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Clinical Evaluation of Switraghna Lepa in Switra

K. Sai Bhavya[1], Ch. Sridurga[2], K. Satyaprabha[3]

1. Final year, M.D(Ayu) Scholar, P.G Department of Rasa Shastra and BhaishajyaKalpana, S.V Ayurvedic Medical college and Hospital, T.T.D, Tirupati, Andhra Pradesh, India
2. Professor and HOD,P.G Department of Rasa Shastra and BhaishajyaKalpana, S.V Ayurvedic Medical college and Hospital, T.T.D, Tirupati, Andhra Pradesh, India
3. Professor and HOD, Department ofRogaVijnana and VikrutiVijnana, S.V Ayurvedic Medical college and Hospital, T.T.D, Tirupati, Andhra Pradesh, India

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ABSTRACT :
Skin is the best indicator of general health. It acts as a mirror that reflects external and internal pathology and thus helps in diagnosis of disease. There is a huge focus on skin health and when it is visually altered or damaged it can make a profound effect on one's quality of life. Switra is one of the skin disorders which is generally caused by the vitiation of the tridosha. According to modern Dermatology, based on the clinical manifestations Switra can be correlated with Vitiligo. Vitiligois a pigmentary disorder of great socio-medical importance and isdefinedasacquired,idiopathic,hypomelanosis ofskinandhair.To fulfill the expectations from the Ayurvedic Rasa Shastrafield and to find out more effective and safe therapy for Switra, Switraghnalepa has been selected for the present study from RasaTaranginiUpadhatwadi Taranga 21, Sloka 252[1].

Key words : Switra, Switraghnalepa, Clinical study

I. INTRODUCTION :

Clinical study is the fundamental tool of any medical system and plays vital role in the drug development process. It is the best method to establish efficacy of a drug.In the present day scenario, with the growing awareness on Ayurveda and its treatment, a drug can be authenticated to have therapeutic effects only when it gets pass through clinical trials.Switrais a chronic clinical condition causing not only cosmetic problem butalso exerts a lot of emotional distress. There are number of medicines available for the management of Vitiligo, but the result with the currently available medicaments is unsatisfactory or rather negligible. Hence, with an intention to test the efficacy of Switraghnalepa in Switra, clinical study was carried out. The ingredients of Switraghnalepa are Shuddha Kasisa, Shuddha Dhatturabeejachurnaand ShuddhaGunjabeejachurna.

II. AIMS AND OBJECTIVES :

Reason for Sample selection and Non-randomized open labelled protocol

- To have a sample of patients with Switrawithin predetermined inclusive criteria, purposive/Restricted type of sampling was taken instead of other sampling methods.
- It is a primary level of study carried out at the institution level within limited period of time. To get optimum un-biased result, a clinical study was designed with single group, small sample size of 30 patients.
- A special case sheet was designed with scoring pattern of specific symptoms of Switra to draw conclusions regarding.

Criteria for inclusion of the patients:

- Patient with symptoms of Switrarogaas per Ayurvedicclassics were selected.

Criteria for exclusion of the patients:

- Switradue to Agnidhagdha
- Shvetaroma(hair turned to white colour in Switraaffected area)
- White patches in nose, lips, genital organs, palms, sole.(epithelial surfaces)
- Switrahistory more than 5years.

Posology:

- External application : Switraghnalepa
- Dose : According to size of patch
- Kala : One time (morning time) and exposure to sun
- Duration of treatment : 60 days
- Follow up: don on every 15th day

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Criteria for assessment:

General Observation :

Various demographic parameter viz. Age, Sex, Nature of work etc. along with specific features of Prakriti, Agni, Satva, etc. were analyzed in the present clinical trial.

Assessment :

Criteria of assessment were kept based on relief in the sign and symptoms of Switrabefore and after the treatment. For practical convenience in assessing specific symptoms, a score index was designed. The symptoms were graded from 0 to 3 according to severity of the symptoms.

Table no. 1: Showing the assessment on basis of percentage relief obtained by the therapy

S.No.	Effect	Percentage of relief
1	Marked improvement	76%-100%
2	Moderate improvement	51%-75%
3	Mild improvement	26%-50%
4	No improvement	Less than 25%

Statistical Evaluation of Results:

The obtained information was analysed statistically in terms of mean scores (X),Standard Deviation (S.D.), Standard Error (S.E.). Paired 't' Test was carried out at the level of 0.05, 0.01 and 0.001 of 'P' levels. For the more effectiveness of therapy Paired 't' Test was carried out. The results were interpreted as.

