

A Randomized Clinico-comparative Trial of *Dwiharidradi Kalk Lepamand Kumkumadi Tailam* in the Management of *Mukhadushika* w.s.r. to Acne Vulgaris – A Original Case Series

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ABSTRACT:

Background: *Mukhadushika* is one of the major diseases, which is being found in wide population of the world due to illiteracy, excessive consumption of oily food material and unhealthy diet etc. The painful eruptions encircled by *Meda*, which are comparable to Shalmali's thorns on the face throughout adolescence age and are known as *Yuvan Pidika*, *Tarunyapidik* and *Mukhadushika*. According to modern view, it is called Acne vulgaris. It is a skin disease of pilosebaceous gland, it characterized by formation of open and closed comedones, papules, pustules and nodulocytic lesions, chiefly on cheeks, forehead, upper trunk, back region etc.

Case Report: Patients attending the O.P.D. of Govt. Dhanwantari Ayurveda Hospital, Ujjain (M.P.) having the signs and symptoms of *Mukhadushika* (Acne Vulgaris) were screened and the diagnosis was achieved based on careful history taking and clinical examination. 40 clinically diagnosed patients of *Mukhadushika* were registered for trial and they were divided randomly in two groups.

Conclusion: It can be concluded that clinically *Dwiharidradi Kalk Lepam* and *Kumkumadi Tailam* combine work better to manage the *Mukhadushika* (Acne Vulgaris).

KEY WORDS: Mukhadushika, Acne vulgaris, Dwiharidradi Kalk Lepam, Kumkumadi Tailam

INTRODUCTION-

Face is considered as an important part of the body as for as beauty and look is concerned. Hence every person in teenagers and youngsters in particular are very conscious about beauty of their face. According to the Global Burden of Disease Study 2010, acne is the 8th most common skin disease in worldwide. It is the world's most frequent skin lesion, more than 90 percent of world population is affected by acne at some point in their life. According to 2017, the estimated prevalence of acne in india was 22 million and however, the prevalence of acne vulgaris is expected to marginally decline over the forecast period 2017-26, due to potential increase in elderly population and newer treatment approaches. By the end of 2026, the number of people affected by acne in India is estimated to reach 23 at a compound annual growth rate of 0.5 %.

Acharya charakahas been not discussed *Yuvanpidika* but he has portrayed in *pidikaas* disease of “*Bahya Roga Marga*” in the same way he has also described pathophysiology of *pidika*.¹ Acharya Sushruta was the first person who described *Mukhadushika* under the heading of *kshudraroga* it is also known as *Yuvanpidika* and *Tarunyapidika*. *Mukhadushika* (Acne) is such a condition that disfigures the face during teenagers to younger age. According to *Sushruta Samhita*, Shalmali thorn like *pidika* on the face due to vitiation of *Kapha*, *Vata*, *Shonita* (*Rakta*) and nature of puberty is known as *Yuvanpidika* or *Mukhadushika*.² In *Ashtang Samgrah*³ & *Ashtang Hridaya*⁴, *Madhav Nidaan*⁵, *Bhavprakash*⁶ etc., follow same pattern of *Sushruta*. Acharya Sharangadhara has listed the disease name under the caption of *Khudraroga*, but not described pathophysiology. Here he has mentioned *yuvanpidikaas mala ofshukra dhatu*.⁷

Reason for publishing the case Series-

- Face is considered as an important part of the body as for as beauty and look is concerned. Hence every person in teenagers and youngsters in particular are very conscious about beauty of their face. Compared to the skin of the body, the skin of the face cannot always be kept covered and acne occurs mainly on the skin of the face.
- It is papules, pustules and itching in predominant symptoms, which disturbed daily life style of the patients.
- Patients often have problems with self-esteem. Self-confidence, social withdrawal, depression, anger and higher unemployment rate.
- At present, increasing problems like adulterated things, oily, Chinese, eating more junk foods and applying cosmetics things.
- In modern medicine, adverse drug reactions are more common.
- *Mukhadushika* can be cure and prevented by *Ayurveda* treatment without any complication than modern medicine.
- According to 85% of teenagers and adult persons every year suffering from *Mukhadushika* in India.

So acne appears to be a big problem even though it is not such a serious disease.

The main objective of Publishing Case Series of *Mukhadushika* was to make people aware of the causes of *Mukhadushika*, to avoid them and to advise them to get proper *Ayurvedic* treatment for *Mukhadushika*.

Due to excessive consumption of oily, junk, unhealthy foods and excessive use of cosmetics and due to hormonal changes in the puberty, disease like *acnevulgaris* are becoming more prevalent in present times.

