

A randomized study of eflornithine cream combined with intense pulsed light versus intense pulsed light treatment alone for hirsutism in women

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Abstract

Objective To document the efficacy of concomitant use of eflornithine cream and intense pulsed light (IPL) in disease clearance in hirsutism in women.

Methods This was a randomized, double-blind, placebo-controlled study of eflornithine cream combined with IPL treatment versus IPL alone for treatment of hirsutism in women. All subjects underwent treatment with IPL every 4 weeks for 8 sessions. Each patient also applied either eflornithine or placebo cream twice daily to each side of face in a double-blinded manner. Patients were evaluated for efficacy via hair count analysis and patient self-assessment.

Results Both treatment modalities were well tolerated by 40 patients. The outcome measures showed significantly better results in favour of eflornithine plus IPL versus IPL alone. At the end of study almost complete hair removal was achieved in 38 of 40 (95%) of eflornithine + IPL sites versus 31 of 40 (77%) for the placebo cream+ IPL treated sites ($P=0.021$). Statistically significant differences in favour of eflornithine were seen.

Conclusion Combination of eflornithine to IPL results in more rapid and complete reduction of unwanted facial hair in women.

Key words

Eflornithine, intense pulsed light, hirsutism.

Introduction

Hirsutism is the excessive hairiness on women in those parts of the body where terminal hair do not normally occur or is minimal for example, a beard or chest hair. It refers to a male pattern of body hair (androgenic hair) and it is, therefore, primarily of cosmetic and psychological concern. Hirsutism is a medical sign rather than a disease and may be a sign of a more serious medical condition, especially if it develops well after puberty. Common causes are polycystic ovary syndrome, Cushing's syndrome,

congenital adrenal hyperplasia, tumors and medications.

The amount and location of the hair is measured by a Ferriman-Gallwey score.

Lasers and intense pulse light (IPL) hair removal are accepted form of long-term hair reduction. However, there are limitations of this procedure like pain, need for multiple sessions and risk of scarring and pigmentation.¹

Eflornithine² (α -difluoromethylornithine or DFMO) is a drug found to be effective in the treatment of facial hirsutism, as well as, African trypanosomiasis. Eflornithine hydrochloride cream for topical application is meant for

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women affected by facial hirsutism. It inhibits hair growth by inhibiting the enzyme ornithine decarboxylase, which results in the reduction of polyamines that are critical building blocks for rapidly dividing tissues such as hair. It takes 8 weeks for significant hair reduction.

It was hypothesized that greater reduction of unwanted hair could be achieved by combining these 2 treatment modalities.³

Methods

The study was designed as a bilateral placebo-controlled trial of eflornithine plus IPL versus vehicle cream plus IPL.

Forty females between 20-40 years of age with unwanted facial hair were enrolled. Digital photography was used to document hair density. Patients with tattoos, severe acne, photosensitivity, pregnancy and lactation were excluded from study.

Patients were advised to discontinue all other modalities of hair removal for 2 weeks before the first IPL treatment session and then throughout the 32 weeks study period.

Combined effect of eflornithine and IPL⁴ was evaluated. Each patient was scheduled to undergo up to 8 sessions at 4 week interval. Treatment was performed with Xenon Flash Lamp between 610-1200 nm wavelength, energy was delivered at fluencies of 28-36 J/cm² using a 12 x 35 mm spot size. For skin types IV-V low fluences and long pulse delay with shorter pulse width were used. For skin type III, high fluences with short pulse delay and longer pulse width were used. The same IPL parameters were used on both sides of face.

Table 1 Grades of hair reduction after intense pulsed light laser.

Grades	Level of response
Grade 0	No Improvement
Grade 1	Improved
Grade 2	Marked Improvement
Grade 3	Clear

Two different topical creams were applied separately to right and left side of face daily throughout the study period. The 2 creams were supplied in blue and red colour coded tubes. One of them contained eflornithine and the other contained vehicle cream. Patients and investigators were blinded to the colour code scheme, and the sealed code was broken after statistical analysis.

Patients were assessed at baseline and at 4 week intervals for IPL treatment sessions. The final assessment for each patient was done 2 weeks after the last IPL treatment session. Treatment efficacy was assessed by hair count analysis and patient self-assessment.

Assessment was based on 4-level scale ranging from 0 to 3 (**Table 1**). Improvement was judged by comparing the appearance on each side with photograph. Patients themselves were asked to independently assess their treatment outcome by comparing the amount of hair present on each side of face.

Results

All 40 female subjects completed the study. The age range was 20 to 40 years. The median fluence was 32 J/cm² (range 28-36 J/cm²).

A hair removal grade of clear (grade 3) was achieved in 38 of 40 (95%) of eflornithine + IPL treated versus 31 of 40 (77%) for the placebo cream+ IPL treated sites ($P=0.021$), statistically significant differences in favour of eflornithine were seen.

Based upon patients' self-assessment at the conclusion of study 38 out of 40 patients (95%) thought the degree of hair reduction was better with eflornithine, whereas none of the patients considered the placebo to be superior.

Discussion

Eflornithine was developed in the 1970s. It was used to treat African trypanosomiasis (sleeping sickness), but in the 1980s, it was discovered that topical application of eflornithine HCl cream inhibits hair growth. Since then it is being used in excessive hair growth on the face in women. Common side effects when applied as a cream include rash, redness, and burning. Its safety during pregnancy or breastfeeding is not established.

IPL is a form of light therapy, used for various dermatological procedures including hair removal. Unlike laser treatments, which have just one specific wavelength emitted depending on the target chromophore, IPL has multiple wavelengths (between 500-1200 nm) that scatter within the skin.

The mechanism of action for eflornithine is reduction in follicular cell growth rate, while IPL photoepilation heats hair and adjacent tissues to suspend growth. We combined these 2 modalities i.e. physical and pharmacological and found it superior to each treatment when given alone.

It is recommended that if a patient can afford she should use both these modalities simultaneously to have better results.

Conclusion

Combination of physical (IPL) and pharmacologic (eflornithine) methods is superior to IPL alone for treating hirsutism.

References

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