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A randomized controlled clinical study to evaluate the efficacy of *Aragwadha Pushpa Lepa* (*Cassia fistula* Linn.) in the management of *Vyanga* with special reference to Melasma

Nanditha M.[1], Mahesh C.D.[2], Seema Pradeep[3]

[1]*Final Year Post Graduate Scholar, Department of PG studies in Dravyaguna, Sri Sri College of Ayurvedic Science & Research, Bengaluru, Karnataka, India.*

[2]*Professor, Department of PG studies in Dravyaguna, Sri Sri College of Ayurvedic Science & Research, Bengaluru, Karnataka, India.*

[3]*Professor & HOD, Dept. of PG studies in Dravyaguna, Sri Sri College of Ayurvedic Science & Research, Bengaluru, Karnataka, India.*

ABSTRACT

Vyanga is one of the *Kshudraroga* mentioned in the classics which are having *Lakshana* like *Niruja*, *Tanu* and *Shyava Mandala*. It can be correlated with Melasma in modern terms, which is also known as Chloasma. Melasma is an acquired pigmentary disorder, causing hyper-pigmented patches to appear on the facial skin. The prevalence varies between 1.5 % and 33.3 % in India. Female to male ratio in India is 4:1, indicating the high prevalence rate among females. *Aragwadha Pushpa Churna* along with *Nimbuka Swarasa* is applied over the hyper-pigmented patches in the condition of *Vyanga* in Cauvery river stretch of Namakkal district of Tamil Nadu as a folklore practice. A randomized clinical study was carried out to compare the efficacy with *Varnya Gana Churna*. The clinical study in the sample size of 30 was carried out in 2 groups with the intervention of Group A being *Aragwadha Pushpa Churna Lepa* and that of Group B being *Varnya Gana Churna Lepa*, with 30 days of drug application period and 15 days of drug-free follow up period. Differential diagnosis was ruled out with the help of Wood's lamp. Assessment was done with the help of criterias like Amount of discolouration, Arbitrary grading and Area of the lesion. Various statistical tests like Parametric, Non-parametric, Friedman repeated measures ANOVA on ranks, etc. were carried out to analyse the results of the study. Both *Aragwadha Pushpa Churna* and *Varnya Gana Churna* have significant effect in the management of *Vyanga* with special reference to Melasma. When improvement in the individual criteria was compared, *Aragwadha Pushpa Churna* showed better results in reducing the amount of discolouration & the number of lesions. Whereas, *Varnya Gana Churna* showed better results in reducing area of the lesion.

Key words: *Aragwadha, Cassia fistula Linn., Chloasma, Melasma, Vyanga*

INTRODUCTION

Normal healthy skin has many important roles and thus should be treated with care. There will be a focus on the skin once there is an abnormality. *Vyanga* is one such *Vyadhi* mentioned in our classics having *Lakshanas* like *Niruja, Tanu* and *Shyava Mandala* on *Mukha Pradesha*,[1] which can be co-related with Melasma, which is considered to be problematic if undesirable. Melasma, which is also called as Chloasma is a pigmentation disorder that causes discoloured patches to appear on the face, which may affect the lifestyle of a person. The prevalence of Melasma varies between 1.5% and 33.3% in India. It also occurs in men, though less common. Men represent 20.5 % - 25.83 % of the prevalence rate.[2] As per the studies, patients of Melasma are facing unsightly effect on personal appearance with the feeling of shame, frustration, embarrassment, low self-esteem and lack of motivation.[3] In contemporary science, prescription of depigmenting agents containing Hydroquinone and Steroids for topical application are given in the condition of Melasma, which may cause adverse effects and are also having high relapse rate.[4] Hence, standardization of Ayurvedic drugs in this context is the need of the hour. *Aragwadha Pushpa Churna* is used

Address for correspondence:
Dr. Nanditha M.
Final Year Post Graduate Scholar, Department of PG studies in Dravyaguna, Sri Sri College of Ayurvedic Science & Research, Bengaluru, Karnataka, India.
E-mail: nandithabhavana@gmail.com

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with *Nimbuka Swarasa* in the form of *Lepa* for *Vyanga* in the Cauvery river stretch of Namakkal district of Tamil Nadu as a folklore practice.[5] As *Aragwadha Pushpa* is abundantly available throughout India & is cost-effective, its action on *Vyanga* was intended to be studied clinically, which contributes in improving the day-to-day practice. *Varnya Gana Lepa*, a combined preparation using 10 drugs of *Varnya Gana* mentioned in *Charaka Samhita*, which is proven to be effective in the management of *Vyanga*,[6] was taken as the control drug to re-establish and compare its efficacy levels with *Aragwadha Pushpa Lepa*.

