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Evaluation of Efficacy of *Dashanga Lepa* (with Sandalwood) & *Dashanga Lepa* (with Red Sandalwood) on Patients of *Mukhdooshika* W.S.R. Acne Vulgaris

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Abstract

The *Mukhdooshika* affects in young age, mainly on the face region, it is having pain, pustules and destroys luster of face, so it is called *Mukhdooshika*, in modern Science it is known as Acne vulgaris. The Acne vulgaris affects almost 90% of the population in their lifetime1 many cases of acne lead to permanent scarring. Due to the change in diet pattern, i.e., spicy food, junk food, increasing habit of eating bakery products, pollution, mental stress, excessive sweating, are the causes for acne or Mukhdushika. In this prospective single blind trial where patients were blind, design in patients having Mukhdooshika Male or female subjects between & including the ages of 14 to 25 years were selected & Labelled as Group A & B. The patients who were eligible to participate, by inclusion & exclusion criteria were provided with investigational product [Dashanga Lepa (with Red Sandalwood) to Group A & Dashanga Lepa (With Sandalwood) to Group B] to apply daily once at home for 2 weeks. At the end of study, it showed that Dashanga Lepa with Sandalwood is more effective than Dashanga Lepa with Red sandalwood in reducing surface area of Acne.

Keywords: *Mukhdushika; Adolescents; Acne; Dashanga Lepa*.

Introduction

According to Ayurveda, an eruption looks like Shalmali spines & appearing at Vaktra (face). Doshas involved - Kapha, Vata & Shonita. (1) These problems particularly form in the youth and generally considered as Acne Vulgaris. It is also known as Yuvanpidaka which means found in the youth. Acne Vulgaris lesions are more commonly known as pimples, whiteheads, blackheads, or zits. These lesions occur when there is a change in the skin cell units known as pilo-sebaceous units that contain sebaceous glands, a substance called sebum, and a hair follicle. When or dead skin cells build up and clog these units, a breakout or lesion is likely to occur. (2)

In Ayurveda this disease has been described under Kshudra Roga (3) as 'Mukh-dooshika' and much yoga have been advocated to alleviate this problem. The Lepa's are explained in Shasti-upakrana (4) and they play an important role in Mukhdooshika management. Dashanga Lepa is mentioned in Sharangadhara Samhita Uttara Khanda. (5) it is also mentioned in Purva khanda of Sharangadhara Samhita that for Kashaya preparation & lepa preparation Rakta Chandana i.e. *Pterocrpus santalinus* Linn. should be used. (6) So a study was planned to prepare Dashanga Lepa (with Red Sandalwood) & Dashanga Lepa (with Sandalwood) & carry out its trial on patients having Acne Vulgaris.

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Objectives

To study the effect of Dashanga Lepa (with Red Sandalwood) to Group A & Dashanga Lepa (Sandalwood) to Group B in relieving symptoms of Acne Vulgaris.

Materials & Method

Procurement of Raw material

Raw Materials were procured by All India Pharmacy Store, Paydhonie, Mumbai, (M.S), India.

All the drugs were authenticated by pharmacognosist at Dept. of Dravyaguna, Smt. KGMP Ayurved College & Hospital, Mumbai, Maharashtra State, India. Their identification is summarized in [Table 1 & 2]

Contents

Table 1: Ingredients of *Dashanga Lepa (with Red Sandalwood)*

Contents	Latin Name	Part used	Proportion
Shireesh	*Albizzia lebbeck* Benth.	Skin	1 part
Yashimadhu	*Glycyrrhiza glabra* Linn.	Root	1 part
Tagar	*Valeriana walichii* DC.	Bark	1 part
Rakta Chandana	*Pterocarpus santalinus* Linn. f.	Bark	1 part
Ela	*Elettaria cardamomum* Maton.	Fruit	1 part
Jatamansi	*Nardostachys jatamansi* DC.	Root	1 part
Haridra	*Curcuma longa* Linn.	Rhizome	1 part
Daruharidra	*Berberis aristata* DC.	Bark	1 part
Kushtha	*Saussurea lappa* C. B. Clarke	Rhizome	1 part
Usheera	Vetiveria zizanioides	Root	1 part

