Dermatology Practical & Conceptual

Topical Metformin Compared with Clobetasol Propionate for Alopecia Areata: Clinical Outcomes from a Comparative Study

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Key words: Alopecia areata, metformin, clobetasol, SALT score

Citation: Saged NM, Obaid ZM, Fouda I. Topical Metformin Compared with Clobetasol Propionate for Alopecia Areata: Clinical Outcomes from a Comparative Study. *Dermatol Pract Concept*. 2026;16(1):5941. DOI: https://doi.org/10.5826/dpc.1601a5941

Accepted: August 26, 2025; **Published:** January 2026

Funding: None.

Competing Interests: None.

Authorship: All authors have contributed significantly to this publication.

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ABSTRACT

Introduction: Alopecia areata (AA) is alopecia of non-scarring type caused by autoimmune mechanism that affects any area of the body with hair various patterns.

Objectives: The aim of this research was to assess the safety and effectiveness of topical metformin 30% versus clobetasol propionate 0.05% in the treatment of patchy alopecia areata.

Methods: Thirty-four adult individuals with patchy alopecia areata participated in a randomized clinical trial and were categorized into two groups: Group I (17 participants) with metformin 30% applied twice daily for 12 weeks, and Group II (17 participants), with clobetasol propionate 0.05% administered twice daily for 12 weeks. The 5-point semiquantitative regrowth score (RGS), SALT score, and dermoscopic examination were done to evaluate the therapeutic response.3-12-0

Results: At week 12, the median hair regrowth score for group I was 2, whereas for the clobetasol propionate group it was 5. There was no difference of significant importance regarding hair regrowth between the two groups, with P=0.133. Significant reductions in SALT score were observed in the two groups, and the reductions were mostly observed in Group II.

Conclusion: Topical metformin represents a promising and well-tolerated option in alopecia areata treatment. Although the effects of metformin 30% and clobetasol propionate 0.05% were not different, clobetasol was more effective than metformin 30% in treating localized alopecia areata.

Introduction

Alopecia areata (AA) is a non-scarring form of hair loss driven by autoimmune processes [1]. Although benign, AA significantly impairs health-related quality of life (HRQoL), primarily affecting psychological and social well-being due to associated alterations in appearance [2]. Affecting 0.5% to 2% of individuals worldwide, AA demonstrates increasing prevalence among younger populations. The condition exhibits equal sex distribution, with a mean onset age of 33 years [3].

AA arises from the collapse of the hair follicle's immune privilege, resulting from genetic alterations affecting innate and adaptive immunity, oxidative stress, and environmental factors (e.g., infections, diet, stress). These triggers activate autoreactive CD8+ T cells targeting anagen-phase follicles. AA pathogenesis involves lymphocytic infiltration around growing hairs (sparing stem cells), causing dystrophic alterations in the hair cycle and premature transition to telogen phase [4].

Therapeutic objectives include stimulating hair regrowth and halting disease advancement. Key determinants for clinical management encompass patient age and severity of alopecia [5]. First-line treatment typically involves topical or intralesional corticosteroids. Initial signs of clinical response generally emerge within six weeks to three months for most patients [6].

AA results from immune-mediated assault on hair follicles. Corticosteroids function in AA management by terminating the active inflammatory phase, protecting follicles from damage, and facilitating normal hair regrowth through suppression of immune responses [7].

Metformin modulates immunity via activation of adenosine monophosphate-activated protein kinase (AMPK), leading to inhibition of mammalian target of rapamycin (mTOR) and Janus kinase/signal transducer and activator of transcription (JAK-STAT) signaling pathways. Suppression of mTOR and JAK-STAT blocks T cell proliferation and differentiation into cytotoxic T lymphocytes, which contribute to follicular damage and release of cytokines (e.g., IL-17, IFN-γ) that disrupt hair follicle immune privilege. Consequently, topical metformin represents a potential therapeutic option for alopecia areata, administered alone or combined with other agents [8].

Objectives

This study aimed to evaluate the safety and efficacy of 30% topical metformin compared to 0.05% clobetasol propionate for managing patchy alopecia areata.

