

## **Acne Vulgaris and its Treatment by Indigenous Drugs SK-34 (Purim) and SK-235 (Clarina)**

**Mamgain, R.K.**, Department of Kayachikitsa,  
Institute of Medical Sciences, Banaras Hindu University, Varanasi, India.

### **ABSTRACT**

*Acne vulgaris is a common dermatological disorder requiring rigorous treatment modalities due to its varied aetiology. In this trial, the herbomineral formulations, SK-34 tablets and SK-235 cream administered concurrently, were evaluated for their efficacy in cases of acne vulgaris. The results were evaluated using the student's paired "t" test. The mean score relief at the end of the second week of study was 1.43 ( $p < 0.01$ ) and 3.13 ( $p < 0.001$ ) at the end of the eighth week. None of the patients showed any skin reaction or other side effects due to both the drugs.*

**Key words:** Acne, Acne vulgaris, Acne lesion score.

### **INTRODUCTION**

Acne vulgaris is a chronic inflammatory disease of the pilosebaceous follicle, characterised by comedones, papules, pustules, cysts, nodules and often scars in certain sites of predilection, namely, the face, neck, upper trunk and arms.

Acne vulgaris is a disorder found in teenagers and young adults, which involves 90% of teenagers to some extent. Associated dermatitis may begin in the twenties or thirties and may persist in adults for many years, wherein 10-20 percent of adults may experience some form of the disorder<sup>1</sup>.

The present modality of treatment for acne varies from local and systemic antibiotics to steroid therapy, all of which have their own side effects and drawbacks in addition to the high cost of treatment. SK-34 and SK-235 are herbomineral preparations formulated to effectively treat acne. SK-34 tablet comprises Triphala, *Azadirachta indica*, *Rubia cordifolia*, *Curcuma longa* and *Andrographis paniculata*. SK-235 cream contains *Berberis aristata*, *Prunus amygdalus*, *Aloe vera* and Yashad bhasma. These ingredients have a proven efficacy in the treatment of various dermatological conditions. A clinical study was conducted to evaluate the efficacy of SK-34 tablets and SK-235 cream administered concurrently in cases of acne vulgaris.

### **MATERIALS AND METHODS**

Thirty seven patients attending the skin unit of Kayachikitsa Department of S.S. Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi, with acne vulgaris were included in the study. The patients were of either sex and in the age group of 17 to 25 years. Patients suffering from acne conglobata, endocrinal and other systemic disorders were excluded from the study.

All the patients were given the trial drug, SK-34, at a dose of two tablets thrice daily and were advised to apply SK-235 cream locally over the lesions both in the morning and evening after a thorough face wash drug treatment continued for four weeks. The patients were followed up at regular fortnightly intervals over a period of eight weeks.

### Criteria of Evaluation

The response to therapy was evaluated at intervals of two weeks upto the eight week by calculating the acne lesion score (ALS) and the efficacy was determined by the percentage reduction in the ALS at the end of eight weeks of treatment. Improvement in the form of reduction in the ALS was graded as shown in Table 1.

Score	0	1	2	3	4
% Reduction in ALS	No reduction in ALS	Less than 25% reduction in ALS	25-49% reduction in ALS	50-74% reduction in ALS	> 75% reduction in ALS
The scoring was inturn correlated with response to the treatment as follows: 0 – no improvement; 1 – poor response; 2 – fair response; 3 – good response; 4 – excellent response					

This dual response assessment provided better treatment evaluation of the therapy.

After calculating the mean reduction in ALS the response was statistically evaluated by using the student's paired 't' test. The final assessment was carried out after the target period of eight weeks.

All the patients were questioned for any untoward effects of the medications for photosensitivity, irritation, hypopigmentation, hyperpigmentation, depigmentation and gastrointestinal disturbances.

### OBSERVATION AND RESULTS

Thirty out of thirty seven patients included in the trial completed the eight weeks of follow up. Seven patients could not complete the scheduled follow up due to their personal problems in visiting the skin unit within the stipulated time. The data of observation was statistically evaluated using paired 't' test. The score relief observed in the patients at fortnightly intervals is given in Table 2.

Score relief	Number of patients			
	2nd week	4th week	6th week	8th week
0	–	–	–	–
1	17	4	2	–
2	13	21	9	5
3	–	5	19	16
4	–	–	–	9

Most patients started responding to the therapy at the end of 2 weeks of treatment. At the 4th week follow up, 70% (i.e. 21 patients) showed a 25-49% reduction in acne lesions, 16.69% of patients showed a 50-74% reduction and only 13.33% of the patients showed less than 25% reduction. At the 6th week's review, 63.33% of the patients showed a good response with 30% of the patients showing a fair improvement and a negligible 6.67% of the patients showed a poor response. By the end of eight weeks of treatment, 30% of the patients showed an excellent response with more than 75% reduction in acne, 53.33% of them showed a 50-74% reduction and only 16.67% patients showed 25-49% reduction in acne lesion. The response to treatment at different intervals in the patients treated for acne vulgaris is given in Table 3. There were no patients left with a poor response by the end of the study period and none of the patients reported any adverse effects during the entire period of the trial. All volunteers displayed an adequate acceptance to the trial medications. No worsening of acne infection was observed in any patient during the trial.

Weeks	Poor	Fair	Good	Excellent
2 <sup>nd</sup>	17 (56.67%)	13 (43.33%)	–	–
4 <sup>th</sup>	4 (13.33%)	21 (70%)	5 (16.69%)	–
6 <sup>th</sup>	2 (6.67%)	9 (30%)	19 (63.33%)	–
8 <sup>th</sup>	–	5 (16.67%)	16 (53.33%)	9 (30%)

The mean score relief at the end of the 2nd, 4th, 6th and 8th week was 1.43 ( $t=15.54, p<0.01$ ), 2.03 ( $t = 19.9, p<0.001$ ), 2.566 ( $t = 22.5, p<0.001$ ) and 3.13 ( $t=25.24, p<0.001$ ) respectively.

