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A COMPARATIVE STUDY TO EVALUATE THE ROLE OF *VIRECHANA* AND *BHRINGRAJADI LEPA* ON *SHWITRA* WITH SPECIAL REFERENCE TO VITILIGO IN CHILDREN

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Abstract : Introdcution: Vitiligo is one such dermatological condition which has been analogues with *Shwitra* in *Ayurveda* literature which is responsible for major cosmetic concern in population. Although *Shwitra* do not produce pain, ulcer or discomfort, but eventually become a cause for an inferiority complex in kids, ending up in totally disturbed social, personnel, psychological and academicals life and at times considered as social stigma. Aim is to evaluate the role of *Bhringrajadi lepa* in diagnosed patient of *Shwitra* and to evaluate the role of *Virechana* in diagnosed patient of *Shwitra* followed by externally apply *Bhringrajadilepa*.Methods: The present study was interventional, open label masking, randomized trial. Total 40 clinically diagnosed patients were selected. Out of them 30 patients completed the study and 10 patients discontinued from the study. Group A were received *Bhringarajadi lepa* as external application with approximate thickness of 0.5-1 cm followed by sun exposure for 15 minutes. Group-B was priory administered with *Samshodhana karma* (*Virechana*) followed by group-A schedule. Follow-up were on every fifteen days for three months. Criteria for assessment after treatment is black spots appearance, colour changes, size changes, changes in VASI grade and photographs of observed white patches. Results: Mean overall result in group A was 50.33% while same in group B was 78.49%. Conclusions: Group B patients administered with *Bhringarajadi lepa* after completion of *Virechana* has shown extremely significance results in comparison to very significance results in group A where only *Bhringarajadi lepa* applied externally.

***IndexTerms - Shwitra, Bhringrajadi lepa, Virudha ahara, Virechana,* Vitiligo..**

I.INTRODUCTION

As the generation passed with changing world, human being also gradually deviated from nature and completely neglected the basic principles of *Ayurveda*, which once a part and parcel of lifestyle. Meanwhile presently existing mechanical lifestyle is one of the worst scenarios ever seen before. Excessive work and desire of earning money with gradual decline in human moral values by sidelining physical, physiological, social, spiritual and moral life has been root cause of many disorders.

Such activities which are antagonist to basic *Ayurveda* principles of life style when practiced for a longtime and generation to generation resulted in certain unknown changes in cellular and genetic level resulting in genetic mutations, autoimmune disorders etc., which destabilize the society and cause qualitative decline of the society. Such disorders will be unsolved challenge for future generation as well as cure is impossible, although we know the cause. Moreover, genetic disorders pass on to next generation by decreasing quality of life.

Human being is always conscious about his/her looks, personality and beauty as it gives personal identity and attraction in the society. Cosmetic concern of the human being is obvious has he wanted to present himself in a better way in the society. Skin is one such tissue of the body which is of major cosmetic concern. Hypo or hyper pigmentation of the skin is always major cause for psycho and social withdrawal in human beings.

Recently rapidly increasing incidences of *Shwitra* is a challenge for medical world. Vitiligo is the pigmentary disorder of certain hereditary and acquired autoimmune causes and characterized by de-pigmented or hypo-pigmented patches those results from absence or depleted melanocytes. Pathogenesis of vitiligo points towards autoimmune hypothesis [1] and disease may start at any age with increased incidences in first and second decade of life. Based on some dermatological out patient records the incidences are roughly estimated to be between 3-4% in India. However vitiligo affects the estimated 1-2% of world population which is quite significant. [2]

Meanwhile any causes which disturbs the color of skin is called as *Kushta* in *Ayurveda*. *Shwitra* is considered amongst the varieties of *kustha* in Ayurveda classics [3]. There will be vitiation of *Dhatu* like *Rasa, Rakta, Mamsa, Meda*[4] *Tridosha* in this disease. Meanwhile depending upon the duration of the disease and the involvement of *Dhatus*, the disease becomes prognostically bad. However it has been also considered under the *Raktapradoshajavikara* [5].

