



## Research Article

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### EFFECT OF A VALUE-ADDED FORMULATION OF VATA PALLAVA MALATHYADI LEPA IN MUKHADUSHIKA

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#### ABSTRACT

Mukhadushika is one of the skin diseases described under kshudra roga. It is having close resemblance with acne vulgaris. It is the 8<sup>th</sup> most common disease worldwide. In conventional medicine various topical therapies are available, but long-term use of these drugs observed to have some adverse effects. Owing the gravity of situation, need was felt for search of new safe and effective medicine. So, the formulation Vata pallava malathyadi lepa is selected. Vata pallava malathyadi lepa mentioned in Sharangadhara Samhita consists of six drugs. Research works of single drugs shows anti-bacterial, anti-inflammatory and antioxidant activities. Value addition is a relative proposition assuming magnanimous importance in today's dynamic world. In general, adding value is the process of changing or transforming a product from its original state to a more valuable state. Value added Vata pallava malathyadi lepa is very convenient and user-friendly dosage form. An effort was made to assess the effect of value-added formulation of vata pallava malathyadi lepa in Mukhadushika. The trial drug was used as an external application. The clinical trial was undertaken as before and after trial with 30 patients for a period of one month and data was collected. Global Acne Grading System (GAGS) is used for the assessment. Grading of pain, swelling, discoloration and oozing before and after treatment were also assessed. The data was tabulated and analyzed using Wilcoxon Signed Rank list. The trial drug showed highly significant effect in reducing acne vulgaris with p value < 0.001.

**Keywords:** Mukhadushika, kshudra roga, GAGS

#### INTRODUCTION

We all live decades longer than our grandparents and will have better health in our later years. With this enhanced longevity, we all want to look as young as we feel. Aspiring to maintain eternal youth and to look good is not just superficial vanity. Our human nature dictates that we take care of ourselves and enhance our appearance.

Ayurveda has given importance to appearance of an individual and has its own share in upkeep of beauty to which health is closely related. The more we nurture ourselves the more radiant we become physically and expressively, regardless of our particular body shapes and proportions. The cosmetic and personal care industry is large economic force today. Now a day, herbal medicines are quite common in the cosmetic industry.

In Ayurveda classics Tarunya pidaka/Mukhadushika is one of the skin diseases described under kshudra roga<sup>1</sup>. Acharya Sushruta was the first and foremost to maintain whole groups of such disease of the skin. These diseases have an adverse effect upon the complexion and personality of individual. First treatment option for Mukhadushika is shamana therapy. This mainly includes mukhalepa<sup>2</sup>. Mukhadushika is having close resemblance with acne vulgaris. It is a common skin disorder primarily of teenagers and young adults. It affects 80% of individual between puberty and 30 years of age, Skin provides individual identification and awareness of personal identity and

self-image. Depression was 2-3 times more prevalent in acne patients. It is the 8<sup>th</sup> most common disease worldwide.

Acne vulgaris is a chronic inflammatory disease of pilosebaceous units<sup>3</sup>. Acne vulgaris occurs when hair follicles become clogged with dead cells and sebum. Lack of cleanliness causes its increase. In acne vulgaris, comedone form in hair follicle due to the blockage of follicular orifice by retention of keratinous material and sebum<sup>4</sup>. The activity of bacteria *Propioni bacterium acnes* in a comedone release fatty acids from sebum, cause inflammation within the cyst. In conventional medicine various topical therapy like benzoyl peroxide, retinoid, systemic therapies like antibiotics and hormonal therapy are available. Long term use of these drugs observed to have some adverse effects. So, the formulation Vata pallava malathyadi lepa is selected. Vata pallava malathyadi lepa mentioned in Sharangadhara Samhita is used in the treatment of Tarunya pidaka<sup>5</sup>. All the ingredients in this formulation possess Katu paka which have the property of sneha and kleda shoshana, shroto vivarana, kushta, kantuhara, Vrana avasdana<sup>6</sup>. All these properties help in the removal of collected sebum and clearing of pores etc. Most of the drugs like vata pallava, lodhra, rakta chandana, Daruharidra are kapha pita shamana. Kapha and rakta are main the doshas involved in the pathogenesis of Tarunya Pidaka<sup>7</sup>. Individually all drugs possess properties like Vrana shodhana, ropana, rakta shodhaka etc. The drug Kushta possesses jantughna property. Vata Pallava, Kushta, Daruharidra are varnya also. Thus, Vata pallava malathyadi lepa is not only effective in Tarunya pidaka but also increases the complexion. By assuming

the above criteria no more potent formulation than Vata pallava malathyadi lepa is there in the treatment of Mukhadushika. Value added vata pallava malathyadi lepa is prepared by using vanishing cream as base and medicines incorporated as hydro alcoholic extracts of the above mentioned drugs<sup>8</sup>.

