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Clinical Study to Evaluate the Efficacy of *Varnyamahakashay* Drugs (*Manjistha, Sariva, Ushir, Yastimadhu* and *Chandan*) in the Management of *Vyanga Roga*

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ABSTRACT

Vyanga is one of the *pitta pradhan, raktadhatu pradoshajajanya kshudraroga*. It is described by *Acharya Sushruta* as *niruja* (painless), *Tanu* (thin), *shyavavarnayukta mandala* (bluish black patches) on the face which can be compared with melasma characterised by dark brownish maculae with irregular contour, especially on the face, forehead, temples and more rarely on the nose, eyelids, chin and upper limbs. It is commonly seen in females than in males.

Vyanga, though painless considerably affects a person's psychological and social wellbeing contributing to lower productivity and self-esteem.

The specific treatment in *Ayurveda* is for the treatment of *pitta* and its proper elimination, which cures the disease at its roots. The trend of using herbs in the field of cosmetology is increasing world-wide. A clinical trial was conducted with a formulation of few *Varnya Mahakashaya* herbs in Govt. Ayurvedic College and Hospital, Guwahati, Assam. The results were highly encouraging.

KEYWORDS

Vyanga, Varnya Mahakashaya, Melasma

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INTRODUCTION

"Beauty is skin-deep", goes an old saying. Skin and beauty are inter-related. A healthy and beautiful skin indicates general health and fitness of a person.

In *Ayurveda*, the skin diseases are described under *Kustha roga* and *Kshudra rogas*. The word *Kshudra* means *swalpa* or small / minor and *Roga* means disease. Thus, *Kshudraroga* refer to small / minor diseases. They are named so because; their *Nidan* (etiology), *Lakshanas* (clinical features) and *Chikitsa* (treatment) are described in *Kshudra* i.e., in short or brief[1].

Vyanga is one of the *pitta pradhan, Rakta dhatu pradoshajajanya Kshudra roga.* It is described by *Acharya Sushruta* as *niruja* (painless), *Tanu* (thin), *shyavavarnayukta mandala* (bluish black patches)[2] on the face which can be compared with Melasma characterised by dark brownish maculae with irregular contour, especially on the face, forehead, temples and more rarely on the nose, eyelids, chin and upper limbs.

There is no satisfactory treatment for *Vyanga* (melasma) and frequent exacerbation and re-missions are common. The trend of using herb in the field of cosmetology is increasing world-wide. The effective treatments for melasma are still under research at various levels.

Varnya Mahakashaya Gana as mentioned in *Charaka Samhita* constitutes of ten drugs i. e, *Chandan, Punnaga, Padmaka, Ushira, Madhuka, Manjistha, Sariva, Payasya, Sita, and Lata*[3].

Out of these ten drugs, five drugs were selected for the present study namely,

1. Manjistha[4,5] (*Rubia cordifolia)* which contains glucosides known as Manjisthin and Purpurine, along with resins, lime salts and colouring agents. Methanolic extract of this herb has been reported inhibition of tyrosinase activity thereby acting as skin whitening agent[6].

2. Sariva[7,8] (*Indian sarsaparilla*) **:** Methanolic extract of its root has been reported to show tyrosinase inhibitory activity when assayed using l-DOPA as the substrate[9].

3. Madhuka[10,11] (*Glycyrrhiza glabra)*: Glycyrrhizetic acid present in madhuka controls the secretion of melanin in skin and it has the effect of reducing dark pigmentation and making the complexion fairer. Methanolic extract of its rhizome has been reported to be a potent tyrosinase inhibitor [12].

4. Ushira[13, 14] (*Vetiveria zizanioides*): Essential oil (VZ-EO) suppresses the β-MSH-induced melanogenesis thereby

decreasing melanin production through tyrosinase inactivation [15].

5. Sweta Chandan[16,17] (*Santalum album*): α-santalol, the major constituent of the sandalwood oil, is a potent inhibitor of tyrosinase (IC50 = 171 µg/mL) as compared to kojic acid and arbutin (IC50 – 149 ug/ml) showing potential for melasma[18].

