A Randomized Clinico-comparative Trial of Dwiharidradi Kalk Lepam and 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 pidika as disease of “Bahya Roga Marga” in the same way he has also described pathophysiology of pidika. 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 Yuvanpidikaor Mukhadushika. In Ashtang Samgrah, Ashtang Hriday, Madhav Nidaa, Bhavprakash etc., follow same pattern of Sushruta. Acharya Sharangadharahas listed the disease name under the caption of Khudraroga, but not described pathophysiology. Here he has mentioned yuvanpidika as mala of shukra dhatu.

Reason for publishing the case Series-

- Face is considered as an important part of the body as far 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, junks, unhealthy foods and excessive use of cosmetics and due to hormonal changes in the puberty, disease like acne vulgaris are becoming more prevalent in present times. Generally, there is a Kandu, Daha, Vedana, Srava, Mehogarba, 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
3. Skin moisture analysis
4. Skin Ph
5. Sebum test/ Skin type test (as per need)
6. 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 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 Samshana37.50%, 7.50% having Aadyashanaand 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 Snigdhaguna dominancy.

50% of patients having Katu rasa dominancy in diet, 30% patients having Madhura type of rasa Satmyafollowed 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% patients 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-Pittajprakruti. Followed by 37.50% having Vata-Kaphajaprakrutiaand 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 Madhyamsaraand 7.5% each were patients of both Pravaraand 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 Susamhataand 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.

Abhyavanaashaktihaving observations that 82.50% patients were having Madhyama, 10% Pravara and 7.50% Avaraaabhyavanaashakti.

Jaranashaktihaving observations that 85% patients were having Madhyama, 7.50% Pravara and 7.50%Avarajaranashakti. 62.50% of patients Madhyamavyayamshakti followed by 32.50% having Avaravyayamshakti and 5% were have Pravaravayamshakti 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 Vishmashana category 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 Raktadushya properties followed by 5% Rasa dushya, 5% having Rasa/Rakta, 2.50% having Rakta/Medadushya and 2.50% having Rakta/Shukradushya properties 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 Artavahasrotasinvolvement and 15% patients were having Artavahasrotasinvolvement.

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 Shalmalikantakara Pidika (Acne), Ruja (Pain), Ghana (Nodules formation), Kandu (Etching), Paka, Shotha (Inflammation) and
**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** - In Ras Panchak, most of the substances of Dwiharidradi Kalk Lep were Sheettaviry, Katuvipak, Tikta, Kashaya and Madhura rasa, Laghu, Snigdh and Ruksha Gun. Tikta Rasahas Aruchi-nashaka, Deepana, Pachana and Shoshka properties that contribute in increasing the Jatharagni and thus pacifying the Aama Dosa. Kashaya Rasa is Sanshamaanaad Kapha, Rakta, Pitta shamaaka. As a result, it is beneficial in both Kapha and RaktaDushti, which are the underlying causes of Mukhadushika. SheetaVeerya 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 Ruksa Guna of Rakta, Pitta and Kapha Dosha andSnigdhaguna helps in relieving the pain. In terms of Doshaghnata, 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 & Daruhradira is Tvakadosahara Vranropana, Kandunashini and Tridoshagna properties. And Vashthimadhu is Anilasrajaant also Vranaphara Properties. Kuchandana, Prapondarika, Padmaka, Tinduka, Plaksha & Varattra is a Kashaya Rasa, SheetaVirya & 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. Kapiatha are Madhura rasa and SheetaVirya properties so reduce a Vatapitta. Milk are Vatpittagnaproperties of the contents, may prove beneficial in breaking the pathogenesis of Acne vulgaris.

Kumkumadi Tail** - Kumkumadi Tail in the context of Bhavprakasha Chikitsa Prakaran., which contains 26 herbs along with sesame oil and milk, Kumkumadi Tailis 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. Dwiharidradikalklep 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. Dwiharidradikalklep and Kumkumadi tail both effectively works on associated symptoms like Vyang, Nilika, Dark spot under the eye etc. Dwiharidradikalklep 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.
REFERENCES-

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

<table>
<thead>
<tr>
<th>Improvement</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Improvement</td>
<td>Less than 10% reduction in chief complaints or recurrence of the symptoms to the similar extent of severity</td>
</tr>
<tr>
<td>Mild Improvement</td>
<td>10 to 25% improvement in chief complaints has been considered as mild improvement</td>
</tr>
<tr>
<td>Moderate Improvement</td>
<td>25 to 50% improvement in chief complaints has been recorded as moderate improvement.</td>
</tr>
<tr>
<td>Marked Improvement</td>
<td>50 to 75% improvement in chief complaints has been recorded as marked improvement.</td>
</tr>
<tr>
<td>Excellent Improvement</td>
<td>75 to &lt;100% improvement in chief complaints has been recorded as excellent improvement.</td>
</tr>
<tr>
<td>Complete relief</td>
<td>100% relief in Chief complaints with no moderate improvement, mild recurrence during follow up study have been considered as complete remission.</td>
</tr>
</tbody>
</table>
Acne presentation in face skin

Before Treatment                      After Treatment
[Figure 1] (Group-1).

Before Treatment                      After Treatment
[Figure 2] (Group-2)
Acne presentation in face skin