Table 2: Ingredients of *Dashanga Lepa (with Sandalwood)*

Contents	Latin Name	Part used	Proportion
Shireesh	*Albizzia lebbeck* Benth.	Skin	1 part
Yashimadhu	*Glycyrrhiza glabra* Linn.	Root	1 part
Tagar	*Valeriana walichii* DC.	Bark	1 part
Chandana	*Santalum album* Linn. f.	Bark	1 part
Ela	*Elettaria cardamomum* Maton.	Fruit	1 part
Jatamansi	*Nardostachys jatamansi* DC.	Root	1 part
Haridra	*Curcuma longa* Linn.	Rhizome	1 part
Daruharidra	*Berberis aristata* DC.	Bark	1 part
Kushtha	*Saussurea lappa* C. B. Clarke	Rhizome	1 part
Usheera	Vetiveria zizanioides	Root	1 part

Method of preparation of Lepa

The above mentioned drugs are powdered individually in a *mortar – pestle to* get fine powder. Equal quantities of powders of individual drugs are taken in a vessel and mixed with normal water to make them into a *lepa* or paste form. (7) This *lepa* is applied over the face.

Study Design

Ethical clearance

Institutional Ethics Committee Approval and Regulatory Compliance

Before the initiation of the study, the study protocol and related documents were reviewed and approved by Institutional Ethics Committee at Smt. KGMP Ayurved College & Hospital, Mumbai, Maharashtra State, India. The study was conducted in accordance with Schedule Y of Drugs and Cosmetics act, India, amended in 2005 and ICMR ethical guidelines for biomedical research on human participants 2006.

IEC Clearance no

KGMP / NOTICE / 1263 / 2009 Dated- 12.04.2014

No. of patients

Total 60 patients were registered in this trial. (30 patients in each group)

The study was carried out in following steps:-

After diagnosis these 60 patients were randomly divided into two groups and were subjected to *Lepa* Therapy.

Group A

In this group, *Dashanga Lepa* (With Red Sandalwood) was given for application.

Group B

In this group, *Dashanga Lepa* (With Sandalwood) was given for application.

Inclusion criteria

- Ages 14-25 years;
- Signed informed consent prior to any study-mandated procedure.
- Willing to comply with daily protocol.
- Having sign & symptoms of Acne Vulgaris.

Exclusion Criteria

- Patient requiring acute medical care.
- Active malignancy, autoimmune condition, or treatment with immunosuppressive drugs
- Patients having psoriasis. Leprosy, Diabetic & non-healing, infective wound, or infective skin diseases
- Major Burns, wet eczema, etc.

Assessment Criteria

Surface area: measured in cms^2

Texture of skin: Dry or Moist

Pain, Discharge, Burning: Absent or Present

Overall effect of Therapy: VAS (Visual Analogue Scale) – 0 to 10

Investigational Product Description	1. Group A - Dashanga Lepa (With Red Sandalwood) 2. Group B - Dashanga Lepa (With Sandalwood)
Dosage form	Lepa
Route of administration	Local application
Single application	20 gm each.
Daily application	Once a day. (Till it dried completely)
Follow up	Every
Total Duration	2 weeks

Method of application of Lepa

It is having three steps

Poorva Karma

The patient was asked to wash the face with lukewarm water prior to application of *lepa.*

Pradhana Karma

Required quantity of *powder* was taken and normal water was added in sufficient amount to convert it in to *Lepa* form. The patients were advised to apply *Lepa* in the opposite direction to hair roots, all over the face. The *Lepa* was applied with a uniform thickness of one fourth of once own thumb width (about 1/4th of an inch). *Lepa* was applied in morning (between 7 and 10 am) and it should be applied over the face for at least forty five minutes to one hour or until *lepa* gets dried up). (8)

Paschat Karma

After the drying up of the *lepa,* the patients were asked to wash the face with normal water and were advised to take routine diet.