AIMS AND OBJECTIVES

❖ Assessment of the selected drugs of Varnya Mahakashaya (Manjistha, Sariva, Ushira, Madhuka and Chandan) in the management of disease Vyanga.

MATERIALS AND METHODS

A comparative clinical trial was conducted on 3 heterogeneous groups namely A, B & C, Where A represents 30 sample size who were administered with *Varnya Ghana Vati*, B represents 30 sample size who were administered with *Varnya* Ointment and C represents 30 sample size who were administered with *Varnya Ghana Vati* and Ointment.

Source of data:

Patients attending the OPD and IPD of Kayachikitsa Department of the Govt. Ayurvedic College and Hospital, Jalukbari, Guwahati-14, Assam were selected for the study.

Method of collection of data:

The cases fulfilling the inclusion criteria of *Vyanga* (Melasma) were selected, regardless of their sex, socio-economic considerations etc. The clinical history was recorded with the help of special proforma prepared for this purpose. The study followed a purposive and snowball sampling technique. A detailed history was taken with reference to the age of onset, evolution of the disease process, seasonal variation, exposure to sunlight or UVR, topical applications, family history of similar type etc. Emphasis was laid on the distribution, colour, size, and the area of involvement, margin and the pattern of the lesions.

Sample size:

A total of 120 cases were registered for the study out of which 90 patients completed the total observational follow-up programme. These 90 patients were divided into three groups as Group A, B and C each comprising of 30 patients.

Groups	Treatment given
Group A (n=30)	*Varnya ghana vati*
Group B (n=30)	*Varnya* Ointment
Group C (n=30)	*Varnya ghana vati* & Ointment

Study design:

Comparative clinical trial.

Inclusion criteria:

Patients presenting with signs and symptoms of vyanga irrespective of sex, socio-economic considerations etc. with the age group between 14-50 years.

Exclusion criteria:

1. Age less than 14 years and more than 50 years.
2. Hyperpigmentation caused since birth like nevus, tumour like malignant melanoma.
3. Vyanga along with other skin diseases.
4. Patients suffering from other systemic disorders like CRF, endocrine system related disorders and hepatic disorders.
5. Pregnant women and lactating mother.

Investigations:

Blood for T.C, DLC, ESR, Hb%, AEC.

Criteria for assessment of results:

The improvement provided by therapy was assessed on the basis of signs and symptoms & assigned score depending upon their severity to assess the effect of the drugs. The details of which are: `

- The colour /darkness graded from 0 to 4:

0	Absent
1	Slight/barely visible hyperpigmentation
2	Mild hyperpigmentation
3	Moderate hyperpigmentation
4	Marked hyperpigmentation

- The size/homogeneity of pigmentation is graded from 0 to 4:

0	Absent (normal skin colour, no hyperpigmentation
1	Specks of involvement
2	Mild (small patches <1.5cm diameter
3	Marked (patches of hyperpigmentation >2cm diameter)
4	Uniform skin involvement without any clear areas

- The area of involvement is graded from 0 to 6:

0	No involvement
1	Less than 10% involvement
2	10% to 29% involvement
3	30% to 49% involvement
4	50% to 69% involvement
5	70% to 89% involvement
6	90% to 100% involvement

- The assessments were done on the measurement in 4 areas

a. (F) forehead which accounts for 30% of the score,

b. (RMR) right and (LMR) left molar region which each account for 30% of the score,

c. (M) chin which accounts for 10% of the score.

- *Kandu* or itching is graded from 0 to 3:

0	Absent
1	Mild (does not disturb routine work)
2	Moderate (Frequent itching, disturbs normal activity but not sleep.)
3	Severe (disturbs both routine and sleep)

- *Daha* or burning sensation is graded from 0 to 3:

0	Absent
1	Mild (occasional, sensation mostly when exposed to sun)
2	Moderate (frequent burning sensation, increases when exposed to the sun)
3	Severe (Continuous burning irrelevant of sun exposure)

- *Rukshata* or dryness is graded from 0 to 3:

0	Absent
1	Mild
2	Moderate (stretching of the skin that a person feels)
3	Severe (Visible dryness, chapping of the skin, hardness of the skin)

Dose:

Oral: Ghana vati of selected drugs, 1gm in divided dose.

