



AN OPEN LABELLED CLINICAL TRIAL TO EVALUATE THE EFFICACY OF VIRECHANA FOLLOWED BY ASANADI GANA KASHAYA & TAILA LEPA IN SHWITRA VIS~A~VIS VITILIGO.

Dr. Bheemreddy Myakal¹, Dr. Mythrey R C²

1. 3rd year PG scholar, Dept. of Kayachikitsa, Government ayurveda medical college and hospital, Mysuru
2. Professor & Head, Dept. of Kayachikitsa, Government ayurveda medical college and hospital, Mysuru.

Department of Kayachikitsa
Government ayurveda medical college and hospital, Mysuru

Postal address: Government Ayurveda Medical College and Hospital,
vishweshwarayya circle, New Sanyaji Rao Road, Mysuru, 570001.

Abstract

Background:

Shwitra is characterised by the whitish patchy discoloration of the skin. It is a *rakta pradoshaja vyadhi* caused due to vitiated *tridosha*, *rakta*, *mamsa* and *medo dhatu*. *Shwitra*, can be correlated with 'Vitiligo' of Western system of medicine.

Vitiligo is an idiopathic, acquired, circumscribed leukoderma which is often associated with a positive family history and is characterized by discrete, pale white macules, few or many in number, that tend to enlarge centrifugally over time. Worldwide prevalence of vitiligo is observed as 1% of the world population.

Currently, the treatment modalities available for the management of vitiligo include topical immunomodulators & steroids, oral corticosteroids, PUVA therapy with excimer laser, phototherapy and Surgical therapies like grafting. Long term usage of topical glucocorticoid is often accompanied by loss of effectiveness and atrophy of the skin.

To disintegrate the *samprapti* of *shwitra* and to increase the duration between relapse, *asanadi gana* was selected which is mentioned in *shodhanadi gana sangrahaniya adhyaya* of *ashtanga hrdaya sutrasthana*. Based on this, the study has been taken up to assess the

combined efficacy of *asanadi gana kashaya* internally and *asanadi gana taila* externally after *samsarjana krama* of *virechana* in the management of *shwitra* vis-à-vis vitiligo.

Objective of the study : To evaluate the combined efficacy of *virechana* followed by *asanadi gana kashaya* internally & *asanadi gana taila* application externally.

Methods:

Study design- An open labelled clinical trial with pre and post-test design.

Intervention- Total 30 subjects were selected incidentally. All the 30 subjects were administered classical *virechana* followed by *asanadi gana kashaya* internally after food and *asanadi gana taila lepa* followed by *suryapada santapa sevana* for 20 minutes in early morning hours (7am – 11am) for 40 consecutive days.

Results: The result of the study revealed that statistically significant improvement was seen in *twak shwetata*, colour, margin, surface area involved, number of lesions & VASI score with P value < 0.001.

Conclusion: It can be concluded from the results that classical *virechana* followed by *asanadi gana kashaya* internally and *asanadi gana taila lepa* externally were effective in treating *shwitra* vis-à-vis vitiligo

Keywords: *Shwitra*, Vitiligo, *Virechana*, *Asanadi gana kashaya*, *Asanadi gana taila*, VASI.

INTRODUCTION

Skin plays very important role in protecting against pathogens. It has been recognized as the ‘Organ of Expression’ and serves as the boundary between ourselves and the outside world, a ‘first point of contact’.

The size and external location of the skin makes it susceptible to various disorders. Skin diseases are mostly caused by infections like bacteria, fungi etc. The other functions of skin are Insulation and temperature regulation, Sensation and Vitamin-D synthesis¹. Patients of skin disease always experience physical, emotional and socio-economic embarrassment in the society. The prevalence of skin diseases in general population has varied from 7.86% to 11.16% in various studies.

Shwitra is a dermatological disorder having its references cited in the Vedas. The term is combination of *Shweta* and *Rak* ². *Shweta* means whiteness and *Rak* is suffix of ‘*Shweta*’ *dhatu*. It is characterised by the whitish patchy discoloration of the skin. It is a *rakta pradoshaja vyadhi* ³ caused due to vitiated three *dosha*, *rakta*, *mamsa* and *medo dhatu*. The *Nirukti* of the term reveals white colour or changes toward white colour. *Shwitra* emerges as a sequel to irregular dietary habits, life style changes, and genetic predisposition ⁴. The disease involves the skin and does not cause pain, ulceration or any secretions. *Shwitra* inflates an inferiority complex in the persons affected because equal distribution of colour all over the body is important to look beautiful.

