



**AN OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFECT OF
VATANKURADI LEPA WITH KHADIRA ARISTA IN THE MANAGEMENT OF
MUKHADUSHIKA VIS-À-VIS ACNE VULGARIS**

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Article Received on 03/08/2022

Article Revised on 24/08/2022

Article Accepted on 13/09/2022

ABSTRACT

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous follicles characterized by comedones, papules, pustules & often scars, chiefly on cheeks, chin, nose & forehead. It is one of the most prevalent skin disorders affecting 80% in adolescent age group around the world. Modern medical treatment which includes oral antibiotics and topical applications are associated with many side effects, bacterial resistance, irritation of the skin, peeling, and recurrence. In Ayurvedic texts, this disease has been described by the name of *Mukhadushika* or *Yuvanapidaka*. *Mukhadushika* is a *kshudraroga* which mainly involves *kapha* and *vata* with *rakta*. In Ayurvedic classics many *shodhana* and *shamana* therapy are considered to be the effective in management of *Mukhadushika*. To remove the aggravated *doshas* locally *Lepa* is considered to be the best form of treatment. *Lepas* not only treat the acne but also increase the skin complexion. Keeping this in mind, the present study was planned to evaluate the effect of vatankuradi lepa as bahya Chikitsa along with Khadirarista internally. An Open Label Single Arm Clinical Study was done on 20 patients of Mukhadushika (Acne Vulgaris) were selected from OPD & IPD of RAMC&RC Bengaluru. Patients were given *Vatankuradi lepa for local application* once a day till *lepa* gets dry along with *Khadira Arista* 15ml was administered internally with equal quantity of water in the morning and evening after food. Total of 30 days study was taken up. The effect of treatment has showed statistically highly significant results with *p* value <0.001 in almost all the parameters.

KEYWORDS: Mukhadushika, Acne Vulgaris, *Vatankuradi lepa*, *Khadirarista*.

INTRODUCTION

Face is one of the most exposed parts of the body, which reflects the self-esteem, personality and confidence of a person. "Face is the index of mind". Thus we can say the personality of a person reflects through his face. Face is the most important and beautiful organ, which reflects the joy, sorrow, anger etc all the expressions. Such an important and beautiful face may get vitiated by the *doshas*, which may indirectly affect the personality of a person. Among them one of the ailment which affects the face is *Mukhadushika*.

Mukhadushika one among the *Kshudra rogas* has parlane with Acne Vulgaris. The incidence rate in adolescence is about 85% and 15% develop Acne ranging from mild to severe. In men and women older than 25 years have 40-54% of Acne. In middle age 12% of women and 3% of men develop acne. The development of Acne in females is earlier than compared to males, as young as 8 to 9 years. The range is peak between 14 to 17 years, and 5 % are affected at the age of 40 years in females. In males the range is peak

between 16 to 19 years and 1% of male are affected at the age of 40 years.^[1]

Acne is a chronic inflammatory disease of pilosebaceous units, characterized by the development of comedones in forms of papules, pustules and less commonly nodules. There are four important factors involved in the pathogenesis of Acne; they are 1) increased sebum production 2) hyper-keratinization of pilosebaceous ducts and 3) inflammation. The affects of Acne are not limited to skin, acne lesions among adolescents and young adults generally occur at a time of heightened emotional sensitivity and may contribute to significant psychological distress, depression and even increased risk of suicide.

In modern cosmetology the treatment of Acne depends on the grade and severity of Acne. In topical treatment, the topical retinoids like adapalene, tretinoin etc., are used. Topical antibiotics for Acne include erythromycin and clindamycin or in combination with benzoyl peroxide and some lipophilic antibiotics such as

doxycycline and minocycline are used which usually cause adverse affect like skin irritation, peeling, redness and associated with sun sensitivity.

Khadirarishta^[2] is a polyherbal fermented Ayurvedic medicine. It is mainly made out by heart wood of *Acacia catechu* along with other herbal ingredients. *Khadirarishta* is the best remedy for skin diseases and almost all the stress related problems are resolved in an Ayurvedic natural way, thus giving no side effects.

In *sushrut samhita chikitsa* it has been mentioned that *Khadira* is effective in all type of *Kushta*. *Khadirarishta* is a very effective *Arishta* in the treatment of skin diseases. It mainly contains *Khadira* which is potent *Krumighna* and *Kandughna dravya*.

