Published online in http://ijam.co.in ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 13 (3), 2022; 651-656

Comparative clinical evaluation of *Manjishta churna lepa* and *Jatiphala churna lepa in Vyanga* (Melasma)

Research Article

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Abstract

Vyanga (Melasma) is condition of localized hypermelanosis which affect face, and continues to be challenging problem as it causes immense mental stress and depression. In ayurvedic texts there is lot of *ahara, aushadha*, and *vihara* which were mentioned to enhance external beauty such as *varnya varg* told by *Acharya Charak*, and *romsanjanan* etc told by *Acharya Shushrut*. Melasma can be correlated with *Vyanga* in Ayurveda. The present study was aimed to evaluate and compare the efficacy of *Manjishtha churna lepa* and *Jatiphala churna lepa* in the management of *Vyanga* with special reference to Melasma. After ethical clearance, 90 patients of *Vyanga* (Melasma) in OPD of Kayachikitsa department of SST's Ayurved Medical College, Sangamner, was selected and assigned randomly in Group A having 45 patients and Group B having 45 patients.Three criteria was assessed for this study- Dimension of affected skin area in sq.cm, Fairness meter score, MASI Score. Student paired t test and Student unpaired t test statistical test was used. On Statistical analysis it was found that- 1) *Manjishtha churna lepa* is effective in the management of *Vyanga* (Group A). 2) *Jatiphala churna lepa* is effective in the management of *Vyanga* (Group B). 3) But, while comparing the Group A vs Group B, the *Jatiphala churna lepa* is more effective than the *Manjishtha churna lepa.*

Key Words: *Vyanga*, Melasma*, Vata, Pitta, Kshudra roga,* MASI Score.

Introduction

In Ayurveda, skin diseases are included under the heading of *Kustha* and *Kshudra roga*. *Vyanga* is one among the *Kshudra roga*. Even though *Vyanga* is a *Kshudra roga*, it produces a great misery for the person due to the dark discoloration of the skin over face. *Vyanga* is a pathological situation of the facial skin with etiopathogenesis pointing towards the vitiation of *Vata* & *Pitta dosha*, also belongs to *Raktapradoshaja vyadhi* producing cardinal features such as *Niruja* (painless),*Tanu* (macules), *Shyava mandala* (bluish black)(1) Ayurveda also refers this condition as associated with *Manasika nidanas* such as *Krodha, Shoka, Ayasa* (2) as the main culprits.

Melasma is characterized by hyperpigmented macules on cheeks, upper lips, chin, nose, forehead. The condition is more common in darker skin type. Melasma is most frequently found in females than males averaging ratio as 4:1.(3) It can be correlated with *Vyanga* in Ayurveda. According to Ayurveda etiopathogenesis of *Vyanga* points towards vitiation of *Vata* and *Pitta* by *Sushrut* (4)and *Pitta* and *Rakta* by *Charak*. As this is not a fatal or life threatening disease, it is mentioned under *kshudra rog* section in Ayurveda.

Hyperpigmentation refers to patches of skin that become darker than the surrounding areas of skin. It occurs when the skin produces excess melanin, the pigment that gives skin its color. It can affect people of all skin types.(5) Melanin is a substance in your body that produces hair, eye and skin pigmentation. The more melanin you produce, the darker your eyes, hair and skin will be.(6) In the present study the efficacy of *Manjishtha churna lepa* and *Jatiphala churna lepa* was assessed and compared to *Vyanga* with special reference to Melasma.

Methodology

After seeking ethical committee clearances with Reference Letter number- SSTAYU/284/1/2020 and dated 15/06/2020 and clinical study was carried out on 90 patients of *Vyanga* (Melasma) in OPD of Kayachikitsa department of SST's Ayurved Medical College, Sangamner. Informed consent was taken from the patients after offering sufficient information and aim of study in a language best understood by them.

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Diagnostic criteria

Patients characterized with *Niruja* (painless), *Shyava* (bluish black), *Tanu Mandalas*(macules) on face were diagnosed to have *Vyanga.*(Melasma)

Inclusive Criteria

- Patients will be selected irrespective of sex & religion between the age group of 18 to 45 years.
- Patient who are not allergic to *lepa* (patch test will be done).
- Patient who are willing to take treatment (with prior informed consent).