The study aims to clinically evaluate the efficacy of value added Vata pallava malathyadi lepa in Mukhadushika.

## MATERIAL AND METHODS

### Objective of the study

To evaluate the effect of value-added formulation of vata pallava malathyadi lepa in Mukhadushika.

### Research approach

The patient selected for the study received the prepared vanishing cream of vata pallava malathyadi lepa. This study was conducted in a single group and the data was collected before and after the trial. Thus, effect in Mukhadushika was assessed and evaluated.

### Research design

It is an interventional study with before and after evaluation of the data in a single group. No control group is taken for comparison. Here the patient's status is noted before and after the treatment. Hence it is an uncontrolled study.

### Study setting

The clinical study was conducted in the outpatient department of Rasa Shastra and Bhaishajya kalpana department, Government Ayurveda hospital Thiruvananthapuram.

### Sampling

For the clinical study a sample from accessible population of sex of age group 12 to 30 were selected from the outpatient department of Rasa Shastra and Bhaishajya Kalpana, Government Ayurveda college Hospital, Thiruvananthapuram. Total 30 patients were selected as per the inclusion and exclusion criteria. Informed consent was taken from patients and study was carried out as per International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP) or as per Declaration of Helsinki guidelines.

### Inclusion criteria

Patients of both sexes aged 12 to 30 years with Acne vulgaris

### Exclusion criteria

Patients who are allergic to cosmetic creams

### Study period

Total duration of study - 30 days  
Assessment will be collected on 30<sup>th</sup> day.

### Data collection

Data will be collected before and after study through case Performa and Global Acne Grading System (GAGS).

Table 1: Outcome assessment as per GAGS

Location with factor (F)	Clinical presentation with grade (G)	Local score before treatment (F×G)	Local score after treatment (F×G)	Local score (follow up) F×G
Forehead (2)	No lesion (0) ≥ one comedone (1) ≥ one papule (2) ≥ one pustule (3) ≥ one nodule (4)			
Right cheek (2)	No lesion (0) ≥ one comedone (1) ≥ one papule (2) ≥ one pustule (3) ≥ one nodule (4)			
Left cheek (2)	No lesion (0) ≥ one comedone (1) ≥ one papule (2) ≥ one pustule (3) ≥ one nodule (4)			
Nose (1)	No lesion (0) ≥ one comedone (1) ≥ one papule (2) ≥ one pustule (3) ≥ one nodule (4)			
Chin (1)	No lesion (0) ≥ one comedone (1) ≥ one papule (2) ≥ one pustule (3) ≥ one nodule (4)			
Chest/upper back (3)	No lesion (0) ≥ one comedone (1) ≥ one papule (2) ≥ one pustule (3) ≥ one nodule (4)			

**Table 2: Score and grade of GAGS**

Global score	Grade	Severity
0	0	None
1 -18	1	Mild
19 – 30	2	Moderate
31 – 38	3	Severe
≥ 39	4	Very severe

Vedana (pain), Shotha (swelling) and Srava (Oozing), Vivarnata (Discoloration) of pidaka (Pimple) assessed through Grading.

**Table 3: Grade of pain on Pitaka**

Clinical Parameter	Severity	Grade	BT	AT
Pain on Pitaka (pain)	No tenderness	0		
	Pain on deep pressure over Pitaka	1		
	Pain on touch	2		
	Pain without touch	3		

BT: Before Treatment, AT: After Treatment

**Table 4: Grade of Swelling in Pitaka**

Clinical Parameter	Severity	Grade	BT	AT
Swelling in Pitaka (Shotha)	No swelling	0		
	Mild swelling	1		
	Moderate swelling	2		
	Severe swelling	3		

BT: Before Treatment, AT: After Treatment

**Table 5: Grade of oozing of Pitaka**

Clinical Parameter	Severity	Grade	BT	AT
Srava of the Pitaka (Oozing)	No srava	0		
	Lasika srava	1		
	Puya srava	2		
	Rakta puya mishram	3		

BT: Before Treatment, AT: After Treatment

**Table 6: Grade of discoloration of Pitaka**

Clinical Parameter	Severity	Grade	BT	AT
Vivarnata of Pitaka (Discoloration)	Normal skin colour	0		
	Brown colour	1		
	Red colour	2		

BT: Before Treatment, AT: After Treatment

#### Assessment criteria

The outcome variables are the efficacy measurement of the clinical trial. In this study, assessments were number of comedones, papule, pustule and nodule.