Hence it is a need of hour to take over a study on such a disease, which is affecting most of the adolescents in their personality developing period and as it has been redefined towards as chronic disease instead of simple and self limiting disease. Considering this the need the present study entitled “An Open Label Single Arm Clinical Study To Evaluate The Effect Of *Vatankuradi Lepa*^[3] With *Khadira Arista* In The Management Of *Mukhadushika Vis-À-Vis Acne Vulgaris*.”

The combined treatment for *mukhadushika* selected as *Vatankuradi Lepa* along with *Khadira Arista* internally for a better result.

OBJECTIVES OF THE STUDY

- To evaluate the therapeutic effect of *Vatankuradi lepa* in the management of *Mukhadushika Vis-À-Vis Acne Vulgaris*.
- To evaluate the effect of *Khadira Arista* in the management of *Mukhadushika Vis-À-Vis Acne Vulgaris*.
- To evaluate the combined effect of *Vatankuradi lepa* with *Khadira Arista* in the management of *Mukhadushika Vis-À-Vis Acne Vulgaris*.

MATERIAL AND METHODS

- 20 Patients presenting with clinical features of *Mukhadushika*(*Acne Vulgaris*) coming under the inclusion criteria approaching the OPD and IPD of Ramakrishna Ayurvedic Medical College, Hospital & Research Centre, Bengaluru were selected for the study. The sample collection was initiated with post approval from the Institutional Ethics Committee.

INCLUSION CRITERIA

- Subjects presenting with *Lakshanas* of *Mukhadushika* like *Shalmali Kantaka Sadrusha Pidaka. Ruja, Ghana Pidaka, Medho Garbha Pidaka*.
- Patients presenting with the signs and symptoms of *Acne Vulgaris*
- Age- More than 12 years and less than 30 years irrespective of gender, religion and occupation.

EXCLUSION CRITERIA

- Subjects with other systemic disorders like thyroid dysfunction.
- Subjects less than the age of 12 years and more than 30years.
- Subjects acne having inflammatory cysts and nodules.
- Subjects with other skin disorders like *Rosacea, Acne fulminans, Acneiform eruptions*.
- In pregnant women and lactating mothers.

INVESTIGATIONS

Investigations are carried out on the patients to rule out other systemic disorders as an optional. The following investigations has been indicated – C.B.C, E.S.R.

INTERVENTION

The study was intervened for a duration of 30 days.

Administration of drug

Patients were given *Vatankuradi lepa* for local application once a day till *lepa* gets dry along with *Khadira Arista* 15ml was administered internally with equal quantity of water in the morning and evening after food.

Assessment criteria

The clinical findings were noted in specially designed case proforma and assessment was done on Day 1 (Before Treatment), Day23 (After Treatment) and Day 30 (After FollowUp).

The assessment was done based on Subjective and Objective parameters.

STATISTICAL ANALYSIS

Statistical Analysis was done using SPSS VER.20.

OBSERVATIONS

Among 20 Subjects there were 13 Female (65%) and 7 Male (35%). 12 patients (60%) were in the age group of 16 to 20 years, 8 patients (40%) in the age group of 21 to 24 years. 12 patients (80%) were Unmarried and 8 patient (20%) were Married. 17 patients (85%) were Students, 2 patient (10%) of were home maker and 1 (5%) patient was executive. 15 patients (75%) belongs to Low middle class group, 4 patients (20%) belongs to Upper middle class group, 1 patient (5%) belongs to Poor Group of Socio-Economical status. 10 patients (50%) were Vegetarian and 10 patients (50%) were having Mixed type of Food Habits. 15 patients (75%) lesions were localized & 5 patients (25%) were generalized. 16 patients (80%) were in the slab of 0 to 2 mm size of *pidaka*, 3 patients (15%) were in the slab of 3 to 4 mm size of *pidakas* and 1 patient (5%) were in the slab of >4 mm size of *pidakas*. 5 patients (25%) had skin colored *pidakas*. & 10 patients (50%) had yellowish brown colored *pidikas*, and 1 patient (5%) had Black colored *pidakas*, 4 patients (20%) had Red colored *pidakas*, 5 patients (25%) had Round Border of *pidakas*,