Analysis of Data

For parametric data, Student's Paired & Unpaired 't' test was used, whereas non-parametric data was evaluated using Fisher's exact test using statistical software Graph pad Instate 3. $p<0.05$ will be considered as level of significance.

Observation & Results

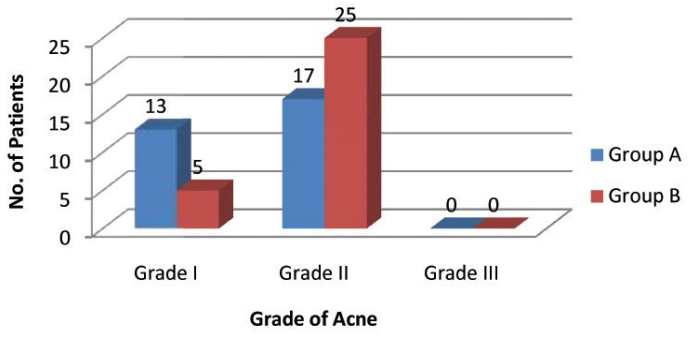
A total number of 60 patients (30 patients per group) having signs & symptoms of Acne Vulgaris were selected for study. All 60 patients completed study. Demographic observations tabulated are as follows

Parameter	Group A	Group B	Total
Sex			
Male	13	10	23
Female	17	20	37
Age (yrs)			
14-20	18	24	42
>20	12	6	18
Diet			
Vegetarian	22	21	43
Mixed	8	9	17
Habit			
Tea	11	14	25
No Habit	19	16	35

Distribution of patients according to Gradation of Acne Vulgaris

The patients recruited in this trial were distributed according to gradation of acne Vulgaris are shown in following chart.

Fig. 1: Distribution of patients accroding to gradation of Acne vulgaris



Effect of Trial Drug on Acne Vulgaris (Area affected) - Group A

Mean area affected by Acne Vulgaris in Group A before treatment was 9.57 ± 7.58 which was reduced to 8.76 ± 6.57 after treatment. The two-tailed P value is 0.1487, considered not significant.

Table 3: Effect of Trial Drug on Acne surface area in Group A

Parameter	Before Treatment	After Treatment	Difference
Mean	9.567	8.758	0.8083
Std deviation	7.558	6.565	2.984
Std error	1.380	1.199	0.5448

Effect of Trial Drug on Acne Vulgaris (Area affected) - Group B

Mean area affected by Acne Vulgaris in Group B before treatment was 9.49 ± 5.0 which was reduced to 6.90 ± 3.98 after treatment. The two-tailed P value is < 0.0001, considered extremely significant.

Table 4: Effect of Trial Drug on Acne surface area in Group A

Parameter	Before Treatment	After Treatment	Difference
Mean	9.492	6.900	2.592
Std deviation	5.004	3.975	3.128
Std error	0.9136	0.7257	0.5710

Comparison of Effect of Trial Drug on Acne surface area between Group A & B

When both groups are compared statistically with unpaired t test for their outcome reveals that trial drug in group B show Significant changes over Group A. The two-tailed P value is 0.1900, considered not significant.

Fig. 2: Comparison of Effect of Trial Drug on Acne surface area (Group A & B)

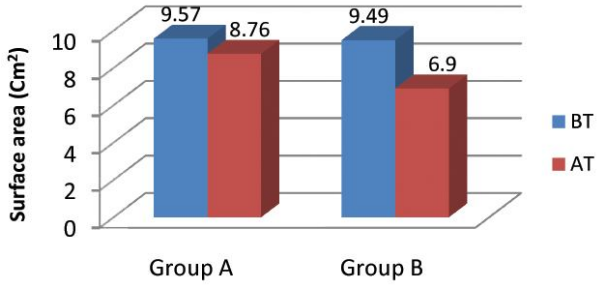


Table 5: Comparison of Effect of Trial Drug on Acne surface area

Parameter	Group A	Group B
Mean	8.758	6.900
Std deviation	6.565	3.975
Std error	1.199	0.7257

Effect of Trial drug on Texture of Skin in Group A

The texture of skin was recorded as dry & moist. At the beginning texture of skin was moist in 28 patients & dry in two patients. At end of study texture of skin was moist in 29 patients & dry in one patient. Fisher's Exact Test applied & it was observed that the two-sided P value is 1.0000, considered not significant.