Insignificant = P>0.05

Significant = P<0.05

HighlySignificant = P<0.01, P <0.001

ExtremelySignificant = P <0.0001

Statistical analysis was carried out using "**Analysis tool pack Add-in of Microsoft Excel- 2019"** and **"Graph pad Prism Version -7"** by applying paired 't'-Test

III. OBSERVATIONS :

- Total 35 patients with sign and symptoms of Switrawere registered. Out of them 30 patients completed the course of treatment and 5 patients were dropped out from the course of treatment due to various reasons.
- In the present study, maximum number of patients i.e.12 (40.00%) were between 16-25 years age group, followed by 8 patients (26.66%) between 46-60 years agegroup,06patients(20%)werebetween36-45years and 04 (13.33%) patients were between 26-35 years; maximum number of patients i.e., 16(53.33%) were female and 14 patients (46.6%) were male; 16 (53.33%) were having Mandagni, 09 patients (30.00%) were having Vishamagni and 05 patients (16.66%) were having Samagni;maximum number of patients 26(86.66%) had no family history, while 04 (13.33%) patients were having family history;maximum number of patients i.e., 15 patients (50.00%) had a chronicity of 1-3 years, 09 patients (30.00%) had chronicity of more than 3 years and 06 patients (20.00%) had a chronicity of below 1 year.Twakshwetata was observed in all patients i.e., 100% while the other symptoms such as TwakRukshata, Daha, Kandu were not observed in any patients; 09 patients (30.00%) had patches on upper limbs, 08 patients (26.66%) had patches on lower limbs, 05 patients (16.66%) had patches on middle part of the body, 05 patients (16.66%) had patches in different parts of the body and 03 patients (10.00%) had patches on face; maximum number of patients i.e., 16 (53.33%) had 2-5 patches while 10 patients (33.33%) had more than 5 patches and 4

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patients (13.33%) had single patch.

IV. RESULTS :

SwitraghnalepashowedstatisticallyExtremelysignificantrelief(p<0.0001)inTwakSvetata,Number of patches, Size of patch and Margins

Table No.2. Showing the effect of Switraghnalepaon Subjective and Objective parameters

	n	Mean		Mean Difference	Relief%	SD		SE		T value	P value
		B.T	A.T			B.T	A.T	B.T	A.T		
TwakSvetata	30	3.00	1.00	2.00	66.66%	0.00	0.74	0.00	0.14	14.74	<0.0001
Number of patches	30	2.37	0.90	1.47	63.38%	0.61	0.61	0.11	0.11	9.80	<0.0001
Size of patch	30	2.37	0.87	1.50	63.38%	0.72	0.73	0.13	0.13	11.23	<0.0001
Margins	30	2.63	0.97	1.67	50.63%	0.56	0.72	0.10	0.13	9.18	<0.0001

Table No 3: Overall assessment of clinical trial :

S.No.	Result	Number of Patients	Percentage of Patients
1.	Marked Improvement	10	33.33%
2.	Moderate Improvement	14	46.66%
3.	Mild Improvement	04	13.33%
4.	No Improvement	02	6.66%

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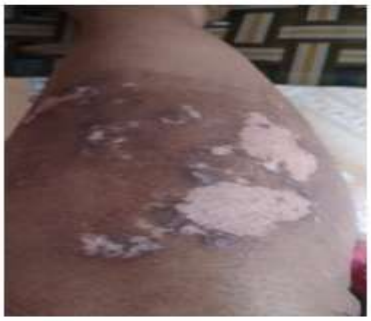
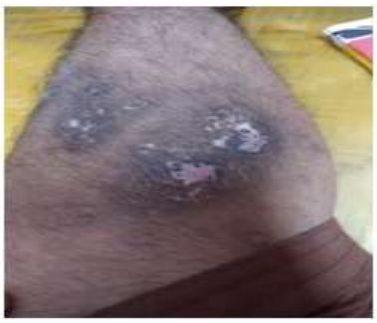
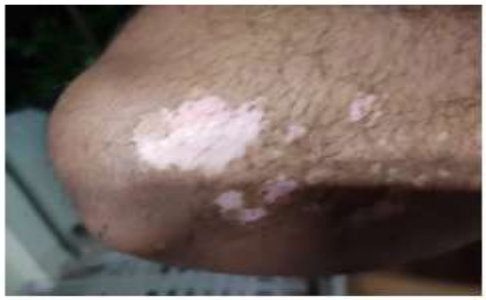
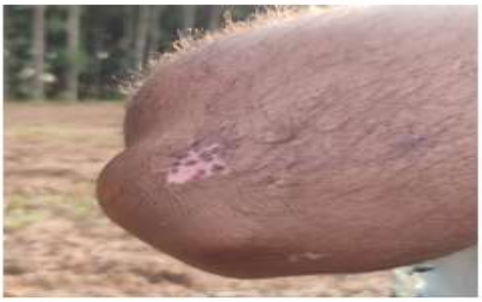