2. Materials and Methods

Study design- This study is an interventional, randomized, open label, prospective parallel group clinical trial with only *Ayurveda* drugs intervention. Before starting this study, permission was obtained from the IEC of the XXX institute. CTRI Registration: This study was registered in Clinical Trial Registry India on XXX. Randomization plan: Http://www.randomization.com created on 12.07.2022 at 09:52:50 am.

Collection and preparation of medicine: The ingredients of *Bhringarajadi lepa*[6] were collected from the shop-XXX and invoice number 1415/19 may 2022 only collection of *Bhringaraja panchanga*, *Harada phala tvak* and rest medicine collected from XXX. The medicine *Shantivardhaka churna*,[7]Moorchita *goghrita*,[8] *Narikela taila*,[9] *Trivritta avaleha*,[10] *Bhringarajadi lepa* and *Kanji* [11] for the purpose of the study all above prepared in the XXX pharmacy [Table 1] as per *Ayurveda* classical references.

Standardization of medicine: Standradization of herbal drugs means confirmation of their identity, quality and purity. According to Ayurvedic Pharmacopia general guidelines for drug development of *Ayurveda* formulation standardization of *Bhringrajadichurna* [Table 2] includes physicochemical assessment was done in the department of *Rasa shastra* and *Bhaisjya kalpana*.

Selection of Patients

Initially, 40 cases of children suffering from *Shwitra* (Vitiligo) were registered from O.P.D of *Kaumarbhritya*/Balroga, XXX. The Randomization done by Http://www.randomization.com was used to allocate children of *Shwitra* into trial & control groups. Out of these only 30 children completed their regular follow-ups therefore, the rest 10 cases were dropout from the study. The children registered in the clinical study, were minors, means below 12 years so written informed consent from the parents and informed assent from children was taken before study enrolment. All registered cases were divided randomly into two groups as per inclusion and exclusion criteria.

Criteria for inclusion

Age between 5-15 years, children diagnosed as *Shwitra* as per clinical features mentioned in Ayurveda.

Criteria for exclusion

Children with Albinism, white anaesthetic spots, which are characteristic of leprosy, old refractory cases not responding after extensive use of modern medicine, patches in genital and lip, vitiligo patches complicated by eczema were excluded.

Screening method

Based on *Ayurveda* text, predesigned proforma, cases were examined thoroughly under the headings like chief complaints with duration, history of present and past illness, personal history, physical and systemic examination.

Table 1: Ingredients of *Bhringrajadi churna*

Ingredients	Botanical name	Part used	Ratio
Bhringraja	Eclipta alba	Whole plant	1 parts
Haritaki	Terminalia chebula	Dried fruit	1 parts
Puskarmula	Inula racemosa	Dried rhizome	1 parts

Table 2: Physiochemical assessment of *Bhringrajadi churna*

Parameters	**Before *Putapaka***	**After *Putapaka***
Loss on drying at 105ºF	6.86% w/w	4.28% w/w
pH (5% aqueous solution)	4.78	4.73
Total ash	7.58% w/w	15.74% w/w
Acid –insoluble ash	1.20% w/w	13.67% w/w
Alcohol-soluble extractive	23.87% w/w	25.66% w/w
Water soluble extractive	39.42% w/w	38.58% w/w
Particle size (#80)	36.15% w/w	84.53% w/w

Intervention

Patients of group A were advised to apply the *Bhringarajadi lepa* daily in the morning with *Kanji*, advised to expose the patches to sun light for 15-20 minutes in the morning (7-9 am). All patients of group B were administered the drugs as follows-
1. *Shantivardhaka churna* in a dose of 100mg/Kg/day body wt. twice daily with *Ushnodaka* as *Anupana* was administered before food for three to four days prior to *Snehapana* for *Deepana* of *Agni* and *Pachana* of any existing *Ama*.
2. *Abhyantara snehapana* starting from 15-30 ml per day with *Moorchita goghruta* by increasing it by another 15-30 ml (depend upon *Snehajirna lakshana*) per day until the appearance of *Kosta snigdha lakshana* as evidenced from oily and loose stools.
3. *Abhyanga* was then carried out with *Narikela taila* daily followed by *Sarvanga mridu nadi swedana* (for five minutes) for three days.
4. Approximate 15-20 gram of *Trivritta avaleha* was then administered with lukewarm water on fourth day after *Abhyanga* and *swedan in the morning in the empty stomach*

