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ORIGINAL RESEARCH

Evaluation of a Novel Topical Nanoformulated Retinoid Gel in the Treatment of Moderate Acne: A Randomized Controlled Trial

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ABSTRACT

Background: Topical retinoids are cornerstone treatments for acne vulgaris due to their comedolytic and anti-inflammatory properties. However, their use is often limited by irritation and poor skin penetration. Nano formulation of retinoids has been proposed to enhance efficacy while reducing side effects. This study aimed to evaluate the clinical effectiveness and tolerability of a novel Nano formulated retinoid gel in treating moderate acne vulgaris. **Materials and Methods:** A prospective, randomized controlled trial was conducted over 12 weeks involving 120 patients aged 16–30 years with clinically diagnosed moderate acne. Participants were randomized into two groups: Group A received the novel Nanoformulated retinoid gel once daily, and Group B received a conventional 0.05% tretinoin cream. Efficacy was assessed using the Global Acne Grading System (GAGS) and lesion count at baseline, week 4, week 8, and week 12. Tolerability was evaluated using a standardized cutaneous irritation scoring system. Statistical analysis was performed using repeated-measures ANOVA with a significance level of $p<0.05$. **Results:** At baseline, mean GAGS scores were comparable between Group A (23.6 ± 2.8) and Group B (23.4 ± 3.1). At week 12, Group A showed a 72.4% reduction in GAGS score (mean: 6.5 ± 2.3), while Group B showed a 58.1% reduction (mean: 9.8 ± 3.0), $p=0.004$. Inflammatory lesion count reduced by 70% in Group A compared to 52% in Group B. Group A also had significantly fewer reports of erythema and peeling (13% vs 38%, $p=0.01$). **Conclusion:** The novel Nano formulated retinoid gel demonstrated superior efficacy and improved tolerability compared to conventional tretinoin cream in patients with moderate acne. These findings support its use as an advanced therapeutic option for acne management.

Keywords: Acne vulgaris, nanoformulation, retinoid gel, randomized controlled trial, topical therapy, skin irritation, GAGS.

INTRODUCTION

Acne vulgaris is one of the most prevalent dermatological conditions affecting adolescents and young adults worldwide, with an estimated global prevalence of 9.4% (1). Characterized by the formation of comedones, papules, pustules, and in severe cases, nodules and cysts, acne can significantly impact the quality of life and psychosocial wellbeing of affected individuals (2). Topical retinoids, including tretinoin and adapalene, remain first-line agents due to their ability to normalize follicular keratinization, reduce inflammation, and enhance the penetration of other topical therapies (3,4). However, conventional formulations are often associated with local skin irritation, including erythema, peeling, and burning sensations, which may reduce patient adherence (5).

Recent advancements in nanotechnology offer promising strategies to overcome these limitations. Nanocarrier-based drug delivery systems, such as nanoemulsions and liposomes, have been shown to improve the stability, skin penetration, and targeted delivery of active compounds while minimizing adverse effects (6,7). Nanoformulatedretinoids are designed to enhance therapeutic efficacy by promoting controlled release and deeper penetration into

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pilosebaceous units, thereby potentially reducing irritation and enhancing patient satisfaction (8).

While preclinical studies have suggested improved pharmacokinetics and bioavailability of nanoencapsulatedretinoids, clinical evidence comparing their efficacy and safety with conventional formulations remains limited. This randomized controlled trial was therefore conducted to evaluate the therapeutic effectiveness and tolerability of a novel topical nanoformulated retinoid gel in comparison with standard tretinoin cream in patients with moderate acne vulgaris.

MATERIALS AND METHODS

A randomized, parallel-group controlled trial was conducted at a tertiary dermatology center over a period of 12 weeks, following approval from the Institutional Ethics Committee. A total of 120 participants aged 16 to 30 years, clinically diagnosed with moderate acne vulgaris based on the Global Acne Grading System (GAGS), were recruited after obtaining informed consent.

Participants were randomly allocated into two groups (n = 60 each) using a computer-generated randomization table. Group A received the investigational topical nanoformulated retinoid gel, while Group B received conventional 0.05% tretinoin cream. Both formulations were applied once daily at bedtime for a duration of 12 weeks. Participants were instructed to avoid using any other topical or systemic acne treatments during the study period. Standardized non-comedogenic sunscreen was provided for daytime use.

Baseline assessments included clinical history, dermatological examination, and GAGS scoring. Lesion counts (non-inflammatory and inflammatory) were also documented. Follow-up assessments were conducted at weeks 4, 8, and 12 to record changes in lesion counts, GAGS scores, and any adverse events. Tolerability was evaluated using a structured 4-point scale for common cutaneous side effects such as erythema, dryness, scaling, and burning.

The primary outcome measure was the percentage reduction in GAGS score at week 12. Secondary outcomes included changes in individual lesion counts and the frequency of reported side effects. Data were analyzed using SPSS version 25. Continuous variables were expressed as mean ± standard deviation. Repeated-measures ANOVA was used to compare outcomes within and between groups over time, and a p-value of <0.05 was considered statistically significant.

RESULTS

A total of 120 participants completed the study, with 60 individuals in each treatment group. Both groups were comparable at baseline with respect to age, gender distribution, and severity of acne based on GAGS score.