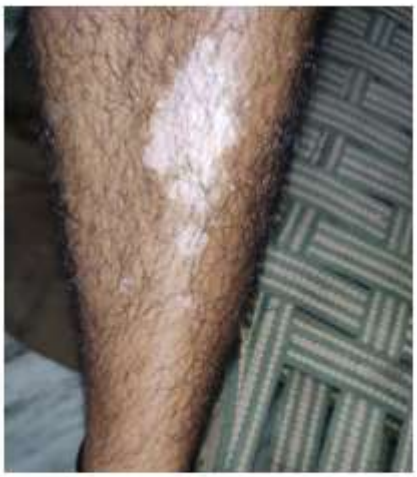


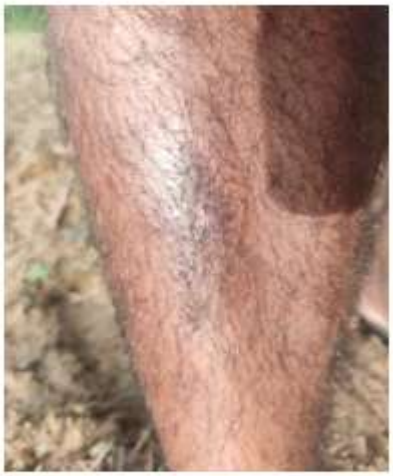
Case 1
Before treatment





Case 2
After treatment





Case 3
Before treatment

Case 3
After treatment

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V. DISCUSSION :

The assessment of the results were made by adopting the standard methods of scoring the signs and symptoms. All the observations regarding the changes in the subjective parameters like TwakShvetataand objective parameters like Number of patches, Size of patch and Margins.

Effect on TwakShvetata : All the 30 patients were having TwakSvetatawith the mean initial score 3.00which was reduced to 1.00 after treatment. The improvement is statisticallyextremely significant (p<0.0001).

Effect on Number of patches : All the 30 patients were having different Number of patches with the meaninitialscoreof2.37whichwasreducedto0.90after thetreatment.Theimprovementisstatisticallyextremelysignificant(P<0.0001).

Effect on Size of patch : Allthe30patients were having different Size of patch, with a mean initial score of2.37which was reduced to 0.87 after the treatment. The improvement is statisticallyextremely significant (P<0.0001).

Effect on Margins : All the 30 patients were having differentMargins, with a mean initial score of 2.63 which was reduced to 0.97 after thetreatment.Theimprovementisstatisticallyextremelysignificant(P<0.0001)

Among 30 patients, 14 patients (46.66%) had moderate improvement, 10 patients (33.33%) had marked improvement, 4 patient (13.33%) had marked improvement and 2 patients had no improvement.

During the course of treatment one patient developed fibrosis of skin which was treated with external application of Mahamarchaditaila.

From this study, it is clear that patients who are treated with Switraghnalepahave favourable response in regards to the clinical parameters of Switra.

Probable mode of action of Switraghnalepa

The action of a compound formulation is decided by the action of a major ingredient or by the synergistic action of all the ingredients. The actions of ingredients of Switraghnalepa are as follows :

TableNo.4 ShowingRasaPanchakaofSwitraghnaLepa

Ingredients	Rasa	Guna	Virya	Vipaka	Karma
Kasisa[2,3,4]	Kashaya	Grahi	Sheeta	Katu	Vata-Kaphahara,Kushtaghna,Switraghna
Gunjabeeja[5,6]	Tikta,Kashaya,	Laghu,RukshaTikshna	Ushna	Katu	Vata-PittaharaKandughnaKushtaghnaVranaropana
Dhatturabeeja[7,8]	Tikta,Kashaya Svadu	GuruRuksha Tikshna	Ushna	Katu	Kaphavatahara,Vishaghna,Kushtahara,KanduharaKrimighna,Varnya

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- Absorption of drugs through body surface deserves special care for its optimum delivery and this can be achieved by Lepakalpana.
- The ingredients of Switraghnalepa are ShuddhaKasisa, ShuddhaDhatturabeejachurnaandShuddhaGunjabee jachurna
- Switraghnalepahas ushnavirya and tikshnaguna which may help the drug to reach deeper layers of the skin, stimulates Bhrajaka pitta and facilitates absorption of the drug aided by exposure to sunrays.

Switraghnalepaworksbyits

- **Hetuprathyanikatva** i.e., - by the specific tridoshahara properties of all the ingredients, Switraghnalepa might be acting against the hetu of the Switra (Pittapradhanatridoshajavyadhi)
- **Vyadhipratyaniatva**i.e., - by theSwitraghna, Kushtaghna, Varnya, Ranjakaproperties of the ingredient, it may be acting againstSwitra

VI. CONCLUSION

Switraghnalepashowed statistically extremely significant relief in Subjective parameters like TwakShvetata and objective parameters like Number of patches, size of patches and margins.The present clinical trial was carried out on a limited number of patients. Hence, an extended study with more clinical parameters and on a large number of patients can be considered to establish the efficacy of the drug.

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