A watch was made for *Kostha sudhi* by observing the number of stools till after noon. After *Samsarjana karma* this patients of group B were advised to apply the *Bhringarajadi lepa* with *Kanji* in the morning (7-9 am) daily for 15-20 minutes on *Shwitra*.

Followup- The total duration of study six months (90 days) for patients were followed-up on every fifteen days.

Scoring system for the assessment of disease status

A standard grading system was developed to assess the improvement in treated cases based on symptomology (black spots, colour, size, VASI grade changes) of the *Shwitra* (Table 3,4,5,6) and Photography recorded periodically before and after treatment

Table 3: Showing grading for No. of black spots for observed patches

In observed patches grading for No. of black spots	**Score**
Absence of a black spot	3
The appearance of 1-2 black spots	2
The appearance of 3-5 black spots	1
The appearance of more than five black spots	0

Table 4: Showing grading for colour change the observed patches

Grading the observed patch for color change	**Score**
No color shift (white spot)	3
The patch's color shifts to a little reddish hue (pinkish)	2
The patches shifts to black color	1
Normal skin color appears in the patch	0

Table 5: Showing grading for size of the observed patches

Grading for size of the observed patch	**Score**
If size increases	3
If size same	2
10% reducing size	1
More than 10% reducing size	0

Table 6: Showing grading for VASI scale of the observed patches

VASI Score	**Grading**
0%-0.24%	0
0.25% -1.50%	1
1.51% -3.00%	2
3.01% -4.50%	3
4.51% -6.00%	4
6.01% -7.50%	5

3. Method of statistical analysis

The clinical study was statistically analysed with graph pad prism version 10.0.2(232) after the treatment for the effect of clinical features. Results of effect on clinical features by using non parametric test Wilcoxon matched signed rank test for intragroup comparison and intergroup comparison by Mann-Whitney test. The result were interpreted as Non-significant ($P > 0.05$), significant ($P<0.05$), very significant ($P<0.01$, $P<0.001$), extremely significant ($P<0.0001$).

4. Observations

Observations were cumulative of both group as 5-10 years age group was the most (56.66 %max.) affected group, female (53.33 %max.) were more prone as compared to male (46.66 %), number of cases was belonging to urban area (76.66 %), Hindu religion (76.66 %), vegetarian diet (66.66 %), spicy-oily food (40 %), lower middle socio- economic status (36.66 %), maximum male (7 %) patients dropout due to other therapy treatment (40.00 %), numbers of cases exhibited chronicity of more than 1 year (50 %), no positive family history of vitiligo (90 %), patients of trial were *Vata-pitta Sharirika prakriti* (46.66 %), *Satva-tama manasika prakriti* (50 %) *mandagni* (50 %) , *Mridu kostha* (46.66 %), *Madhyama satva* (40 %), *Ahara-shakti* (46.66 %), *Vyayama-shakati* (43.33 %) , *Jangala-desha* (83.33 %), *Katu-amla rasa* (73.33 %), fast-food1-4 times/week (56.66 %), *Virudha-ahara* habit (56.66 %), *Krisha-aakriti*, *Ruksha-sparsha*, *Samanya-drika*, *Nirama mala* (53.33 %) and *Jivha* (53.3 %). Maximum patients of trial were immunized and earlier allopathic treatment history present. Maximum patients were found with no black spot in observed patches (70 %), negative koebner phenomenon (76.66 %), first white patch appears on face (46.66 %) and lower limb (36.66 %) in segmental pattern (53.33 %). Maximum patients were found with white colour patches (63.33 %) with maximum 1-10 Patches (50 %). Maximum patients were found with 5-10 square cm size of patches (53.33) with VASI grade-1st in 43.33 %patients (A-46.66 B-40 %) Maximum

patients were found fist effect of *Lepa* 31-45 days (50 **%**) with pinkish colour appears on white patches in maximum patients (60 **%**).

