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TOPICAL EFLORNITHINE TREATMENT FOR HIRSUTISM IN WOMEN: SUMMARY OF FINDINGS

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ABSTRACT

Introduction: Hirsutism impacts 5–10% of women of reproductive age, characterized by excessive male-pattern terminal hair growth. Excess facial hair is notably distressing given its visibility, commonly diminishing women's perceptions of femininity. Evidence from clinical studies reveals that eflornithine attenuates facial hair proliferation and conspicuousness, thereby ameliorating quality of life.
Aim of the study: This study aims to provide a comprehensive analysis of the scientific evidence on the effectiveness of topical eflornithine preparations in the treatment of hirsutism in women. The analysis focused specifically on monotherapy with eflornithine or in combination with other therapies such as laser and intense pulsed light treatments. Pharmacokinetics and safety of use were also evaluated. The data collected were synthesized descriptively to support a comparative assessment of different eflornithine-based treatment strategies.
Material and method: This study used a systematic literature review methodology to synthesize the scientific evidence on the efficacy of topical eflornithine in the treatment of hirsutism in women. The literature review was compiled using the PubMed and Google Scholar platforms, including articles published between 2001 and 2006.
Results: Topical eflornithine emerges as an efficacious intervention for hirsutism in women, demonstrating superior clinical outcomes whether employed as monotherapy or adjunctively with laser or IPL therapies.

KEYWORDS

Hirsutism Treatment, Topical Eflornithine, Intense Pulsed Light, Laser Hair Removal

CITATION

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Introduction

Hirsutism manifests as excessive terminal hair growth in a male-pattern distribution in women, featuring coarse, dark hairs on the face, neck, chest, abdomen, lower back, buttocks, or thighs (Almuwallad et al., 2023; Martin et al., 2018). This condition affects 5–10% of reproductive-age women. Diagnosis is established via a Ferriman-Gallwey score of ≥8, though patients often regard lesser hair quantities as troubling (Blume-Peytavi & Hahn, 2008; Wolf et al., 2007). Unwanted facial hair proves especially distressing due to its visibility, frequently eroding women's sense of femininity (Lapidoth et al., 2010; Malhotra et al., 2001). Hirsutism markedly impairs self-perception and self-esteem, engendering shame, depression, and compromised quality of life (van Zuuren et al., 2015). Predominantly, it arises from hyperandrogenism, wherein polycystic ovary syndrome constitutes the principal cause. Unidentified etiologies are classified as idiopathic hirsutism (Lapidoth et al., 2010; Martin et al., 2018). Therapeutic options comprise pharmacological agents and direct hair removal techniques, deployable independently or conjointly. Pharmacotherapy entails oral contraceptives that suppress androgen synthesis or peripheral androgen antagonists such as flutamide or spironolactone (Kumar et al., 2016; Martin et al., 2018). Although laser hair removal yields enduring reduction, it incurs high costs, demands multiple sessions, induces discomfort, and carries scarring risks. A 13.9% eflornithine hydrochloride cream has garnered FDA (Food and drug Administration) approval as a topical agent for unwanted facial hair in women. By irreversibly inhibiting ornithine decarboxylase, it attenuates hair growth rates. Treatment effects manifest after 6–8 weeks, accompanied by minimal systemic absorption, supporting its application as monotherapy or alongside other interventions like laser or intense pulsed light therapy (Martin et al., 2018).

Methodology

This investigation adopted a systematic literature review methodology to synthesize the scientific evidence regarding the efficacy of topical eflornithine for treating hirsutism in women. Eighteen clinical studies were examined, including randomized controlled trials, pilot studies, and clinical guidelines published between 2001 and 2026, sourced from PubMed and Google Scholar databases. Exclusion criteria encompassed non-English publications and studies unrelated to eflornithine use for hirsutism in women. All titles and abstracts from the search were screened, with full-text reviews conducted for relevant records. The analysis particularly emphasized eflornithine monotherapy in topical form or in combination with other therapies, such as laser and intense pulsed light treatments. Pharmacokinetics and safety were also evaluated. Collected data underwent descriptive synthesis to support comparative evaluation of diverse eflornithine-based treatment strategies.