Generally, there is a *Kandu*, *Daha*, *Vedana*, *Srava*, *Medogarbha*, *Vaivarnayta*, *Raktima* and *Shothain* the *Mukhadushika*. *Roopa* or symptoms are those that are completely exhibited and reflect a certain ailment.

In *Ayurvedic* scriptures, various treatments are prescribed locally and internally. Local application is more useful in skin disorders as it acts directly on the wound.

So, the drug can reverse the condition which has the property of *Kaphapitta Shamaka* and *Raktashodhaka*, and can be used for a long time on skin diseases without any harm. In the present study *Dwiharidradi Kalk Lepam* (face pack) and *Kumkumadi Tailam* have been selected as local application and both have been selected to conduct comparative study in treatment of *Mukhadushika*. This study was conducted to evaluate the efficacy of the above subject.

AIMS AND OBJECTIVE-

1. To evaluate and compare the efficiency of *Dwiharidradi Kalk Lepam* and *Kumkumadi Tailam* administered in the management of *Mukhadushika*.
2. (A) Reducing a new by being *Mukhadushika*.

(B)Healing an Acne papules, Pustules and Black spots.

MATERIAL AND METHOD-

Source of data:

40 patients suffering from *Mukhadushika* (Acne vulgaris) who fulfilled the inclusion criteria were selected and placed in two groups by simple randomization process from OPD of Kayachikitsa Department of Govt. Dhanwantari Ayurveda Hospital, Ujjain (M.P.). Written consent of each patient was taken on prescribed proforma. The study was conducted under a strict protocol to prevent bias and to reduce the source of error in the study.

Criteria for selection of patients:

Patients attending the O.P.D. of Govt. Dhanwantari Ayurveda Hospital, Ujjain (M.P.). Having the signs and symptoms of *Mukhadushika* (Acne vulgaris) were screened and the diagnosis was achieved on the basis of careful history taking and clinical examination.

A. Criteria for inclusion -

1. Patient between 12 – 32 years of age.
2. Patients presenting with classical sign & symptoms of *Mukhadushika*.
3. Patients willing to sign the consent form.
4. Both sex with students randomly selected.
5. Total Acne lesion count 2 – 40.
6. Patient fit for taken in this medicine.

B. Criteria for exclusion –

1. Patients below 12 year and above 32 year of age.
2. Pregnant women and lactating mother.
3. Patients on steroid therapy.
4. Patients who have undergone surgery.

Investigations-

The following investigations were done before and after the treatment-

1. CBC
2. ESR
2. Skin moisture analysis
3. Skin Ph
4. Sebum test/ Skin type test (as per need)
5. Hormonal test (as per need)

METHOD

Site/s of study: Govt. Dhanwantari Hospital, Ujjain (M.P.)

Health condition / Problem studied: *Mukhadushika* / Acne vulgaris.

Study Design: A single blind, Randomized, clinical, comparative study.

Method of generating randomization sequence: Computer generated.

Primary outcome/s: Reducing a new by being *Mukhadushika*.

Secondary Outcome: Healing an Acne papules, Pustules and Black spots.

Sample population: All Acne patients were reported to Kayachikitsa department OPD.

Target sample size: 20 patients in both group.

Duration of Study: The study will be of 4-week duration.

Ethical Clearance: Clinical study was started after getting clearance from Institutional Ethics Committee (Letter No./2020/3290, dated 30/09/2020) and study was also registered under CTRI (CTRI/2021/01/030543).

Grouping: 40 clinically diagnosed patients of *Mukhadushika* (Acne vulgaris) were registered for trial and they were divided randomly in two groups:

Group I: 20 patients will be given *Dwiharidradikalklep* used in locally daily.

Group II: 20 patients will be given to 5 – 15 drops of *Kumkumadi tail* used in locally daily.

Doses and Duration of trial:

1. *Dwiharidradikalklep*: Dose– 1/4 self-finger proof

Mode of administration – locally (external use)

Duration - The study will be of 4-week duration

2. *Kumkumadi tail*: Dose– 5-15 drops

Mode of administration – locally (external use)

Duration - The study will be of 4-week duration

Followed up:

Patient will be advised to visit the hospital every week during the treatment & for 15 days after the treatment as follow up.

ASSESSMENT CRITERIA –

During this clinical trial patients will be assessed on following parameters.