5. Results

The effect of therapy in both the groups showing in table 7, 8.

Table 7: Showing effect of therapy on group-A (Wilcoxon matched-pairs signed rank test, n=15)

Signs of patch	Group	Mean		Mean diff. ±	Diff. %	S. D.	S. E.	P value	Interference
		B.T.	A.T.						
No. of black spots	A	2.467	0.800	1.666	67.53%	0.975	0.252	0.0002	Extremely significant
	B	2.533	0.400	2.333	92.10%	1.060	0.273	0.0001	Extremely significant
Color changes	A	2.733	1.733	1.0	36.58%	0.755	0.195	0.0005	Extremely significant
	B	2.533	0.533	2.0	78.95%	0.925	0.239	0.0001	Extremely significant
Size changes	A	1.467	0.667	0.666	45.39%	0.560	0.144	0.0010	Very significant
	B	1.733	0.333	1.4	80.78%	0.632	0.163	0.0001	Extremely significant
VASI grade	A	1.800	0.866	0.933	51.83%	0.798	0.206	0.0010	Very significant
	B	2.467	0.933	1.533	62.14%	1.407	0.363	0.001	Very significant

Table 8: Showing effect of therapy on group B (Wilcoxon matched-pairs signed rank test, N=15)

Signs of patches	Mean		Mean diff. ±	Diff. %	S. D.	S. E.	P value	Interference
	B.T.	A.T.						
No. of black spots	2.533	0.400	2.333	92.10%	1.060	0.273	0.0001	Extremely Significance
Color changes	2.533	0.533	2.0	78.95%	0.925	0.239	0.0001	Extremely Significance
Size changes	1.733	0.333	1.4	80.78%	0.632	0.163	0.0001	Extremely Significance
VASI grade	2.467	0.933	1.533	62.14%	1.407	0.363	0.001	Very Significance

S.D.-Significance difference S.E.-Standard error B.T.-Before treatment. A.T.-After treatment

Intergroup Comparison

To analyse the effect of two therapies intergroup comparison was done, we used non-parametric Mann Whitney test for statistically analysis (Table 9, 10, 11 and 12).

Table 9: Showing intergroup comparison of group A & B in results of black spots in observed patches (Mann Whitney Test)

Group	Mean	S. D.	S. E.	U	P value	Interference
A	0.8000	0.9411	0.2430	83.50	0.1983	Non-Significance.
B	0.4000	0.7368	0.1902			

Table 10: Showing intergroup comparison of group A & B in results of colour changes in observed patches (Mann Whitney Test)

Group	Mean	S. D.	S. E.	U	P value	Interference
A	1.7333	0.5936	0.1533	36	0.0006	Extremely Significant
B	0.5333	0.8338	0.2153			

Table 11: Showing intergroup comparison of group A & B in results of decrease in size in observed patches (Mann Whitney Test)

Group	Mean	S. D.	S. E.	U	P value	Interference
A	0.6667	0.8165	0.2108	90	0.3309	Non-Significance
B	0.3333	0.4880	0.1260			