15 patients (75%) had irregular border of pidakas. 18 patients (90%) had pidakas on the face, 2 patients (10%) had pidakas on upper chest. 10 patients (50%) had mild chronicity of illness. 7 patients (35%) had moderate chronicity of illness, 3 patients (15%) had severe chronicity of illness. 2 patient (10%) had Samagni, 12 patients (60%) had Mandagni, 5 patients (25%) had Teekshnagni and 1 patient (5%) had Vishamagni. 12 patients (60%) had pidakas due to exposure to sunlight, 7 patients (35%) had pidakas due to use of Cosmetic. 1 patient (5%) had pidakas due to use of oral contraceptives. 8 patients (40%) were having Krodha as Manasika Hetu, 10 patients (50%) were having Ayasa as Manasika Hetu, 2 patients (10%) were having Shoka as mansika Hetu. 8 patients (40%) had Ghana pidakas,

11 patients (55%) had Medhogarbha pidakas, 1 patient (5%) had Ruja. 4 patients (20%) were in the IGA scale of G1 to G2. 8 patients (40%) were in the IGA scale of G3 to G4. 7 patients (35%) were in the IGA scale of G5 to G6 and 1 patient (5%) were in the IGA scale of G7 to G8.

RESULTS

The assessment was done Before treatment (BT), After treatment (AT) and After Follow UP(AF), the assessment parameters like *Vedana of Pidaka*, *Srava of Pidika*, Number of *Pidika*, Size of *Pidika*, *Vivamata of Pidaka* and IGA Scale were subjected to Wilcoxon Signed Ranked Test to compare the Mean Rank.

Effect of Treatment on *Vedana of Pidaka*

Parameter	Ranks		Mean rank	Sum of rank	Z value	P value	Remarks
	NR	0					
BT - AT	NR	0	8	120	-3.520	< 0.001	HS
	PR	15					
	Ties	5					
AT - AF	NR	0	5.5	55	-3.162	< 0.01	HS
	PR	10					
	Ties	10					
BT - AF	NR	0	9	153	-3.720	< 0.001	HS
	PR	17					
	Ties	3					

The Wilcoxon Signed Rank Test on *Vedana of Pidaka* revealed statistically highly significant result from BT-AT (Z = -3.520, p < 0.001), AT-AF (Z= -3.162, p < 0.01) and BT-AF (Z=-3.720, p < 0.001).

Effect of treatment on *Srava of Pidaka*

Parameter	Ranks		Mean rank	Sum of rank	Z value	P value	Remarks
	NR	0					
BT - AT	NR	0	6	66	-3.035	< 0.01	HS
	PR	11					
	Ties	9					
AT - AF	NR	0	-	-	-	> 0.05	NS
	PR	0					
	Ties	20					
BT - AF	NR	0	6	66	-3.035	< 0.01	HS
	PR	11					
	Ties	9					

The Wilcoxon Signed Rank Test on *Srava of Pidaka* revealed statistically highly significant result from BT-AT (Z = -3.035, p < 0.01), BT-AF (Z= -3.703, p < 0.01) and non significant from AT-AF as there was no difference in the parameters so statistical analysis cannot be done.

Effect of treatment on Number of *Pidaka*.

Parameter	Ranks		Mean rank	Sum of rank	Z value	P value	Remarks
	NR	0					
BT - AT	NR	0	8	120	-3.626	< 0.001	HS
	PR	15					
	Ties	5					
AT - AF	NR	0	4.5	36	-2.828	< 0.01	HS
	PR	8					
	Ties	12					
BT - AF	NR	0	10	190	-3.963	< 0.001	HS
	PR	19					
	Ties	1					

The Wilcoxon Signed Rank Test on No. of Pidaka revealed statistically highly significant result from BT-AT ($Z = -3.626$, $p < 0.001$), AT-AF ($Z = -2.828$, $p < 0.01$) and BT-AF ($Z = -3.963$, $p < 0.001$).

Effect of treatment on Size of Pidaka

Parameter	Ranks		Mean rank	Sum of rank	Z value	P value	Remarks
BT - AT	NR	0	7.5	105	-3.638	< 0.001	HS
	PR	14					
	Ties	6					
AT - AF	NR	0	4.5	36	-2.828	< 0.01	HS
	PR	8					
	Ties	12					
BT - AF	NR	0	10.5	210	-4.234	< 0.001	HS
	PR	20					
	Ties	0					

The Wilcoxon Signed Rank Test on Size of Pidaka revealed statistically highly significant result from BT-AT ($Z = -3.638$, $p < 0.001$), AT-AF ($Z = -2.828$, $p < 0.01$) and BT-AF ($Z = -4.234$, $p < 0.001$).