- A. Subjective Criteria – Shalmalikantakara Pidika (Acne), Ruja (Pain), Ghana (Nodules formation), Kandu (Etching), Daha (Burning Sensation)
- B. Objective criteria –CBC, ESR, Skin moisture analysis, Skin Ph, Sebum test/ Skin type test (as per need), Hormonal test (as per need)

Statistical analysis of the result-

The result having P value less than <0.05 were considered as statistically significant in this study.

Criteria for assessment of overall effect-

Overall effect of the therapy was assessed in terms of complete relief, excellent Improvement, marked Improvement, moderate Improvement, mild Improvement and no Improvement by adopting the criteria shown in table 1

OBSERVATIONS

20 patients were registered in Group A & 20 in Group B and all the 40 patients completed the treatment and none of the patients were dropout.

Female patients were slightly higher than male patients 57.50%. Male patients were 42.50%. But the universal data is expounded about Acne vulgaris that women is prone for this disease. But after this study we can say that today's life style & dietary habits are very dominating factor for the origin of Acne vulgaris than the gender.

The maximum no. of patients (97.50%) were Hindus and only 2.50 % patients were Muslim.

Maximum no. of patients were the Teenage and young age group persons of above 20 years of aged 60% followed by up to 20 years age group (40%).

12.50% patients were married and 87.50% patients were unmarried. This marital status shows only social norms because there is no specific role of marriage in the development of *Acne vulgaris*.

42.50% patients were graduated followed by high school 30%, post graduate 7.50% and 5% Illiterate. Education level does not have much effect on *Mukhadushika*.

In patients' study, 87.50% patients were students followed by 10% were house holder and only 2.50% patients were service. Occupation level does not have much effect on *Mukhadushika*.

77.50% patients were belonging to middle class, rich 17.50% were and 5% were poor class. Socio-Economic Status level does not have much effect on *Mukhadushika*.

65% patients belonging to urban area and 35% belonging rural area. Urban area people more prone to acne because more use junk food, oily food, fast food and false diet routine.

Majority of the patients were having habit of *Vishmashana*(50%) followed by habit of *Samshana*37.50%, 7.50% having *Aadhyashana*and 5% having *Viruddhashana*.

Maximum no. of patients found in vegetarian diet class (72.50%), 25% were having mixed type of diet and 2.5% were having nonveg type of diet.

22.50% of patients having *Guru guna* dominancy in diet, 15% patients having *Ushnaguna*, 5% people were used to *Rukshya*, 5% people were used to *Laghuguna* and 2.50% people were used to *Snigdhashgana* dominancy.

50% of patients having *Katu rasa* dominancy in diet, 30% patients having *Madhura* type of *rasa* *Satmya* followed by 17.50% people were used to *Sarvarasa* and 2.50% patients having *Madhura/Katu rasa* dominancy in diet.

Most of patients (55%) having *Samagni* followed by 40% were having *Vishmagni* and 5% of *Mandagni*.

65% patients were having *Madhyamakoshtha*, 30% patients belong to *Mradukoshtha*and 5% having of *Krurakoshtha*.

In 65.50% patient's regular bowel habits and 34.50% were irregular habits.

In the study we found that 67.50% patents having Sound sleep, 25% were of Disturbed, 5% Moderate and 2.50% less sleep.

We have observed that maximum no. of patients (62.50%) was Normal in mental status as well as 12.50% of Aggressive in nature. Followed by 10% were have Tensile, 7.50% were of Anxious, 5% Tensile/ Depressed and 2.50% were such kind of jolly in nature.

In this research study observed that 60% of the patients having *Vata-Pittajaprakruti*. Followed by 37.50% having *Vata-Kaphajaprakruti*and 2.50% were have *Pitta-Kaphajaprakruti*. Generally, according to the scriptures, patients with *Kapha*, *Vata* and *Rakta* nature suffer more from *Mukhadushika*, but during the trial, more patients with *Vata*, *Pittaj Prakruti* were found who had *Mukhadushika*. In the scriptures, the properties of *Pitta* are generally considered to be similar to that of *Rakta*. Hence, it is also true to some extent.

95% patients were *Rajasikain* nature and 5% were *Tamasika* in nature. No patient with *Satvikaprakruti* was found during the trial. *Manasaprakruti* has an effect on *Mukhadushika*, mainly the people of *Rajas prakruti* have more *Mukhadushika*.

85% patients were *Madhyamsara*and 7.5% each were patients of both *Pravara*and *Avarasara*. People with *Rakta sara* are more prone to the problem of *Mukadushika*.

There was an average range found in *Samhanana* that 80% of *Madhyama*, 17.50% were *Susamhata*and 2.50% were *Asamhata*. *Samhanana* level does not have direct effect on *Mukhadushika*.