Exclusive criteria

- Patient having age group below 18 years and above 45 years.
- Patient having *Vyanga* (Melasma) other than face.
- Patient with known case of PCOD, other hormonal pathologies, pregnancy, lactation.
- Patients taking oral contraceptive pills or injected depot contraceptive preparations.
- Patients suffering from skin diseases like nevi and drug induced Pigmentation changes etc.

Pre assessment test

Both drug was Authenticated and Standardized and found as per Ayurvedic Pharmacopoeia of India(API) Standards.

Skin sensitivity Test (Patch Test) :

- Skin sensitivity test was carried out to evaluate the adverse effect of *Manjishtha churna lepa* and *Jatiphala churna lepa.*
- This test was performed before prescribing to the patients.

Group A

Route of administration: *Lepa* (Topical application) on the affected area.
Dosage form: *Lepa* with *Madhu*
Dose: As per requirement of affected area, of thickness of 6-8 mm.
Time: Twice daily - Morning and Evening
Duration of Therapy: 28 days. (4 weeks)

Group B

Route of administration: *Lepa* (Topical application) on the affected area.
Dosage form: *Lepa* with water
Dose: As per requirement of affected area of Thickness of 6-8mm.
Time: Twice daily- Morning and Evening
Duration of Therapy: 28 days. (4 weeks)

For this clinical study we are having references in ayurvedic samhita -Bhavprakash samhita

We can use different vehicle for external application. In this study both drug are in powder form so to make external application (*lepa*) we had used madhu and water.

1) *Manjishtha churna lepa* with *madhu* (7)
2) *Jatiphala churna lepa* with water (8)

At the end of the study we can assessed different efficacy of different vehicle. (*Lepa* with *madhu* and *lepa* with water)

Study Design

The selected patients were assigned randomly in Group A having 45 patients and Group B having 45 patients.

Method of Assessment

1) Dimensions of affected area.
2) Fairness meter test
3) Melasma area severity index [MASI] score.

Posology

Lepa (paste) was prepared by using fine powder of *Manjishtha churna* with *Madhu* and *Jatiphala churna* with water as media for mixing. *Lepa* should always be applied in the opposite direction of hair follicles (*pratiloma*). The drugs get absorbed through their hair roots, sweat glands and capillaries. Patients were advised to apply freshly prepared *Lepa* twise daily (morning and evening).Patients advised to wash with water onces the *Lepa* gets dried (15-20min).

Assessment criteria

The effect of therapy was assessed on the basis of following objective criteria-

1) Dimension of affected skin in sq. cm
2) Fairness meter score
3) MASI score (Melasma area severity index)

1) Dimensiom of affected skin in sq. cm-

Dimensions of affected area were measured in sq. cm with help of transparent graph paper sheet, with minimum possible size of measurement as 1 sq. mm. Carried out before and after treatment.

2) Fairness meter test:

This special test was carried out before and after treatment.The Standard Garnier Fairness meter scale was used to measure the Lesion color. The fairness meter scale was having 16 different Colour shades grade of human skin.

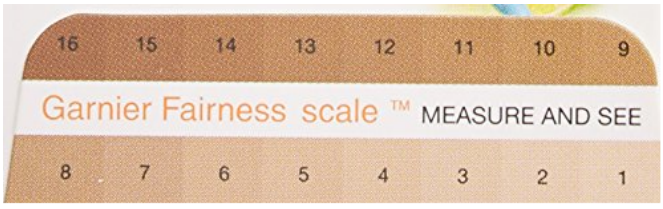


Fig no.1

3) Melasma Area Severity Index [MASI] Scores

The Melasma Area Severity Index [MASI], which was developed by Kimbrough-Green et al based on a scoring system devised for psoriasis, is a globally accepted criteria for melasma assessment.(9)The Melasma are severity index (MASI) score is calculated by assessment of three - Area (A),darkness (D), and homogeneity (H) of involvement where in forehead (f)

30%, right malar region(RM) 30%, left malar region(LM) 30%, and chin (C) 10%. The total score range 0-48. Higher the score, higher the severity.

