



A RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF AMLIKA MOOLA LEPA AND AMLIKA BEEJA LEPA IN THE MANAGEMENT OF VYANGA WITH SPECIAL REFERENCE TO MELASMA

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ABSTRACT

Background & Objectives: Natural complexion of the body since birth is termed as Prakrutha Varna, where in Prakrutha avastha of Varna indicates healthy and radiant skin. Any changes in Prakrutha Varna can be considered as Roga and one among them is Vyanga. Vyanga is one among Kshudra Roga which might produce distress for the person due to hyperpigmentation of the skin over the face. This, on the basis of clinical features can be compared with Melasma. Melasma is the commonly reported pigmentary disorder in the Indian population. Unsightly blemishes or lesions on face affects emotional and mental wellbeing of a person, which in turn would affect self-confidence causing social stigma leading to the isolation of oneself from the community. In the contemporary science, the expensive topical steroids have been described in management of Melasma, which exhibit adverse reactions like rashes and irritation. Therefore, it is a high time to find a better, safe, inexpensive alternative treatment. Amlika being an abundantly available drug is indicated in Skin disorders. Acharya Vagbhata in Astanga Sangraha has mentioned application of Amlika moola in the management of Vyanga in the form of lepa. Also, Amlika moola (*Tamarindus indica* Linn.) is proven to have antityrosine and antioxidant properties. Though, Moola is described to be indicated in Skin disorders according to classical literatures, no studies have been conducted on Melasma. Also, Seed coat extract of Same drug, *Tamarindus indica* Linn. (Amlika) is proven to inhibit tyrosinase enzyme, which is responsible for production of melanin. Hence, the above study was taken up to evaluate and compare the efficacy of Amlika beeja and Amlika moola lepa in the management of Vyanga. **Methods:** In this study 30 subjects diagnosed with Vyanga w.s.r Melasma, were randomly selected and assigned into two groups, with 15 subjects in each group. The diagnosis was done by clinical features of Vyanga w.s.r Melasma. The trial drug Amlika moola Lepa was administered to the subjects of Group A and the trial drug Amlika beeja Lepa was given to subjects of Group B. Intervention was given for 21 days and study period was of 35 days. Assessment was done on 0 th day, 14 th day, 21st day, 35th day by using Fairness meter scale, Grid method, Arbitary grading, Photographs. The data obtained was statistically analysed by using Parametric test and non-Parametric test, the results were represented in forms of tables and graphs. **Results:** Within Group A and Group B, there was statistically highly significant difference in reducing the amount of discolouration. Between the groups, Amlika beeja Lepa showed statistically better results than Amlika moola Lepa. No adverse drug reactions were observed during the course of study. **Interpretation & Conclusion:** Both Amlika beeja Lepa and Amlika moola Lepa was effective in reducing the amount of discolouration due to their Vatahara and Pittahara properties. Also due to the presence of various phytochemicals, both interventions acted as an antioxidant and had an impact on any stage in the process of melanogenesis. Amlika beeja lepa was effective in reducing the area of the lesion than Amlika moola lepa. Thus, both the interventions can be used since beeja is cost effective and easily available it can be readily used in Vyanga w.s.r. Melasma.

INTRODUCTION

Skin is the largest organ which acts as a physical, biochemical and immunological barrier between outside world and the body. The concept of beauty having an age-old origin is expressed through the skin which is manifested in the form of complexion. In Ayurveda it is understood in terms of Varna. Natural complexion of the

body since birth is termed as Prakrutha Varna, where in Prakrutha avastha of Varna indicates healthy and radiant skin and any changes in Prakrutha Varna can be considered as Roga^[1] and one among them is Vyanga. Vyanga is one among Kshudra Roga which might produces distress for the person due to hyperpigmentation of the skin over the face which on the basis of clinical

features can be compared with Melasma.