Patients and Methods

This randomized clinical trial enrolled 34 adults (18–45 years) of both sexes with patchy alopecia areata. Exclusion criteria included alopecia totalis (AT), alopecia universalis (AU), non-scalp AA involvement, pregnancy/lactation, recent (≤1 month) topical or systemic AA therapy, and age <18 or >45 years. All participants provided written informed consent.

Participants were randomized into two groups: Group I (N=17) applied 30% topical metformin twice daily for 12 weeks, while Group II (N=17) received twice-daily applications of 0.05% clobetasol propionate for 12 weeks. Approval was obtained from Al-Azhar University's Damietta Faculty of Medicine Institutional Review Board (DFM-IRB 00012367-23-12-003).

Treatment response was evaluated using a 5-point semi-quantitative regrowth score (RGS) and the Severity of Alopecia Tool (SALT). RGS criteria are detailed in Table 1.

The SALT I system partitions the scalp into four quadrants. Site-specific scores were calculated as [(length × width) × (% hair loss)/100]. Assessments occurred at baseline, week 4, week 8, and week 12. Posttreatment outcomes were analyzed via serial photographic comparison of SALT scores and hair regrowth.

Objective dermoscopic evaluation (DermLite DL4) identified disease activity markers (tapering hairs, broken hairs, black/yellow dots) and improvement indicators (vellus/terminal hairs). Monthly follow-up assessed treatment persistence and detected disease relapse.

Statistical Analysis

Data analysis was performed using IBM SPSS Statistics version 22.0 (Chicago, IL). Descriptive statistics summarized continuous variables as either median with range (for non-normally distributed data) or mean ± standard

Table 1. Semiquantitative Regrowth Score (RGS) criteria.

RGS	Hair Regrowth Percentage	Interpretation
0	< 10%	Minimal regrowth
1	11–25%	Mild regrowth
2	26–50%	Moderate regrowth
3	51–75%	Significant regrowth
4	> 75%	Extensive regrowth
5	≥ 90%	Complete/near-complete regrowth

deviation (SD) (for normally distributed data). Categorical variables are expressed as frequencies and percentages. Inferential statistical analyses employed the Mann-Whitney U test, Monte Carlo simulation, Fisher's exact test, chi-square test, and Student's t-test, as appropriate. Statistical significance was defined as $P<0.05$, while $P<0.01$ denoted high significance. Results with $P>0.05$ were considered statistically non-significant.

Results

Baseline characteristics demonstrated no statistically significant difference between groups (Table 2). The cohort consisted of 25 males (73.5%) and 9 females (26.5%). Mean ages were 30.65 ± 9.74 years (Group I, metformin) and 29.06 ± 9.15 years (Group II, clobetasol). Disease onset was abrupt in 19 patients (55.9%) and gradual in 15 (44.1%), while clinical course was stationary in 20 (58.8%) and progressive in 14 (41.2%). Baseline median SALT scores measured 4 (Group I) and 7 (Group II).

SALT scores showed no significant difference between groups at week 12 ($P=0.455$). Both therapies significantly reduced SALT scores from baseline ($P=0.011$ metformin; $P=0.001$ clobetasol), with clobetasol demonstrating greater reduction (median: 7→0 vs. metformin: 4→3). Similarly, Regrowth Hair Scores (RGS) increased substantially within both groups by week 12 ($P=0.007$ metformin; $P=0.001$ clobetasol), though intergroup RGS differences remained non-significant ($P=0.133$). Complete regrowth (RGS 5) occurred in 35.3% (6/17) of metformin patients versus 58.8% (10/17) with clobetasol. Dermoscopy revealed persistent disease activity in 23.5% (4/17) of metformin patients (broken/black dots) versus 11.8% (2/17) with clobetasol (yellow dots) (Table 3).

Topical metformin demonstrated superior tolerability, with no reported adverse effect in Group I (0/17). In contrast, clobetasol-treated patients (Group II) exhibited significantly higher rates of pruritus (64.7%, $P<0.001$) and erythema (35.3%, $P=0.007$). Less frequent side effects included folliculitis (17.6%), telangiectasia (11.8%), and atrophy (5.9%), though these did not reach statistical significance (Table 4).