Effect of treatment on Vivarnata of Pidaka

Parameter	Ranks		Mean rank	Sum of rank	Z value	P value	Remarks
BT - AT	NR	0	8	120	-3.571	< 0.001	HS
	PR	15					
	Ties	5					
AT - AF	NR	0	-	-	-	> 0.05	NS
	PR	2					
	Ties	18					
BT - AF	NR	0	8	120	-3.535	< 0.001	HS
	PR	15					
	Ties	5					

The Wilcoxon Signed Rank Test Vivarnata of Pidaka revealed statistically highly significant result from BT-AT ($Z = -3.571$, $p < 0.001$), BT-AF ($Z = -3.535$, $p < 0.001$) and non significant from AT-AF as there was no difference in the parameters so statistical analysis cannot be done.

Effect of treatment on IGA Scale

Parameter	Ranks		Mean rank	Sum of rank	Z value	P value	Remarks
BT - AT	NR	0	10	190	-3.903	< 0.001	HS
	PR	19					
	Ties	1					
AT - AF	NR	0	6	66	-3.207	< 0.01	HS
	PR	11					
	Ties	9					
BT - AF	NR	0	10.5	210	-3.966	< 0.001	HS
	PR	20					
	Ties	0					

The Wilcoxon Signed Rank Test on IGA Scale revealed statistically highly significant result from BT-AT ($Z = -3.903$, $p < 0.001$), AT-AF ($Z = -3.207$, $p < 0.01$) and BT-AF ($Z = -3.966$, $p < 0.001$).

DISCUSSION

Mukha Dooshika is described by Acharyas as a *Kshudra roga*.^[4] It has not occupied a place of independent disease entity, but it has been described with some minor diseases. According to Sanskrit English dictionary *Mukha Dooshika* means an eruption disfiguring the face. *Yuvana pidaka* is the synonym of *Mukha Dooshika*. In the brief description available of disease '*Mukhadooshika*' all the Samhitas have mentioned *Kapha*, *Vata*, *Rakta*, as the causative factors of the

disease while *Bhavprakasa* mentioned *Svabhava* as the cause of the disease.^[5] In *Sarangdhara Samhita* the *Vaktrasnigdhatta* and *Pidika* have been mentioned as due to *Sukradhatumala*.^[6] So it may be concluded that due to *Svabhava* of the particular age, excess production of *Sukra Dhatu* and its *Mala* is a natural process, which along with the imbalanced state of *Tridosha*, and *Rakta* produce the disease '*Mukhadooshika*'. Acharya *Sharangdhar* has accepted *mukha snigdhatta* and *Yuvan Pidika* as *Mala* of *Shukra Dhatu*. So according to him

Samprapti of Yuva Pidika may be due to *Kapha, Vata, Rakta* are vitiated by their *swanidanas* leading to *Raktadi Dhatvagni* and *Shukragni vaishamya*, through which the mala of Shukra dhatu appears as *Vaktre-nigdhawam* and *Mukhadushika*.

Acne Vulgaris is the most common dermatological problem seen in daily practice affecting nearly all adolescence and young adults to some degree. The pathophysiology of Acne is complex. Increased sebum production by sebaceous glands and abnormal desquamation of hair follicles occurs in response to increasing androgen levels with the onset of puberty. Obstruction of follicles causes follicular distention, which is often accompanied by the proliferation of the bacteria *Propionibacterium acnes* and the activation of an inflammatory response.

