

Effectiveness and safety of triple-diode laser with or without adjunctive topical eflornithine in female hirsutism

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Abstract

Objective: To compare the efficacy of triple diode laser with and without topical eflornithine in hair growth reduction.

Method: The cross-sectional study was conducted at the outpatient clinic of the Department of Dermatology, Dow University of Health Sciences, Karachi, from March to August 2024, and comprised females with hirsutism aged 18-50 years. The patients were divided into two groups. Group A subjects were given monthly laser sessions alone, while group B patients received a combination of monthly laser sessions with topical eflornithine applied twice daily on affected sites. Laser sessions were given monthly for 6 months in both the groups. Hair growth reduction was calculated using the Global Aesthetic Improvement Scale by two independent dermatologists at the 3rd and 6th sessions as well as six months after the 6th session. Data was analysed using SPSS version 26.

Results: Of the 60 women, 30(50%) were in group A with mean age 35.73 ± 9.50 years, and 30(50%) were in group B with mean age 33.96 ± 8.72 years. At the 6-month follow-up, the difference in both groups was significant compared to baseline and 3-month follow-up ($p < 0.05$). At the 12-month follow-up, results were similar to that at the 6-month follow-up ($p > 0.05$). Intergroup difference was significant at 3-month ($p < 0.04$), but not at 6-month and 12-month follow-ups ($p = 0.329$).

Conclusion: Addition of topical eflornithine to laser hair removal resulted in a more rapid and almost complete terminal hair reduction.

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Introduction

Excessive hair growth due to any cause involving certain body sites is a common cosmetic problem in Asian population, affecting around 5-10% of females in the reproductive age.¹ Hirsutism is androgenic hormone-dependant male-pattern growth of terminal hairs in females, while hypertrichosis is androgenic hormone-independent growth of vellus hair in nonsexual areas.² Hypertrichosis is excessive growth of hair anywhere on human body. Irrespective of gender, age and sites, there are many factors responsible for this excessive unwanted hair growth. Classically, hirsutism has been regarded as a marker of increased androgenic hormones in females due to excessive production either by the adrenal glands, or due to ovarian disease, or over-sensitivity of hair follicles to natural levels of circulating androgenic hormones. Idiopathic hirsutism accounts for about 20% of cases with normal androgen levels.²

There are many pharmacological and non-pharmacological methods of temporary hair removal, like the use of

depilatory creams or chemicals, waxing, threading, and shaving, etc.³ These measures can cause skin irritation as well as infection, and require maintenance as well.⁴ Laser hair removal has now become a more effective and popular treatment choice, especially if combined with certain pharmacological medicines topically.⁵ For this purpose, many lasers are available in the market like intense pulse light (IPL), triple diode (Alexandrite 755nm, Diode 808nm, neodymium yttrium aluminum garnet (Nd:YAG) 1064nm.⁶ There are different lasers, and patient-related parameters are important for selecting suitable options that influence the outcome of the treatment.⁷ For lasers, wavelength, fluence, spot size, frequency of sessions, number of sessions, and their pulse duration influence the outcome.⁸ Pulse duration is set according to the type of hair and skin type. On an average, vellus to intermediate hair require a pulse duration of 10-30ms, and terminal hairs require a pulse duration of 50-70ms. Fluence ranges 9-25 J/cm² and is set according to the method of delivery. Spot size varies from 17×12mm to 20×9mm. The number of bars correlates with the number of photons delivered in a given time. More number of bars with bigger spot size can complete a procedure faster. A bigger spot size is helpful in dealing with larger body surface areas. Patient factors are skin as well as hair colour, thickness and the site of excessive hair growth. Lasers target the melanin of hair, which is more abundant in thick black and coarse hair compared to grey hair. Satisfactory result to laser hair reduction occurs when

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the treated hair has high levels of chromophores. It targets hair in the anagen phase through selective photolysis, and converts terminal hair into vellus hair. This process is known as miniaturisation.⁹⁻¹¹ Although long-lasting hair reduction is not experienced in all cases, reduction of hair denseness and diameter are.¹² Laser photo-epilation has become a popular choice for hair growth reduction, although its effectiveness can be variable, with only 50-90% of hairs being permanently removed with no relapse.¹³