Also, the signs such as Vedana (pain), Shotha (swelling), Srava (oozing) and Vivarnata of Pitaka (discolouration)

#### Sampling technique

Consecutive cases till satisfying the sample size

#### Intervention schedule

Medicine - Value added formulation of Vata pallava malathyadi lepa

Route of administration - External application

Duration - 1 month

Dispensing - 20 grams of creams in well tight wide mouthed bottles.

#### Mode of application

The cream is applied 2 times daily, after washing the face with Lukewarm water.

### RESULT AND DISCUSSION

#### Clinical study

The present study was conducted at Outpatient Division of Rasa Shastra and Bhaishajya Kalpana Department, Government Ayurveda College, Thiruvananthapuram. The criteria of selection of patients were based on Case Performa. Patients of both sexes between the age group of 12 to 30 years were selected. Medicines were given for 1 month and analyzed the criteria before and after treatment.

#### Demographic data

Out of the total 30 patients, 46.7% belonged to the age group 20 – 25 years, 36.67% belonged to 12 – 19 years and 16.6% belonged to 26 – 30 years. It is clear that most number is seen in youth. Among 30 patients 67% were female and 33% were male.

Among the total 73% belongs to middle social status, 87 % patients were not doing exercise or doing irregularly. Among the total 30 patients, 60% patients were having chronicity more than 2 years, 27% belonged to 1-2 years and 13% were with chronicity <1 year. Out of 30 patients, 77% were with greasy face and 47% patients having history of family background.

**Response of treatments**

On individual assessment of all the cases, there was a relief of major symptoms like Oozing, discoloration, pain and swelling.

On examining the data of pain of patient, before treatment 13.3% patients had severe pain, 40% had moderate pain, 26.7% mild and 20% had no pain. After treatment it was changed to 6.7% moderate, 40% mild and 53.3% had no pain. The effectiveness of treatment of pain was statistically significant (p < 0.001).

By assessing the data of oozing, 26.7% patients had severe oozing before treatment, which is changed to 0% after treatment. 46.7% had moderate oozing, which is changed to 20% after treatment. Likewise, 20% patient had mild and 6.7% had no oozing, which is changed to 36.7% and 43.3% respectively after treatment. Wilcoxon signed rank test showed that the treatment had significant effect with P value < 0.001.

By assessing on swelling, it is seen that 16.7% patients had severe swelling, which is changed to 0% after treatment. 46.7% had moderate swelling, which is changed to 13.3% after treatment. 23.3% had mild and 13.3% had no swelling before treatment, which becomes 26.7% and 60% respectively after treatment. Wilcoxon signed rank test showed that the treatment had significant effect with P value < 0.001.

On assessing discoloration, it is seen that 46.7% patients had moderate discoloration, 36.7% mild and 16.7% had no discoloration before treatment, which is changed to 0% moderate, 66.7% mild, 33.3% no discoloration after treatment. Wilcoxon signed rank test showed that the treatment had significant effect with P value < 0.001

On assessing the overall grade using GAGS, it is seen that 6.7% patients were in very severe grade, 50% severe, 26.7% moderate, 16.7% mild grade before treatment, which is changed to 0% very severe, 0% severe, 16.7% moderate and 83.3% mild after treatment. Before treatment 29.43 mean with standard deviation of 7.63 was changed to 12.17 with Standard deviation of 5.48 after treatment. Wilcoxon signed rank test showed that the treatment had significant effect with P value < 0.001.

**Tables representing outcome variables before and after treatment**

**Table 7: Global score**

	N	Global Score		Paired difference		Paired t test	
		Mean	Sd	Mean	Sd	T	P
BT	30	29.43	7.63	17.267	5.232	18.076	< 0.001
AT	30	12.17	5.48				

BT: Before Treatment, AT: After Treatment

**Table 8: Effect of treatment of pain on Pitaka**

Pain	BT		AT	
	N	%	N	%
None	6	20.0	16	53.3
Mild	8	26.7	12	40.0
Moderate	12	40.0	2	6.7
Severe	4	13.3	0	0
Total	30	100.0	30	100.0

**Probable mode of action**

The route of administration applied in the present study was external application. In Ayurvedic classics Sushruta acharya describes that Bhrajaka agni which is situated in the skin and it enables the digestion and utilization of substances used through abhyanga, parisheka and alepana etc. Vagbhata acharya also observes that Bhrajaka pitta is situated in the skin.

In Mukhadushika, kapha and vata are main doshas and rakta is the dushya. The signs and symptoms show that it is thick (Ghana) in consistency, painful and impregnated with fat like substance (Medogarbha). The associated vata dosha kopa occurs due to shrotorodha by kapha dosha. Mukhadushika is mainly located on upper part of the body, which is kapha sthana. So, the treatment option of Mukhadushika is langhana. Vagbhata acharya mentioned that first should take shamana therapy as mukhalepa. The medication should have kapha vata hara property, varnya, rakta prasadana property.