## DISCUSSION AND CONCLUSION

Acne is a family of disorders that varies greatly in pathogenesis and clinical manifestation. Accordingly, no simple recipe for the treatment can be given. Treatment options vary with the stage and severity of the disease<sup>9</sup>. An understanding of the factors that cause acne lesions is of great value in selecting the appropriate therapy for treating the case. Such therapy should be aimed at correcting wherever and to whatever degree possible, the various pathogenic mechanisms of the disease.

The stimuli for acne are undoubtedly multiple while the responsive “target tissue” or organ of response is always the same structure. The organ of response in acne is the pilosebaceous apparatus consisting of the hair follicle and its sebaceous glands. The most potent stimuli are undoubtedly the steroid sex hormones of which the androgen/oestrogen ratio is of prime importance. Other factors are (1) faulty anatomy of the pilosebaceous unit which obstructs the normal flow of sebum, emergence of hair, etc. (2) faulty keratinisation at the follicular neck resulting in plugging of this opening, (3) altered physical and chemical characteristics of the sebum resulting in its abnormal flow, and (4) an inflammatory response<sup>6</sup>.

Various treatment modalities are adapted to treat acne. These include locally applicable antibacterial agents like erythromycin that may produce a transient, increased density of cutaneous erythromycin-resistant (Emr) coagulase negative staphylococci<sup>2</sup>, to topical tretinoin. Various systemic drugs from tetracycline and spiranolactone to cimetidine have

been used with varying success. These medications have their own contraindications and side effects.

The herbal formulation, SK-34, contains herbs beneficial in various skin disorders. *Azadirachta indica* contains many essential oils that have antipyretic and anthelmintic properties. It helps in normalising the biliary secretion and purifies the blood. It is a good remedy for splenic enlargement<sup>14,18</sup>. *Rubia cordifolia* has astringent and antiseptic properties and is useful in skin infections, ulcers, inflammation and other skin problems<sup>10,4</sup>. It has shown good antibacterial property. The extract inhibited passive cutaneous anaphylaxis in various studies<sup>17,3</sup>. *Curcuma longa* has anti-inflammatory, antibacterial and anti-oedematous activity, removes excessive bile pigments from the blood. It is used in inflammatory and ulcerative conditions of the skin<sup>12</sup>. *Andrographis paniculata* has anthelmintic and tonic properties<sup>15</sup>. It helps in eliminating toxins from blood. SK-235 contains *Berberis aristata* and is an important ingredient in various Ayurvedic preparations used to treat burns and wounds<sup>13,11</sup>. *Prunus amygdalus* has emollient and demulcent properties which are useful in skin diseases<sup>7</sup>. *Aloe vera* is useful in skin diseases, and is used for local application in painful inflammation and chronic ulcers<sup>8</sup>. Yashad bhasma is a preparation of calcinated zinc containing chiefly zinc oxide<sup>16</sup>. Zinc oxide is well known for its mild astringent and antiseptic properties and accelerates wound healing<sup>5</sup>.

The study reveals that 53% of the patients had more than 50% of improvement and 30% of the patients experienced excellent relief from acne. Sixteen percent of the patients showed a fair response to the treatment with SK-34 and SK-235. None of the patients complained of any side effects or untoward reactions. The above observations show that SK-34 tablets and SK-235 cream have a positive role in treating acne lesions effectively without any side effects and contraindications.

#### **ACKNOWLEDGEMENT**

The Authors wish to express their sincere thanks to Prof. Ojha. D. Head, Kayachikitsa Department, Institute of Medical Sciences, B.H.U., Varanasi, for his kind permission to carry out this work and to Dr. Mitra, S.K., Executive Director, Research & Technical Services R&D and Mr. Pandey, A.S., Scientific Officer, The Himalaya Drug Company, for their timely co-operation and supply of medicines.

#### **REFERENCES**

1. Andrews diseases of the skin, WB Saunders Co., 8th edition, pg. 250, 1990.
2. *Antimicrob. Agents Chemother.*, 1996; 40(11): 2598.
3. *Chem. Abstr.*, 1990; 112: 340457 , 41764.
4. Chopra *et al. Indian J. Pharm.*, 1956; 18: 374.
5. Clinical pharmacology, Laurence and Bennett, 6th Edition, pg. 734, 1988.
6. Dermatology Diagnosis & Treatment, Oxford & IBH Publishing Co., Calcutta, 2nd Edition, Pg. 249, 1965.

7. Indian Medicinal Plants, a compendium of 500 species, Orient Longman, Volume 4, pg. 363, 1995.
8. Indian Medicinal Plants, a compendium of 500 species, Orient Longman, Volume 1, pg. 103, 1994.
9. *J. Am. Acad. Dermatol.*, 1997; S92-5: 36 (6 Pt 2)
10. Joshi & Magar, *J. Sci. Industr. Res.*, 1952; 11B: 261
11. Mandal & Sasimal, *Indian J. Ind. Med.*, 1991; 8: 9
12. Medicinal Plants of India, ICMR, 1976; I: 313.
13. Mukherjee & Banerjee, *Calcutta Med. J.*, 1989; 86: 137
14. Nadkarni, A.K., *Indian Materia Medica*, 1992; I: 784
15. Nadkarni, A.K., *Indian Materia Medica*, 1992; I: 101.
16. Nadkarni, A.K., *Indian Materia Medica*, 1996; II: 130.
17. Pandya, *et al.*, *Indian Drugs*, 1989; 27: 157.
18. Parshad, O., *et al.*, *Phytother. Res.*, 1997; 11: 398.