coryfolia*) has been proven to be anti-vitiligo by H. Irshad *et al.* Moreover, D Ajay *et al.* (Dhanik *et al.*, 2011) used Shwitrahara Kashaya orally and Shwitrahara Lepa as a local application in 50 patients suffering from vitiligo and obtained promising results in their preliminary study.

In Charaka Samhita, Vitiligo is described as Kilas in the Kustha chikitsa chapter. Two terms, Shwitra and Kilas, are synonymously used in Ayurvedic texts. (*Charaka Samhita by Shukl, n.d.2016*) Tridosha is vitiated to cause Shwitra and Rasa, Rakta, Mamsa, and Meda Dhatu to be seen as involved (Barad *et al.*, 2021). There are two methods of treatment in Ayurveda: Panchakarma or Shodhan Chikitsa and only Ayurvedic medicines or Shaman Chikitsa. Panchakarma is advised as the mainstay in the treatment of vitiligo. However, there has yet to be a study carried out on Vamana Karma. Therefore, this study was carried out.

In this study, the conventional Ayurvedic drugs used in our hospital were administered to one group. In contrast, the same drugs were administered after Vamana Karma in the other group, assessing the results. The research question we tried to answer is “is Vamana Karma with Shaman Chikitsa more efficacious than Shaman Chikitsa alone in managing vitiligo?”

Our aim is to determine whether Vamana Karma with Shamana Chikitsa is more efficacious than Shamana Chikitsa alone in managing vitiligo. Therefore, the present study was carried out to study the efficacy of Vamana Karma and Shamana Chikitsa in managing vitiligo and to compare the efficacy of the combined effect of Vamana Karma and Shaman Chikitsa and Shaman Chikitsa alone in managing vitiligo.

Material and Methods

A randomized controlled clinical trial (RCT) was planned. A simple random sampling technique was used. No blinding was performed, as Vamana is a procedure. Therefore, this was an open study. A

total of 30 patients suffering from vitiligo were included and divided into two groups (Figure 1) (Table 1).

Table 1: Table showing details of intervention

Procedure	Drug & dose	Duration in days/weeks
Deepana Pachana	- Trikatu Churna 3 gm twice a day	3
Snehapana	Ghruta	3-7
Abhyanga Swedana	- Tila Taila (Abhyanga)	2
Vamana Karma	Madanphala pippali 4 gm., Vacha 2 gm, Saindhav 1 gm, Madhu, as per the requirement	1
Samsarjana Krama	Diet as per Shuddhi	3-7
Shamana chikitsa	Swayambhu Guggulu 2tab thrice/day with Go-mutra	6 weeks
External application	Savarnkar Lepa	6 weeks
Swayambhu Guggulu	Two tabs thrice/day with Gomutra	6 weeks
Savarnkar Lepa	External application once a day	Six weeks

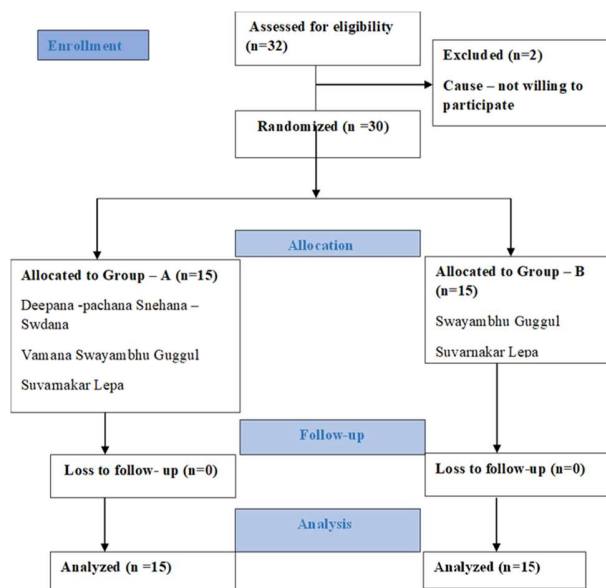


Figure 1: Randomized controlled trial (RCT) flow chart

Group A: Vamana group - 15 patients of Shwitra (Vitiligo) were treated with classical Vamana followed by internal administration of Swayambhu Guggulu with Gomutra and external application of Savarnkar Lepa for six weeks.