Table 2. Baseline characteristics of the studied patients.

Variables	Group I (Metformin 30%) [N=17]	Group II (Clobetasol propionate 0.05%) [N=17]	Test of sig.
Age (Years)			
Mean ± SD	29.06 ± 9.15	29.06 ± 9.15	t = - 0.490 *P*=0.628
Sex			
Males	12 (70.6%)	13 (76.5%)12 (70.6%)	FET= 0.151 *P*=0.697
Females	5 (29.4%)	4 (23.5%)	
Onset			
Insidious	7 (41.2%)	8 (47.1%)	$\chi2$ = 1.053 *P*=0.591
Sudden	10 (58.8%)	9 (52.9%)	
Course			
Progressive	7 (41.2%)	7 (41.2%)	$\chi2$ = 0 *P*=1
Stationary	10 (58.8%)	10 (58.8%)	
Affected site			
Vertex	7 (41.2%)	3 (17.6%)	MC = 9.245 *P*=0.142
Frontal	0 (0%)	5 (29.4%)	
Occipital	7 (41.2%)	5 (29.4%)	
Parietal	1 (5.9%)	2 (11.8%)	
Temporal	2 (11.8%)	2 (11.8%)	
Basal SALT			
Median (IQR)	4 (3 – 8)	7 (4.5 – 10)	z = - 1.535 *P*=0.125
Range	2 – 10	2 – 10	

Abbreviations: t: independent samples t-test; χ^2: chi-square test; z: Mann-Whitney U test; MC: Monte Carlo simulation; FET: Fisher's exact test; *P*: p-value; IQR: interquartile range. *Statistical notes: All tests compared baseline characteristics between Group I and Group II. $P<0.05$ indicates statistical significance.

Table 3. Comparison of the percentage of improvement between the two studied groups according to SALT and hair regrowth score.

Variables	Group I (Metformin 30%) [N=17]	Group II (Clobetasol propionate 0.05%) [N=17]	Test of sig.
Basal SALT			
Median (IQR)	4 (3 – 8)	7 (4.5 – 10)	z = - 1.535 *P*=0.125
Range	2 – 10	2 – 10	
SALT at 12 weeks			
Median (IQR)	3 (0 – 5)	0 (0 – 6)	z = - 0.747 *P*=0.455
Range	0 – 8	0 – 8	
P	0.011*	0.001*	
Regrowth hair score at 4 weeks			
Median (IQR)	0 (0 – 0)	0 (0 – 0)	z = - 0.346 *P*=0.716
Range	0 – 3	0 - 3	
Regrowth hair score at 12 weeks			
Median (IQR)	2 (0 – 5)	5 (1 – 5)	z = - 1.503 *P*=0.133
Range	0 – 5	0 – 5	
P	0.007*	0.001*	

Abbreviations: z, Mann-Whitney U statistic; *P*, p-value for between-group comparisons; *P*: p-value for within-group changes from baseline (Wilcoxon signed-rank test); IQR, interquartile range. *Statistical significance: **P*<0.05

During the 3-month follow-up period, none of the participants who achieved complete hair regrowth (RGS 5) experienced disease recurrence.

Representative cases illustrate the therapeutic progression in both treatment groups.

Metformin-Treated Patient (Group I): A 45-year-old female with patchy alopecia areata demonstrated progressive clinical improvement over 12 weeks of topical metformin therapy. Baseline evaluation revealed a well-defined patch of alopecia (Figure 1A), which showed partial regrowth by week 8 (Figure 1B) and near-complete resolution by week 12 (Figure 1C). Dermoscopic evaluation correlated with clinical findings: baseline black dots (Figure 2A, blue arrow) persisted at week 8 (Figure 2B) before transitioning to terminal hairs by week 12 (Figure 2C), confirming follicular recovery.

Clobetasol-Treated Patient (Group II): A 30-year-old male with similar patchy involvement exhibited more rapid response to clobetasol propionate 0.05%. The baseline alopecic patch (Figure 3A) showed substantial regrowth by week 8 (Figure 3B), with complete coverage achieved by week 12 (Figure 3C). Dermoscopy mirrored this progression, with baseline black dots (Figure 4A, blue arrow) diminishing by week 8 (Figure 4B) and fully replaced by terminal hairs at endpoint (Figure 4C).