Shwitra, can be correlated with ‘Vitiligo’ of Western system of medicine. Normal skin colour is dependent on hemoglobin (in both the oxygenated and reduced state), carotenoids and melanin pigment.

An acquired skin disease of progressive melanocyte loss, is clinically characterized by well defined milky- white macules that may also include white hairs, or poliosis⁵. Worldwide prevalence of Vitiligo is observed as 1% of the world population. Highest incident has been recorded in India and Mexico. Based on dermatological out patient record, it is estimated between 3-4% in India has been reported.

Currently, the treatment modalities available for the management of vitiligo include topical immunomodulators & steroids, oral corticosteroids, PUVA therapy with excimer laser, phototherapy and Surgical therapies like grafting⁶. Long term usage of topical glucocorticoid is often accompanied by loss of effectiveness and atrophy of the skin. Most of the treatment modalities have some limitations and having potent side effects.

Considering the above reasons, it is relevant to search for an alternative management, which is effective and which gives long term remission.

Various *shodhana* and *shamana chikitsa* have been mentioned in the ayurvedic classics for the management of *shwitra*. The disease *shwitra* should be treated intensively in the initial stages due to its *bheebhatsa* nature and tendency to turn *asadhya* at the earliest⁷. So to disintegrate the *samprapti* and to increase the duration between relapse, *asanadi gana*⁸ was selected. A formulation which has not only *shwitraghna* effect but also works at the level of *dhatvagni* encountering *kaphapitta dosha*. Hence the current study is taken up to assess the clinical efficacy of *asanadi gana kashaya* internally and *asanadi gana taila* externally for 40 days after *samsarjana krama* of *virechana* in the management of *Shwitra vis-à-vis* Vitiligo.

AIMS AND OBJECTIVES

To evaluate the combined effect of *virechana* followed by *Asanadi gana kashaya* internally & *Asanadi gana taila lepa* externally in the management of *shwitra vis-à-vis* Vitiligo.

MATERIALS AND METHODS

Source of data: Subjects were incidentally selected from OPD & IPD of Government Ayurveda Medical College and Hospital, Mysuru and Government Hi-Tech Panchakarma Hospital, Mysuru.

Source of drug: *Asanadi gana kashaya* and *Asanadi gana taila* was specially prepared & procured for the study from a GMP certified pharmacy, SDP Remedies & Research centre Puttur (Parladka) .

Method of collection of data:

Study design: A single group open labelled clinical trial with pre and post test design.

Sample size: 30 subjects were registered for the study.

- Study was conducted in 30 subjects of *shwitra vis-à-vis* vitiligo.

Duration of the intervention- 40 days after *virechana* .

Inclusion criteria:

- Subjects between the age group of 18 to 60 years irrespective of gender, religion, occupation, and socio economic status were included.
- Subjects having lesions of *shwitra* (*twak shwetata*) vis-a-vis vitiligo were selected.
- Both fresh cases and treated cases of *shwitra* vis-a-vis vitiligo were included .

A. Fresh cases include freshly detected and untreated cases of *Shwitra* vis-a-vis vitiligo.

B. Treated cases include already diagnosed as *Shwitra* vis-a-vis vitiligo, who had voluntarily discontinued the treatment with the flush out period of 7 days.

Exclusion criteria:

- Patients with Systemic disorders like Thyroid dysfunction, uncontrolled DM (RBS >250mg/dl), uncontrolled HTN (>150/100 mm Hg) which interferes with the course of treatment were excluded.
- Patients unfit for *virechana* were excluded.
- Secondary depigmentation disorders caused due to burns & wounds were excluded.
- Lesions / Patches appeared over groins, palms, lips were excluded.
- Pregnant and lactating women were excluded.

DIAGNOSTIC CRITERIA

Subjective parameter – *Twak shwetata*, Colour, Margin.

Objective parameter – Surface area involved (Calculated by Rule of Nine), Number of lesions & VASI score

***Twak shwetata*:**

Grade I	< 25%
Grade II	26 - 50 %
Grade III	51 – 75%
Grade IV	76 – 100%

Colour:

Grade I	Normal pigmentation
Grade II	Red
Grade III	Coppery Red
Grade IV	White

Margin:

Grade 0	Differentiable
Grade I	Thin
Grade II	Thick
Grade III	Extending
Grade IV	Non differentiable

ASSESSMENT CRITERIA:

- To assess the effect of intervention, the scoring method of Vitiligo Area Severity Index (VASI) was adopted.

