Treatment of Acne Vulgaris with New Polyherbal Formulations, Clarina Cream and Purim Tablets

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ABSTRACT
One hundred and five patients with active lesions of acne vulgaris were included in the open clinical trial. All the patients were administered Purim tablets, at a dose of 2 tablets twice daily for four weeks. Simultaneously, they were instructed to apply Clarina cream twice daily on the affected area of acne lesion twice daily for four weeks.

The response to treatment was excellent in Grades I and II after 4 weeks of treatment. In Grade III acne with large papules and pustules, the response was also significantly good, in healing the papules and pustules. The Grade IV acne required other adjuvant treatment. There were no local or systemic side effects seen in all these patients. Thus, Clarina cream along with Purim tablets was useful in treating patients with various degrees of acne.

INTRODUCTION
Acne vulgaris is a multifactorial disease affecting the pilosebaceous follicle characterised by comedones, papules, pustules, nodules and scars. Acne is prevalent among 95% and 83% of teenager boys and girls, respectively. In recent times, there has been a significant increase in patients above the age of 20 consulting the dermatologist for acne\(^1\,^2\). This shift in the incidence of acne from teenagers to the older age groups has led to a demand for new drugs.

Follicular keratinisation, seborrhoea, and colonisation of the pilosebaceous unit with Propionibacterium acne are central to the development of lesions. Genetic and hormonal factors also play a role, possibly by optimising the follicular environment suitable for the growth of P. acne or by influencing the inflammatory response and thus the nature of the lesions. Such understanding has led to the use of antibiotics, sebum reducing agents and anti-androgens and estrogens in conventional treatments.

The severity of acne can be graded for therapeutic study according to the Leeds grading scale, but in the general treatment of acne vulgaris, most doctors would divide the condition into mild, moderate and severe\(^4\). Mild disease consists of open and closed comedones, moderate
acne encompasses more frequent papules and pustules with mild scarring and severe disease contains all of the above, plus nodular abscesses or cysts that leads to extensive scarring.

*Benzoyl peroxide* is a potent oxidising agent with antibacterial and keratolytic properties. The main adverse effects are bleaching of clothes, transient skin irritation, and occasional allergic contact dermatitis. *Azelaic acid* is keratolytic, it can cause local irritation and photosensitisation and presently treatment is limited to a maximum of six months.

*Topical retinoid preparations* are useful for mild to moderate acne and can be applied once or twice daily. Side effects include erythema, desquamation, occasional hyperpigmentation or hypopigmentation, and sensitisation of the skin to sunlight. These products are derivatives of vitamin A, and there have been reports of malformed infants born to women who have used topical retinoids during early pregnancy.

*Topical antibiotics* are particularly useful in mild to moderate acne and in acne which is resistant to benzoyl peroxide. The development of antibiotic resistance in *P. acne* may limit the prescription of topical antibiotics. Therefore a study was undertaken in which two herbal preparations were used. These include a topical cream, Clarina, and tablets called Purim. Clarina cream is an herbal formulation comprising *Aloe barbadensis, Prunus amygdalus, Alternanthera sessilis, Rubia cordifolia, Borax and Zinc oxide*. Purim contains extracts of *Azadirachta indica, Tinospora cordifolia, Embelia ribes, Eclipta alba, Andrographis paniculata, Curcuma longa, Cassia fistula* and *Triphala*.

**MATERIAL AND METHODS**
One hundred and five patients with active lesions of acne vulgaris were included in the clinical trial. The grading of acne vulgaris was as follows:

- **Grade I:** Mild acne with only papules
- **Grade II:** Moderate acne with papules and comedones
- **Grade III:** Severe acne with papules and pustules
- **Grade IV:** Very severe acne with papules, pustules and cysts

These patients were instructed to apply Clarina cream twice a day on acne lesions on the face and Purim tablets were recommended at a dose of 2 tablets twice a day. The duration of the treatment was for 4 weeks. They were clinically assessed every week for four weeks.