Group B: Shamana group – In this group, 15 Shwitra (Vitiligo) patients were treated with

Svayambhu Guggulu with Gomutra internally and Savarnkar Lepa for local application for six weeks. Classical Vamana Karma includes Deepana, Pachana, Snehapana, Abhyanga and Swedana, and the Vamana and Samsarjana Karma administration. We used the following inclusion criteria: patients showing classical signs and symptoms of Shwitra (segmental Vitiligo), patients between the ages of 18 and 60 years, and patients with a chronic condition for less than five years. Patients indicated for Vamana as per Ayurvedic classics. We used the following exclusion criteria: patients with all other depigmentary disorders, patients with serious cardiac, renal, and hepatic diseases, patients with systemic diseases such as hypertension, cardiac diseases, and diabetes, patches due to burning, chemical explosion, patients with known drug hypersensitivity, pregnant and lactating women, and patients with ongoing medications such as systemic corticosteroids, systemic or local photosensitizers or drugs that have been scientifically proven to cause hyperpigmentation on local application or systemic administration. The institutional ethics committee cleared the study (IEC No.69 Dated: 13/07/2016). The study was started after registration in the Clinical Trial Registry of India. (CTRI) Ref. CTRI/2018/04/013129, Registered on: 10/04/2018). Informed written consent was obtained on a printed consent form before enrollment in this study. This study was conducted in the OPD and IPD of Panchakarma, Akhandananda Ayurvedic College (Government) and Hospital, Ahmedabad, India, from 2016 to 2018. The materials, such as the drugs required for the local application, were obtained from the pharmacy of Akhandananda Ayurvedic College, Ahmedabad, and standardized in the Dravyaguna department, Akhandananda (Government) Ayurvedic College, Ahmedabad. Vamana was performed in the Panchakarma department, and the drugs and other materials required for Vamana were obtained from the Panchakarma department. (Table 2). Vamana involves Deepana – Pachana, Snehapana as a preparatory procedure, Vamana (drug-induced vomiting) as the primary procedure, and Dhoompana, dietary regimen as the postoperative procedure. It was performed per our institute's

standard operating procedure (SOP). Svayambhu Guggul is a preparation mentioned in the 'Bhavprakash'. (Bhavprakash Nighantu 2017.) The

Table 2: Table showing drug name and proportion

Drug	Latin name	Proportion (In gram)
Svayambhu Guggul		
Bakuchi	<i>Psoralea corylifolia</i>	200
Shilajit	<i>Asphaltum punjabinum</i>	200
Swarnmakshik	<i>Copper pyrite</i>	200
Loha	<i>Iron sulfate</i>	400
Mundi	<i>Sphaeranthus indicus</i>	400
Haritaki	<i>Terminalia chebula</i>	200
Amalaki	<i>Emblica officinalis</i>	200
Karanja	<i>Pongamia pinnata</i>	200
Khadir	<i>Acacia catechu</i>	200
Guduchi	<i>Tinospora cordifolia</i>	200
Trivrut	<i>Operculina terpenanthum</i>	200
Danti	<i>Boliospermum montanum</i>	200
Musta	<i>Cyperus rotundus</i>	200
Vidang	<i>Embelia ribes</i>	200
Haridra	<i>Curcuma longa</i>	200
Kutaja	<i>Holarrhena antidysenterica</i>	200
Nimba	<i>Azadirachta indica</i>	200
Guggul	<i>Commiphora mukul</i>	400
Madhu	Honey	200
Suvarnakara Lepa		
Bakuchi	<i>Psoralea corylifolia</i>	1 part
Hartal	Yellow arsenic sulfide	1/4 th part
Gomutra	Cow urine	As required

medicine was used orally at 250 mg in the morning and the same dose (total dose – 500 mg/day) in the evening after dinner with hot water. It is a Herbo-mineral preparation containing 19 constituents. Suvarnakar Lepa is a preparation mentioned in the text 'Ashtanghridayam' (*Ashtang Hridaya by Vagbhata*, 2019). It has three ingredients. It contains 'Hartal', a toxic substance (arsenic sulfide); therefore, it was used only after purification, as mentioned in the text. A fine powder of the above ingredients was prepared and given to the participants, and they explained the procedure of Lepa in the local language. Then, they were asked to add fresh cow urine or cow urine prepared from Gomutra Arka if fresh was unavailable. The patients were assessed after the

intervention. In both groups, the intervention was given for six weeks, and on the 7th week, the participants were called to assess the outcome measures. We used the Vitiligo Area Severity Index (VASI) score (Hamzavi *et al.*, 2004) for the assessment.

