A Comparative Clinical Study of Mukhaprasadana Lepa along with Its Modified form as a Cream in Mukhadushika

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Abstract- Ayurveda is an ideal medical science which has acquired different concepts from almost all the Indian philosophies. As an aphorism says "A thing of beauty is a joy forever", here the word joy in particular is an excellent state of physique and psyche. In present situation, people are very much aware about their health as well as complexion. Thus, health and complexion can be understood as the two faces of a single coin. The present article is aimed to provide the details of clinical evaluation of mukhaprasadana lepa and its modified form as cream. Total 40 patients were included and treated with Total study duration including follow-up of 21 days. Finally, it was concluded that there is no significant difference in all assessment criteria. Both the groups were statistically significant. While considering the present-day scenario, the cream will be the better choice because of its user-friendly nature.

Key words: varya lepa, yavanapidaka, mukhadushika

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INTRODUCTION

Ayurveda is a transnational model. Ultimate aim of any ayurvedic formulation is its clinical application and by enlarges for the benefit of entire society. Quality of any formulation is an ascertained by its clinical efficacy which becomes a part of biological standardization. In Kashyapa samhitha sutrasthana[1] states that internal characteristics, relates with the external expression of an individual, thus face reflects the personality of person. Hence face is most sensitive part of our body. Yauvana Pidaka is most common skin ailment and usually a self-limiting condition of teenagers and young adults but, it disfigures the appearance of most essential part of the body i.e. face. As well the term mukhadhooshika and yauvanapidaka are considered as synonym in most of the classics[2.] As it is used chiefly in the treatments of mukhadhooshika or yauvanapidaka occurring in face, so the selected present reference of varnya lepa is been termed as Mukhaprasadana lepa. It is one among six varnya lepa mentioned in Sharangadhara samhitha, which is mainly using for mukhadhooshika[3]. pharmaceutically modified forms of herbal formulations have not only increased their market value but also for enhancing the therapeutic efficacy, shelf life and acceptability. When considering evolutionary changes in malahara kalpana, it was used in the form of Kalka in Vedic period. Later in samhitha kala, madhuchishta, sarjarasa etc were used in gritha and taila kalpanas which give a semi solid consistency to the product and can be easily applied over the affected area. In adhunika kala creams[4] and ointments play a major role in external route of administration of drugs.

AIM & OBJECTIVES

To clinically evaluate both the forms of formulations in management of Mukhadhooshika.

MATERIALS AND METHODS

Ingredients of Mukhaprasadana lepa

Table 01:

s.n	Ingredient	Scientific name	Useful part	Quantity
1.	*Vatapatra*	*Ficus bengalensis*	Ripen leaf	1 part
2.	*Malathi*	*Jasminum grandiflora*	Flower	1 part
3.	*Rakthchandana*	*Pterocarpus santalinus*	Heart wood	1 part
4.	*Kushta*	*Saussuria lappa*	Root	1 part
5.	*Lodhra*	*Symplocos racemosa*	Bark	1 part
6.	*Kaliyaka*	*Berberis aristata*	Root	1 part

Method of preparation:

The drugs are individually powdered and sieved through sieve no.120 to get a micro fine powder. All the powders are mixed well and preserved in airtight containers. The fine powder of this mixture is mixed with water/rose water to make lepa.

Ingredients of Mukhaprasadana Cream:

Sr.no	Ingredients	Quantity
1	Decoction of drugs	800ml
2	Stearic acid	300gm
3	Bees-wax	20gm
4	Glycerin)	5ml
5	KOH	30gm
6	Rose water)	200ml
7	Methyl paraben (preservative	0.01gm

Preparation of cream involves 3 steps:

Step 1- Preparation of Decoction (preparation of aqueous phase)

Step 2-Preparation of oil phase (Melting of bee wax and Stearic acid.)

Step 3- Mixing of aqueous phase and oil phase by use of an emulsifying agent.

Sources of data:

Drug source:

All the ingredients except vata patra were collected and purchased from Ayurpharam Ayurveda Pharmacy Nagarcoil, Tamilnadu and vata patra collected from nearby areas in Manipal karanataka.

