CLINICAL EVALUATION OF A POLYHERBAL AYURVEDIC FORMULA (*PHAF*) IN THE MANAGEMENT OF ACNE VULGARIS

Dr. G. V. P. Samaranayake*[1] and A. A. J. Pushpakumara[2]

[1]Temporary Lecturer, Department of Shalya Shalakya, Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Sri Lanka.
[2]Senior Lecturer, Department of Shalya Shalakya, Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Sri Lanka.

*Corresponding Author: Dr. G. V. P. Samaranayake

Temporary Lecturer, Department of Shalya Shalakya, Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Sri Lanka.

ABSTRACT

Acne vulgaris is the most common disease among young generation. A preliminary trail was conducted in the Shalya Clinic in Gampaha Wickramarachchi Ayurvedic Hospital, to assess the safety and efficacy of a Polyherbal Ayurvedic Formulation in the management of Acne vulgaris on scientific parameter. Twenty five patient were clinically assessed and diagnosed on the basis of thorough history. Then Polyherbal Ayurvedic Formulation was administered locally once at night for a period of 45 days. The severity of acne and efficacy of treatment was assessed by Cook's acne grading scale. The results showed significant reduction in the Cook's acne grading scores of post-treatment group ($p<0.01$) as compared to pre-treatment scores. Further, Polyherbal Ayurvedic Formula was found safe and fairly well accepted by the patient. It was therefore concluded that Polyherbal Ayurvedic Formulation can be used safely and effectively for the treatment of Acne vulgaris.

KEYWORDS: Acne vulgaris, Polyherbal Ayurvedic Formulation.

INTRODUCTION

Acne vulgaris is a common chronic skin disease involving blockage and / or inflammation of pilosebaceous units (hair follicles and their accompanying sebaceous gland). Acne can present as non-inflammatory lesions, inflammatory lesions, or a mixture of both, affecting mostly the face but also the neck and chest. Acne affects 85% – 100% of people at some point in their lives, and it usually begins at puberty. Acne can persist into the 30s and beyond. In fact, 5% of people over 45 still have acne. People of all ethnic backgrounds get acne.

According to Ayurveda, Acne is known as "*Yuwan Pidaka*". It believes that the *Tridoshas* in the form of tissues controls all activities of the body and aggravated *doshas* are main reasons in eruption of acne. This is found more often in adolescent when there is excessive secretion from the oil glands, according to Ayurveda distortion in the air (*Vata Dosha*) and phlegm (*Kapha Dosha*) causes further distortion of the blood or *Rakta Dhatu*. *Vata* when gets vitiated due to unhealthy diet and lifestyles affected other two *doshas* (*Kapha* and *Pitta*) to aggravate them. Aggravated *Pitta* affects *Rakta Dhatu* or blood. The vitiated blood affects the skin and causes excess secretion of oil from sebaceous glands. Acne due

to a *Pitta* vitiation are generally red, soft, small, and tend to be aggravated in hot weather.

Kapha was sticky property. Aggravated *Kapha* imparts the stickiness to the oil produced by sebaceous glands of skin. Thus the thick sebaceous plugs are formed in skin pores and hair follicles leading to erupt the acne. The lesions are pale, hard, fairy large, have an oily secretion and tend to aggravate in cold weather.

The mainstay for the treatment of acne is use of topical and or systemic antibiotics and retinoids but the long term use of these drugs produce significant side effects like erythema, peeling, burning and drying of the skin. Moreover, the development of antibiotic resistance to *Propioni bacterium acne* may limit the use of topical antibiotics. Therefore, there is a dire need to develop herbal therapeutic modalities for the treatment of acne. Fortunately physicians of Indian System of Medicine like Ayurveda have been practicing many herbo-mineral formulations for the treatment of acne since antiquity. Thus the present study was conducted to validate the safety and efficacy of a Poly Herbal Ayurvedic Formula (*PHAF*) on modern scientific parameters. The formulation was selected for the study from Ola leave manuscript in library of Gampaha Wickramarachchi Ayurveda Institute. Its ingredients are *Aloe vera*, *Santalum album*, and Bee honey 50 grams each.

Bee Honey

Santalum album

Aloe vera

MATERIAL AND METHODS

The present study was an open, pre and post evaluation, non-randomized trial conducted at the Shalya Clinic in Gampaha Wickramarachchi Ayurveda Hospital, Yakkala. A total of 25 patients were selected. The patients were clinically assessed and diagnosed on the basis of history and dermatological examination. All the findings were recorded on the case record Performa, designed for the study. At the end of the study, 5 patients were lost to follow-up and were excluded, leaving behind 20 patients who completed the trial.

Patients of either gender in the age group of 12-30 years were enrolled in the trail. Patients below 12 years and above 30 year, patients with any systemic illness such as diabetes mellitus, patients with other variants of acne like acne fulminans, acne rosacea, dermatophytosis, psoriasis and eczema were excluded from the study. Similarly, patients who had taken any local or systemic treatment for their disease in the past one month period prior to the trail were also excluded.

Routine investigations like complete haemogram, and Random blood sugar were done before treatment in order to exclude the other systemic ailments.