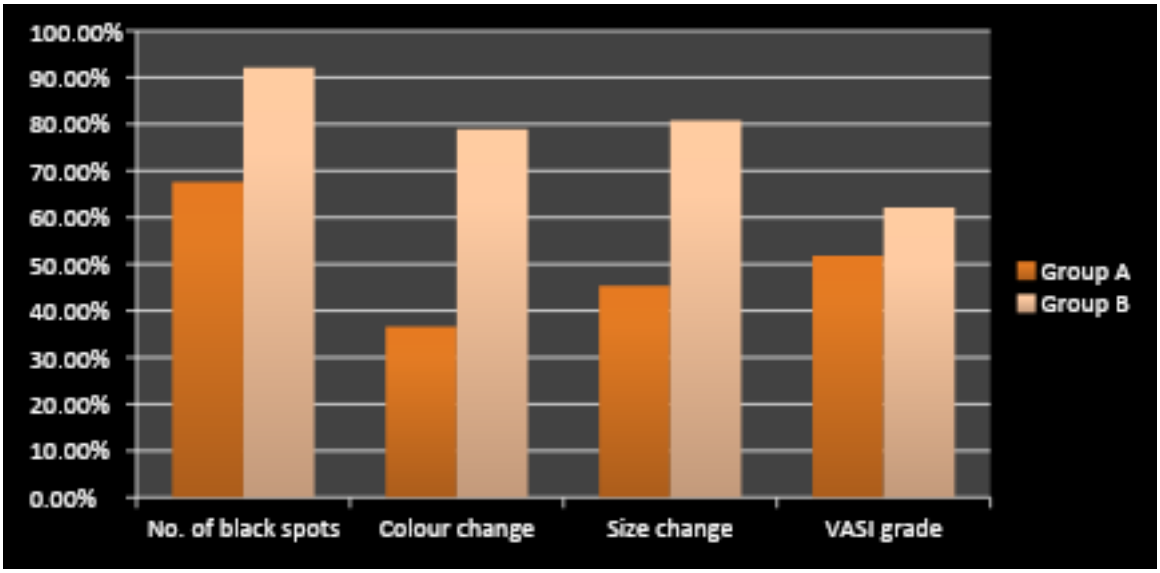
Table 12: Showing intergroup comparison of group A & B in results of change in VASI grade in observed patches (Mann Whitney Test)

Group	Mean	S. D.	S. E.	U	P value	Interference
A	0.8667	0.7432	0.1919	105.5	0.7351	Non-Significance
B	0.9333	0.5936	0.1533			

Subjective parameter: Comparison between group A and B (Table 13 and Graph 1)

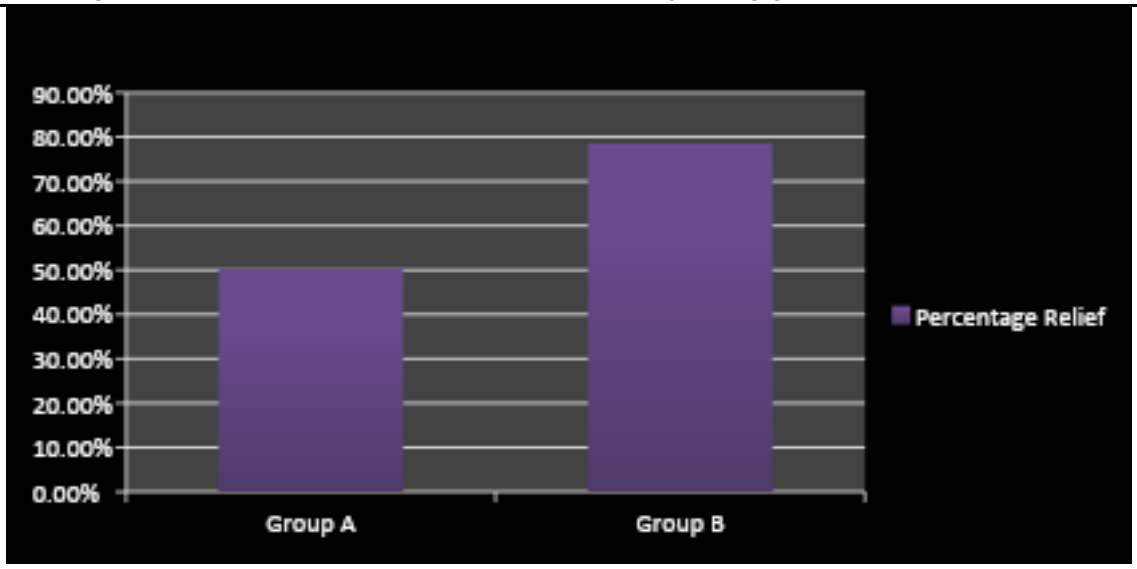
Table 13: Showing effect of therapy in term of percentage relief- subjective parameter

Subjective parameter	% Relief	
	Group A	Group B
No. of black spots in observed patches	67.53%	92.10%
Color changes in observed patches	36.58%	78.95%
Size changes in observed patches	45.39%	80.78%
VASI grade in observed patches	51.83%	62.14%



Graph 1 Showing effect of therapy in terms of percentage relief.