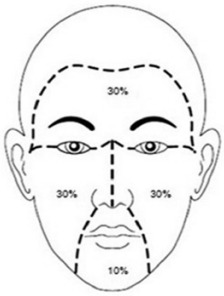


Fig no.2

Formula for MASI score calculation

Forehead Right Malar Left Malar Chin

MASI = 0.3 (D+H) A + 0.3 (D+H) A + 0.3 (D+H) A + 0.1 (D+H) A

- A – 0 = no involvement,
- 1 = <10% involvement,
- 2= 10-29% involvement,
- 3= 30-49% involvement,
- 4= 50-69% involvement,
- 5= 70-89% involvement,
- 6= 90-100% involvement.

D - 0 = normal skin color without evidence of hyper pigmentation,

- 1 = barely visible hyper pigmentation,
- 2 = mild hyper pigmentation,
- 3 = moderate hyper pigmentation,
- 4 = severe hyper pigmentation.

H - 0 = normal skin color without evidence of hyper pigmentation,

- 1 = specks of involvement,
- 2 = small patchy areas of involvement <1.5 cm diameter,
- 3 = patches of involvement >2 cm diameter,
- 4 = uniform skin involvement without any clear areas

Table no.1:Total Assessment criteria

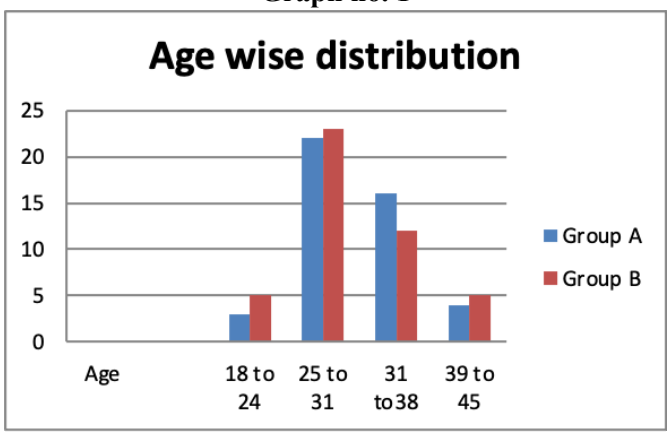
0%	Unchanged
1% - 25%	Least improvement
26% -50%	Mild improvement
51%- 75%	Moderate improvement
76 %- 100 %	Marked improvement

Observations

Out of 90 patients observation revealed that-(Group A-45 patients),(Group B- 45 patients)

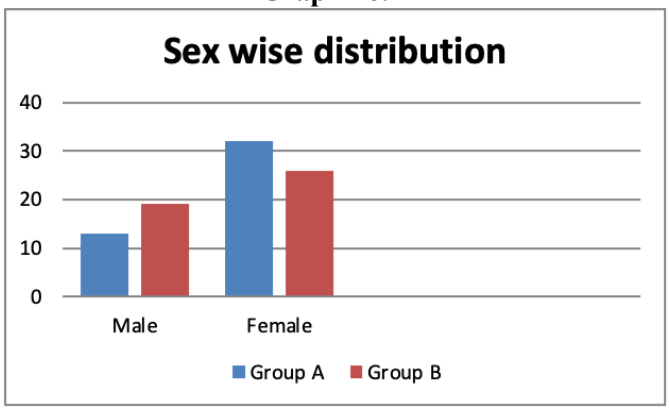
In group A, 3 patients (6.7%) were having age between 18 – 24 years, 22 patients (48.9%) belonged to age group 25 – 31 years , 16 patients (35.5%) were from age group 32 – 38 years, 4 patients (8.9%) were from age group 39 – 45 years. **In group B**, 6 patients (11.11%) were having age between 18 – 24 years, 23 patients (51.11%) belonged to age group 25 – 31 years, 11 patients (26.66%) were from age group 32 – 38 years, 5 patients (11.11%) were from age group 39 – 45 years.

