ORIGINAL RESEARCH

Assessment of efficacy of clindamycin 1% nano-emulsion gel formulation for the treatment of Acne Vulgaris

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ABSTRACT
Background: Acne vulgaris is a common skin condition that primarily affects the face, back, and shoulders. The present study was conducted to assess efficacy of clindamycin 1% nano-emulsion gel formulation for the treatment of Acne Vulgaris. **Materials & Methods:** 74 patients of Acne Vulgaris of both genders were divided into 2 groups of 37 each. Group I patients received treatment with clindamycin nano emulsion gel formulation and group II, the active control i.e. a marketed conventional clindamycin gel formulation. The total number of lesions, including inflammatory lesions (papules, pustules, nodules and cysts) and non- inflammatory lesions (open and closed comedones) were recorded. **Results:** With inflammatory lesions, there was 74% reduction in group I and 61% in group II. With non- inflammatory lesion, there was 65% reduction in group I and 47% reduction in group II patients. The difference was significant (P< 0.05). Outcome in group I and group II was excellent in 92% and 85%, good in 8% and 13% and fair in 0 and 2% respectively. The difference was significant (P< 0.05). **Conclusion:** Clindamycin 1% nano-emulsion gel formulation has demonstrated a trend towards a superior tolerability profile and is more effective than its conventional formulation.
Keywords: Acne vulgaris, clindamycin, nano-emulsion

INTRODUCTION

Acne vulgaris is a common skin condition that primarily affects the face, back, and shoulders. It typically begins during puberty but can occur at any age. It is mostly on the face, neck, chest, back, and shoulders and is characterized by the appearance of nodules, blackheads, whiteheads, cysts, and pimples.[1] While it can affect adults, acne is more common in adolescents.

The emergence of acne is influenced by multiple variables. Sebum is an oily material produced by the skin's sebaceous glands. Overproduction of sebum can result in plugged pores, which are perfect breeding grounds for bacteria that cause acne.[2] Occasionally, excessive sebum can combine with normal skin cell shedding to form a blockage in the hair follicles.

This clog may inflame the area by capturing microorganisms. A species of bacteria called Propionibacterium acnes (P. acnes) resides on the skin and can cause acne to appear when hair follicles become clogged.[3]

Current evidence has shown that inflammatory events can precede microcomedone formation and that the development of follicular duct plugs is also influenced, to some degree, by inflammation caused by Propionibacterium acnes. P. acnes is an anaerobic organism present in the sebaceous glands which contributes to the pathophysiology of acne in several ways. Clindamycin is one of the topical antibiotics that is frequently administered for acne vulgaris in the Dermatology Section.[4] Its efficacy has remained higher over time. Additionally, clindamycin contains anti-inflammatory qualities that probably play a major role in its therapeutic actions against acne. The medication's concentration in the pilosebaceous ducts influences how well topical antibacterial medicines work. Furthermore, low and inconsistent medication concentrations found in the pilosebaceous ducts are also correlated with the formation of resistance.[5] The

present study was conducted to assess efficacy of clindamycin 1% nano-emulsion gel formulation for the treatment of Acne Vulgaris.

MATERIALS & METHODS

The present study was conducted on 74 patients of Acne Vulgaris of both genders. All gave their written consent to participate in the study.

Data such as name, age, gender etc. was recorded. They were divided into 2 groups of 37 each. Group I patients received treatment with clindamycin nano emulsion gel formulation and group II, the active control i.e. a marketed conventional clindamycin gel formulation. Patients were instructed to apply a thin film of the study medication twice daily for 12 weeks and the patients were followed-up at weeks 4, 8 and 12. The total number of lesions, including inflammatory lesions (papules, pustules, nodules and cysts) and non- inflammatory lesions (open and closed comedones) were recorded. Results thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Mean percentage reductions in acne lesions

Characteristics	Group I	Group II	P value
Inflammatory	74%	61%	0.05
Non- inflammatory	65%	47%	0.01

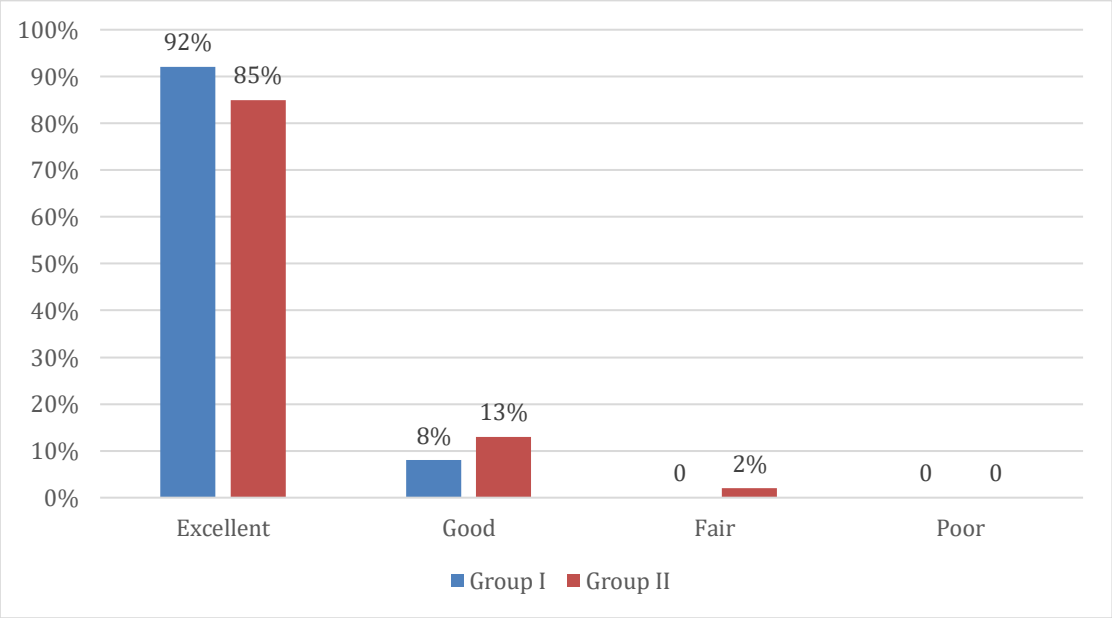
Table I shows that with inflammatory lesions, there was 74% reduction in group I and 61% in group II. With non- inflammatory lesion, there was 65% reduction in group I and 47% reduction in group II patients. The difference was significant (P< 0.05).