The triple diode laser is emerging as one of the best treatment options for Asian skin for hair reduction.¹⁴ It works with three different wavelengths (1064nm, 810nm and 755nm) that penetrate hair at different depths of hair follicles, providing better results in less time than with a single wavelength. Different wavelengths are assigned to different body sites and skin colours, like 1064nm and 810nm have deep penetration capability, and, therefore focus on darker skin types (types 4 and 5). Besides, the 1064nm wavelength is especially useful for pubic and axillary regions, while for regions, such as arms, legs and cheeks, the 810nm wavelength is more effective, and the 755nm wavelength is more useful for eyebrows and upper lip areas.¹⁵ The main factors controlling the adverse effects and for better tolerance during procedures are prior cooling of treatment area and proper selection of wavelength and fluency.

Eflornithine (difluoromethylornithine) has been investigated since 1980, and was initially used as an antineoplastic drug. Topical eflornithine was approved in 2000 by the Food and Drug Administration (FDA) for facial hirsutism. It irreversibly inhibits ornithine decarboxylase, an enzyme that catalyses synthesis of intracellular polyamines, which are essential building blocks of rapidly dividing tissues, like hair. It is used twice a day on affected sites. It does not eradicate hair, but reduces the rate of hair growth.

The current study was planned to compare the efficacy of triple diode laser with and without topical eflornithine in hair growth reduction.

Patients and Methods

The cross-sectional study was conducted at the outpatient clinic of the Department of Dermatology, Dow University of Health Sciences (DUHS), Karachi, from March to August 2024. After approval from the institutional ethics review committee, the sample size was calculated using PASS version 16 based on two independent sample proportion with 95% confidence interval (CI), 85% power, and proportion of hair reduction in group A (P1) 57.58% and 90.91% in group B (P2).¹⁷ The sample size formula used was:

$$n = \frac{\left\{ z_{1-\alpha/2} \sqrt{2\bar{P}(1-\bar{P})} + z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)} \right\}^2}{(P_1 - P_2)^2}$$

Those included were females with hirsutism aged 18-50 years.

Those excluded were pregnant and lactating women, those with photosensitivity disorder, eczema or any active skin lesion at the site of treatment, patients allergic to eflornithine, patients currently receiving another treatment for hirsutism, and those having had hair bleaching, threading or waxing in the preceding six months.

After taking informed consent from the patients, they were divided into two groups. Group A patients were subjected to triple diode laser session monthly, while group B patients received a combination of monthly laser sessions with topical eflornithine hydrochloride 13.9% that contained 1.3mg/gm of eflornithine hydrochloride monohydrate (150mg/gm) application twice daily. Operational laser parameters were adjusted appropriately to patient's skin type and hair thickness. The sessions were given monthly for 6 months in all patients. The patients were observed every 4 weeks till 24 weeks. The patients were followed up till 6 months after the last laser session. Hair reduction by at least 50% after 6 treatment sessions compared to the baseline was considered efficacious. Efficacy of both the treatments was assessed using the Global Aesthetic Improvement Scale (GAIS) by two dermatologists, and the patients were also asked to check out hair growth reduction independently by comparing the number of hairs or hair growth by their rough estimate. GAIS is a 5-point scale, which categorises outcomes as 0% = no result, 0-25% = poor, 25-50% = average, 50-75% = good, and 75-100% = excellent.¹⁸

Data was analysed using SPSS. Mean±standard deviation was calculated for continuous data. Frequencies and percentages were calculated for qualitative variables. Independent sample *t*-test was used for intergroup comparison of age as a continuous variable. Chi-square test was used as appropriate. Intragroup comparison at 3 months, 6 months and 12 months was done using the Friedman test, while post-hoc pairwise comparison was done using the Wilcoxon signed-rank test. Bonferroni correction was applied, and the adjusted significance level was set at $\alpha = 0.017$ (0.05/3). Overall, $p < 0.05$ was considered significant.

Results

Of the 60 women, 30(50%) were in group A with mean age 35.73 ± 9.50 years, and 30(50%) were in group B with mean age 33.96 ± 8.72 years. The most common site for treatment was face, and the most common skin type was type 4 in

Table-1: Intergroup comparison of baseline characteristics (n=60).