Pharmaceutical study of Mukha prasadana lepa & Mukha prasadana cream were done in the practical hall of department of Rasashastra & Bhaishajya Kalpana, Muniyal Institute of Ayurveda medical science, Manipal, Karnataka.

Patient source: 40 subjects fulfilling the diagnostic and inclusion criteria were selected randomly irrespective of sex, religion, occupation, socio-economic status and assigned into two equal groups (Group A and Group B). The cases were selected from the O.P.D. / I.P.D. of P.G. Department of *kayachikitsa* , Muniyal institute of Ayurveda medical sciences Manipal, karnataka after taking informed written consent.

Methods of data collection:

Design of the study: Open labeled randomized comparative clinical study

Criteria for selection of patients:

- Inclusion criteria: Patients having symptoms of Mukhadushika as mentioned in Classics are included. Patients between the age group of 13 years to 30 years were included. As per the clinical features of Mukhadushika mentioned in classics, cases were diagnosed based on the following lakshanas:-
- Shalmalikantaka Sadrusha Pidaka (pimple looks similar to *salmelia malabarica* prickles)
- Saruja (With pain)
- Medogarbha (with pus)
- Ghana Shotha (Swelling)
- Exclusion criteria : Patients having Pidakas of other Kshudra Roga and Kushta were excluded.

Patients associated with any Systemic and metabolic disorders were excluded.

Patients of the age group less than 13 years and more than 30 years were excluded.

LABORATORY INVESTIGATIONS:

There are no diagnostic tests for Acne Vulgaris and diagnostic is clinical . The clinical diagnosis of Acne Vulgaris is usually straight forward.

Intervention:
Group- A: Mukhaprasadana lepa mixed with water:
Subjects were asked to wash the face with lukewarm water prior to application of lepa. Churna to be mixed with water and applied as lepa over the face with a thickness of 1/4th Angula in morning and evening. Lepa to be kept on face till it dries, and then face to be washed with lukewarm water.
Total study duration including follow-up: 21 days
Observational period: Application of lepa is done for 21 days. Subjects are assessed B.T and 21st day.

Group- B: Mukhaprasadana cream:
Subjects were asked to wash the face with lukewarm water prior to application of cream. Sufficient amount of cream was taken and applied over the face in the opposite direction of hair follicles. Massage gently for 1-2 minute and Keep it for 30 min. It was advised to apply in morning and evening. After 30 minutes cream application subjects were advised to wash face with lukewarm water.
Total study duration including follow-up: 21 days.
Observational period: Application of lepa is done for 21 days. Subjects are assessed B.T and 21st day.

CRITERIA FOR ASSESSMENT
The improvement provided by therapy were assessed on the basis of classical signs and symptoms, all the signs and symptoms were assigned with a score depending upon their severity to assess the effect of the drugs objectively.
SUBJECTIVE AND OBJECTIVE CRITERIA:

Table C.A 1: Showing subjective and objective parameters

SUBJECTIVE PARAMETERS	OBJECTIVE PARAMETERS
Vedana in the Pidaka	Number of Pidaka
Shotha in the Pidaka	Size of Pidaka
Srava in the Pidaka	Paka in the Pidaka
	Vivarnata of the Pidaka

GRADING OF SUBJECTIVE CRITERIA:
TABLE C.A 2: Showing grading of subjective criteria

(A)	SUBJECTIVE PARAMETERS		GRADE
1	Vedana of Pidaka	No tenderness	0
		Pain on deep pressure over the Pidaka	1
		Pain on touch over the Pidaka	2
		Pain without touch over the Pidaka	5
2	Shotha in the Pidaka	Without Shotha	0
		With Shotha	1
3	Srava In the Pidaka	No Srava	2
		Lasika Srava	3
		Puya Srava	4
		Pinjara Srava	5

GRADING OF OBJECTIVE CRITERIA:
TABLE C.A 3: Showing grading of objective criteria

(B)	OBJECTIVE PARAMETERS		GRADE
1	Number of Pidakas	No Pidaka	0
		1-5 Pidakas	1
		5-10 Pidakas	2
		More than 10 Pidakas	3
2	Size of Pidaka	No Pidaka	0
		0 to 2 mm	1
		In between 2 to 4 mm	2
		More than 4 mm	3