**ASSESSMENT SCHEDULE**

- Pre-test assessment was done before administering *virechana*.
- Post-test assessment was done after the completion of intervention i.e After administering *shamana aushadhi* (i.e on 40th day)

STATISTICAL METHODS: The result was compared and analyzed statistically by using the following statistical methods:

- Descriptive Statistics- Mean, Standard deviation, Frequency, Percentile.
- Inferential Statistics – Chi-square test, Wilcoxon signed rank test, Paired sample “T” test .

All the statistical methods were done using SPSS windows.

INTERVENTION:

The interventions were as follows:

All the subjects were administered with *virechana karma* before starting the intervention as a pre requisite.

Virechana karma was administered as follows.

- *Deepana pachana* was carried out with *Agnitundi vati* 250mg thrice a day with lukewarm water before food till *nirama lakshana* were evident (3-5 days).
- *Shodhananga snehapana* was administered with *Pancha tiktaka guggulu ghrita* from the day of *nirama lakshana* till *samyak snigdha lakshana* were seen. The dosage of everyday's snehapana varied from 30 ml- 120 ml.
- *Sarvanga abhyanga* with *Moorchita tila taila* followed by *mrudu swedana* was done for 3 days.
- *Virechana* was administered with *Trivrit lehya* {25-70gm} based on *agni, koshta*, and *bala* followed by *Samsarjana Krama* (3-7 days based on the type of *Shuddhi*).
- *Shamana aushadhi* was started after completion of *Samsarjana krama*:

Shamana aushadhi : For 40 days.

a) *Asanadi gana kashaya* 30 ml in two equally divided doses (15ml/ dose) with lukewarm water after food internally.

b) *Asanadi gana taila lepa* followed by *suryapada santapa sevana* for 20 minutes in early morning hours (7am - 11am).

OBSERVATION AND RESULTS

Observations:

Complete treatment was administered to 30 patients in total. Maximum number of patients were in the age group of 31-40 years. Majority of the patients were Females.

Most of the patients were taking mixed type of diet. Most of the patients were from Upper middle class. Most of the patients presented upper limb followed by lower limb as a site of onset.

Results-

Table no. 1 showing results of objective parameters .

Parameter	Before Treatment		After Treatment		BT – AT
	Mean	SD	Mean	SD	t - value
Surface Area Involved	6.817	4.268	5.517	4.384	13.31
Number of lesions	10.833	7.057	8.567	6.942	9.66
VASI	1.624	1.310	1.196	1.275	7.72

Table no. 2 showing results of subjective parameters .

Parameter	AT- BT	
	Z - value	Chi-Square value
Twak Shwetata	-3.568	29.158
Colour	-4.917	46.667
Margin	-4.928	51.941

Results on severity of *twak shwetata*:

The result of pre-test & post-test assessment obtained regarding the parameter- *twak shwetata* showed statistically significant result with P value < 0.001

Results on colour:

The result of pre-test & post-test assessment obtained regarding the parameter - Colour showed statistically significant result with P value < 0.001

Results on Margin:

The result of pre-test & post-test assessment obtained regarding the parameter - Margin showed statistically significant result with P value < 0.001 .

Results on surface area involved:

During pre-test assessment i.e. Before *virechana* the Mean & Standard deviation of 30 subjects were 6.82 & 4.27 respectively. During post test assessment i.e After completing *shamanaushadhi* the Mean & Standard deviation of 30 subjects were 5.52 & 4.38 respectively. The result of pre-test & post-test assessment obtained regarding the parameter - Surface area involved showed statistically significant result with P value < 0.001 .

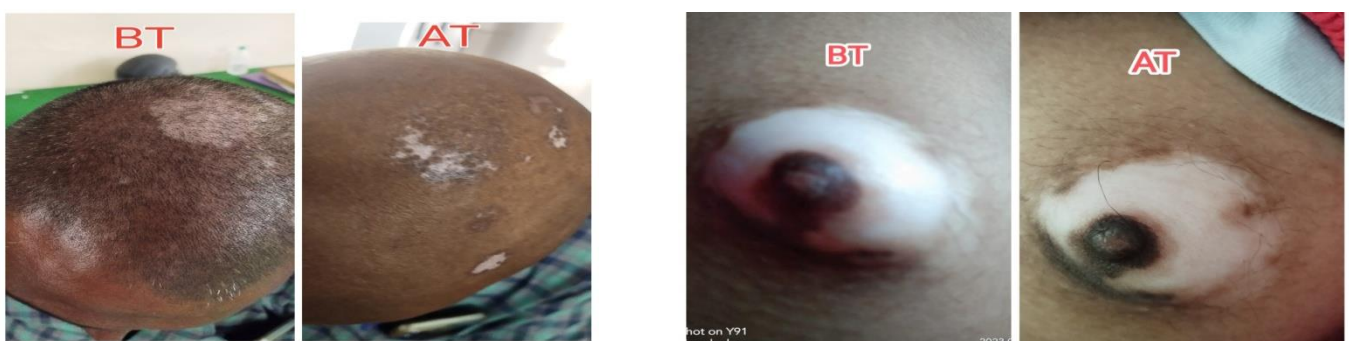
Results on number of lesions:

During pre-test assessment i.e. Before *virechana* the Mean & Standard deviation of 30 subjects were 10.83 & 7.06 respectively. During post test assessment i.e After completing *shamanaushadhi* the Mean & Standard deviation of 30 subjects were 8.57 & 6.94 respectively. The result of pre-test & post-test assessment obtained regarding the parameter - Number of lesions involved showed statistically significant result with P value < 0.001 .

Results on Vitiligo Area Severity Index (VASI):

During pre-test assessment i.e. Before *virechana* the Mean & Standard deviation of 30 subjects were 1.62 & 1.31 respectively. During post test assessment i.e After completing *shamanaushadhi* the Mean & Standard deviation of 30 subjects were 1.20 & 1.28 respectively. The result of pre-test & post-test assessment obtained regarding the parameter - Vitiligo area severity index (VASI) showed statistically significant result with P value < 0.001 .

CASE STUDY PHOTOGRAPHS





DISCUSSION-

Virechana as a pre requisite:

Shwitra is one among the *rakta pradoshaja vyadhi*. Shwitra is *Kaphapitta pradhana tridoshaja vyadhi*. As the *chikitsa sutra* of *rakta pradoshaja vyadhi* is *raktapitta hara kriya*, *virechana*, *upavasa* and *shonita sravana*⁹. In *shwitra* there is hypofunctioning of *bhrajaka pitta* (a type of *pitta*). In any *pittaja vyadhi*, *virechana* is the prime treatment¹⁰. It is considered if there is *bahu doshavastha* and it acts as *shreshta pitta dosha nirharana*. By doing *shodhana* (here *virechana*) the *shamana aushadhi* reach to the targeted organ very fast due to *sroto shuddhi* effect of *shodhana*. Hence *virechana* is administered as a pre requisite before administering *shaman aushadhi* here.

Probable mode of action Asanadi gana kashaya:

The majority of drugs present in *asanadi gana* posses *tikta kashaya rasa*, *laghu ruksha guna*, *sheeta veerya*, *katu vipaka* providing *kaphapittahara* action. As *shwitra* is one among the *rakta pradoshaja vikara*, *tikta kashaya rasa*, *laghu ruksha guna* and *sheeta veerya* helps in *rakta prasadana* action due to *ashraya ashrayee bhava* of *pitta & rakta*. As *shweta varna* of *shwitra* signifies the *kaphamedo dushti*, *Kashaya tikta rasa*, *laghu ruksha guna*, *katu vipaka* of *asanadi gana* helps in correcting this *dushti*. As *shwitra* is *rakta pradoshaja vikara*, most drugs in *asanadi gana* are having *kushtaghna*, *shwitraghna*, *Varnya*, *rakta prasadana*, *twachya* property which will help in correcting *rakta dhatu* and *pitta dosha*. This helps in repigmentation of skin colour from abnormal colours (here white colour to normal one).

Asanadi gana contains drugs that are having properties of Anti-inflammatory, Immunomodulatory action, Balancing oxidant- antioxidant system, Inhibitory action which helps in the correction of melanocyte dysfunction leading to normal pigmentation by acting on multiple pathogenesis.

Probable mode of action Asanadi gana taila:

Asanadi gana taila is prepared using *asanadi gana kwatha*, *asanadi gana kalka* and *sarshapa taila* as a base. Here *sarshapa taila* is selected because it is having *teekshna ushna guna*, *katu vipaka*, *kaphavatahara*, *kanduhara*, *kotahara*, *kushtahara*, & *shwitrahara* properties.

It is also having action of *deepana* which can be understood as *bhrajaka agni deepana* as it is used for *lepa*. As in *shwitra* there is *shweta varnata* of *twak* that is caused due to to

increased *kapha* & hypo-functioning of *bhrajaka agni*. *Acharya sushruta* suggests usage of *katu taila* as *abhyangartha* ¹¹ followed by exposure to sun in *shwitra* treatment hence it is selected as *lepartha* in this study.