In the present competitive era, importance of beauty and personality is increasing. Melasma is the commonly reported pigmentary disorder in the Indian population. Unsightly blemishes or lesions on face affects emotional and mental wellbeing of a person which in turn would affect self-confidence causing social stigma which might lead to the isolation of oneself from the community. In the contemporary science, the expensive topical steroids have been described in management of Melasma, which exhibit adverse reactions like rashes and irritation. Therefore, it is a high time to find a better, safe, inexpensive alternative treatment. Acharya Vagbhata in Astanga Sangraha has mentioned application of Amlika moola in the management of Vyanga in the form of lepa.^[3] Amlika is abundantly available and seed coat extract of *Tamarindus indica* Linn. is proven to inhibit tyrosinase enzyme which is responsible for production of melanin.^[4] Amlika (*Tamarindus indica* Linn.) moola is having antityrosine and antioxidant properties.^[5]

Hence the above study is taken up to evaluate and compare the efficacy of Amlika beeja and Amlika moola lepa in the management of Vyanga.

MATERIALS AND METHODS

AIMS and OBJECTIVES

- To evaluate the efficacy of *Amlika moola lepa* in the management of *Vyanga* with special reference to Melasma.
- To evaluate the efficacy of *Amlika beeja lepa* in the management of *Vyanga* with special reference to Melasma.
- To compare the efficacy of *Amlika moola lepa* and *Amlika beeja lepa* in the management of *Vyanga* with special reference to Melasma.

Intervention

Table No. 1: Intervention.

Features	Group A	Group B
Sample size	15	15
Intervention	Amlika moola churna lepa	Amlika beeja churna lepa
Medium of Application	Jala	Jala
Dosage	Quantity sufficient	Quantity sufficient
Time of Administration	Morning	Morning
Trial period	21 days	21 days
Follow up	35 th Day	35 th Day

Criteria for assessment of treatment

Objective criteria:

1. Arbitrary grading on the symptom, Mandalam visrijati: Mandalakara^[9]

Table No 2: Arbitrary grading on the symptom, Mandalam visrijati.

Sl. no	Features	Score
A	More than five circular lesion present over face.	4
B	4 to 5 circular lesion present over face.	3
C	3 to 4 circular lesion present over face.	2

(a) Inclusion criteria

- Subjects of either gender within the age group between 20 - 50 years were selected.
- Subjects fulfilling the diagnostic criteria of Vyanga with special reference to Melasma were randomly selected irrespective of religion, occupation, socio-economic status.

(b) Exclusion criteria

- Females on oral contraceptive pills, pregnant women, lactating women.
- Hyperpigmentation since birth.
- Any other condition interfering with course of treatment.

Diagnostic criteria

Subjects will be diagnosed with clinical signs and symptoms of Vyanga^[6,7]

- Niruja
- Syama
- Mandala
- Tanu

Cases of Melasma were diagnosed using- Woods lamp^[8]

Grouping

Thirty subjects fulfilling the criteria were selected and randomly assigned into two groups of 15 each.

- Group A: Amlika moola
- Group B: Amlika beeja

Plan of the study

Simple Randomized clinical trial

Simple randomization – Lottery method was adopted

D	1 to 2 circular lesion present over face.	1
E	No such circular lesion present on face.	0

2. Area of the lesion assessed by grid method^[10]

The area affected were assessed by adopting the grid method that is the area affected were measured by marking the margins of the patches one by one on a transparent paper. This sketched transparency paper was put on a graph paper and surface area is noted in square

millimeters.

3. Amount of discoloration

The discoloration was scored according to the density of pigmentation using Garnier standard fairness scale along with normal skin.



4. Photographs with Woods lamp

Photographs of the subjects was taken before and after

treatment using digitalcamera.

OBSERVATION AND RESULTS

AGE

Table No. 3: Showing age wise distribution.

Age in years	Total	Percentage%
21-30yrs	4	13.3%
31-40yrs	12	40%
41-50yrs	14	46.6%

In the present study, it was observed that 13.3% of subjects were in the age group of 21-30 years, 40% were

in the age group of 31-40 years and 46.60% in the age group of 41-50 years.