Overall effect of therapy: Mean overall result in group A was 50.33% while same in group B was 78.49%. This proves that group B patients administered with *Bhringarajadi lepa* after completion of *Virechana* has shown extremely significance results in comparison to very significance results in group A where only *Bhringarajadi lepa* applied externally (Graph 2).



Graph 2 Showing overall effect of therapy in both groups.

6. Discussion

Demographic profile: The most common age for appearance of vitiligo patches will be around 5-10 years but onset of vitiligo could be possible at any age although more common in childhood[12]. There are no known racial and gender variations in the prevalence of vitiligo[13] but higher number of female children in the present study is also supported by study conducted by Chauhan PS et al. 2020 Oct.[14] Dominancy of Hindu population in present study. However, a study conducted by Khiangte et al. 2023[15] supported that higher incidence of vitiligo disease in Hindu as compare to other religion. Higher level of faulty lifestyle, faulty food habits in urban area due to mechanical life style might have been resulted in above observation[16]. Usually deficiency of phenylalanine amino acids in the vegetarian diet may causes acquired vitiligo. However phenylalanine plays a significant role in pathology of vitiligo as it is an amino acid and precursor of melanin. Moreover, study conducted by Serena Gianfldoni et.al[17] also supported the same. Rare cause of vitiligo is positive family history. However, a study supporting positive family history by Spritz RA et al. 2017[18] in manifestation of vitiligo also suggests the same[19].

Constitutional profile: *Mridu kostha* indicates the dominancy of *kaphapitta dosha* and the childhood period is also *Kapha dominancy* and spicy food habbits (*Pittaja ahara*). *Shwitra* is a disease with *Kpaha pradhan tridosha*[20] with involvement of *Bhrajaka pitta*.

Ayurveda explains spicy and oily foods one known to vitiate *Pitta dosha* leading to further vitiation of the *Bhrajaka Pitta* ending up in *Shwitra* and same is reflected in the present study[21]. *Sara* of every person probably decided at the time of *Shukra-shonita samyoga* but it can be altered and modified due to abnormal *Ahara* and *Vihara*. The *nidana* of *Kustha roga* can also detoriate the *Tvakasarata* leading to *Shwitra*[22]. Absence or inadequate *Vyayama shakti* causes *Santarpana* which further leads to *Santarpanotha vyadhi*[23] like *Shwitra*. High incidence of patients belonging to *Jangala desha*[24-27]. A survey also supports conducted by The Economic Times 2023[28]. *Katu* and *Amla rasa* dominace foods vitiate *Pitta Dosha* leading to further vitiation of the *Brajaka Pitta* ending up in *Shwitra* and same has been reflected in the present study[29]. Packed foods are type of *virudha ahara* which triggers the immune system upon its continuous intake in larger quantity which further disturbs the melanogenesis. However multiple studies suggest role of Antioxidant-rich (deficient in fast/junk/packed) foods in preventing cellular damage and limiting inflammation[30]. Present clinical study shows high incidence of patients indulging in *Virudha ahara*[31] and same has been also supported by Robins et al.[32] theory of autoimmune cause of vitiligo.

Incidence of Clinical profile: The incidence of Koebner phenomenon has been reported as occurring high in the patients of nonsegmental vitiligo but in the A.J.Kanwar et. al. 2013 study shows maximum patients related to segmental vitiligo[33]. High incidence of face as first part of white patch appearance than lower limb and upper limb and in minimum cases it is trunk area. Study conducted by Aamir habib et al. 2012[34] also suggests the same. A study by Juliette Mazereeuw-Hautier et al. 2012[35] suggest that compared with segmental vitiligo, nonsegmental vitiligo was associated with a higher number of lesions. Present clinical study suggesting high incidence of *Shwitra* is first grade VASI before treatment. Present study suggesting that maximum participants had 31-45 days of first effect of *Lepa* was pink colour appearance.