Table 6: Effect of Trial drug on Texture of Skin in Group A

	Moist	Dry	Total
BT	28 (47%)	29 (48%)	57 (95%)
AT	2 (3%)	1 (2%)	3 (5%)
Total	30 (50%)	30 (50%)	60 (100%)

Effect of Trial drug on Texture of Skin in Group B

The texture of skin was recorded as dry & moist. At the beginning texture of skin was moist in 28 patients & dry in 2 patients. At end of study texture of skin was moist in 26 patients & dry in 4 patients. Fisher's Exact Test applied & it was observed that The two-sided P value is 0.6707, considered not significant.

Table 7: Effect of Trial drug on Texture of Skin in Group B

	BT	AT	Total
Moist	28 (47%)	26 (43%)	54 (90%)
Dry	2 (3%)	4 (7%)	6 (10%)
Total	30 (50%)	30 (50%)	60 (100%)

Effect of Trial drug on Pain at site of Acne in Group A

The pain at the site of acne was recorded as present & absent. At the beginning pain was absent in 25 patients & present in 5 patients. At end of study pain was absent in 26 patients & dry in 4 patients. Fisher's Exact Test applied & it was observed that The two-sided P value is 1.0000, considered not significant.

Table 8: Effect of Trial drug on Pain at site of Acne in Group A

	BT	AT	Total
Absent	25 (42%)	26 (43%)	51 (85%)
Present	5 (8%)	4 (7%)	9 (15%)
Total	30 (50%)	30 (50%)	60 (100%)

Effect of Trial drug on Pain at site of Acne in Group B

The pain at the site of acne was recorded as present & absent. At the beginning pain was absent in 27 patients & present in 3 patients. At end of study no change was found. Fisher's Exact Test applied & it was observed that The two-sided P value is 1.0000, considered not significant.

Table 9: Effect of Trial drug on Pain at site of Acne in Group B

	BT	AT	Total
Absent	27 (45%)	27 (45%)	54 (90%)
Present	3 (5%)	3 (5%)	6 (10%)
Total	30 (50%)	30 (50%)	60 (100%)

Effect of Trial drug on Discharge in Acne in Group A

The discharge at the site of acne was recorded as present & absent. At the beginning discharge was absent in 25 patients & present in 5 patients. At end of study it was absent in 27 patients & present in 3 patients. Fisher's Exact Test applied & it was observed that the two-sided P value is 0.7065, considered not significant.

Table 10: Effect of Trial drug on Discharge in Acne in Group A

	BT	AT	Total
Absent	25 (42%)	27 (45%)	52 (87%)
Present	5 (8%)	3 (5%)	8 (13%)
Total	30 (50%)	30 (50%)	60 (100%)

Effect of Trial drug on Discharge in Acne in Group B

The discharge at the site of acne was recorded as present & absent. At the beginning discharge was absent in 25 patients & present in 5 patients. At end of study it was absent in 27 patients & present in 3 patients. Fisher's Exact Test applied & it was observed that the two-sided P value is 0.7065, considered not significant.

Table 11: Effect of Trial drug on Discharge in Acne in Group B

	BT	AT	Total
Absent	25 (42%)	27 (45%)	52 (87%)
Present	5 (8%)	3 (5%)	8 (13%)
Total	30 (50%)	30 (50%)	60 (100%)

Effect of Trial drug on Burning in Acne in Group A

Burning was recorded as present and absent. At the beginning of trial burning was present in 05 patients whereas it was absent in 25. At the end of study i.e. at day 15th no change was found. The two-sided P value is 1.0000, considered not significant.

Table 12: Effect of Trial drug on Burning in Acne in Group A

	BT	AT	Total
Absent	25 (42%)	25 (42%)	50 (83%)
Present	5 (8%)	5 (8%)	10 (17%)
Total	30 (50%)	30 (50%)	60 (100%)

Effect of Trial drug on Burning in Acne in Group B

Burning was recorded as present and absent. At the beginning of trial burning was present in 05 patients whereas it was absent in 25. At the end of study i.e. at day 15th burning present in 03 patients & absent in 27 patients. The two-sided P value is 0.7065, considered not significant.