$$\text{Total Body VASI} = \sum [\text{all body sites}] \times [\text{residual depigmentation}] \div [\text{hand units}]$$

In this study, the measurement of VASI requires area in palm units. This is because many lesions are within a palm area. Therefore, it is difficult to note it in palm units. To make the calculation, we divided the palm into 4 parts: $\leq 1/4$ palm = 0.25%, $1/4$ to $1/2$ palm = 0.5%, $1/2$ to $3/4$ palm = 0.75%, and $> 3/4$ to 1 palm = 1%. Measurements of the lesions were taken. All the parameters are mentioned in grades, so the VASI scores are given in 6 grades to make and compare calculations. The VASI score was noted in the study group, and the minimum score was calculated. For the overall assessment, we recorded repigmentation as unchanged (0%), 'mild' (> 25%), 'moderate' (> 50%), 'marked' (>75%), and complete remission (< 75%).

Results and Discussion

Of the 30 patients, more males (n= 19, 63.33%) were involved in the study than females (n= 11, 36.67%). Of the age groups, the 18 – 30 age group had a higher percentage than the others. The Hindu religion category consists of more patients. In the profession, students are at the top. More educated patients suffered from vitiligo in our study. The middle-class more than others. More rural residents are seen than urban residents. More married individuals were found than unmarried individuals in our study. Kapha – Pitta Prakriti individuals were more numerous than other Prakriti individuals. Among the Koshtha, Madhyam was seen to be more prevalent (Table 3). In Group 1, Vamana was performed. During Vamana, Madhyam Shuddhi was found in more individuals. In the skin color, white was seen more than others. In the area involved, the body parts hand and legs were commonly seen.

Table 3: Categories of Patient studied

VARIABLE	DATA		
	Gr.1 (n=15)	Gr.2 (n=15)	Total (n=30)
Sex			
Male	11 (57.89)	8 (42.11)	19 (63.33)
Female	4 (36.37)	7 (63.63)	11 (36.67)
Age (in years)			
18 – 30	7 (46.67)	8 (53.33)	15 (50.00)
31 – 40	5 (71.42)	2 (28.58)	7 (23.33)
41 – 50	2 (33.34)	4 (66.66)	6 (20.00)
51 – 60	1 (50.00)	1 (50.00)	2 (06.60)
Religion			
Hindu	13 (50.00)	13 (50.00)	26 (86.66)
Muslim	2 (50.50)	2 (50.00)	4 (13.33)
Occupation			
Students	4 (36.37)	7 (63.63)	11 (36.36)
Housework	5 (50.00)	5 (50.00)	10 (33.33)
Laborer	3 (60.00)	2 (40.00)	5 (16.66)
Business or job	3 (75.00)	1 (25.00)	4 (13.33)
Education level			
Less educated	6 (42.86)	8 (57.14)	14 (46.67)
Highly educated	9 (56.25)	7 (43.75)	16 (53.33)
Economic status			
Poor	3 (50.00)	3 (50.00)	6 (20.00)
Middle class/rich	12 (50.00)	12 (50.00)	24 (79.99)
Habitat			
Urban	3 (42.86)	4 (57.14)	7 (23.24)
Rural	12 (52.17)	11 (47.83)	23 (76.66)
Marital status			
Married	11 (57.9)	8 (42.10)	19 (63.33)
Unmarried	4 (36.37)	7 (63.63)	11 (36.66)
Prakriti			
Vata-Pitta	3 (37.5)	5 (62.5)	8 (26.66)
Vata -Kapha	5 (83.33)	1 (16.67)	6 (20.00)
Kapha – Pitta	7 (43.75)	9 (56.25)	16 (53.33)
Koshtha			
Krura	1 (25.00)	3 (75.00)	4 (13.33)
Mridu	3 (57.15)	7 (42.85)	10 (33.33)
Madhyam	11 (68.75)	5 (31.25)	16 (53.33)
Shuddhi in Vamana			
Pravara	6 (40.00)	-	6 (40.00)
Madhyam	8 (53.55)	-	8 (53.55)
Avara	1 (6.66)	-	1 (6.66)
Color of patches with a score			
Normal skin (1)	0 (0)	0 (0)	0(0)
Red (2)	2 (33.33)	4 (66.67)	6 (20.00)
Whitish/reddish (3)	6 (60.00)	4 (40.00)	10 (33.33)
Red to white (4)	3 (50.00)	3 (50.00)	6 (20.00)
White (5)	4 (50.00)	4 (50.00)	8 (26.66)
Area involved			
Scalp	4 (80.00)	1 (20.00)	5 (16.66)
Face	3 (50.00)	3 (50.00)	6 (20.00)
Hands	9 (42.85)	12 (57.15)	21 (70.00)
Legs	13 (54.16)	11 (45.89)	24 (80.00)
Buttocks	2 (50.00)	2 (50.00)	4 (13.33)
Trunk	2 (28.57)	5 (71.43)	7 (23.33)
Back	8 (66.66)	4	12 (40)