Mode of action of *Bhringarajadi lepa* in the current study

Altering the pH of the nearby skin area: *Ushna virya* and *Katu vipaka* property of drugs when administered locally over affected patches of skin serve to change the local pH of the skin patches through a variety of methods, facilitating *Mamsadhara kala* absorption of the medication. Maintaining the skin pH by *Kanji* facilates easy absorption of drugs. This probably acts by rising *Twak gata agni*, which in turn stimulates the melanocytes secreting cells, this also aids in enhancing the local *Bhrajaka Pitta*.

Action by Increasing the Circulation of Local Capillary Blood: Trial drug have *Ushana* and *Teekshna* properties, as well as *Katu rasa* and *Katu vipaka* properties, which aid to raise the *Pitta dosha*. *Pitta* and *Rakta* which always exist in the *Ashraya-asrayi bhava*. Hence raising *Pitta* also increases *Rakta* to move to the affected patches. The enhanced blood flow to the hypopigmented

area transports the necessary micronutrients and amino acids required for the synthesis of melanin. A study conducted by Chen SZ et al 2005 and Khushboo et al. 2013[36] also supported.

Action of the trail drug by its irritant nature over the skin: The drug ability to cause localised irritation is further reinforced by Anuradha Pathak et al. 2018[37] research showing that its *Ushna-teekshna* characteristics promote *Bhrajaka pitta*, which enhances melanogenesis.

Action by stimulation of sensory receptors of the skin: Trial drugs contain *Vatavardhaka guna* and increased *Vata* stimulates the hormonal axis of the melanaocyte stimulating hormones, which mediates through the central nervous system, in addition to the local sensory receptors. By way of *Sarva daihika* effects of *Vata* it stimulates skin pigmentation. This viewpoint is also supported by research conducted on same by Pharmaceutico-Analytical study of *Bhringaraja* oil and its Conversion into Lotion supported by Mishra et al. 2004 study[38].

Action by *Rasayana* property of trial drug by inducing the Anti-oxidant property: *Rasayana* properties of the herbs *Bhringaraja*, *Haritaki*, *Pushkaramula* and *Kanji* are known to counteract oxidative alterations and hasten the recovery of the disease. A study J.N.Govil et al. 2017[39] further supports this anti-oxidant potential. Utilising multiple assays, the antioxidant activity of Eclipta Alba. The methanol and hydrolyzed extract of Eclipta Alba Hassk has been assessed for its antioxidant potential in both in vitro and ex vivo models. The in vitro antioxidant activity was evaluated through 2, 2-diphenyl-1-picrylhydrazyl (DPPH) free radical scavenging and nitric oxide radical inhibition activity supported study by G. Kaur et al.2009 and Sindhu et al 2014[40,41].

Effect of sunlight to nourish *Bhrajaka pitta*: *Pitta* in the form of *Agni* that is found in the body. *Bhrajaka* variety of *Pitta*, which is present in the skin, is deficient in *Shwitra*. According to *Samanya vishesha siddhanata* by consuming *Samana guna*, *Karma*, and *Dravyas* can raise Agni or Pitta in the body. As a result, when patients were exposed to sunlight, which symbolizes the *Tejo mahabhuta*, enhances Agni of body. Furthermore, studies have shown that UVA and NBUVB (narrow band UVB) are both effective melanocyte stimulants for depigmentation. Additionally, UV light has an immunosuppressive impact on skin with vitiligo while at the same time increasing the number of remaining melanocytes and having the desirable consequences[42]. Facultative skin color characterizes the increase in melanin pigmentation above the constitutive level and arises from the complex interplay of solar radiation and hormones upon the genetically endowed melanogenesis of the individual and a study Pathak *et al*.1976 supported relation between sunlight and melanin pigmentation[43].