Discussion

Topical corticosteroids remain the cornerstone initial therapy for patchy alopecia areata (AA), particularly favored for younger patients due to their relatively manageable side effects when applied correctly. These agents also serve as valuable adjuncts in more extensive or recalcitrant cases [9]. Concurrently, topical metformin formulations (30%) have demonstrated efficacy in diverse dermatological conditions, including acne vulgaris, acanthosis nigricans, and melasma [10-13], suggesting potential utility in AA that our study sought to evaluate.

In our cohort, clobetasol propionate 0.05% demonstrated robust efficacy with 10 patients (58.8%) achieving complete hair regrowth (RGS 5) after 12 weeks. This aligns closely with Sajjad et al.'s report where 74.3% of clobetasol-treated patients exhibited >75% improvement [14]. Further corroboration comes from Molinelli et al., where 45.7% of participants attained significant regrowth (RGS 4) at the 12-week mark [15]. Our findings also resonate with Ullah et al.'s comparative analysis, which established clobetasol's superiority over tacrolimus 0.1% [16].

Regarding scalp coverage metrics, clobetasol prompted substantial SALT score reductions (median: 7→0), consistent with multiple independent studies: Nassar et al. documented significant SALT decreases (*P*=0.03) [17], Gupta et al. reported scores declining from 10.45±5.25 to 5.98±4.32 (*P*=0.0007) by week 24 [18], and Bhusal et al. noted superior efficacy versus bimatoprost (*P*=0.282) [19].

While metformin's application in AA is novel, its immunomodulatory foundation is well-substantiated. By activating AMP kinase, metformin suppresses mTOR and JAK-STAT pathways [8], key drivers of autoimmune follicular attack.

Table 4. Adverse event frequency comparison between treatment groups.

Variables	Group I (Metformin 30%) [N= 17]	Group II (Clobetasol propionate 0.05%) [N= 17]	Test of sig.
Pruritus	0 (0%)	11 (64.7%)	FET= 16.261 *P*<0.001*
Erythema	0 (0%)	6 (35.3%)	FET= 7.286 *P*=0.007*
Atrophy	0 (0%)	1 (5.9%)	FET= 1.030 *P*=0.310
Folliculitis	0 (0%)	3 (17.6%)	FET= 3.290 *P*=0.070
Telangiectasia	0 (0%)	2 (11.8%)	FET= 2.125 *P*=0.145

Abbreviations: FET: Fisher's exact test. *Statistical significance: **P*<0.05.