Effect on VASI

The VASI score decreased from 59.67 to 27.20 ± 18.28 in Group A and from 42.6 to 36.2 ± 7.58 in

Group B. The P value is statistically significant in Group A and nonsignificant in Group B (Table 4).

Overall Assessment

The overall assessment showed that 6 (40%) patient

in Group A reported marked improvement, while 9 (60%) patients had moderate improvement. In group B, 8 (53.5%) reported moderate improvement, while 7 (46%) reported mild improvement (Table 5 and Figure 2).

Table 4: Table showing effect on VASI score

Score	Gr	Mean		Mean Difference	%	Diff SD±	Diff SE±	't'	'p'	S
		BT	AT							
VASI	A	59.67	27.20	32.47	53.42↓	18.28	4.721	6.878	<0.001	HS
	B	42.6	36.2	6.4	15.02↓	29.38	7.58	0.843	>0.05	IS

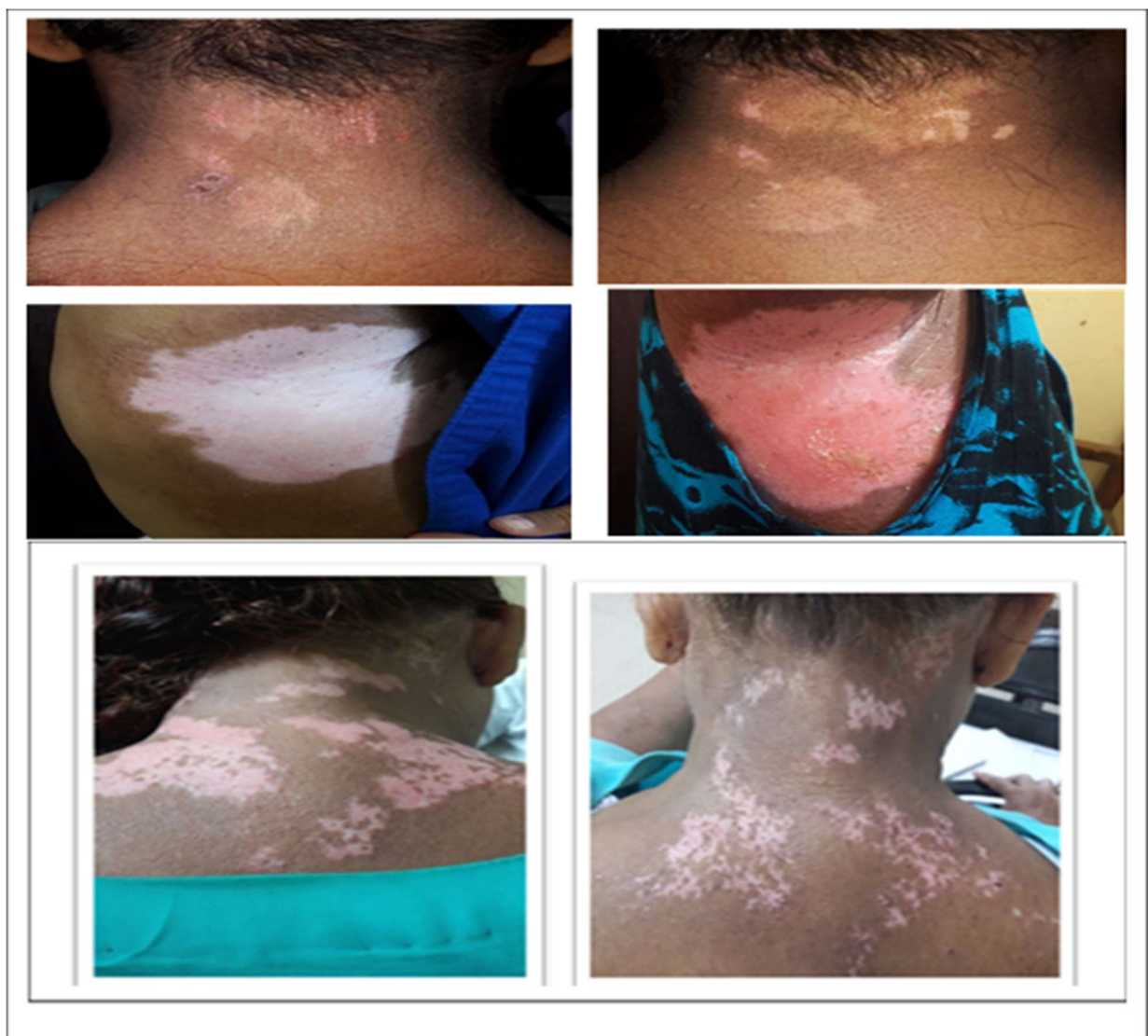


Figure 2: Figure showing before and after treatment pictures of patient

Table 5: Table showing overall assessment

Gradation	Group A (n=15)	Group B (n=15)
Complete remission	0	0
Marked improvement	6 (40)	0
Moderate Improvement	9 (60)	8 (53.53)
Mild improvement	0	7 (46.67)
Unchanged	0	0

This trial was aimed to determine whether Vamanakarma with Shaman Chikitsa is more efficacious than Shaman Chikitsa alone. The 30 randomly selected Vitiligo patients were divided into two groups: in one group, Vamana Karma was administered with Shamana Chikitsa, and in the other group, only Shaman Chikitsa was administered. The assessment criteria were the VASI scale and the overall assessment. The Vamana Group showed statistically significant results compared with Shaman Chikitsa alone. We found more males (19, 63.33%) than females (11, 36.67%), which is in contrast to the findings made by N Sama, S Chakraborty, S Poojary et al. (Sarma *et al.*, 2020) who found 0.86 and 0.93% in their study. We found 50% of patients in the age group 18-30 years (23%), 20% in 31-40 years, 41-50 years and 51-6 years, which was also found by N Sama, S Chakraborty, S Poojary et al. (Sarma *et al.