Gender

Table no. 4: Showing gender wise distribution.

Gender	Total	Percentage%
Male	4	13.3%
Female	26	86.6%

In the present study, it was observed that males were 13.3% and females were 86.6%.

Religion

In the present study, it was observed that 100% of the subjects belonged to Hindu religion.

Table 5: Showing religion wise distribution.

Religion	Group A	Percentage%	Group B	Percentage%	Total	Percentage%
Hindu	15	100%	15	100%	30	100%

Marital status

Table 6: Showing marital status wise distribution

Marital status	Total	Percentage%
Married	27	90%
Unmarried	3	10%
Widow	0	0
Divorce	0	0

Occupation

In the present study, it was observed that 46.6% of the

subjects were Professionals, 40% unskilled laborers 10% were Housewife and 3.3% were student.

Table No. 7: Showing occupation wise distribution.

Occupation	Total	Percentage
Student	1	3.33%
Housewife	3	10%
Professionals	14	46.6%
Unskilledlabour's	12	40%

Duration of disease

In the present study, it was observed that 43.3% of subjects had duration of disease since 1 to 2 years, 16.6%

had history since 1year,13.3% had history for 3-4 years and10% in the last 2-3 years .

Table 8: Showing duration of disease

Duration of disease	Total	Percentage%
1- 5months	5	16.6%
5-12 months	5	16.6%
1-2years	13	43.3%
2-3years	3	10%
3-4years	4	13.3%

Course of disease

In the present study, it was observed that 46.6% of

subjects had Progressive nature,43.3% had relapsing, 10% Stationary.

Table No. 9: Showing course of disease.

Course of disease	Total	Percentage%
Progressive	14	46.6%
Relapsing	13	43.3%
Stationary	3	10%

Distribution based on Psychological aggravating factor

In the present study, it was observed that 43.3% had Chinta as aggravating factor, 40% of subjects had

Krodha as aggravating factor, 30% had history of Shoka, 26.6% had history of all the factors, and 10%, 13.3% as nothing specific and 3.3% as Baya.

Table no. 10: Showing psychological aggravating factor.

Psychologicalaggravating factor	Total	Percentage%
Chinta	13	43.3%
Shoka	9	30%
Baya	1	3.3%
Krodha	12	40%
All the above	8	26.6%
Nothing specific	4	13.3%

Water intake**Table No. 11: Showing water intake wise distribution.**

Waterintake	Total	Percentage%
1liters	15	50%
2liters	11	36.6%
3 liters	4	13.3%

In the present study, it was observed that 50% of subjects were having 1 l of water/day, 36.60% were having 2 l of

water / day, and 13.3% were having 3 l of water/ day.

H/o Hereditary**Table No. 12: Showing history of hereditary wise distribution.**

H/o Hereditary	Total	Percentage
No	24	80%
Yes	6	20%

Woods lamp assessment

In the present study, it was observed that 40% subjects

had Dermal layer involvement and 30% of subjects had epidermal and 30% mixed involvement .

Table No. 13: Showing woods lamp assessment.

Woods lamp assessment	Total	Percentage%
Epidermal	9	30%
Dermal	12	40%
Mixed	9	30%

Presentation of recorded data obtained in both the groups is presented in tables, diagrams and chart.

Statistical analysis was done using SPSS software version 20. In the present study following statistical tests were done.

For the assessment of Arbitrary grading on the symptom of *Mandala* (Number of lesion) and Amount of discoloration (*Shyavata*), Friedman’s test was applied to assess before and after treatment results within the group and Mann Whitney U test was applied to assess the results between the group.

For the assessment of Area of the lesion assessed by Grid method, by repeated Measures of ANOVA within the group and Unpaired t test was applied between the group.^[11,12]

The data was collected using fairness meter scale for assessing amount of discoloration on 0th, 14th, 21st and 35th day. The obtained data was analysed statistically. To assess the efficacy of interventions within the groups Paired t test was used and between the groups Unpaired t test was used. The results are represented in tables and graphs. Analysis within the groups.