Groups Variables	Group A n (%)	Group B n (%)	Pearson Chi-Square (p-value)
Mean Age (years)	35.73±9.05	33.96±8.72	0.440
Age (years) Groups			0.630
18 – 28	7 (41.2)	10 (33.3)	
29 – 38	10 (33.3)	10 (33.3)	
39 – 50	13 (43.3)	10 (33.3)	
Skin type			0.062
2	0 (0.0)	1 (3.3)	
3	10 (33.3)	3 (10)	
4	20 (66.6)	26 (86.6)	
Body Site			-
Face	27 (90)	27 (90)	
Trunk	1 (3.3)	1 (3.3)	
Arms	2 (6.6)	2 (6.6)	

Group A: Laser treatment alone; Group B: Combined laser and eflornithine; Skin type 2: Light colour, usually burns, tans minimally; Skin type 3: Slightly dark skin, burns mildly, tans usually; Skin type 4: Moderately brown, burns minimally, always tans well.

Table-2: Intergroup comparison of Global Aesthetic Improvement Scale (GAIS) scores.

Groups Variables	Group A (Triple diode laser) n (%)	Group B (Eflornithine + laser) n (%)	Between group p-value
GAIS score after the 3rd Session			0.04*
Poor /0-25% reduction in hair growth	10 (33.3)	3 (10)	
Average /25-50% reduction	7 (23.3)	5 (16.7)	
Good/50-75% reduction	13 (43.3)	22 (73.3)	
GAIS score at 6th Session			0.329
Good/50-75% reduction	6 (20)	3 (10)	
Excellent /75-100% reduction	20 (66.7)	25 (83.3)	
GAIS score 6 months after the 6th Session (at 12 month)			0.329
Average /25-50% reduction	4 (13.3)	2 (6.7)	
Good/50-75% reduction	6 (20)	3 (10)	
Excellent /75-100% reduction	20 (66.7)	25 (83.3)	
Within group; p-value	<0.001*	<0.001*	Overall
3th session. vs. 6th session; p-value	<0.001*	<0.001*	Multiple group
6th session vs. after 6 months; p-value	1	1	comparison

Chi-square test was used for intergroup comparison; while Friedman test was used for intragroup comparison with post-hoc pair-wise comparison. Wilcoxon signed rank test with a bonferroni correction factor was applied; * $p < 0.05$.

both the groups (Table 1). Overall, 54(90%) of the females had moderate to severe hirsutism due to polycystic ovarian disease and had high androgen levels in their blood along with ovarian cysts, while 6(10%) had moderate to severe hirsutism of unknown cause with normal androgens and scans.

At the 6-month follow-up, the difference in both groups was significant compared to baseline and 3-month follow-up ($p < 0.05$). At the 12-month follow-up, results were similar to that at the 6-month follow-up (Table 2).

Intergroup difference was significant at 3-month ($p < 0.04$), but not at 6-month and 12-month follow-ups ($p = 0.329$).

Regarding side-effects, 30(50%) of the patients in both the groups experienced mild to moderate pain during the laser sessions, and the procedure was well-tolerated by the rest of the patients. In 15(25.5%) patients, mild redness was noted after the procedure which soon disappeared. No patient experienced blisters post-procedure. With respect to topical eflornithine in group B, sensation of burning and stinging occurred after few applications in 12(39.5%) women, redness in 2(5%) and acneform eruption also in 2(5%) patients.

Discussion

Hirsutism, which is not a rare problem in females, negatively impacts quality of life irrespective of severity and may even lead to social isolation.¹⁹

The prime goal of the current study was to analyse whether a synergistic treatment of physical (laser) and pharmacological (topical eflornithine) methods would be preferable to laser alone for treating unwanted facial hair in women. The results demonstrated significantly reduced hair growth in patients who were treated with both laser and eflornithine, with excellent hair reduction of about 64% after 4 weeks of the 6th laser session compared to 35.9% in patients with laser treatment alone ($p = 0.006$).

Azam N.B. et al.²⁰ have shown that effectiveness of combined therapy with laser and topical eflornithine was 92.50% compared to 72.50% in the patients treated with laser alone.

The synergistic approach to hair removal has been reported to be safe and more efficacious²¹ in various skin types.

The current study has limitations as it did not follow the patients for more than six months after hair reduction was achieved, which means that long-term effects eflornithine were not noted. Further studies are required to examine its role in preventing regrowth after photo epilation.

Conclusion

Additive effects of topical eflornithine with triple diode laser increased the rate and degree of hair reduction.

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