82.50% of *Samapramana*, 15% of *Hinapramana* and 2.50% having *Adhikapramana*. *Pramana* level does not have direct effect on *Mukhadushika*.

Most of the patients having *Madhyamasatmya*(85%), 12.50% having *Pravarasatmya*and 2.50% were have *Avarasatmya*.

Most of the patients having *Madhyamasatva*(67.50%), 27.50% having *Pravarasatva*and 5% were have *Avarasatva*.

*Abhyavaranashakti*having observations that 82.50% patients were having *Madhyama*, 10% *Pravara*and 7.50% *Avaraabhyavaranashakti*.

*Jaranashakti*having observations that 85% patients were having *Madhyama*, 7.50% *Pravara*and 7.50%*Avarajaranashakti*.62.50% of patients *Madhyamavyayamshakti* followed by 32.50% having *Avaravyayamashakti* and 5% were have *Pravaravyayamshakti* habit. *Vyayamshakti* level does not have direct effect on *Mukhadushika*.

Most of the patients having *Madhyamavaya*(83.50%), 17.50% having *Balavaya*.

50% of patients *Vishmashanacategory* followed by 37.50% having *Samshanacategory*, 7.50% having *Aadhyashanacategory* and 5% were have *Viruddhashanacategory*.

42.50% of patients NA category followed by 40% regular menstrual history, 17.50% having irregular menstrual history. Irregular menstrual history has more prone on *Mukhadushika*.

85% of patients *Raktadushyaproperties* followed by 5% *Rasa dushya*, 5% having *Rasa/Rakta*, 2.50% having *Rakta/Medadushya* and 2.50% having *Rakta/Shukradushyaproperties* are found.

97.50% patients absent of any systemic disease and 2.50 patients having head injury found.Systemic Examinations does not have direct effect on *Mukhadushika*.

Most of patients (97.50%) having No *Swedvahasrotasinvolvement* and 2.50% patients were having *Swedvahasrotasinvolvement*.

Maximum no. of the patients (92.50%) having No *Shukravahasrotasinvolvement* and 7.50% patients were having *Shukravahasrotasinvolvement*.

85% patients absent of *Artavavahasrotasinvolvement* and 15%patients were having *Artavavahasrotasinvolvement*.

90% patients found *Diva Swapna* properties, 5% patients *Ativyayama* and 5% patents found *Vegadharanaproperties*.

In all 40 patients were not found any specific risk factors.

No any associate symptoms found in all (40) patients.

57.50% patients were suffering since 5 month- 1 year of onset of Acne. 22.50% patients having history of Acne for 1-2 month followed by 20% patients having 1-3-year history of Acne.

RESULT-

All the results was calculated by using In Stat Graph Pad Prism 8 software. The 't' and p- values for each of the group from the analysis result of "PAIRED T- TEST WITHIN GROUPS".

The 'F' and 'p-values' in the row designated "Between group comparison: One-way ANOVA" have been come from "ANALYSIS OF VARIANCE BETWEEN GROUPS"

Since between groups comparisons were non-significant for both-before and after treatment for all of the parameters, the POST-HOCK TEST comparisons showing significant difference are blank.

Interpretation of result was done as: Non-significant (NS) $p > 0.05$, Significant (S) $p < 0.05$, Very Significant (VS) $p < 0.001$, Extremely significant (ES) $p < 0.0001$.

Group A: Extremely significant result was obtained in Subjective parameters like *ShalmalikantakaraPidika* (Acne), *Ruja* (Pain), *Ghana* (Nodules formation), *Kandu* (Etching), *Paka*, *Shotha*(Inflammation)and

Daha (Burning Sensation) Significant results were achieved in *Srava* (Discharge), No. of *Pidika* and Area of Acne *Pidika*. **Group B:** Extremely significant result was obtained in parameters like *Ruja* (Pain), *Kandu* (Etching), and *Daha* (Burning Sensation) Significant results were achieved in *Ghana* (Nodules formation) *Kandu* and *Vedna*. No significant result was seen in *Srava* (Discharge) of Acne *Pidika*. **Comparative effect of both the groups:** Objective parameters like Lymphocytes, Monocytes and Eosinophils are significant in Group A, Hemoglobin are significant in Group A and not significant in group B, PH values are significant in Group B and not significant in group A and 09 Subjective parameters (No. of *Pidika*, Area of *Pidika*, *Kandu*, *Vedna*, *Daha*, *Medogarbha*, *Vranvastu*, *Paka*, *Shotha*) out of 10, was significant in both groups.