Local application: Ointment prepared from the selected drugs twice a day.

Duration of the treatment: 60days.

Follow up: A total of three follow-ups were done at an interval of 20 days.

RESULTS AND DISCUSSION

The data obtained were analysed using appropriate statistical tools such as Frequency distribution, Arithmetic mean, percentages, standard deviation paired t-test and one way ANOVA test using SPSS and Graph pad prism.

Results of the therapeutic trial:

Table 1: Paired t- test for Group A (*Varnya Ghana Vati*)

		Paired Differences		T	df	Sig.(2-tailed)
		Mean	SD			
Pair 1	Colour (BT –AT)	.367	.556	3.612	29	.001
Pair 2	Size (BT –AT)	.300	.466	3.525	29	.001
Pair 3	Area (BT –AT)	.300	.466	3.525	29	.001
Pair 4	Itching (BT –AT)	.333	.547	3.340	29	.002
Pair 5	Dryness (BT –AT)	.200	.407	2.693	29	.012
Pair 6	Burning sensation (BT –AT)	.233	.430	2.971	29	.006

Comment: -

The calculated t values were highly significant. From the above chart it appears that the mean difference is more in case of colour (before and after treatment) i.e., 0.367 and t value is 3.612 and p value is <

0.001 (Table-1). Hence, Group A is more effective in reducing the colour T (table-1).

Table 2 :-Paired t test value for GROUP-B (*Varnya* ointment)

		Paired Differences		T	df	P
		Mean	SD			
Pair 1	Colour (BT –AT)	.633	.615	5.641	29	<.001
Pair 2	Size (BT –AT)	.433	.568	4.176	29	<.001
Pair 3	Area(BT –AT)	.433	.568	4.176	29	<.001
Pair 4	Itching (BT –AT)	.533	.507	5.757	29	<.001
Pair 5	Dryness(BT –AT)	.300	.466	3.525	29	<.01
Pair 6	Burning sensation (BT –AT)	.333	.606	3.010	29	<.01

Comments:-

From the above chart it appeared that the calculated t values were highly significant (t <0.001) so the treatment administered in Group B was effective in reducing all the assessment parameters. The mean difference is more in case of itching (before and after treatment) i.e., 0.533. The 't' value is 5.757 and p value is < 0.001 (Table-2). Hence, reduction in itching sensation or *kandu* was more evident in Group B.

Table 3 - Paired t test Table for GROUP-C (*Varnya Ghana Vati* + *Varnya* Ointment):

		Paired Differences		T	Df	Sig. (2-tailed)
		Mean	Std. Deviation			
Pair 1	Colour (BT –AT)	.933	.640	7.992	29	.000
Pair 2	Size (BT –AT)	.700	.651	5.887	29	.000
Pair 3	Area(BT –AT)	.600	.621	5.288	29	.000
Pair 4	Itching (BT –AT)	.800	.664	6.595	29	.000
Pair 5	Dryness(BT –AT)	.567	.568	5.461	29	.000
Pair 6	Burning sensation (BT –AT)	.500	.509	5.385	29	.000

Comments:-

Paired t tests for all the assessment criteria were highly significant. From the above chart it appears that the mean difference is more in case of colour (before and after treatment) i.e.,, 0.933, 't' value is 7.992 and p value is < 0.001 (Table-3). Hence, Group C is more significant in reducing the colour.