Graph no. 1



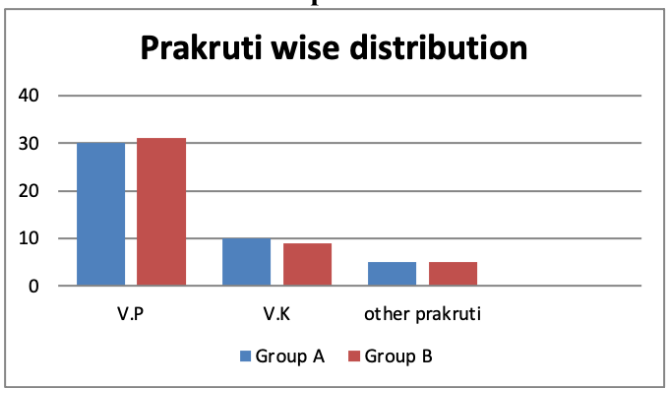
In group A, 13 patients (28.9%) were male and 32 patients(71.1%) were female. In **Group B**, 19 patients were male (42.2%) and 26 patients are female(57.8%).

Graph no. 2



In group A, 30 patients belonged to *vata pitta prakruti* with 66.7%, 10 patients belonged to *vata kapha prakruti* with 22.2%, 5 patients belonged to other *prakruti* with 11.1%. **In group B,** 31 patients belonged to *vata pitta prakruti* with 68.9%, 9 patients belonged to *vata kapha prakruti* with 20.0%, 5 patients belonged to other *prakruti* with 11.1%.

Graph no. 3



In group A, 15 patients were having severe *krodha* (anger) with 33.3%, 22 patients are have Moderate

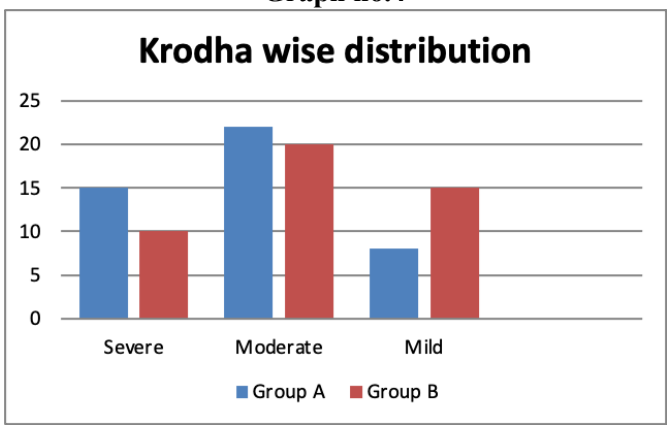
krodha (anger) with 48.9%, 8 patients are have mild *krodha* with 17.8%. **In group B,** 10 patients were having severe *krodha* with 22.2%, 20 patients were having Moderate *krodha* with 44.4%, 15 patients were having mild *krodha* with 33.3%.

Assessment criteria for krodha (anger)

Assessment of krodha (anger) had done with the help of clinical anger scale (Psy tool kit).(10)

The Clinical anger scale (CAS) has 21 items with 4 choices each(which are scored 0,1,2,3,4). The clinical anger scale (CAS) score is simply the sum of the item scores. Thus, scores on the Clinical anger scale can range from 0 to 63. A higher score means that the patients has more anger symptoms.

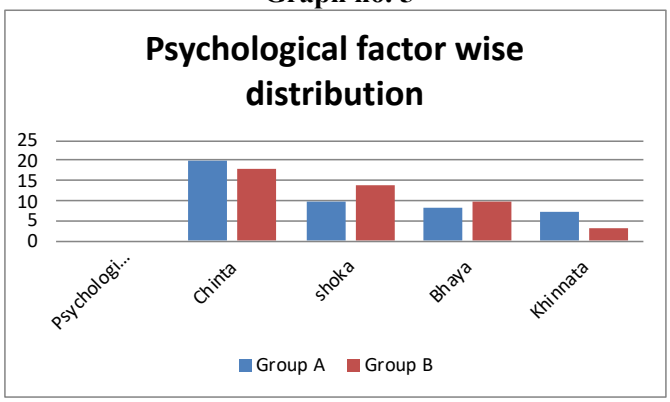
Graph no.4



In group A, 20 patients were suffering from *Chinta* (anxiety) with 44.4% , 10 patients were suffering from *shoka* (sorrow) with 22,2%, 8 patients were suffering from *bhaya* (fear) with 17.8%, 7 patients were suffering from *khinnata* (depression) with 15.5%.**In group B,** 18 patients were suffering from *Chinta* with 40.0% , 14 patients were suffering from *shoka* with 31.1%, 10 patients were suffering from *bhaya* with 22.2%, 3 patients were suffering from *khinnata* with 6.7%.