Hypothesis

- Null hypothesis (H_0) = The efficacy of *Aragwadha Pushpa Lepa* is equivalent to the efficacy of *Varnya Gana Lepa* in the management of *Vyanga* with special reference to Melasma.
- Alternate Hypothesis (H_1) = The efficacy of *Aragwadha Pushpa Lepa* is different from the efficacy of *Varnya Gana Lepa* in the management of *Vyanga* with special reference to Melasma.

METHODOLOGY

Sample source

Thirty subjects fulfilling the inclusion criteria of *Vyanga* with special reference to Melasma, irrespective of their gender, religion, occupation, socio-economic status, and who were willing to give written informed consent were selected for the present study, who were visiting Out Patient Department (OPD) or In Patient Department (IPD) of Sri Sri College of Ayurvedic Science and Research Hospital, Kanakapura road, Bengaluru. Subjects were also selected from referral sources.

Study design

A randomized open-labelled parallel group active-controlled pre and post-test clinical study.

Inclusion criteria

1. Subjects of either gender with the age group between 21 - 60 years were selected.
2. Subjects fulfilling the diagnostic criteria of *Vyanga* with special reference to Melasma were randomly selected, irrespective of their religion, occupation and socio-economic status.

Exclusion criteria

1. Female on oral contraceptive pills, pregnant women and lactating women.
2. Who were on any hormonal therapy.
3. Known hyperpigmentation since birth.
4. Known inflammatory pigmentation.
5. Known malignant melanoma.
6. Any other condition interfering with the course of the treatment.

Diagnostic criteria

Subjects were diagnosed with the clinical signs and symptoms of *Vyanga*:

- *Niruja*
- *Tanu*
- *Shyava*
- *Mandala*

Cases of Melasma were also diagnosed with the help of Wood's lamp.

Grouping

Thirty subjects fulfilling the criteria were selected and randomly assigned into two groups of fifteen each:

- Group A: *Aragwadha Pushpa Lepa* (Trial group)
- Group B: *Varnya Gana Lepa* (Control group)

Sampling technique

Subjects were randomly assigned into two groups by lottery method.

Intervention

Table 1: Showing the description of intervention

Features	Group A	Group B
Sample size	15	15
Intervention	*Aragwadha Pushpa Lepa*	*Varnya Gana Lepa*

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Medium for application	*Nimbuka Swarasa*	*Sukhoshna Jala*
Dosage	Quantity sufficient	Quantity sufficient
Time of Administration	Morning	Morning
Trial period	30 days	30 days
Follow up	45th day	45th day

Method of application

Subjects were instructed to wash the face and wipe with a dry cloth. The drug powder was mixed with quantity sufficient lemon juice to attain the consistency of a paste, and was applied over the affected area. The *Lepa* was retained on the face till it dried and then the subjects were instructed to remove the *Lepa* with lukewarm water.

Thickness of *Lepa* - Thickness of *Ardra Mahisha Charma* (approximately 2.5 mm).

Time of application - Morning.

Duration of application - The *Lepa* was retained on the face till it dried.

Route of administration - *Bahya Marga* / External application.

Duration of the study - 45 days (30 days trial period + 15 days of drug-free follow up).

Ethical clearance -

The ethical clearance was obtained from Sri Sri Institutional Ethical Committee for commencing the study, with the Ethical clearance number - SSIEC/207/2021.

CTRI registration -

CTRI registration was done before starting the trial with the Registration number -CTRI/2022/07/043645.

Assessment criteria

1. Arbitrary grading on the symptom *Mandalakara*:

Table 2: Showing scores for Arbitrary grading

Features	Score
More than five circular lesions present over the face	4
5 circular lesions present over the face	3
3 to 4 circular lesions present over the face	2
1 to 2 circular lesions present over the face	1
No such circular lesions present over the face	0

2. Area of the lesion assessed by Grid method:

The area affected was assessed by adopting the Grid method. That is, the area affected was measured by marking the margins of the patches one by one on a transparent paper. The sketched transparent paper was then put on a graph paper and surface area was noted down in square millimeters.