ANOVA TEST INTERPRETATION

Table 4 Colour/darkness of the lesion

Sl	Source	Df	SS	MS	F	P-value
1	Treatments	2	4.822	2.411	6.6593	0.0020
2	Error	87	31.500	0.362		
	Total	89	36.322			

Comments: The calculated F value is 6.66 and P= 0.0020 i.e., P≤0.001 (Table-4). F value is significant. So, there is significant difference between the three groups. Mean

severity score of group C is more than group B & group A. So, group C is more effective in terms of reducing the colour of the lesions.

Table 5 Size/homogeneity of lesions

Sl	Source	Df	SS	MS	F	P-value
1	Treatments	2	2.489	1.44	3.8713	0.0245
2	Error	87	27.967	0.321		
	Total	89	30.456			

Comments: The calculated F value is 3.87 and P=0.0245 i.e., P≤0.05 (Table-5), so, there is less significance of difference between the three groups in terms of reducing the size of the lesions. The three Groups are more or less equally effective in terms of reducing the size of the lesions.

Table 6 Area of involvement

Sl	Source	Df	SS	MS	F	P-value
1	Treatments	2	1.067	0.533	1.8535	0.1628
2	Error	87	25.033	0.288		
	Total	89	26.100			

Comments: The calculated F value is 1.8535 and P= 0.1628 i.e., P>.01(Table-6). The F value is not significant i.e., there is no significant difference between the three groups. All groups are equally effective in reducing the area of involvement of the lesions.

Comments: The calculated F value is F=2.012 and P=0.1398 i.e., P >.01 (Table-7). So there is no significant difference in efficacy between the three groups in terms of reducing burning sensation.

Table 7 Daha/burning sensation

Sl	Source	df	SS	MS	F	P-value
1	Treatments	2	1.089	0.544	2.0127	0.1398
2	Error	87	23.533	0.270		
	Total	89	24.622			

Table 8 Rukshata/dryness

Sl	Source	df	SS	MS	F	P-Value
1	Treatments	2	2.422	1.211	4.8706	0.0099
2	Error	87	21.633	0.249		
	Total	89	24.056			

Comments: The calculated F value F=4.870 and P=0.0099 i.e., P≤0.01 (Table-8). F value is significant. So, there is highly significant difference between the three groups. Mean severity score of group C is more than group B & group A. So, Group C was more effective in terms of reducing the *rukshata*/dryness of the skin.

Table 9 Kandu/itching

Sl	Source	df	SS	MS	F	P-Value
1	Treatments	2	4.267	2.133	5.4375	0.0060
2	Error	87	34.133	0.392		
	Total	89	38.400			

Comments: The calculated F value is F=5.44 and P= 0.006 i.e., P≤0.01 (Table-9). F value is significant. So, there is highly significant difference between the three groups. Mean severity score of group C is more than group B & group A. so; group C has more efficacies in terms of *Kandu*/Itching sensation of the lesions.

Table 10 Effect of the treatment in terms of complete relief, moderate relief, mild relief and no relief in group A in 30 patients of *Vyanga*

Results	No. of patients	Percentage
Complete relief	8	26.66%
Moderate relief	12	40%
Mild relief	6	20%
No relief	4	13.33%
Total	30	100

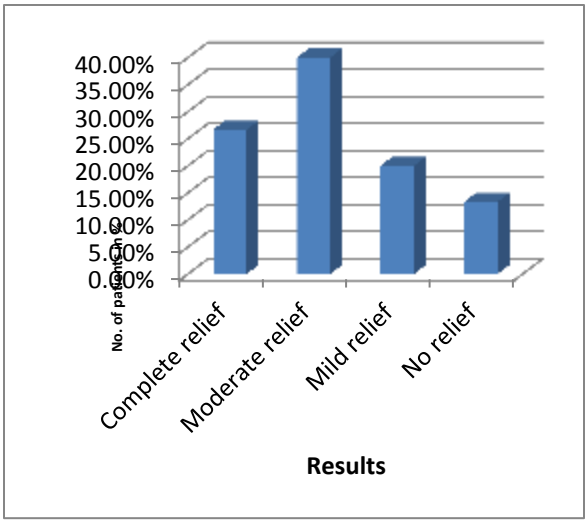

Figure 1 Effect of the treatment in terms of complete relief, moderate relief, mild relief and no relief in group A in 30 patients of *Vyanga*

Comments: In response to the treatment for 60days in Group A, 26.66% of the total cases got complete relief, and 12 patients i.e., 40% showed moderate relief, 6 patients showed mild relief i.e., 20% and 4 patients i.e., 20% showed no relief (Table-10 and Figure 1).