Chinta (anxiety) was assessed by interrogating each and every patients.

Graph no. 5



Statistical analysis

As the data was Quantitative, paired and parametric, the test used is Student paired t test and for Quantitative, Unpaired and parametric data, the test used is Student unpaired t test.

Results

Table no.2: Comparative efficacy of above stated factors before treatment and after treatment (Group A)

Criteria	Mean		Differences of mean	Standard deviation of differences	t value	P value	Significant
	Before treatment	After treatment					
Forehead region	0.7977	0.6288	-0.1689	0.2835	3.996	0.0002	Yes
Rt. malar region	9.0888	8.6266	-0.4622	0.3325	9.324	<0.0001	Yes
Lt. malar region	5.4444	5.1288	-0.3156	0.3067	6.902	<0.0001	Yes
Fairness score	10.7777	9.8666	-0.9111	0.5144	11.88	<0.0001	Yes
MASI score	6.3155	5.7066	-0.6089	0.3783	10.80	<0.0001	Yes

Since the P value is < 0.05, the level of significance for factors Forehead region, right malar region, Left malar region, Fairness meter score and MASI score.

Table no. 3: Comparative efficacy of above stated factors before treatment and after treatment (Group B)

Criteria	Mean		Difference of means	Standard deviation of differences	t value	P value	Significant
	Before treatment	After treatment					
Forehead region	0.4666	0.2155	-0.2511	0.6720	2.507	0.0160	Yes
Rt. malar region	7.4222	6.6466	-0.7756	0.4578	11.36	<0.0001	Yes
Lt. malar region	5.9111	3.8444	-2.067	0.7486	18.52	<0.0001	Yes
Fairness score	12.1333	7.6888	-4.444	1.159	25.72	<0.0001	Yes
MASI score	7.58	4.4088	-3.171	1.197	17.78	<0.0001	Yes

Since the P value is < 0.05, the level of significance for factors Forehead region, right malar region, Left malar region, Fairness meter score and MASI score.

Statistical analysis was done only after completion of treatment. Before and after treatment mean was given in table no. 2 and table no. 3

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Table no.4: Comparative efficacy of therapy on above stated factors Trial Group A Vs. Trial Group B

Criteria	Mean Group A	Mean Group B	Diff. between Mean(B-A) ± SEM	t value	P value	Significant
Forehead region	0.6289	0.2156	-0.4133 ± 0.1771	2.333	0.0219	Yes
Rt. malar region	8.627	6.647	-1.980 ± 0.6038	3.279	0.0015	Yes
Lt. malar region	5.129	3.844	-1.284 ± 0.5160	2.489	0.0147	Yes
Fairness score	9.867	7.689	-2.178 ± 0.3531	6.168	<0.0001	Yes
MASI score	5.707	4.409	-1.298 ± 0.4293	3.023	0.0033	Yes

In comparison of Trial Group A to Trial Group B, t calaculated is greater than t table.

So, the effect of therapy is statistically significant on factors Forehead region, right malar region, Left malar region, Fairness meter score and MASI score.

Table no.5: Overall Percentage of efficacy of Group A (*Manjishtha churna lepa*)

Assessment criteria	% Improvement	Total Improvement
1)Forehead	21.51	10.11%
2)Right malar	5.06	
3)Left malar	5.88	
2)Fairness meter score	8.44	
3)MASI score	9.66	

Thus, overall average efficacy of *Manjishtha churna lepa* assessed in study of Group A (45 patients), by above criteria shows **10.11%** efficacy.

Table No.6 : Overall Percentage of efficacy of Group B (*Jatiphala churna lepa*) in *Vyanga* (Melasma)

Assessment criteria	% Improvement	Total Improvement
1)Forehead	54.34	35.7%
2)Right malar	10.51	
3)Left malar	35.02	
2)Fairness meter score	36.68	
3)MASI score	41.95	

Thus, overall average efficacy of *Jatiphala churna lepa* assessed in study of Group B (45 patients), by above criteria shows **35.7%** efficacy.