3. Amount of discolouration:

The discolouration was scored according to the density of pigmentation using a standard fairness scale (Fair & Lovely Fairness Meter).

Assessment schedule

Table 3: Showing assessment schedule in both the groups

0th day	Pre-study assessment
15th day	Assessment during trial period
30th day	Post-study assessment
45th day	Follow-up assessment

Observation and Results

Presentation of recorded data obtained in both the groups are represented in tables and graphs. Statistical analysis was done by using the software SigmaStat 3.1. Both *Aragwadha Pushpa Churna* and *Varnya Gana Churna* have significant effect in the management of *Vyanga* with special reference to Melasma. When improvement in the individual criteria was compared, *Aragwadha Pushpa Churna* showed better results in

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reducing the amount of discolouration & the number of lesions. Whereas, *Varnya Gana Churna* showed better results in reducing area of the lesion.

Changes in amount of discolouration

Within the group: Table no. 4 and Figure 1 represents the changes in amount of discolouration within the group.

Table 4: Showing changes in amount of discolouration using paired sample test for within the group.

	Group A					Group B				
	Mean	SD	SEM	P Value	Sig.	Mean	SD	SEM	P Value	Sig.
BT	14.07	2.94	0.76	0.0002	HS	15	3.36	0.87	0.0006	HS
AT	12.27	2.94	0.76			13.47	2.85	0.74		

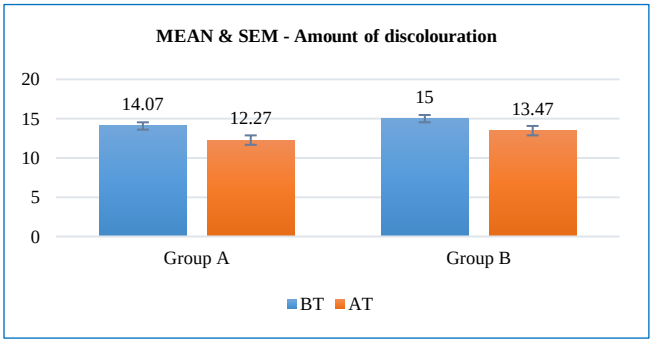

Figure 1: Showing Mean & SEM of amount of discolouration before treatment (BT) & after treatment (AT) in both groups.

Between the groups: Table no. 5 represents the changes in amount of discolouration between the groups.

Table 5: Showing changes in amount of discolouration using unpaired sample test for between the groups.

Groups	Mean	SD	SEM	T Value	P Value	Sig.
Group A	12.27	2.94	0.76	1.1352	0.2659	NS
Group B	13.47	2.85	0.74			

Changes in Arbitrary grading

Within the group: Table no. 6 and Figure 2 represents the changes in Arbitrary grading within the group.

Table 6: Showing changes in Arbitrary grading using paired sample test for within the group.

	Group A					Group B				
	Mean	SD	SEM	P Value	Sig.	Mean	SD	SEM	P Value	Sig.
BT	2.67	1.18	0.30	0.0230	S	2.80	1.32	0.34	0.0266	S
AT	2.07	1.10	0.28			2.27	1.28	0.33		

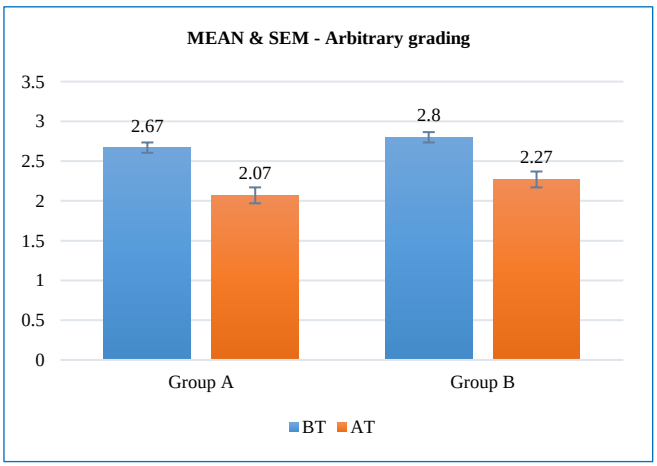

Figure 2: Showing mean & SEM of Arbitrary grading before treatment (BT) & after treatment (AT) in both groups.

Between the groups: Table no. 7 represents the changes in Arbitrary grading between the groups.

Table 7: Showing changes in Arbitrary grading using unpaired sample test for between the groups.