Note: When Pidakas are multiple, the Size of the largest Pidaka is considered.			
3	Paka of the Pidaka	No Paka/ No inflammatory changes	0
		With Paka/ Inflammatory changes	1
4	Vivarnata of the Pidaka	Normal skin colour	0
		Black colour	1
		Brown colour	2
		Red colour	3

Result:

STATISTICAL ANALYSIS

The effect of the drugs used has been critically analyzed by the statistical data. Descriptive Statistical Data which includes Mean, Median, Standard Deviation, Standard Error, t-value, and P- value were calculated for all the variables. Post therapeutic effect of the drug administered is assessed by Mann-Whitney test. Comparative study of each parameter of either group by Wilcox son, matched, signed ranks test. For all tests, a "P" value of < 0.001 is considered as the statistical significance level for obtaining absolute result.

Results of Therapeutic Trial:

Comparison between two groups representing vedana of pidaka

Table R 1: Showing comparison between two groups; Vedana of Pidaka

No	Symptom	Group	N	Mean GROUP-A & GROUP-B	(SE) (±)	Mann-Whitney U- statistic	Z	P
1	Vedana in Pidaka	Group A	20	0.450		174	0.689	0.362

The mean score of Vedana in pidaka of 40 patients was 0.450 in Group-A & in Group-B 0.200. Statistical analysis showed Mann- Whitney U-Statistic value of 174 , Z Value 0.689 & p value = 0.362. There is no statically significant change.

Comparison between two groups representing srava in pidaka

Table R 2: Showing comparison between two groups; Srava in Pidaka.

No	Symptom	Group	N	Mean GROUP-A & GROUP-B	(SE) (±)	Mann-Whitney U- statistic	Z	P
1	Srava in Pidaka	Group A	20	0.350	0.131	178	0.581	0.44
		Group-B	20	0.200	0.091			

The mean score of Srava in Pidaka of 40 patients was 0.350 in Group-A & in Group-B 0.200. Statistical analysis showed Mann- Whitney U-Statistic value of 178, Z Value 0.581 and p value 0.44. There is no statically significant change.

Comparison between two groups representing Number of pidaka

Table R 3 : Showing comparison between two groups; Number of Pidakas

No	Symptom	Group	N	Mean GROUP-A & GROUP-B	(SE) (±)	Mann-Whitney U- statistic	Z	P
1	No. of Pidaka	Group A	20	1.050	0.153	206	0.013	0.84
		Group-B	20	1.050	0.135			

The mean score of number of Pidaka of 40 patients was 1.050 in Group-A & in Group-B 1.050. Statistical analysis showed Mann- Whitney U-Statistic value 206, Z Value 0.013 and p value = 0.84. There is no statically significant change.

Comparison between two groups representing Size of pidaka

Table R 4: Showing comparison between 2 groups in size of Pidaka

No	Symptom	Group	N	Mean GROUP-A & GROUP-B	(SE) (±)	Mann-Whitney U- statistic	Z	P
1	Size of Pidaka	Group A	20	0.800	0.091	210	0.256	0.696
		Group-B	20	0.850	0.081			

The mean score of size of Pidaka of 40 patients was 0.800 in Group-A & in Group-B 0.850. Statistical analysis showed Mann- Whitney U-Statistic value of 210, Z Value of 0.256 and p value 0.69 there is no statically significant change.

Comparison between two groups representing Vivarnata of Pidaka

Table R 5: Showing comparison between two groups in Vivarnata of Pidaka

No	Symptom	Group	N	Mean GROUP-A & GROUP-B	(SE) (±)	Mann-Whitney U- statistic	Z	P
1	Vivarnata of Pidaka	Group A	20	0.350	0.109	190	0.256	0.751
		Group-B	20	0.300	0.105			

The mean score of Vivarnata of Pidaka of 40 patients was 0.350 in Group-A & in Group-B 0.300 Statistical analysis showed Mann- Whitney U-Statistic value of 190, Z Value 0.256 and p value 0.75 There is no statically significant change.

Distribution of patients According to symptoms

The follow-up of patients has been done as regards the symptomatic improvement has been monitored 1st and 21st day.