Implication of the study:

It has been evaluated that along with antioxidant, antimicrobial and melanin pigment resynthesize inducer activity of "*Bhringarajadi churna* with *Kanji*" play a key role in future therapies of hypopigmentation. The trial drug is safe and effective in treatment of vitiligo by reducing drug resistance.

Limitation of the study:

It was difficult to cure all types of hypopigmentation disorder completely by using only local application of single drug. The trial drug *Bhringarajadi lepa* with *Kanji* also have limitation to treat hypopigmentaion patches with koebner phenomenon completely. However In the present study the sample size was very small only 30 patients and the duration of trail is also very short. As *Shwitra* runs in chronic course it necessitates long duration treatment. Hence advanced study with longer sample size has been recommended to draw the final conclusion. This clinical study gives idea of conjoint use of *Samshodhana* therapy followed by oral drugs and local application of *Lepa*.

7.Conclusion

However patients administered with *Samshodhana Karma* in the form of *Virechana* prior to *Bhringarajadi lepa* has showed extremely significant results on reducing size and hypopigmentaion of Vitiligo patches or *Shwitra*. Nevertheless, intergroup comparison shows significant results in effect of therapy in group B compared to group A on normalizing the skin pigmentation and fast reduction in the size of white patches.

8. Acknowledgement

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10.Conflicts of interest

There are no conflicts of interest

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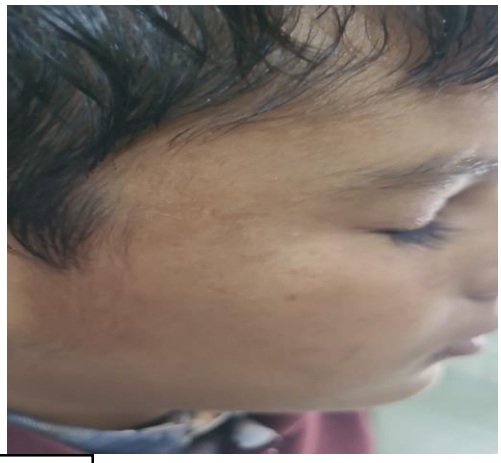
Group-A

Before Treatment

Registration No.33202200049678

After Treatment



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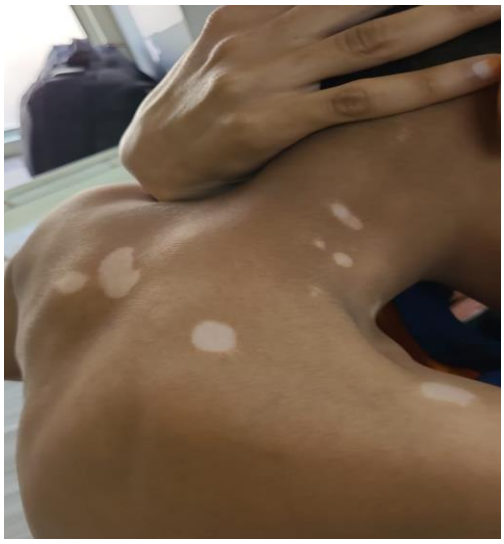

Group-B

Before Treatment

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After Treatment

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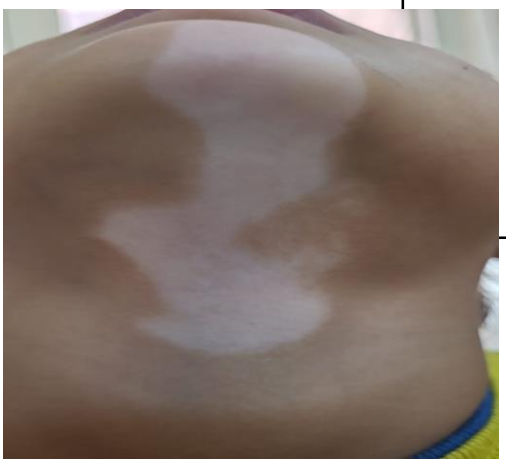

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