Amount of discoloration

Table No. 14: Amount of discoloration findings.

Amount of discoloration	GROUP								p value between the groups	Effect size between the group
	GROUP A (N=15)				GROUP B (N=15)					
	Mean	SD	Effect size	P value	Mean	SD	Effect size	P value		
0th day	15.27	1.100		0.001	13.67	2.554		.001	0.100	0.736
14th day	15.13	1.246	0.119	(HS)	13.53	2.475	0.055	(HS)	(NS)	
21st day	13.33	1.397	1.366		11.60	2.898	0.716			0.630
35th day	13.27	1.387	0.043		11.47	2.800	0.045		0.066(NS)	0.713

Arbitrary grading

Table No. 15: Arbitrary gradings findings.

Arbitrary grading	Group								p value between the groups	Effect size between the group	
	Group A (N=15)				Group B (N=15)						
	Mean	SD	Effect size	p value	Mean	SD	Effect size	P value			
0th day	1.27	.594	0	1.000 (NS)	1.60	.632	0	0.112 (NS)	0.182(NS)	0.538	
14th day	1.27	.594	0		1.60	.633	0				
21st day	1.27	.594	0		1.47	.516	0.225			0.182(NS)	0.359
35th day	1.27	.594	0		1.47	.516	0				

Area of the patch

Table no. 16: Area of the patch findings.

Area of the patch	Group								P value between the groups	Effect size between the group
	Group a (n=15)				Group b (n=15)					
	Mean	Sd	Effect size	P value	Mean	Sd	Effect size	P value		
0th day	3.7200	1.09574	0	.334 (ns)	4.3833	1.95226	0	.014 (s)	.095 (ns)	0.417
14th day	3.7200	1.09574			4.3833	1.95226				
21st day	3.6833	1.09848	0.036		3.7667	1.51618	0.354			0.060
35th day	3.6833	1.09848	0		3.7667	1.51618	0			

DISCUSSION AND RESULTS

Tamarind tree has been widely cultivated since ancient

times, its descriptions are found in the Brahma samhitha scriptures and Vishnu Dharma Sutra. It has been

mentioned in Caraka Samhita, Susruta Samhita, Ashtanga Sangraha with the name 'Amleeka' under Amla varga (group of sour drugs). Its synonyms, properties, and action were narrated in various Nighantus like Raja Nighantu, Dhanwantari Nighantu, Sodhala Nighantu, Bhavaprakasa Nighantu, Madanadi Nighantu, and Nighantu Adarsh. The researchers showed *Tamarindus indica* Linn has wide range of potentials like anti-diabetic, antimicrobial, antivenomic, antioxidant, antimalarial, cardioprotective, hepatoprotective, antiasthmatic, laxative and antihyperlipidemic activity. *Tamarindus indica* is a medicinal plant having immense therapeutic potential as per Ayurvedic literature. But many of them are unexplored and are not clinically utilized. Tamarind tree is often planted as an avenue tree along road sides and as an ornamental tree in gardens and is found throughout the tropics. Amlika being an abundantly available drug is indicated in Skin disorders. Acharya Vagbhata in Astanga Sangraha has mentioned application of Amlika moola in the management of Vyanga in the form of lepa. Also, Amlika moola (*Tamarindus indica* Linn.) is proven to have antityrosine and antioxidant properties. Amlika beeja is cost effective cheap and easily available, and seed is a by-product of the tamarind pulp industry, Whole tamarind seed and seed kernel are rich sources of protein.

Acharya Vagbhata in Astanga Sangraha has mentioned application of Amlika moola in the management of Vyanga in the form of lepa. Amlika beeja is easily, commonly available and in folklore claim the seed decoction of Amlika is used in facial blemishes. Vyanga is one among Kshudra Roga which might produces distress for the person due to hyperpigmentation of the skin over the face which on the basis of clinical features can be compared with Melasma. There are not many statistics to prove the exact frequency of Melasma in this country but the general impression is 10-20 percent of patients seek medical advice for this condition.