Table NoR 6: Showing symptomatic improvement in group-A and group-B

SL. NO	SYMPTOMS	GROUP A				GROUP B			
		BT	AT	DIFF	% OF RELIEF	BT	AT	DIFF	% OF RELIEF
	Vedana in Pidaka	43	9	34	79	38	04	34	89
	Srava in Pidaka	37	07	30	81	35	04	31	88
	No. of Pidaka	60	21	39	65	60	21	39	65
	Size of Pidaka	30	16	14	46	26	17	09	34
	Vivarnata of Pidaka	18	07	11	61	20	06	14	70

ASSESMENT OF TOTAL EFFECTOF THE THERAPY

Table R 7 : Overall Effect of Group-A

EFFECT OF TREATMENT IN GROUP-A		
CLASS	GRADING	NUMBER OF SUBJECT
0-25%	No Improvement	2
26-50%	Mild Improvement	1
51-75%	Moderate Improvement	10
76-99%	Marked Improvement	6
100%	Complete Remission	1

Table R 8: Overall Effect of Group-B

EFFECT OF TREATMENT IN GROUP-B		
CLASS	GRADING	NUMBER OF SUBJECT
0-25%	No Improvement	0
26-50%	Mild Improvement	2
51-75%	Moderate Improvement	10
76-99%	Marked Improvement	8
100%	Complete Remission	0

DISCUSSION

For a product to be effective in the management of mukhadhooshika, it is expected to have certain basic qualities. All the ingredients of the product have raktashodhaka action. Rakthchandana and Daruharidra also act as varnya. Kushta and Daruharidra have tikta- Kashaya property and vata-kapha and kapha- pitta samaka action respectively. Lodhra has katu- tikta and act as kapha- pittahara. Malathi pushpa has tikta-kashaya rasa and act as tridoshahara, mainly kapha-pitta samaka. Rakthchandana with tikta- madura rasa also act as kapha-pittahara. Mukhadhooshika is generally due to vitiation of vata, kapha and rakta. However, due to ashraya-ashrayi bhava and the symptoms like paka, pitta has an important role to play. Hence these ingredients at a synergy act relieving the symptoms of mukhadhooshika. Individual ingredient of Mukhaprasadana lepa/cream are have established anti acne properties.

Vatapatra processes anti inflammatory,[5] analgesic,[6] and anti bacterial[7] activities there by it helps in reducing pain and inflammation of can. It also processes wound healing capacity and hence in healing unless formed by squeezing the acne. A study carried out on kushta has shown its efficacy against microbial colonization of propionibacterium acnes which is a resistant organism involved in the manifestation of acne. Similar action is observed in Lodhra ie, Symplocos racemosa also.[8] Malathi pushpa due to its contents like benzyl acetate and essential oil is found to be effective in dermatological conditions including acne.[9] Rkathachandana processes anti microbial ulcer healing and anti inflammatory activity is used in most of the herbal cosmetic preparations. In vitro anti acne activity of ethanolic extract of stem of Berberis aristata is established. An analysis of various scientific studies carried out has revealed that each and every ingredients of Mukhaprasadana lepa-Mukhaprasadana cream has anti acne activity which may be due to various modes of action like anti-inflammatory, analgesic, wound healing, anti-microbial, anti-oxidant effects etc. Hence these ingredients together have shown synergistic therapeutic effect in the management of Mukhadhooshika/acne vulgaris.

CONCLUSION

When the probable mode of action is considered, it is cited from various scientific studies that, each and every ingredient of Mukhaprasadana lepa and Mukhaprasadana cream has anti acne activity which may be due to the various mode of actions like anti-inflammatory, analgesic, wound healing anti-microbial and anti-oxidant etc effects in the management of Mukhadhooshika/Acne vulgaris.

In clinical study evaluation while comparing the two groups, there is no significant difference in all assessment criteria. Both the groups were statistically significant. While considering the present-day scenario, the Mukhaprasadana cream will be the better choice because of its user-friendly nature.

Mukhaprasadana lepa and Mukhaprasadana cream both are equally effective in the treatment of Mukhadhooshika W.S.R to Acne vulgaris is accepted.

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