*, 2020) We also found more Hindu patients (26%) than Muslims (4%), students (11%) than housework (10%), laborers (5%), and business or job workers (4%). vitiligo is seen with a varied presentation. The state of Gujarat has the highest prevalence of vitiligo (8.8%) in India. This study was carried out in Gujarat (Bergqvist and Ezzedine, 2020) Therefore, there are some contrasting findings compared to previous studies that apply to all of India. In the VASI score, Group A had statistically significant results, and overall assessment, Vaman Karma showed better results. It causes drastic changes in the epidermis and dermis of the skin. Normally, the epidermis consists of dead or about-to-die cells in large amounts. Vamana Karma may stimulate the rapid disposal of dead cells. It may also stimulate melanocyte production. The patients accepted Vamana Karma well, and we did not find any complications of Vamana. Vitiligo is very chronic and very refractory to any treatment. However, it should be noted that marked changes occurred in the vitiligo during Vamana Karma and the administration of medicines. The milky white

appearance of the skin began to change into pink, red, or brown in some cases. The boundaries of the vitiligo patches stopped spreading further. However, the patches were sometimes very refractory and did not change. This study has many limitations. We could not perform a long follow-up to check the viability of these effects. It is essential to follow up at least for a year to see the changes in the vitiligo patches. A sample size of 30 is low. Vamana being a procedure, blinding was not possible.

Conclusion

The Vamana Karma group showed a better effect than palliative therapy (Shaman Chikitsa) alone in managing vitiligo. This study highlights the importance of Vamana Karma before Shaman Chikitsa. Therefore, Vamana Karma should be performed in Vitiligo. However, the results are primary, and longer follow-up needs to be conducted.

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Conflict of interest

The authors declare that they have no conflict of interest.

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