In Vata pallava malathyadi lepa, Jati, Raktachandana, Kushta and Lodhra possess katu paka. Katu paka has the property of sneha and kleda shoshana, shroto vishodhana, kushta, Kandu hara, vranavasadana. The sneha and kleda achooshana property help in the removal of collected sebum. Shroto vishodhana property help in clearing of pores (70% of the patient in the present study is having greasy face). In this formulation three drugs possess ushna Veerya and the other three is having Shita Veerya. So, it does not vitiate kapha as well as vata and at the same time act as rakta prasadana.

Vata pallava, lodhra and rakta chandana having kapha pita shamana property, kushta is having kapha vata hara property. Kapha, vata and rakta are main doshas evolved in the Samprapti of Mukhadushika. The drug Kushta is having jantughna property. This helps in the prevention of spreading of bacterial action (Propionic bacteria is the main bacteria causing the spreading of acne vulgaris). Vata pallava, kushta and Daruharidra have varnya property. This will help to remove the discoloration and maintain natural complexion.

The present study showed significant reduction in Mukhadushika. The formulation also showed effect to achieve the normal skin color. As this formulation is in the form of vanishing cream, it becomes more users friendly.

**Table 9: P and Z value of pain**

	Z	P
Wilcoxon signed rank test	4.203	< 0.001

**Table 10: Effect of treatment of oozing on Pitaka**

Oozing	BT		AT	
	N	%	N	%
None	2	6.7	13	43.3
Mild	6	20.0	11	36.7
Moderate	14	46.7	6	20.0
Severe	8	26.7	0	0
Total	30	100.0	30	100.0

BT: Before Treatment, AT: After Treatment

**Table 11: P and Z value of oozing**

	Z	P
Wilcoxon signed rank test	4.782	< 0.001

**Table 12: Effect of treatment of swelling on Pitaka**

Swelling	BT		AT	
	N	%	N	%
None	4	13.3	18	60.0
Mild	7	23.3	8	26.7
Moderate	14	46.7	4	13.3
Severe	5	16.7	0	0
Total	30	100.0	30	100.0

BT: Before Treatment, AT: After Treatment

**Table 13: P and Z value of swelling**

	Z	P
Wilcoxon signed rank test	4.660	< 0.001

**Table 14: Effect of treatment of discoloration on Pitaka**

Discoloration	BT		AT	
	N	%	N	%
None	5	16.7	10	33.3
Mild	11	36.7	20	66.7
Moderate	14	46.7	0	0
Total	30	100.0	30	100.0

BT: Before Treatment, AT: After Treatment

**Table 15: P and Z value of discoloration**

	Z	P
Wilcoxon signed rank test	4.146	< 0.001

## CONCLUSION

The study was focused on the clinical evaluation of Value added Vata pallava malathyadi lepa in Mukhadushika.

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous units, when hair follicle plugged with sebum and dead skin cells. It is having close similarity with acne vulgaris. Vata pallava malathyadi lepa mentioned in Sharangadhara Samhita is effective in the management of Mukhadushika. In Vata pallava malathyadi lepa, Jati, Raktachandana, Kushta and Lodhra possess katu paka. Katu paka has the property of sneha and kleda shoshana, shroto vishodhana, kushta, Kandu hara, vranavasadana. These properties help in curing Mukhadushika. In this formulation three drugs possess ushna Veerya and the other three is having Shita Veerya. So, it does not vitiate kapha as well as vata and at the same time act as rakta prasadana.

Vata pallava, lodhra and rakta chandana having kapha pita shamana property, kushta is having kapha vata hara property. Kapha, vata and rakta are main doshas evolved in the Samprapti of Mukhadushika. The drug Kushta is having jantughna property. This helps in the prevention of spreading of bacterial action. Vata pallava, kushta and Daruharidra have varnya property. This will help to remove the discoloration and maintain natural complexion. Its value-added formulation is user friendly also. The clinical trial was undertaken as before and after trial with 30 patients for a period of one month and data was collected. Formulation is safe and no adverse effects were observed during the study period. Drug had not produced any irritation during external application. Global Acne Grading System (GAGS) is used for the assessment. Grading of pain, swelling, discoloration and oozing before and after treatment were also assessed. The data was tabulated and analyzed using Wilcoxon Signed Rank list. The trial drug showed highly significant effect in reducing acne vulgaris with p value < 0.001. Based on the observation and analysis made, it can be concluded that value added Vata pallava malathyadi lepa is effective in Mukhadushika.

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