All the patients were advised to apply the 6-10 grams of *PHAF* on the affected area once at night and then wash the area lukewarm water in the morning. The total duration of treatment was 45 days. The *PHAF* was supplied in an individual pack for each patient and their compliance was checked after completion of treatment. No additional medication was allowed.

The primary outcome of this study was pre and post treatment comparison of efficacy and safety of *PHAF* on Acne vulgaris. The severity of acne and evaluation of efficacy of *PHAF* was done weekly by employing Cook's System of Acne Grading. The response of the treatment, at the end of study, was recorded on five point scale as follows.

Excellent response was considered as improvement of three basal grades of acne; Good response – improvement of two basal grades; Poor response- improvements of one basal grade only; No response – no change in basal grade at all and worse response as increase in basal grade at the end of treatment.

The pre- and post-treatment scores were statistically analyzed by using Wilcoxon signed rank test and the level of significant difference was chosen as $p<0.005$.

RESULTS AND DISCUSSION

Demographic data of patients is shown in Table1. The present study conducted on 25 patients of acne grade between 12-30 years showed the highest incidence (40%) of acne in the age group of 17-21 years, while the least (15%) was seen in the age group of 27-31 years. This finding corroborates with the findings of a pioneer epidemiological study on acne in which a peak was found in the incidence between 14-17 years in case of females and between 16-19 years in case of males.

Table 1: Baseline demographic and clinical profile of patients.

Parameter	No. of patients	Percentage
Age in years	**Mean age**	**18.52±9.12**
12-16	5	25
17-21	8	40
22-26	4	20
27-31	3	15
Total	20	100
Gender		
Male	8	40
Female	12	60
Family history		
Present	12	60
Absent	8	40
Socioeconomic status		
Upper	4	20
Upper middle	5	25
Lower middle	8	40
Upper lower	2	10
Lower	1	5
Duration of Disease		
1-5 months	2	10
6 months- 1 year	4	20
2-3 years	8	40
4-5 years	6	30
Site of lesion		
Face	11	55
Face and chest	3	15
Face and back	4	20
Face and shoulder	2	10

Effect of *PHAF* on Cook's Acne Grading

Cook's acne grading scale is a commonly used grading scale for acne, and it involves the evaluation of the overall severity of acne on 0-8 scale anchored to photographic standards. All patients were clinically assessed weekly and total lesion counts were performed at baseline and at 1,2,3,4,5 and 6th weeks. At the end of treatment, there was a significant improvement ($p < 0.001$) in acne grading as depicted in Table 2. The overall assessment of efficacy of treatment is shown in Table 3.

Table 2: Cook's system of acne grading.

Grade	Baseline	1st wk	2nd wk	3rd wk	4th wk	5th wk	6th wk
	No. of Pts (%)	Pts.	Pts.	Pts.	Pts.	Pts.	Pts.
0	0	0	0	0	1	3	5(25)*
2	3(15)	3	5	8	9	11	12 (60)*
4	10(50)	10	8	6	7	4	2(10)*
6	6(30)	6	6	5	2	2	1(5)*
8	1(5)	1	1	1	1	0	0

No= Number, Pts=Patients, wk=week, Test used: Wilcoxon signed rank test *$p < 0.001$ very significant with respect to baseline.

Table 3: Efficacy assessment of treatment.

Response	No. of patient (%)
Excellent	6(30)
Good	11(55)
Poor	2(10)
No response	1(5)
Worse	0

This improvement may be attributed to various pharmacological activities of the ingredients of *PHAF*. These herbs possess anti-inflammatory, emollient, antiseptic and anti-microbial properties. These herbs might have inhibited the proliferation and growth of follicular micro flora and resolved the inflammatory process that led to the overall improvement in acne vulgaris at the end of treatment. This is in consonance with the pharmacological actions described in classical Ayurvedic literature and in various clinical studies. Further, significant and fast improvement in acne flare was noticed implying greater compliance of the treatment. Cutaneous tolerance was evaluated by erythema, scaling, dryness, burning and pruritis. No obnoxious adverse effects were observed and the *PHAF* was found safe and fairly well accepted by the patients.

In the light of above discussion, it may be concluded that *PHAF* is safe and statistically effective in the treatment of acne vulgaris. Although the study showed remarkable response, its limitations include lack of blinding, lack of randomization, small population and no control group studied. Therefore, studies with randomized standard controlled designs on large sample with long duration and long follow-up period need to be carried out for further exploration of efficacy and safety of *PHAF*.

REFERENCES

1. Ola leave manuscript 45, Library of Gamapaha Wickramarachchi Ayurveda Institute, University of Kelaniya.
2. Hunter JA, Savin JA, Hahl MV, Clinical Dermatology, 3rd ed, Blackwell Publishing Ltd, 2003; 148-55.
3. Sinal I, 4th Delhi; Eijaz Publishing House, Al Quanoon Fil Tib, 2010; 1432.
4. Cook CH, Centner RL, Michael SE. An acne grading method using photographic standards, Arch Dermatol, 1979; 115: 571-5. [PubMed].
5. Gopal MG, Farahana B, Efffectiveness of herbal medications on the treatment of acne vulgaris- a pilot study. The Indian Practitioner, 2001; 54: 10-723.
6. Sachindanand YN, Kumar AB, Treatment of acne vulgaris with new poly herbal formulation. Indian J Dermatol, 2001; 46: 138-41.