**RESULTS**
Out of one hundred and five cases, 12 cases had grade I acne, 27 cases had grade II acne, 61 had grade III acne and 5 cases had grade IV acne. The results were obtained through the non-parametric statistical analysis tool.

In Grade I acne, there were excellent results in 6 cases and good results in 6 patients (Wilcoxon z = 3.071 *P* < 0.002 thus showing relief in all the patients. In Grade II acne, there were excellent results in 13 cases and good results in 14 patients (Wilcoxon z = 3.920
Again showing significant recovery and healing. In Grade III acne, the papules were completely cured in 12 cases while in 48 patients there was a good response. One patient did not respond to the treatment. The patients with pustules in Grade III there was an excellent response in 32 cases, 13 cases with good response while there was a no too encouraging response in the remaining 16 patients (Wilcoxon z = 5.412 P < 0.0001). These patients were prescribed regular antibiotics for a complete cure. There were 5 cases of an extremely severe form of acne vulgaris Grade IV. They were prescribed antibiotics + Clarina cream + Purim tablets. One patient with papules had an excellent response while 4, had a good response. Three patients with pustules had an excellent response and one patient each had a good and moderate response. One patient presenting with cysts had excellent response, three had a good response and one did not respond to treatment (Table).

**DISCUSSION**

Systemic antibiotics remain the main line of treatment for acne and tetracycline remains the treatment of first choice. The adverse effects of oral antibiotics including that of tetracycline include gastrointestinal upset, vaginal candidiasis, and hyperpigmentation with high dose of minocycline. A rapid induction of antibiotic resistance in *P. acne* accompanied by relapse of acne has been found with topical erythromycin, clindamycin, systemic tetracycline, erythromycin and doxycycline. High dose antibiotics such as tetracycline or erythromycin 1.5-2 g daily or minocycline 200 mg daily may be used in severe acne, however, the oral retinoid isotretinoin is much more effective.

Although isotretinoin is expensive, its use in moderate to severe acne vulgaris is considerably more cost effective than long term use of antibiotics. Adverse reactions to isotretinoin are common. Mucocutaneous reactions such as cheilitis, xerosis, blepharoconjunctivitis and epistaxis are dose related and occur in most cases. Myalgia and arthralgia occur in both male and female patients and may limit sporting activity.

Since the therapy for acne has limitations in modern medicine, herbal remedies can offer an alternative therapy for acne vulgaris. Our study shows that Clarina cream and Purim tablet combination can be effective therapy in grade I and II acne vulgaris. In grade III and IV, better results are obtained when combined with antibiotics for at least one week.

**Table: Showing response to treatment**

<table>
<thead>
<tr>
<th>Grade</th>
<th>No. of patients</th>
<th>Main features</th>
<th>Excellent</th>
<th>Good</th>
<th>Equivocal</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>12</td>
<td>Papules</td>
<td>6</td>
<td>6</td>
<td>–</td>
</tr>
<tr>
<td>II</td>
<td>27</td>
<td>Papules</td>
<td>13</td>
<td>14</td>
<td>–</td>
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<tr>
<td></td>
<td></td>
<td>Comedones</td>
<td>13</td>
<td>14</td>
<td>–</td>
</tr>
<tr>
<td>III</td>
<td>61</td>
<td>Papules</td>
<td>12</td>
<td>48</td>
<td>1</td>
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<tr>
<td></td>
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<td>Pustules</td>
<td>32</td>
<td>13</td>
<td>16</td>
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<tr>
<td>IV</td>
<td>5</td>
<td>Papules</td>
<td>1</td>
<td>4</td>
<td>–</td>
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<tr>
<td></td>
<td></td>
<td>Pustules</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cysts</td>
<td>1</td>
<td>3</td>
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</table>
CONCLUSION
We therefore conclude that the combination, Clarina cream and Purim tablets is an alternative remedy for acne vulgaris.
We would like to thank Dr. Rangesh Paramesh, M.D(Ay) for his kind help.

REFERENCES