Table 13: Effect of Trial drug on Burning in Acne in Group B

	BT	AT	Total
Absent	25 (42%)	27 (45%)	52 (87%)
Present	5 (8%)	3 (5%)	8 (13%)
Total	30 (50%)	30 (50%)	60 (100%)

Overall Effect of trial drug on Acne Vulgaris by visual analogue scale (Group A)

Visual Analogue Scale was recorded at initial stage & end of study. The mean score of VAS at initial stage was 7.333 $\pm$ 12.01 which was increased to 38.667 $\pm$ 15.02. It shows encouraging results within individuals / patient after using trial drug. The two-tailed P value is < 0.0001, considered extremely significant.

Table 14: Overall Effect of trial drug on Acne Vulgaris by VAS (Group A)

Parameter	Before Treatment	After Treatment	Difference
Mean	7.333	38.667	-31.333
Std deviation	12.015	15.025	16.132
Std error	2.194	2.743	2.945

Overall Effect of trial drug on Acne Vulgaris by visual analogue scale (Group B)

Visual Analogue Scale was recorded at initial stage & end of study. The mean score of VAS at initial stage was 1.667 $\pm$ 6.47 which was increased to 47.167 $\pm$ 12.01. It shows highly encouraging results within individuals / patient after using trial drug. The two-tailed P value is < 0.0001, considered extremely significant.

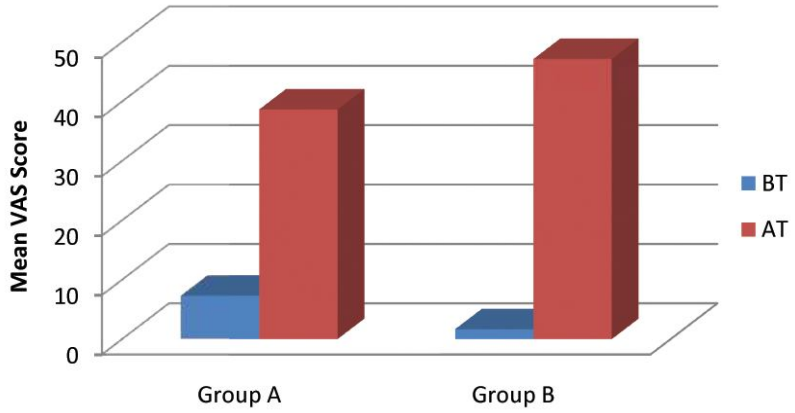
Table 15: Overall Effect of trial drug on Acne Vulgaris by VAS (Group B)

Parameter	Column A	Column B	Difference
Mean	1.667	47.167	-45.500
Std deviation	6.477	12.012	14.524
Std error	1.183	2.193	2.652

Comparison of Effect of trial drug on Acne Vulgaris by visual analogue scale (Group A & B)

When both groups are compared statistically with unpaired t test for their outcome reveals that trial drug in group B show highly encouraging results over Group A. The two-tailed P value is 0.0187, considered significant.

Fig. 3: Comparison of Effect of trial drug on Acne vulgaris by visual analogue scale (Group A & B)



Summary of Data

Parameter	Column A	Column B
Mean	38.667	47.167
Std deviation	15.025	12.012
Std error	2.743	2.193

Discussion

The present study was conducted to evaluate efficacy of Dashanga Lepa (with Red sandalwood) & Dashanga Lepa (with sandalwood) on patients of Mukhdooshika w.s.r. Acne vulgaris. The study was divided in two groups i.e. Group A (Dashanga Lepa with Red sandalwood) & Group B (Dashanga Lepa with sandalwood). Total 82 patients screened & 67 patients fulfilling inclusion criteria were included in study. Out of 67patients 60 patients have completed study. 7 dropped out due to unable to contact patient (lost to follow up). Not a single case of ADR has been reported throughout the study.