Table 11 Effect of the treatment in terms of relief in group B in 30 patients of *Vyanga*

Results	No. of patients	Percentage
Complete relief	10	33.33%
Moderate relief	15	50%
Mild relief	4	13.33%
No relief	1	3.33%
Total	30	100

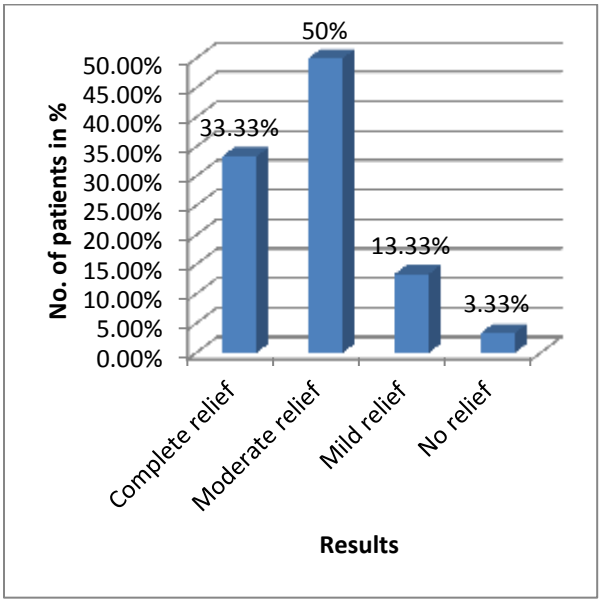

Figure 2 Effect of the treatment in terms of complete relief, moderate relief, mild relief and no relief in group B in 30 patients of *Vyanga.*

Comments: In response to the treatment for 60 days in Group B, 10 patients i.e.,33.33%

of the total cases got complete relief, 15 patients i.e., 50% showed moderate relief, 4 patients i.e., 13.33% showed mild relief and only 1 patient i.e., 3.33% showed no improvement (Table-11 and Figure 2).

Table 12 Effect of the treatment in terms of relief in group C in 30 patients of Vyanga

Results	No. of patients	Percentage
Complete relief	16	53.33%
Moderate relief	11	36.66%
Mild relief	3	10%
No relief	0	0%
Total	30	100

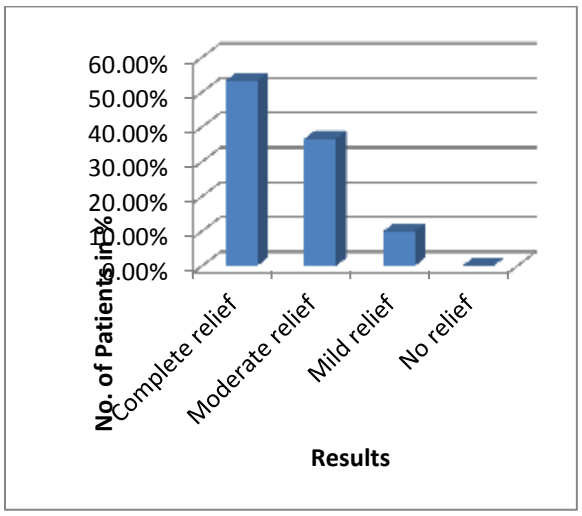

Figure 3 Effect of the treatment in terms of complete relief, moderate relief, mild relief and no relief in group C in 30 patients of *Vyanga.*

Comments: In response to the treatment for 60 days in Group C, 16 patients i.e.,53.33% of the total cases got complete relief, 11 patients i.e., 36.66% showed moderate relief, 3patients i.e., 10 % showed mild relief (Table-12 and Figure 3). The percentage of complete relief was more in Group C. This reveals that Group C was more effective in *Vyanga* than Group B and Group C.