DISCUSSION-

Dwiharidradi Kalk Lep in Group A and *Kumkumadi Tail* in Group B helped to reduce the major and associated complaints of *Mukhadushika*. The following are the details of their probable mode of action- *Dwiharidradi Kalk Lep*⁸-In *Ras Panchak*, most of the substances of *Dwiharidradi Kalk Lep* were *Sheetavirya*, *Katu vipak*, *Tikta*, *Kashaya* and *Madhura rasa*, *Laghu*, *Snigdha* and *Ruksha Guna*. *Tikta Rasahas Aruchi-nashaka*, *Deepana*, *Pachana* and *Shoshka* properties that contribute in increasing the *Jatharagni* and thus pacifying the *Aama Dosha*. *Kashaya Rasa* is *Sanshamana* and *Kapha*, *Rakta*, *Pitta shamaka*. As a result, it is beneficial in both *Kapha* and *Rakta Dushti*, which are the underlying causes of *Mukhadushika*. *Sheeta Veerya* has *Dahashamaka*, and *Rakta-Pittashamaka* property. It improves both local and overall metabolism. As a result, it will correct *Dhatu Poshana Krama*. In addition, decreases the *Ruksha Guna* of *Rakta*, *Pitta* and *Kapha Dosha* and *Snigdha guna* helps in relieving the pain. In terms of *Doshagnata*, the contents of *Dwiharidradi Kalk Lep* have a *Tridosha Shamaka* effect, which aids in balancing the *Vata Dosha*, as well as *Pitta* and *Kapha*. According to *Bhavprakasha Haridra & Daruharidra* is *Tvakadoshahara Vranropana*, *Kandunashini* and *Tridoshagna* properties. And *Vashthimadhu* is *Anilasarajta* and also *Vranophara* Properties. *Kuchandana*, *Prapondarika*, *Padmaka*, *Tinduka*, *Plaksha & Vatpatra* is a *Kashaya Rasa*, *Sheeta Virya & Kaphapittagna* properties. *Kaliyaka* Root one of the best *Vranaropana*. *Kumkuma* is a removing black spot due to formation of *Mukhadushika*. *Manjishtha* and *Padya* has also *Vranopaka* properties. *Kapittha* are *Madhura rasa* and *Sheeta Virya* properties so reduce a *Vatapitta*. Milk are *Vatpittagna* properties of the contents, may prove beneficial in breaking the pathogenesis of Acne vulgaris.

*Kumkumadi Tail*⁹- *Kumkumadi Tail* in the context of *Bhavprakasha Chikitsa Prakaran.*, which contains 26 herbs along with sesame oil and milk, *Kumkumadi Tail* is prepared from these 26 herbs, which is a *Daah Shamak* (reduces burning sensation), *Varana Ropak* (Healing ulcers), *Vedna Shamak* (reduces pain) and *Shotha Nashaka* (anti-inflammatory) and cures all the symptoms arising in acne.

CONCLUSION-

Mukhadushika, described in *Ayurveda* can be nearly correlated with Acne vulgaris. *Dwiharidradi kalklep* gives quick relief in acne of oily skin and gives better relief in acne of dry skin and no chance of recurrence but *Kumkumadi tail* works better in acne of dry skin and it has less chance of recurrence. *Dwiharidradi kalklep* and *Kumkumadi tail* both effectively works on associated symptoms like *Vyang*, *Nilika*, Dark spot under the eye etc. *Dwiharidradi kalklep* and *Kumkumadi tail* combine work better to manage the *Mukhadushika* (Acne vulgaris). Both clinically and statistically, the therapy given in Group A works better than Group B for the management of *Mukhadushika*.

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[TABLE 1]: CRITERIA FOR ASSESSMENT OF OVERALL EFFECT.

Improvement	Percentage (%)
No Improvement	Less than 10% reduction in chief complaints or recurrence of the symptoms to the similar extent of severity
Mild Improvement	10 to 25% improvement in chief complaints has been considered as mild improvement
Moderate Improvement	25 to 50% improvement in chief complaints has been recorded as moderate improvement.
Marked Improvement	50 to 75% improvement in chief complaints has been recorded as marked improvement.
Excellent Improvement	75to <100% improvement in chief complaints has been recorded as excellent improvement.
Complete relief	100% relief in Chief complaints with no moderate improvement, mild recurrence during follow up study have been considered as complete remission.



Before Treatment

After Treatment

[Figure 1] (Group-1).



Before Treatment

After Treatment

[Figure 2] (Group-2)

Acne presentation in face skin