In ancient Vedic literature there is description of skin diseases and the various beautifying yoga. Acharya Charaka mentions Vyanga as a disease manifested by the suppression of chardi vega. He also explains the brief samprapti of Vyanga as vitiated.

Pitta gets lodged in Rakta leading to Vyanga. Acharya Sushruta has explained the nidana, lakshana and chikitsa of Vyanga. In Ashtanga sangraha and ashtanga hrudaya, types of Vyanga are told. Acharya Madhavakara, Bhavamishra, Sharangadhara, Yoga ratnakara and many other authors explains the nidana, samprapti, lakshana and chikitsa of Vyanga.

The disease predominantly afflicts the Raktavaha Srotas. Dosh getting localized in the facial skin produce cardinal features such as niruja, tanu, shyava mandala.

Melasma/ Chloasma is a disorder of increased pigmentation confined to face. Vyanga is bahya

rogamargashrita that is eka margaja, also the hetu, purvarupa and rupa are alpa and there is no upadrava for Vyanga. There are various modes of treatment for Vyanga. Nidana parivarjana is the first line of treatment which is adopted are Shodhana like Raktamokshana, Nasya and Shamana in the form of external application of drugs in the form of Lepa, Abhyanga, Udvartana, Prakshalana

As per the modern parlance the action of drug is to minimize pigmentation by following mechanisms in Melasma.

- 1) Reducing tyrosinase activity
- 2) Absorb Ultra-violet rays
- 3) Anti-scavenging
- 4) Anti-oxidant

Hydroquinone is the most frequently prescribed depigmenting agent worldwide and it has remained the gold standard for the treatment of melasma, particularly of the epidermal type.

Long term usage of Hydroquinone has various side effects such as contact dermatitis, along with ochronosis. Hence a comparative study was planned to assess and compare the effect of Amlika moola lepa and Amlika beeja lepa in Vyanga.

Phyto-chemical analysis was carried out with the cold extract of *Tamarindus indica* Linn in hydro-alcohol. All the major active constituents are found in hydro-alcoholic extract of *Tamarindus indica* Linn that is the presence of Flavonoids, Polyphenols, Proteins, Tannins, Steroids, Carbohydrates, Triterpenoids and Saponins.

Quantification of Phyto-chemicals exhibits that the higher percentage of Tannins in *Tamarindus indica* Linn seed and 1.4% of Polyphenols in both root and seed.

- Tannins are naturally occurring substances having mild anti-oxidant, astringent, photo-protection properties. Tannins have significant anti-inflammatory response induced by UV rays.
- The seed contain gallic acid, major fatty acids like palmitic acid, oleic acid, stearic acid.
- The expression and activation of tyrosinase is important in the control of melanogenesis, since it acts as the catalyst in the rate limiting reaction of the melanogenic pathway, Tamarind seed coat extract inhibits the tyrosinase activity and the percentage of melanin reduction is about 20-30%.^[13]
- In addition, Polyphenols, such as epicatechin, epigallocatechin and epicatechin, 3-gallate, isolated from the plants also have proved to be effective inhibitors of tyrosinase. Flavonoids exhibit anti-melagenic effect by inhibiting tyrosinase enzyme via transcriptional factor.
- Gallic acid inhibited both melanin synthesis and tyrosinase activity helps in reduction of hyperpigmentation.