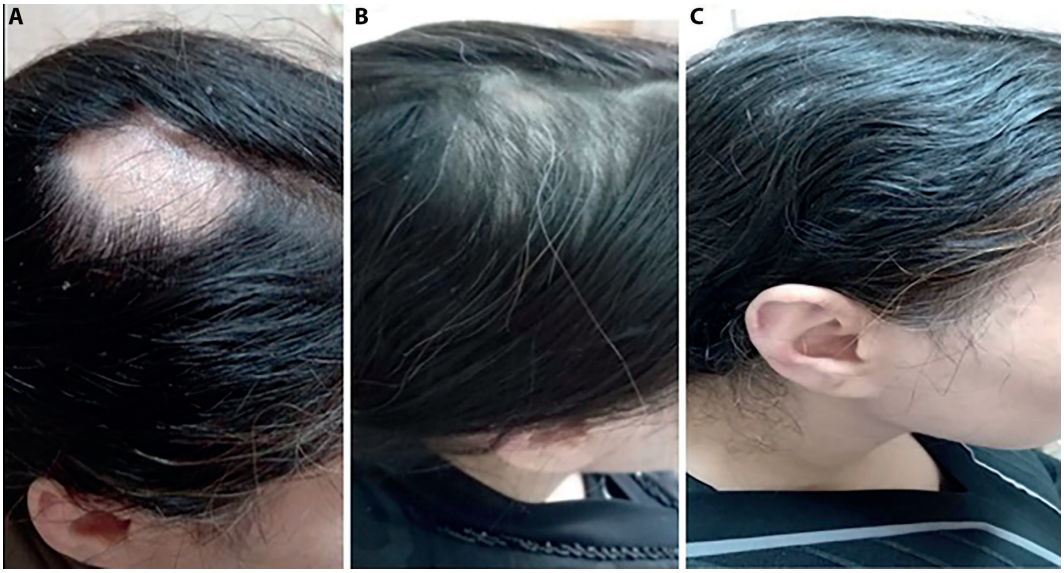

Figure 1. Clinical response to topical metformin 30%. Clinical photographs of 45-year-old female with patchy alopecia areata: A) baseline lesion, B) partial regrowth at week 8, C) near-complete regrowth at week 12.

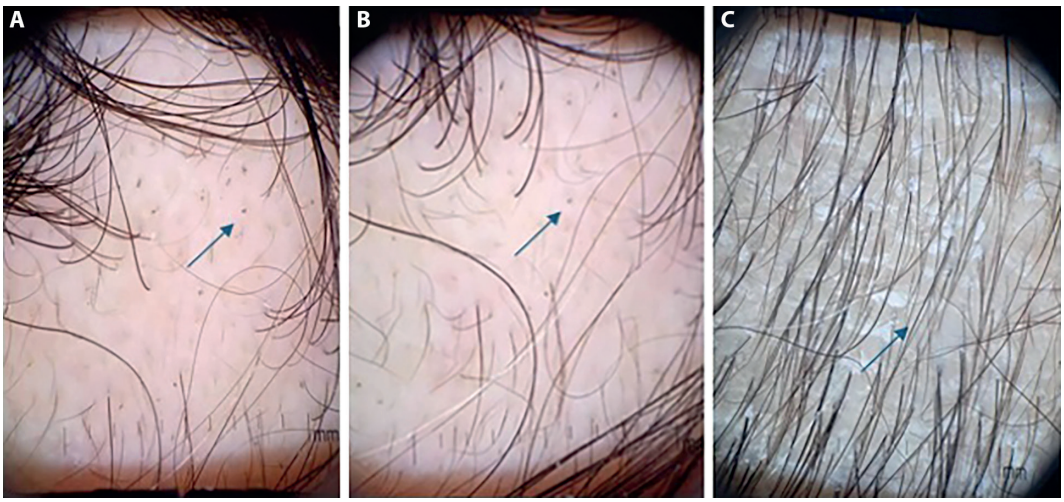

Figure 2. Dermoscopic progression with metformin therapy. DermLite DL4 images (Case 1): A) baseline black dots (blue arrow), B) persistent black dots at week 8 (blue arrow), C) terminal hair regrowth at week 12 (blue arrow).

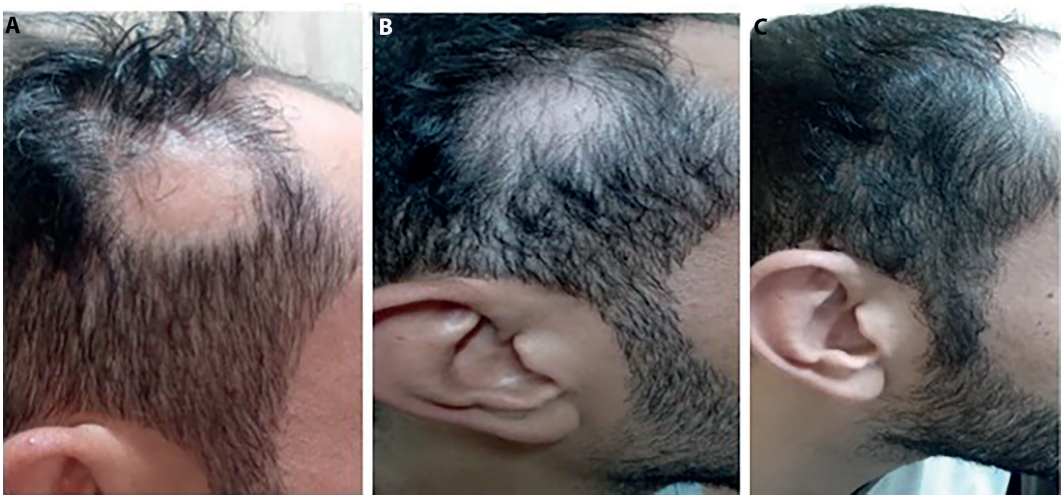

Figure 3. Clinical response to clobetasol propionate 0.05%. Clinical photographs of 30-year-old male with patchy AA: A) baseline involvement, B) early regrowth at week 8, C) complete regrowth at week 12.