Monotherapy with Eflornithine

Vissing et al. conducted a randomized controlled trial to evaluate the efficacy of topical eflornithine (11.5% cream) in sustaining hair reduction in patients who had previously undergone intense pulsed light therapy (IPL). The study cohort consisted of 22 participants who had completed a regimen of five to six IPL sessions and were monitored over a six-month follow-up period. Utilizing a split-face experimental design, participants applied the eflornithine cream twice daily to a randomly assigned half of the face and neck, while the contralateral side served as an untreated control. The therapeutic impact was quantified by comparing baseline hair counts with clinical photographic assessments at intervals of one, three, and six months. The findings demonstrated that eflornithine application reduced hair regrowth by 14% at one month, 9% at three months, and 17% at six months relative to the control group. Furthermore, subjective patient-reported outcomes indicated a longitudinal increase in perceived efficacy. By the six-month mark, the proportion of participants reporting substantial clinical improvement had doubled compared to the assessments recorded after one month of treatment (Vissing et al., 2016). John E. Wolf and associates synthesized data from two multicenter, randomized controlled trials involving 594 women clinically diagnosed with hirsutism. The study

participants were randomized to apply either a 13.9% eflornithine hydrochloride cream or a placebo vehicle to the face and neck twice daily for 24 weeks, which was followed by an 8-week treatment-free observation period. Quantitative assessments using clinical photography and videography revealed that eflornithine administration resulted in a 26% decrease in hair mass and a 23% reduction in hair length, significantly outperforming the control group's respective reductions of 5% and 4%. Physician Global Assessment metrics further established the clinical efficacy of the intervention, with 32% of the eflornithine cohort achieving clinical success (defined as clear or significant improvement) compared to only 9% in the control group. However, the researchers noted that these therapeutic gains were not permanent. Hair length measurements reverted to baseline levels following the cessation of the cream, and the statistical significance between the groups vanished within 8 weeks of treatment discontinuation (Wolf et al., 2007). Subsequently, Joseph Jackson and colleagues analyzed data from the same two multicenter randomized controlled trials, assessing the efficacy of a 13.9% eflornithine hydrochloride cream via patient-reported outcomes. For this evaluation, they utilized the ESTEEM scale, consisting of six questions on hirsutism-induced discomfort in social settings and during facial hair removal, with responses captured on a visual analog scale. Assessments were conducted at weeks 8, 16, 24, and 32. At study initiation, participants reported high baseline levels of perceived discomfort, with average values ranging between 79% and 89%. However, multivariate analysis at week 24 indicated that patients receiving the active eflornithine treatment experienced significantly less distress and functional inconvenience compared to the placebo cohorts. Despite these clinical gains, the therapeutic effect was not sustained following the cessation of the intervention. An eight-week treatment-free period resulted in a regression of discomfort scores to levels comparable with the control group, leading to a loss of statistical significance (Jackson et al., 2007). The next study included 25 women with unwanted facial hair (UFH). For 4 months, the patients applied a cream containing 11.5% eflornithine to their upper lip twice a day. The patients were assessed at the beginning of the study and after 1, 2, and 4 months of therapy. TrichoScan, a combination of contact skin microscopy and digital image analysis, was used as the method for evaluating the effectiveness of the therapy in this study. The study showed that after only one month of treatment, there was a significant reduction in hair density (-11.4 hairs/cm², p=0.014), cumulative length (-7.104 mm, p=0.001), and growth rate (-0.015 mm/day, p=0.004) had significantly decreased. Only the average hair length did not change significantly (Hoffmann, 2008).