CONCLUSION

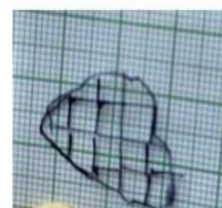
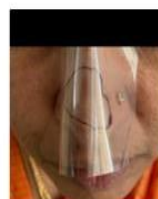
In the present study, Amlika beeja showed comparatively better results than Amlika moola in treatment of Vyanga. Tannins, polyphenols found in higher concentration in Amlika beeja compared with Amlika moola which in turn exhibiting tyrosinase inhibition and having anti-melanogenic property is proving its effectiveness in Vyanga. The activity of Amlika moola and beeja is found to be effective in Vyanga as per the reference of Ashtanga Sangraha, and folklore claim Amlika beeja is cost effective, will not be environmental burden since its easily available hence uprooting of tree can be avoided and conservational aspects can be taken care of.

Scope for further study

- *Amlika beeja and Moola* in the form of different Kalpana (taila or cream) consistency can be formulated to see the efficacy.
- MASI score for assessment of Melasma can be adopted for further accuracy of the results.
- Study can be carried out in a larger sample size and longer duration to analyze the results.
- Study can be carried out after Shodhana Chikitsa of patient along with Shamana Chikitsa (internal administration) for better results.



Before treatment



After treatment

GROUP A
AMLIKA
MOOLAGROUP B
AMLIKA
BEEJAAssessment of Skin
discoloration**ACKNOWLEDGEMENT**

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REFERENCES

1. Pallavi G, Gupta KV, Shreevathsa M, Chate VA, Balakrishna DL. Clinical evaluation of Varnya gana lepa in Vyanga (Melasma). AYU [Internet], 2015 [cited 2020 Jan 30]; 36(2): 151-6. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4784124/> DOI:10.4103/0974-8520.175543
2. Angadi SS, Gowda ST. Management of Vyanga (facial melanosia) with Arjuna Twak lepa and Panchanimba Churna. AYU [Internet], 2014 [cited 2020 Jan 30]; 35(1): 50. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4213969/> DOI: 10.4103/0974-8520.141924
3. Vriddha Vagabhata, Astanga Samgraha with commentary of Indu edited by Acharya Jyothirmithra, Uttarastantra, Varanasi: Chaukhamba Sanskrit Sansthan, 2012; 821: 37 - 18.
4. Pillaiyar M T, Manickam M, Namasivayam V. Skin Whitening agents: Medicinal chemistry perspective of tyrosinase inhibitors. Journal of Enzyme Inhib Med Chem, 2017 [cited 2020 Jan 30]; 32 (1): 403-25. Available from: <https://pubmed.ncbi.nlm.nih.gov/28097901/> DOI:

- 10.1080/14756366.2016.1256882
5. The Ayurvedic Pharmacopoeia of India. New Delhi: The Controller of Civil Lines, 2004; 1: 16-17.
 6. Pandey GS. Dravyaguna Vijnananam. Varnasi: KrishnadasAcademy, 2002; 120: 2.
 7. Madhavakara, Madhava Nidana, Madhukosha.2nd Edition. Varanasi:Chaukambha; Sanskrit, 1998; 280
 8. Paul K. Taylor SC. Dermatology for skin of color. New York. McGraw hillcompanies, 2009; 332.
 9. Nath R, Mandal SK. Classical diagnostic approach of the disease Vyanga. Journal of Scientific and Innovative Research, 2017; 1, 6(4): 135-137.
 10. Sreelatha R. A randomized comparative clinical study to evaluate the effect of topical formulation in Vyanga (chloasma) [dissertation].Bengaluru: RGUHS, 2012.
 11. Sarpodar S, Bhor S, Bhor IS. Parametric tests. In: Ranade S, Deshpande RR, editors .Research Methodology and Medical Statistics.Pune: Manakarnika Publication, 2015; 10, 3: 244-50.
 12. Sarpodar S, Bhor S, Bhor IS. Familiarization with the use of Statistical software. In: Ranade S, Deshpande RR, editors. Research Methodology and Medical Statistics.Pune: Manakarnika Publication, 2015; 15, 3: 290.
 13. Phetdee K, Rattanamanee K, Teaktong T, Viyoch J. Tamarind seed coat extract reduces melanin production via tyrosinase in melanocyte. J Biol Sci, 2012; 20, 12(4): 239-45.