So, comparing in **Group A** and **Group B** overall efficacy of *Jatiphala churna lepa* has better result than *Manjishtha churna lepa*.

Discussion

Affected area measurement in sq. cm.

There was significant improvement in reduction of affected area for Group B (*Jatiphala churna lepa*) as compared to Group A (*Manjishtha churna lepa*) after application of drug for 28 days. Area wise improvement after treatment both groups as follows;

- Forehead **21.51%** improvement for Group A and **54.34 %** improvement for Group B.
- Right malar **5.06 %** improvement for Group A and **10.51 %** improvement for Group B .
- Left malar **5.88 %** improvement for Group A and **35.02 %** improvement for Group B.

Fairness meter score:

Fairness meter score of lesion is 8.44 % for Group A and 36.68 % for Group B.

MASI Score:

MASI score for Group B (*Jatiphala churna lepa*) has better result than Group A (*Manjishtha churna lepa).*

- MASI Score for Group A is 9.66 %
- MASI Score for Group B is 41.95 %

Mode of Action of *Manjishtha* and *Jatiphala*

According to Ayurveda, *guna* of ***Manjishtha*** *is Madhura, Tikta* and *Kashyaya rasa*, *Katu-vipaka, Ushna-veerya, Guru, Ruksha* may pacifies *Vata, Pitta* and Purify *rakta*, nourishes the skin. Thus it may do *Varna prasadana* as well as *twak prasadana* as overall lusture softness of skin was also improved.(11*) Kashay* and *Madhur rasa* of ***Manjishtha*** reduce the *Pitta* which is the main cause of the disease. *Ruksha guna* of *Manjishtha* alleviates the *Snigdha guna* of *Pitta.Guru guna* of *Manjishtha* reduce the *Laghu guna* of *Vata*. So, both *guna* break the *samprapti* of *Vyanga*. Again *Manjishtha* having *Rakta shodhak,Kusthaghna*, and *Varnya* property.

Guna of ***Jatiphala*** is *Tikta, Katu* rasa*, Katu vipaka*, *Ushna veerya,Teekshna* & *Snigha* pacifies *Vata* & *Kapha* and also nourishes the skin. Thus it does *Varna prasadana* and *twak prasadana* also along with Rakta shodhana and *Twaka doshahara* action.(12) The *katu, Tikta, Kashaya rasa* of *Jatiphala* tackles *Srotodushti* caused by *Agnisada* which forms *Aama* and leads to *Srotodushti.* The *Tikta ras* of *Jatiphala* causes *Pitta Shamak* which is vitiated due to intake of *Pitta Ahara Dravyas*. Since the disease *Vyanga* is considered the disease of disturbed *Bhrajaka Pitta, Rasa, Raktavaha Srotodushti, Vata* and *Pitta prokop* also involving *Kapha* which obstructs *Rasavaha Srotas* leading to *Shyavatvam* of the skin by causing the *Prakopita Bhrajaka Pitta* to be deposited below the skin layers that is in epidermis.

Tikta rasa, Usna virya of *Jatiphala* mitigates *Vata dosha* and the same time it stimulates *Bhrajaka Pitta* and help in scraping of the rough, thick, black dark layers formed on the skin. The *Laghu, Tikshna guna* and *Ushna Virya* properties along with *katu ras* clears the channels helping the healthy *Bhrajaka Pitta* and opens the free movement of *Bhrajaka Pitta* on to the skin. Also *Jatiphala* removes excessive *kleda* from skin and do the *shodhana* (Purification) of *Rasa- Rakta dhatu*, thereby improving *Varna*.

Conclusion

With the help of observations/ data collected during entire clinical trial, assessment of criteria and statistical analysis of data, it can be concluded that -

- *Manjishtha churna lepa* is effective in the management of *Vyanga* ((Group A).
- *Jatiphala churna lepa* is effective in the management of *Vyanga* (Group B).
- But, while comparing the Group A vs Group B, the *Jatiphala churna lepa* was found to be more effective than the *Manjishtha churna lepa* in the management of *vyanga (melasma)*.

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