Combination therapy (Laser/IPL)

A six-month randomized controlled trial was conducted at the Dermatology Department of Lady Reading Hospital in Peshawar to evaluate the therapeutic superiority of integrating intense pulsed light (IPL) with topical eflornithine compared to IPL monotherapy for idiopathic facial hirsutism. The study enrolled 78 participants, who were equally randomized into two cohorts. Subjects in Group A received a combination treatment consisting of twice-daily eflornithine applications alongside IPL sessions scheduled every four weeks, while Group B was treated with IPL therapy exclusively. Both cohorts completed a standardized regimen of six IPL sessions over the duration of the study. The clinical outcomes at the six-month follow-up demonstrated a significantly higher percentage of terminal hair reduction in the combination therapy group (90.44 ± 2.89) compared to the group receiving only IPL intervention (59.23 ± 10.59). Furthermore, the investigation reported a 100% treatment efficacy rate within Group A, whereas only 48.7% of participants in Group B achieved comparable results (Zahoor et al., 2019). Another study from 2025 examined more closely the effectiveness of combining intense pulsed light with topical application of eflornithine, specifically testing whether such a multidirectional approach could increase the effectiveness of hair reduction compared to IPL monotherapy. This randomized controlled trial involved the enrollment of 152 women with idiopathic facial hirsutism. All participants received six intense pulsed light sessions spaced 4 weeks apart, while the 76 patients assigned to combination therapy additionally applied a 13.9% eflornithine hydrochloride cream topically to their facial skin twice daily. Evaluations via the modified Ferriman-Gallwey scale were performed at baseline and week 24. Within the combination therapy group, 89.5% attained a minimum one-grade reduction, versus 69.7% in the IPL monotherapy group. Additionally, 83% of combination therapy recipients rated outcomes as “very satisfactory” or “exceptionally satisfactory” on the Likert scale, compared to 57% in the control group (Nawaz et al., 2025). In a randomized controlled trial, Hamzavi and associates examined whether the adjunctive use of topical eflornithine could enhance the efficacy of laser-assisted hair removal in a cohort of 31 women. The clinical protocol involved up to six sessions of a long-pulse alexandrite laser administered at four-week intervals. Utilizing a double-blind, split-face methodology, participants applied a 13.9% eflornithine hydrochloride cream to one side of the upper lip and a vehicle placebo to the contralateral side twice daily.

Treatment assignments were blinded through the use of color-coded tubes. The therapeutic response was evaluated at four-week intervals and concluded with a final assessment two weeks after the terminal laser session, utilizing investigator-led efficacy ratings, patient self-assessments, and objective hair count analyses. Clinical observations indicated that near-complete or complete hair clearance was achieved in 93.5% (29 of 31) of the regions treated with the combination of eflornithine and laser, compared to 67.9% (21 of 31) in areas receiving the laser and placebo combination. Furthermore, subjective outcomes favored the eflornithine-treated side, with 41.9% of participants reporting superior results on that side, while no patients preferred the placebo-treated area. Quantitative hair count data at the study's conclusion further corroborated these findings, showing a 7.9% greater reduction in hair density on the side treated with eflornithine (Hamzavi et al., 2007). Stacy R Smith and colleagues in their randomized controlled trial also analyzed whether the combination of laser therapy and eflornithine therapy would bring greater benefits to patients with unwanted facial hair than laser therapy alone. The study enrolled 54 participants over a 34-week observation period, employing a split-face design where 13.9% eflornithine cream and a vehicle placebo were applied to contralateral sides of the face twice daily. In addition to the topical regimen, subjects underwent laser sessions using either Nd:YAG or alexandrite systems at weeks 2 and 10. Evaluation of therapeutic efficacy was based on a Physician's Global Assessment and patient-reported outcomes. Results from the subjects' self-assessments consistently demonstrated a significant preference for the eflornithine-treated side, with participants reporting superior hair reduction on both the chin and upper lip at every follow-up visit. Furthermore, the PGA corroborated these findings, indicating that the combined treatment approach yielded a statistically significant decrease in hair growth from week 6 through week 22 compared to the areas treated with laser and placebo alone (Smith et al., 2006).