Groups	Mean	SD	SEM	T Value	P Value	Sig
Group A	2.07	1.10	0.28	0.4590	0.6498	NS
Group B	2.27	1.28	0.33			

Changes in area of the lesion

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Within the group: Table no. 8 and Figure 3 represents the changes in area of the lesion within the group.

Table 8: Showing changes in area of the lesion using paired sample test for within the group.

	Group A					Group B				
	Mean	SD	SEM	P	Sig.	Mean	SD	SEM	P	Sig.
BT	61.5333	77.5603	20.0260	0.0176	S	42.2333	46.8659	12.1007	0.0045	S
AT	20.5333	22.7282	5.8684			12.1833	14.0326	3.6232		

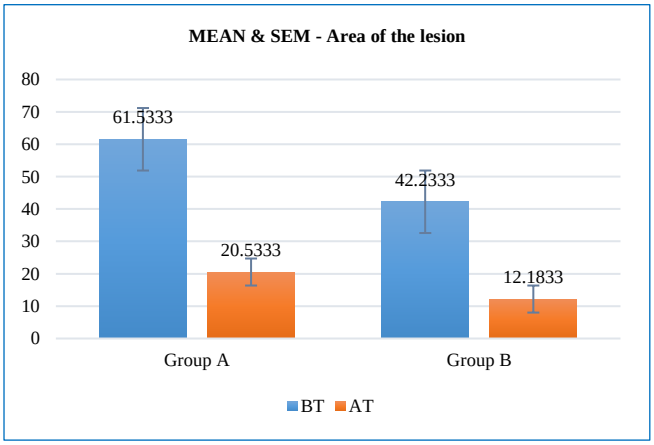

Figure 3: Showing mean & SEM of area of the lesion before treatment (BT) & after treatment (AT) in both groups.

Between the groups: Table no. 9 represents the changes in area of the lesion between the groups.

Table 9: Showing changes in area of the lesion using unpaired sample test for between the groups.

Groups	Mean	SD	SEM	T Value	P Value	Sig
Group A	20.5333	22.7282	5.8684	1.2107	0.2361	NS
Group B	12.1833	14.0326	3.6232			

Figure 4: Represents the CONSORT flow chart or the study flow chart.

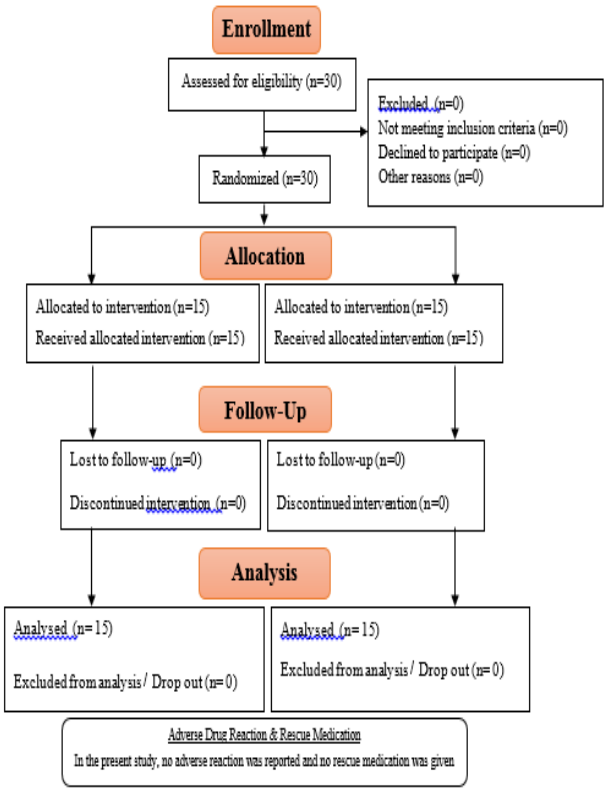

Figure 4: Showing the study flow chart

DISCUSSION

Vyanga is a *Kshudra Roga* mentioned in our classics having *Lakshanas* like *Niruja, Tanu* and *Shyava Mandala* on *Mukha Pradesha*,[1] which can be co-related to Melasma. Melasma is a pigmentation disorder that results in hyper-pigmented patches on the facial skin, which may affect interpersonal interactions. Studies have shown that patients with Melasma experience a negative effect on their appearance due to the persistent exposure of patches, along with feelings of shame, aggravation, embarrassment, low self-esteem and lack of motivation that can lead to suicidal thoughts.[3] In India, the prevalence of Melasma ranges from 1.5 % to 33.3 %. Despite being less frequent, men account for 20.5 % to 25.83 % of the prevalence rate.[2] In the present study also, maximum number of subjects were females, supporting the global prevalence rate. In Contemporary medicine, depigmenting medications with steroids and hydroquinone are prescribed, but