In the present study the effect of treatment on parameter *Vedana of Pidaka* was found to be better on the mean rank. Mainly *vata* is responsible for pain. In *mukhadushika*, there will be association of *vata* and *kapha*. In the study many patients complained of pain. Pain was when they were exposed to wind or sunlight. Some of the patients complained pain on touch. The pain is mainly because of the inflammation which may be due to infection. In the parameter *Vedana of pidakas* is reduced may be due to anti-inflammatory effect of *vatankuradi lepa*. *Srava of Pidaka* was significantly reduced due to *kapha pittahara* action by the *lepa* as well as *pittahara karma* by *Khadirarista*. The number of *Pidaka* denotes contributes in one among the factor determining the severity of the disease. The *Karma* and *Guna* contained by the ingredients used in *Lepa* helps in decreasing the disease prognosis and clearing the *pidakas* which is a sign of improvement. The overall effect of treatment on parameter *Size of Pidaka* was found to be better on the mean rank. This may be due to drugs of *vatankuradi Lepa* such as *Raktachandan, Manjista, Lodhra, Priyangu, Vatankur, Kushta, Masur* which has *Vata-Kaphahara* properties and additional effect of *lepa* procedure which reduces and clears the pilosebaceous ducts because procedure action. There is significant difference in after treatment on the parameter *vivarnata of pidaka* due to the action provided by *Varnya, Twaka Doshahara, Shothahara, Kushtaghna* and *vranashodhan-ropan* action of the *lepas* and *Khadira Arista* have reduced the *Viavarnata of pidika* and bring back the normal *Varna* of skin. A decrease in *IGA* score relates to an improvement in signs and symptoms. The action and *Guna of Lepa* and *khadira arista* provide a environment in reducing the *IGA Scale* thus an improvement in signs and symptoms.

CONCLUSION

- The disease is named after the site of illness i.e, *Mukha* is mainly the affected part in this disease, so it is called as *Mukhadushika*. The incidence rate of disease is more in the age group of 12-30 years (93%) hence it can be called as *Yavanapidaka*. The incidence rate of disease

is more in Females when compared with Males as the early hormonal changes are seen in females. *Mukhadushika* in modern view has similarity with *Acne Vulgaris* which is called to be a Physically and Psychologically scarring disease. The Quality of life scales have assessed that the impact of *Acne* is as similar as *Epilepsy* or *Asthma* and redefined it as chronic disease instead of simple and self-limiting. In this disease patients have greater impairment in mental health and associated with psychological disturbances like *embracement, anxiety*. In the study many of the patients had *manasikalakshanas* like *krodha, ayasa, shoka*, which aggravates *vata-dosha*. In the study, sunlight is the main cause for *Mukhadushika*. In the line of treatment of *Kshudrarogas*, the role of *Lepa* has been explained by all *acharyas* and it is explained as the first line of treatment. This shows the importance of *Lepa*. In *Sushrut samhita chikitsa 6/19* it has been mentioned that *khadira* is effective in all type of *kushta*. *Khadirarishta* is a very effective *Arishta* in the treatment of skin diseases. *Khadira Arista* given combinedly as treatment internally in patients of *Mukhadushika* for a better result. The reoccurrence was seen in relieved patients who were not following the *pashchat karma* and probably requires another course of treatment.

REFERENCE

- Harrison's Principles of Internal Medicine, editor Anthony S. Fauci. (et al). 14th edition. New York: McGraw. Hill-Health Professions Division, 1998; P.303.
- Kaviraj Shri Govind Das Sen. In: Dr. G Prabhakara Rao, Bhaisajya Ratnavali, First edition, Varanasi, Chaukhambha Orientalia, p. 365-370.
- Dr. Bramhananda Tripathi, Sharangdhara Samhita of Sharangdhara Acharya, Vyakyakara-, Publication- Chaukhambha Sanskrit Prakashan, Reprint- 2006, Chapter- Prathama khanda 5th chapter, Kaladikakhyaadyaya,-Page no-57, sloka no-26. Madyama khanda, 6th chapter, Churna kalpana, Page no- 173, sloka no-1, Uttara khanda, 11th chapter, sloka no-1,2. Sa Alepa nama and parinama, Page no-391.
- Dr. Kaviraj Ambikadatta Shastry edited Sushruta Samhitha, Nidanasthana, chapter 13, Edition Reprint 2005, Pub: Chaukhambha Sanskrit Sansthan, Varanasi-221001 page no 281.
- Sri Bhramshankar Mishra edited Bhavaprakasha with Vidhyotini commentary, Madhyamakhanda chapter-61 sloka 32 Edition Reprint 1969, Pub: Chaukhambha Sanskrit series office, K37/99, Gopal mandir lane post box No. 1008, Varanasi. Page no 587.
- Sharangadhara, Adamalla, Kashirama. Madhyam Khanda. Sharangadhara Samhita with Deepika and Gudarthadipika commentary. Reprint Edition, 2012. Varanasi, Chaukhambha Orientalia, p. 60-65.