Pharmacokinetics and safety

Malhotra et al. conducted an open-label, three-phase investigation to assess the percutaneous absorption and pharmacokinetic profile of eflornithine following topical application of a 13.9% eflornithine hydrochloride cream. The trial enrolled ten women with facial hirsutism and spanned 15 days. Phase A (4 days) entailed a single 0.5 g application of isotopically labeled cream, removed after 8 hours. Phase B (7 days) comprised twice-daily applications of non-labeled cream at 8-12 hour intervals. Phase C (4 days) replicated the single-dose labeled application. Following 14C-eflornithine administration in Phases A and C, no radioactivity was detected in blood or plasma. Moreover, 8-hour recovery rates averaged 72.2% for the initial dose and 84.8% for the subsequent dose from application and removal materials, affirming minimal transdermal penetration. Plasma elimination exhibited mean half-lives of 11 hours and 8 hours, with steady-state minimum concentrations achieved after 4 days of twice-daily dosing. Multiple applications did not alter elimination kinetics. All participants completed the study without serious adverse events (Malhotra et al., 2001). Hickman et al. reported findings from four dermatological investigations evaluating the safety profile of a 13.9% eflornithine hydrochloride cream with respect to contact sensitization, irritation, phototoxicity, and photoallergy. In the contact sensitization trial, which enrolled 230 healthy women, an ample quantity of eflornithine cream was applied occlusively to the upper back during a 21-day induction phase, while vehicle cream was similarly administered to a contralateral site. Following a 14-day rest period, challenge doses were applied to previously untreated skin areas. During induction, eflornithine induced erythema with edema in 38.9% of sites, compared to 4.8% for vehicle-treated areas. However, provocation elicited no reaction or minimal erythema in 98.1% of eflornithine sites. A cumulative irritation study involved 30 participants, each receiving three distinct occlusive patches for three weeks containing eflornithine cream, vehicle alone, or 0.5% sodium lauryl sulfate in petrolatum as a positive control. Eflornithine sites yielded a total irritation score of 701, surpassing vehicle scores but remaining below those of the irritant. Phototoxicity assessment after single-dose application followed by ultraviolet exposure showed no reaction in 40% of evaluated sites, with mild erythema in the remainder resolving within 24 hours in 14 of 15 cases. Similarly, photocontact allergy testing with eflornithine cream or vehicle - with or without irradiation - produced no reactions or transient mild erythema that resolved within 24 hours (Hickman et al., 2001). Electrospun nanofibers loaded with eflornithine hydrochloride (EFH) offer an innovative solution to the pharmacokinetic and safety challenges of conventional hirsutism treatments. Developed by Almuwallad et al. from polyvinylpyrrolidone and hyaluronic acid, these nanofibers exhibit a biphasic release profile. In vitro studies demonstrated a rapid initial burst release of approximately 80% EFH within the first 5 minutes, followed by complete release after 360 minutes. This behavior stems from the nanofibers' high surface-to-volume ratio and their near-instantaneous disintegration - within about 2 seconds - upon contact with moisture, thereby enhancing transdermal penetration and potentially providing more effective targeting of hair follicles than standard twice-daily cream applications.