DISCUSSION ON ASSESSMENT TOOL:

There are many scales like Vitiligo Area Severity Index (VASI), Vitiligo Disease Activity score (VIDA), Vitiligo European Task Force Score assessment (VETF), Area Estimating System (AES Software) using Simulation Techniques, Potential repigmentation index (PRI), Vitiligo activity index (VAI) and Vitiligo Extent Tensity Index (VETI) score. As VETF requires woodlamp examination this method was not selected because of lack of facility. AES software is yet to develop for overlapping irregular patches, disjoint vitiligo patches and patches extended in two sides in body parts thus this software was not implied. PRI & VAI are not numerical index for measuring the extent and severity of vitiligo. VETI is a recently developed score which is yet to be globally accepted.

CONCLUSION:

Shwitra is *kaphapitta pradhana tridoshaja vyadhi* & one among the *rakta pradoshaja vikara*. *Shweta varna mandala* and *aparishrava* are the two cardinal symptoms of the *shwitra* disease. Based on the clinical features it can be correlated to vitiligo of contemporary medicine. The prevalence of vitiligo is 3% to 4% in India. Stable type of vitiligo is the most common type and Lower limbs are the most common site of onset of vitiligo. The symptom *twak shwetata* (whitish discolouration of skin) in the form of macules & patches were observed in subjects. Here *virechana* is done as a pre-requisite before administering *shaman aushadhi* (*Asanadi gana kashaya* internally & *asanadi gana taila* externally). The combined effect of *virechana* and *shaman aushadhi* showed statistically significant improvement in *twak shwetata*, colour, margin, surface area involved, number of lesions & VASI score. No adverse effects of drugs were reported in the present study.

BIBLIOGRAPHIC REFERENCES

- 1) P.N.Behl, Practice of dermatology, published by S.K.Jain for CBS Publishers and Distributors, Delhi, 9th edition, reprint, 2002, p.no.-9-10.
- 2) Vachaspathi bhattacharya (1970), Vachaspathyam volume 2, Varanasi chaukambha Sanskrit series, 3rd edition P.5161
- 3) Chakrapani's commentry on Agnivesha: Charaka Samhita revised by Charaka and Dridhabala with Ayurveda Dipika commentary by Chakrapani Datta; Edited by Vaidya Jadavaji Trikamji Acharya; Published by Chaukhamba Prakashan; Varanasi; Edition-reprint2009; Sutra Sthana 28/11-14 ,P-327.
- 4) Chakrapani's commentry on Agnivesha: Charaka Samhita revised by Charaka and

Dridhabala with Ayurveda Dipika commentary by Chakrapani Datta; Edited by Vaidya Jadavaji Trikamji Acharya; Published by Chaukhamba Prakashan; Varanasi; Edition-reprint2009; Chikitsa Sthana 8/177 ,P-727.

- 5) Sewon kang, Masayuki amagai et. Al, Fitzpatrick's Dermatology, 9th edition Volume I, Chapter no.76 Vitiligo p.no.1330
- 6) Mauro Picardo Alain taieb ed. Chapter 48 3.7.2., 2010, Vitiligo Springer Heidelberg Dordrecht London New York, pp 410.
- 7) Vagbhata, Ashtanga hridaya ,Sarvanga Sundara Commentary of Arunadatta, 9th edition, Varanasi: Chowkamba orientalia,2002, Chikitsa sthana 20/1, pp. 718.
- 8) Vagbhata, Ashtanga hridaya ,Sarvanga Sundara Commentary of Arunadatta, 9th edition, Varanasi: Chowkamba orientalia,2002, Sutra sthana 15/19-20, P-238
- 9) Agnivesha: Charaka Samhita revised by Charaka and Dridhabala with Ayurveda Dipika commentary by Chakrapani Datta; Edited by Vaidya Jadavaji Trikamji Acharya; Published by Chaukhamba Prakashan; Varanasi; Edition-reprint- 2009; Sutra Sthana 24/18, P 490
- 10) Agnivesha: Charaka Samhita revised by Charaka and Dridhabala with Ayurveda Dipika commentary by Chakrapani Datta; Edited by Vaidya Jadavaji Trikamji Acharya; Published by Chaukhamba Prakashan; Varanasi; Edition-reprint- 2009; Sutra Sthana 25/40, P508
- 11) Sushruta Samhita, Nibandha Sangraha Commentary of Dalhanacharya and Nyayachandrika commentary of Gayadas. Edited by Vaidya Yadavji Tikamji Acharya, published by Chowkambha Orientalia, Varanasi, 1992, Chikitsa sthana 9/15, P-782

Conflicts of Interest – None

Funding Support - None