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they may be associated with negative side effects and a high relapse rate.[4] *Aragwadha Pushpa Churna* along with *Nimbuka Swarasa* is applied in the condition of *Vyanga* in the Cauvery river stretch of Namakkal district of Tamil Nadu as a folklore practice.[5] As *Aragwadha* is abundantly available throughout India, and as *Pushpa* is the part used, which makes the *Dravya Sangrahana* easier, the study was undertaken to compare the efficacy with *Varnya Gana Churna* mentioned in our classics & which is proven to be effective in the management of *Vyanga*.[6] This gave advantageous results as *Aragwadha Pushpa Churna* proved efficacious than *Varnya Gana Churna*, replacing ten *Dravya* by one.

Discussion on amount of discolouration - There is a highly significant difference from before the treatment to after the treatment with a p value <0.001 in both the groups. The effect size is better in Group A than in Group B. This indicates that *Aragwadha Pushpa Churna* is more beneficial in reducing the amount of discolouration.

Discussion on Arbitrary grading - There is a significant difference from before the treatment to after the treatment with a p value <0.05 in both the groups. The effect size in Group A is better than in Group B. This indicates that *Aragwadha Pushpa Churna* is more beneficial in reducing the number of hyper-pigmented lesions.

Discussion on area of the lesion - There is a significant difference from before the treatment to after the treatment with a p value <0.05 in both the groups. The effect size in Group B is better than in Group A. This indicates that *Varnya Gana Churna* is more efficacious in reducing the area of the lesion.

Discussion on relapsation of the condition - During the drug-free follow up period, 46.66 % of the subjects of Group B had relapsation of the condition i.e., area of the lesion measured was more than the 30th day (AT). Whereas in Group A, 100 % of the subjects did not have relapsation in any of the criterias. This indicates that *Aragwadha Pushpa Churna* is more efficacious in the management Melasma and also in preventing relapsation.

Discussion on mode of action - *Nidana Sevana* leading to the *Prakopa* of *Vata* & *Pitta Dosha* causes *Dushti* of *Rasa* & *Rakta* which can be tackled by *Tikta Rasa* and *Snigdha Guna* of *Aragwadha Pushpa*. *Sthanasamshraya* of *Dushta Rasa* & *Rakta* in *Mukha Pradesha* can lead to *Sanga* & *Vimarga Gamana* causing the *Lakshana* like *Niruja*, *Tanu* and *Shyava Mandala*. *Snigdha Guna* helps in increasing the *Mardavata* of *Tvacha* and decreases *Vata Dosha*. As it is *Varnakara*, it helps in the maintenance of *Varna*. *Tikta Rasa* helps in subsiding *Pitta Dosha* and it is also having *Kushtahara* property, which helps in reducing the condition. *Vishada Guna* and *Shodhana Karma* of *Tikta Rasa* does *Srotoshodhana*, which helps in tackling *Srotosanga*.

CONCLUSION

Outcome of the present study proved that *Aragwadha Pushpa Churna* showed better results in the management of *Vyanga* when compared clinically with *Varnya Gana Churna*. But the statistical comparison revealed that the efficacy of *Aragwadha Pushpa Lepa* and *Varnya Gana Lepa* were equivalent in the management of *Vyanga*, supporting the null hypothesis. The practice of *Aragwadha Pushpa Churna Lepa* with *Nimbuka Swarasa* was found to be effective in the condition of *Vyanga*, as per the folklore claim. Relapse rate was almost nil among the subjects of *Aragwadha Pushpa* group in the drug-free follow up period, showing the long time effect the *Dravya* has in the condition of *Vyanga*. *Aragwadha Pushpa* is easily available and is cost effective. Also, uprooting of the trees may be avoided unlike the drugs of *Varnya Gana* which are having *Moola* as the useful part, hence contributing to the conservation of medicinal heritage. Result of the present study also highlighted the superiority of *Ekamoolika Prayoga*, as a single drug is as effective as a formulation in the management of *Vyanga*.

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