Table II Overall global assessment of tolerability

Outcome	Group I	Group II	P value
Excellent	92%	85%	0.05
Good	8%	13%	0.04
Fair	0	2%	0.05
Poor	0	0	0

Table II, graph I shows that outcome in group I and group II was excellent in 92% and 85%, good in 8% and 13% and fair in 0 and 2% respectively. The difference was significant (P< 0.05).

Graph I Overall global assessment of tolerability



DISCUSSION

One of the most important aspects of treating acne vulgaris is the use of antibiotics against P. acnes.[6] Topical antibiotics are more widely accepted due to their less adverse effects and interactions, even if systemic antibiotics have been used for a number of years to lower the population of P. acnes.[7,8] Using a special nano-emulsion technology, a topical nano-emulsion gel preparation with 1% w/w of clindamycin (as phosphate) as the active ingredient has been created. Because they have a significantly larger surface area than conventional macro-emulsions, nano-emulsions are more effective because they can effectively penetrate the pilo-sebaceous glands.[9,10] The present study was conducted to assess efficacy of

clindamycin 1% nano-emulsion gel formulation for the treatment of Acne Vulgaris.

We found that with inflammatory lesions, there was 74% reduction in group I and 61% in group II. With non- inflammatory lesion, there was 65% reduction in group I and 47% reduction in group II patients. Bhavsar et al[11] assessed the comparative efficacy and safety of a nano-emulsion gel formulation of clindamycin with its conventional formulation in the treatment of acne vulgaris of the face. A total of 200 patients (97 males) were included for Intention to Treat analysis in the trial with 100 patients in each group. Reductions in total (69.3 vs. 51.9%; $p<0.001$), inflammatory (73.4 vs. 60.6%; $p<0.005$) and non-inflammatory (65.1 vs. 43.7%; $p<0.001$) acne lesions were reported to be significantly greater with the nano-emulsion gel formulation as compared to the conventional gel formulation. Significantly more reduction in the mean acne severity score was noticeable with the nano-emulsion gel formulation (-1.6 ± 0.9 vs. -1.0 ± 0.8; $p<0.001$) than the comparator. A trend towards better safety profile of the nano emulsion gel formulation was reported.

We observed that outcome in group I and group II was excellent in 92% and 85%, good in 8% and 13% and fair in 0 and 2% respectively. Zouboulis CC et al[12] compared the efficacy and safety of a fixed clindamycin 1%/tretinoin 0.025% gel formulation applied once daily and a clindamycin 1% lotion formulation) applied twice daily in the treatment of moderate to severe acne vulgaris. At week 12, the mean percentage reduction in non-inflamed lesions (open and closed comedones) was greater in the CTG group compared with the CLN group ($P = 0.05$). Absolute reductions in open and closed comedones were also greater in the CTG group, consistent with the comedolytic activity of tretinoin. There was a significantly greater absolute reduction in inflamed lesions (pustules, papules and nodules) from baseline to both end-point (last observed efficacy outcome; $P = 0.043$) and week 12 ($P = 0.018$) in the CTG group compared with the CLN group. Evaluation of the calculated overall acne severity score, considering all five lesion subtypes, demonstrated a significantly greater mean percentage reduction in the CTG group compared with the CLN group, both at end-point ($P = 0.01$) and at week 12 ($P < 0.01$). The more subjective assessment of overall acne severity according to the Cook scale also demonstrated a significantly greater mean reduction in the CTG group than the CLN group after 12 weeks of therapy ($P = 0.007$). CTG had a more rapid effect on the onset of improvement compared with CLN; a 50% reduction in total lesion counts by day 60 was found in 77% of patients on CTG compared with 56% receiving CLN ($P = 0.003$). This was largely due to the reduction in open comedone counts ($P = 0. 0006$). For all other variables, CTG was at least as effective as CLN. Both treatments were well tolerated.

The shortcoming of the study is small sample size.

CONCLUSION

Clindamycin 1% nano-emulsion gel formulation has demonstrated a trend towards a superior tolerability profile and is more effective than its conventional formulation.

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