DISCUSSION

The calculated values for paired t test in **table-1**, were highly significant (t <0.001). It appears that the mean difference is more in case of colour (before and after treatment) i.e., 0.367, t value is 3.612 and p value is < 0.001. Hence, the effect of trial drug *Varnya ghana vati* was more evident in reducing the colour of the lesions.

The calculated values for Paired t test in **table-2**, were highly significant (t <0.001). So the treatment administered in Group B was effective in reducing all the assessment parameters. The mean difference is more in case of itching (BT-AT).Hence, reduction of itching or kandu was more evident.

The calculated values for Paired t test in **table-3** for all the assessment criteria were highly significant (P<0.001). The mean difference is more in case of colour (before and after treatment) i.e., 0.933, t value is 7.992 and p value is < 0.001. Hence, the effect of trial drug administered in Group C is more significant in reducing the colour of the lesions.

The calculated F value in **table-4**, from the One way ANOVA test for the colour of the lesion of the three groups is 6.66 and P=

0.0020 i.e., P≤0.001F value is significant. So, there is significant difference in efficacy between the three groups. Mean severity score of group C is more than group B & group A. So, group C is more effective in terms of reducing the colour of the lesions.

The calculated F value in **table-5**, from the One way ANOVA test for the size or homogeneity of the lesion is 3.87 and P=0.0245 i.e., P≤0.05 so, there is less significance of difference between the three groups in terms of reducing the size of the lesions. The three Groups are more or less equally effective in terms of reducing the size of the lesions.

The calculated F value in **table-6**, for the area of involvement is 1.8535 and P= 0.1628 i.e., P>0.01. The F value is not significant i.e., there is no significant difference between the three groups. All groups were equally effective in reducing the area of involvement of the lesions.

The calculated F value in **table-7**, for the *daha*/burning sensation is F=2.012 and P=0.1398 i.e., P >.01. So there is no significant difference in efficacy between the three groups in terms of reducing burning sensation.

The calculated F value in **table-8**, for *rukshata*/dryness of the skin is F=4.870 and P=0.0099 i.e., P≤0.01.F value is significant. So, there is highly significant difference between the three groups. Mean severity score of group C is more than group B & group A. So, Group C was more effective in terms of reducing the dryness of the skin.

The calculated F value in **table-9**, for *Kandu*/Itching is F=5.44 and P= 0.006 i.e., P≤0.0. F value is significant. So, there is highly significant difference between the three groups. Mean severity score of group C is more than group B & group A. So, group C was more effective in terms of reducing *Kandu*/Itching sensation of the lesions.

The Overall effect of therapy was highly encouraging**.** The percentage of the effect of the treatment in terms of complete relief, moderate relief, mild relief in group C was more than Group B and Group A. (**Table 10,11,12**)

Thus, the present study reveals that the trial drug was more effective when administered both locally and orally at the same time as in Group C.

The rationality on the mode of action of the selected drugs can be analysed in the following way. The *rasas* of the drugs which were administered are mainly *madhura, tikta*, *Kashaya* which prevents further vitiation of *pitta dosha* which is the main catalyst of *Vyanga*. The selected drugs

possessed *snigdha* (unctuous), *laghu* (light) and *Ruksha gunas*. *Snigdha Guna* is responsible for the *Mardava* and *Varna prasadana*. *Laghu* and *ruksha* being the properties of *Agneya Dravya* are responsible for *prabha*, *prakash* and *Varna*. The drugs were mainly having *shita virya* (cold potency) and thus responsible for *rakta prasadana karma*. The *madhura vipaka* of the selected drugs causes *kapha vardhana* and thus improves complexion. Some of the drugs have *rasayana* properties so it nourishes all *dhatus* as well as *twaka* by influencing the proper circulation of *rasa* and *rakta*.