By the end of 12 weeks, Group A (nanoformulated retinoid gel) demonstrated a more pronounced reduction in acne severity compared to Group B (0.05% tretinoin cream). The mean GAGS score in Group A decreased from 23.6 ± 2.8 at baseline to 6.5 ± 2.3 at week 12, indicating a 72.4% reduction. In contrast, Group B showed a reduction from 23.4 ± 3.1 to 9.8 ± 3.0, equating to a 58.1% decrease ($p = 0.004$) (Table 1).

In terms of lesion count, inflammatory lesions in Group A declined from an average of 21.3 ± 5.0 to 6.3 ± 2.5, while Group B showed a reduction from 20.9 ± 4.7 to 10.1 ± 3.1 ($p = 0.002$). Non-inflammatory lesions followed a similar trend, with a 68% decrease in Group A and a 53% decrease in Group B (Table 2).

Adverse effects were more frequently reported in Group B. Erythema, peeling, and dryness were observed in 38% of Group B patients compared to 13% in Group A ($p = 0.01$). Burning sensation was reported by 30% in Group B versus 10% in Group A (Table 3).

Table 1. Comparison of Mean GAGS Scores at Baseline and Week 12

Time point	Group A (Nano-Retinoid)	Group B (Tretinoin 0.05%)	p-value
Baseline	23.6 ± 2.8	23.4 ± 3.1	0.82
Week 12	6.5 ± 2.3	9.8 ± 3.0	0.004
% Reduction	72.4%	58.1%	—

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Table 2. Change in Lesion Counts from Baseline to Week 12

Lesion Type	Group A (Baseline)	Group A (Week 12)	Group B (Baseline)	Group B (Week 12)	p-value
Inflammatory Lesions	21.3 ± 5.0	6.3 ± 2.5	20.9 ± 4.7	10.1 ± 3.1	0.002
Non-Inflammatory Lesions	28.6 ± 6.2	9.1 ± 3.0	28.2 ± 5.9	13.3 ± 3.7	0.007

Table 3. Incidence of Adverse Events

Adverse Effect	Group A (%)	Group B (%)	p-value
Erythema	13%	38%	0.01
Dryness	15%	32%	0.03
Peeling	10%	27%	0.02
Burning Sensation	10%	30%	0.009

These findings indicate that the nanoformulated gel was not only more effective in reducing acne lesions but also better tolerated with significantly fewer side effects compared to the conventional formulation.

DISCUSSION

This randomized controlled trial demonstrated that the novel nanoformulated retinoid gel provided superior clinical efficacy and tolerability in managing moderate acne vulgaris compared to conventional 0.05% tretinoin cream. Over the 12-week period, patients using the nano-retinoid showed a significantly greater reduction in both GAGS scores and lesion counts, accompanied by fewer treatment-related adverse effects.

Topical retinoids remain the gold standard for comedonal acne due to their ability to normalize keratinocyte desquamation, reduce microcomedone formation, and exert anti-inflammatory effects (1,2). However, skin irritation is a major limitation, frequently causing treatment discontinuation or non-adherence (3,4). Our findings are consistent with previous reports indicating that nanoformulation enhances therapeutic efficiency while minimizing side effects by facilitating deeper skin penetration and controlled drug release (5,6).

Nanotechnology-based drug delivery systems such as solid lipid nanoparticles, nanoemulsions, and liposomes have been employed to improve the bioavailability and cutaneous targeting of retinoids (7,8). In this study, the nanoformulated gel resulted in a 72.4% reduction in GAGS score, surpassing the 58.1% reduction seen in the conventional group. These findings align with previous work that showed nano-encapsulation enhances follicular targeting, thereby increasing drug concentration at the site of action (9,10).

Moreover, a significant decline in inflammatory and non-inflammatory lesions in the nanoformulated group supports the hypothesis that sustained drug delivery enhances anti-inflammatory action while reducing the cumulative irritant dose on the skin surface (11,12). Similar benefits were observed in studies utilizing nanoscale tretinoin and adapalene vehicles, which reported faster clinical improvement and reduced erythema and dryness (13,14).

Importantly, the tolerability profile in our study further reinforces the advantages of nanoformulation. Fewer patients in Group A reported erythema, peeling, and burning sensations—adverse events that have been strongly associated with conventional retinoid use (15). These results are in agreement with earlier trials showing improved skin compatibility with nanoscale delivery systems due to slower drug diffusion and better skin hydration retention (16,17).

Another notable strength of this study is the inclusion of both objective (lesion counts, GAGS score) and subjective (adverse effect reports) assessments over multiple time points, providing

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a comprehensive evaluation of the treatment's impact. However, limitations include the relatively short follow-up duration and absence of long-term recurrence data. Future studies should explore extended treatment timelines and comparative analysis with other nanocarrier-based dermatological agents.

CONCLUSION

In conclusion, this study supports the clinical utility of nanoformulated topical retinoids in acne therapy. By offering enhanced efficacy with reduced cutaneous irritation, such formulations represent a significant advancement in topical acne management, particularly for patients who are sensitive to traditional retinoid treatments.

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