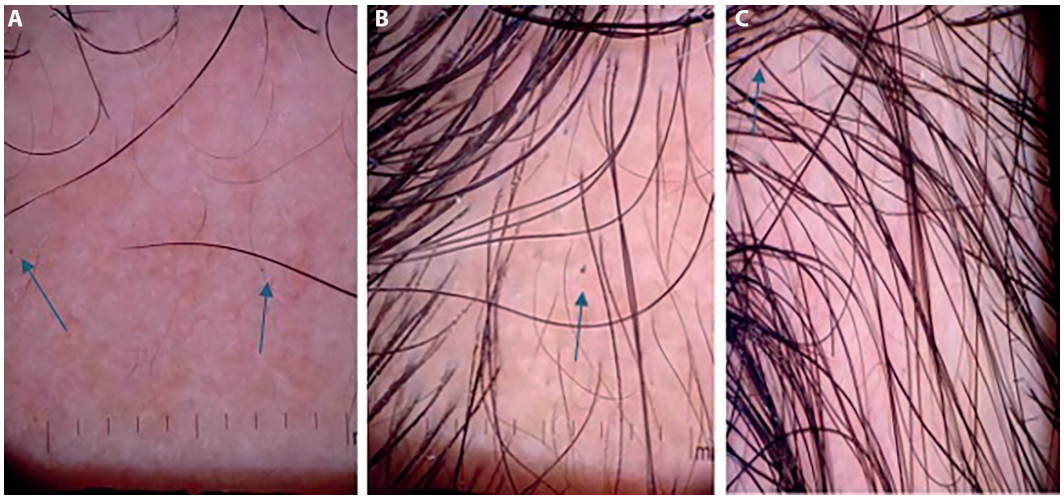

Figure 4. Dermoscopic evolution with clobetasol therapy. Dermoscopic series (Case 2): A) baseline black dots (blue arrow), B) residual black dots at week 8 (blue arrow), C) terminal hair predominance at week 12 (blue arrow).

Preclinical work by Sun et al. lends biological plausibility, demonstrating metformin-enhanced hair follicle regeneration via dermal cell modulation in murine models [20]. Clinically, Araoye et al. and a recent case report observed hair regrowth with topical metformin in corticosteroid-refractory central centrifugal cicatricial alopecia [21,22]. Metformin's additional anti-inflammatory actions, particularly AMPK-mediated upregulation of IL-10 and TGF-β [23], may offer synergistic benefits for patients with comorbid inflammatory conditions like psoriasis.

The adverse effect profiles revealed clinically meaningful divergence.

Clobetasol group: Pruritus affected 11 patients (64.7%), erythema six (35.3%), folliculitis three (17.6%), telangiectasia two (11.8%), and atrophy oone (5.9%). This mirrors Molinelli et al.'s report of telangiectasia and moderate pruritus [15] and aligns with Bhusal et al.'s documentation of pruritus (22%), erythema (16%), and folliculitis (12%) [17].

Metformin group: No treatment-related adverse event emerged: a potentially transformative advantage for chronic management.

Limitations

This study is limited by its absence of long-term evaluation and modest cohort size. We consequently recommend future research on larger populations with extended follow-up to optimize metformin formulations, validate clinical efficacy, and investigate synergistic potential with corticosteroids or JAK inhibitors within integrated treatment regimens.

Conclusion

Topical metformin 30% emerges as a promising, well-tolerated therapeutic option for alopecia areata. Though no statistically significant difference was observed between metformin and clobetasol propionate 0.05% in primary endpoints,

clobetasol demonstrated superior clinical efficacy in treating localized AA. This positions metformin as a viable steroid-sparing alternative for patients prioritizing tolerability.

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