Out of total 60 patients 23 (38.33%) were males & 37 (31.66%) were females, indicating adolescent & young women are more prone to acne than men. It may be due to hormonal variations in females during pubertal age. Large numbers of patients were from age group of 14-20 yrs. i.e. 42 (70%) & other 18 (30%) from 20-25 years group which shows incidence of Acne is more in adolescent stage. 43 (71.66%) patients out of 60 were having vegetarian diet & 17 (28.33%) were having mixed diet.

Group A

Mean area affected by Acne Vulgaris in Group A before treatment was 9.57 $\pm$ 7.58 which was reduced to 8.76 $\pm$ 6.57 after treatment which is not considered to be significant. The texture of skin was recorded as dry & moist. At the beginning of study texture of skin in patients was moist in 28 patients & dry in two patients, which is near about same after study i.e. moist in 29 patients & dry in one patient. It means moisture of skin was maintained. This indicates that Dashanga Lepa with Red sandalwood doesn't cause any dryness if used frequently. The pain at the site of acne was recorded as present & absent. At the beginning pain was absent in 25 patients & present in 5 patients which was unchanged at end of study. The discharge at the site of acne was recorded as present & absent. At the beginning discharge was absent in 25 patients & present in 5 patients. At end of study it was absent in 27 patients & present in 3 patients. It indicates that Dashanga Lepa with Red sandalwood doesn't cause any augment in discharge but in some cases (2) it showed reduction in discharge. Burning was recorded as present and absent. At the beginning of trial burning was present in 05 patients whereas it was absent in 25. At the end of study i.e. at day 15th no change was found.

Visual Analogue Scale was recorded at initial stage & end of study. The mean score of VAS at initial stage was 7.333 $\pm$ 12.01 which was increased to 38.667 $\pm$ 15.02. It shows encouraging results within individuals / patient after using trial drug.

Group B

Mean area affected by Acne vulgaris in Group B before treatment was 9.49 ± 5.0 which was reduced to 6.90 ± 3.98 after treatment which is considered to be significant. The presence of Sandal wood Dahanga lepa has augmented the results to reduce the affected area in Acne. The texture of skin was recorded as dry & moist. At the beginning texture of skin was moist in 28 patients & dry in 2 patients. At end of study texture of skin was moist in 26 patients & dry in 4 patients. The pain at the site of acne was recorded. At the beginning pain was absent in 27 patients & present in 3 patients. At end of study no change was found. The discharge at the site of acne was recorded as present & absent. At the beginning discharge was absent in 25 patients & present in 5 patients. At end of study it was absent in 27 patients & present in 3 patients. It indicates that Dashanga Lepa with sandalwood doesn't cause any augment in discharge but in some cases (2) it showed reduction in discharge. Burning was recorded as present and absent. At the beginning of trial burning was present in 05 patients whereas it was absent in 25. At the end of study i.e. at day 15th no change was found.

Visual Analogue Scale was recorded at initial stage & end of study. The mean score of VAS at initial stage was 1.667 ± 6.47 which was increased to 47.167 ± 12.01. It shows highly encouraging results within individuals / patient after using trial drug.

Comparison of Group A & B

When both groups are compared statistically for effect on surface area of Acne with unpaired t test for their outcome reveals that trial drug in group B show Significant changes over Group A. These changes might be due to presence of Sandalwood in Dashanga Lepa which along with turmeric showed excellent results in reducing affected area of Acne.

Both the trial drugs showed minimal effects on symptoms like texture of skin (dry / moist), pain & discharge in Acne. But when both groups are compared statistically for effect on VAS (Visual Analogue Scale) with unpaired t test for their outcome reveals that trial drug in group B show highly encouraging results over Group A.

Conclusion

It can be concluded that the both drugs Dashanga Lepa (with Red sandalwood) & Dashanga Lepa (with sandalwood) are effective and safe to use in patients with Acne Vulgaris. Dashanga Lepa (with sandalwood) is more effective than Dashanga Lepa (with Red sandalwood) in reducing surface area of Acne according to the present study. We also recommend a larger, multicentric study to confirm & enrich our study.

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