The active principles of the drug which are applied externally come in contact with *roma* and *romakupa* which are connected to *tiryak dhamanis*. There is *paka* of the *dravyas* on the skin by the action of *Bhrajakagni and rasa dhatwagni*[19].The *ushna guna* of *Bhrajaka pitta* takes up and metabolises the *dravyas* that are applied on the skin restores normalcy of colour and complexion of the *twaka*.

The total duration of the study was of 60 days only during which no adverse side effects were observed in any of the patients. The overall therapeutic results were highly encouraging. The conventional skin creams and drugs suppress the condition but it does not completely cure Melasma. The specific treatment mentioned in *Ayurveda* is for the treatment of *pitta* and its proper elimination. Thus relapses are minimal.

CONCLUSION

The therapeutic trial has shown notable anti-hyperpigmentary effects (figure- 4,5 and 6,7). The related data has been discussed above, the salient features of which are as follows:

1. The calculated t values of all the assessment parameters i.e., colour, size, area of involvement, *kandu, daha and rukshata*, were highly significant.
2. One way ANOVA revealed that the overall response of the treatment was better in Group C than Group A and Group B.
3. In response to the treatment for 60days in Group A, 8 patients i.e., 26.66% of the total cases got complete relief, and 12 patients i.e., 40% showed moderate relief, 6 patients showed mild relief i.e., 20% and 4 patients i.e., 20% showed no relief.
4. In response to the treatment for 60 days in Group B, 10 patients i.e.,33.33% of the total cases got complete relief, 15 patients i.e., 50% showed moderate relief, 4 patients i.e., 13.33% showed mild relief and only 1 patient i.e., 3.33% showed no improvement.

5. In response to the treatment for 60 days in Group C, 16 patients i.e.,53.33% of the total cases got complete relief, 11 patients i.e., 36.66% showed moderate relief, 3patients.i.e.,10% showed mild relief. Thus it can be concluded that *Varnya Ghana Vati* and Ointment when administered together at a time gave better results.

6. The trial drug also improves the complexion of the patient which may be due to the *Varnya* property of the drugs (figure-4, 5 and 6, 7) .

7. No adverse side effects were observed in any of the patients.

Thus it can concluded that the trial drug prepared from a few *Varnya Mahakashaya* drugs can be used externally and internally, and it is safe and effective treatment for *vyanga roga* (melasma).

Recommendation for further studies:

Regarding the future prospects of the present work, certain improvement can be done: The study should be done on a large number of patients and for a longer duration. The tyrosinase inhibiting activity of the trial drug should be carried out in order to establish it in a scientific manner which may open new avenues in the exploration of *Ayurvedic* cosmetics.

Figure 4 Before Treatment

Figure 5 After Treatment

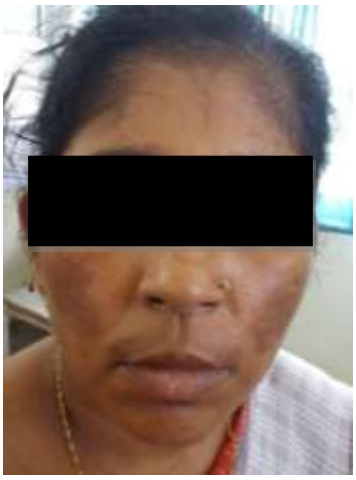

Figure 5: Before Treatment

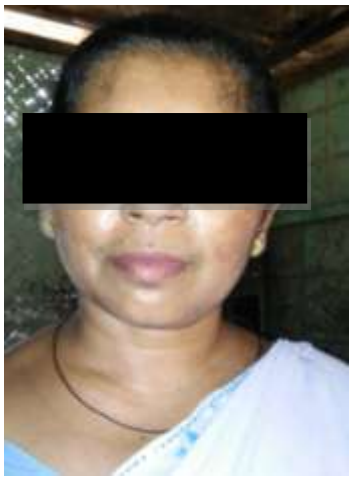

Figure 6: After Treatment

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