Regarding safety and biocompatibility, the nanofiber face mask outperforms conventional 13.9% EFH creams. Commercial products like Vaniqa frequently cause adverse skin reactions such as erythema, burning, and dryness, whereas this system uses biocompatible polymers with only active ingredients and no irritating additives. Cytotoxicity studies on human skin fibroblasts confirmed its high safety profile across concentrations of 15.625-500 µg/ml over 24 hours. Almuwallad et al. also performed an in vivo pilot study in C57BL/6 mice to assess the nanofibers' safety and hair growth inhibition potential. Hair regrowth appeared on day 11 in the control group but was delayed in the EFH-treated group. By day 21, noticeable hair growth was observed in approximately 75% of control mice and 66% of those treated with blank nanofibers, compared to only 50% in the EFH-nanofiber group. Although the delay in hair regrowth lacked full statistical significance due to the small sample size, the authors concluded that the delivery system effectively inhibited growth in half of the treated mice without inducing skin irritation (Almuwallad et al., 2023). Amit Kumar and colleagues proposed a strategy to enhance the efficacy of topical eflornithine, potentially enabling reduced application frequency. Using a mouse model, they assessed whether microneedle pretreatment of the skin prior to eflornithine cream application augments its hair growth inhibitory effects. In vitro penetration was evaluated via Franz diffusion cell, while Vaniqa cream was applied twice daily for up to 36 days on the backs of mice following hair removal by trimming, plucking, or chemical depilation. Treatment efficacy was determined by the onset of noticeable hair regrowth. As anticipated, microneedling followed by eflornithine cream yielded the greatest inhibition, with no regrowth observed in any of the four treated mice over 36 days. By comparison, three of four mice receiving eflornithine cream post-trimming alone exhibited substantial regrowth. Notably, plucking or chemical depilation without eflornithine prompted regrowth within 12 days, whereas trimming - irrespective of subsequent microneedling and eflornithine - delayed regrowth until day 28 (Kumar et al., 2016).

Discussion and Conclusions

Hirsutism constitutes a multifaceted disorder that profoundly affects patients' quality of life (van Zuuren et al., 2015). While its psychosocial ramifications in women are extensively documented, evaluations in clinical trials have predominantly depended on objective metrics extrinsic to the patient, such as the extent of hair growth or clinicians' global assessments (Jackson et al., 2007). Monotherapy with eflornithine reliably diminishes critical objective indicators of hair growth, encompassing mass, length, density, and rate. This therapeutic efficacy is substantiated by two multicenter randomized controlled trials (RCT) assessing 24-week regimens of 13.9% eflornithine cream, which yielded a 26% decrease in hair mass and a 23% reduction in length-outcomes markedly superior to those in control cohorts (Wolf et al., 2007). Conversely, a 4-month course of 11.5% eflornithine engendered substantial decrements in hair density, cumulative length, and growth velocity as early as one month (Hoffmann, 2008). Patient-reported evaluations likewise corroborate eflornithine's utility in mitigating unwanted facial hair, thereby ameliorating attendant discomfort and functional impairments (Jackson et al., 2007). Although permanent hair reduction is attainable via direct modalities like electrolysis and photoepilation, supplementary interventions are requisite to augment and sustain their efficacy (Nawaz et al., 2025). A single RCT established eflornithine monotherapy as a viable maintenance strategy post-intense pulsed light therapy, achieving hair regrowth inhibitions of 14%, 9%, and 17% at 1, 3, and 6 months, respectively (Vissing et al., 2016). Additional RCTs affirm that IPL combined with topical eflornithine surpasses IPL monotherapy in managing idiopathic facial hirsutism, with analogous enhancements observed when eflornithine augments laser hair removal (Hamzavi et al., 2007; Nawaz et al., 2025; Smith et al., 2006; Zahoor et al., 2019). Investigations of 13.9% eflornithine hydrochloride cream indicate minimal transdermal permeation, devoid of photosensitizing or allergenic effects, and no phototoxicity (Hickman et al., 2001; Malhotra et al., 2001).

In conclusion, topical eflornithine emerges as an efficacious intervention for hirsutism in women, demonstrating promising clinical outcomes whether employed as monotherapy or adjunctively with laser or IPL therapies. Nevertheless, owing to the persistent clinical challenges in hirsutism treatment and its marked adverse impact on patients' quality of life, further investigation is required to advance eflornithine therapies, particularly for sustained long-term use.

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