ORIGINAL ARTICLE

Combination of Intense Pulse Light and Topical Eflornithine Therapy versus Intense Pulse Light Therapy alone in the Treatment of Idiopathic Facial Hirsutism: A Randomized Controlled Trial

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Abstract

Objective: To compare the efficacy of combination of Intense Pulse Light and topical eflornithine therapy versus Intense Pulse Light therapy alone in the treatment of idiopathic facial hirsutism.

Methology: A total of 78 patients were included in the study, and were divided into two groups, having 39 patients each. Patients in group A were subjected to combined treatment i.e., topical eflornithine to be applied twice a day and IPL session to be received by patients once a month. Patients in group B were subjected to receive IPL monthly sessions alone. Treatment was continued for 6 months in both groups. After completion of treatment, average number of terminal hair and percentage hair reduction were calculated to see the efficacy.

Results: Out of 78 patients, 39 patients were included in group A, and similar number of patients were included in group B. The age of patients ranged from 22-42 years with mean age of 29.59±5.29. Maximum number of patients were in their third decade of life. Mean age in group A was 29.23±5.44, while in group B it was 29.95±5.19. Efficacy in group A was 39(100%) with mean percentage hair reduction of 90.44%, while efficacy in group B was 19 (48.7%) with mean percentage hair reduction of 59.23%, with statistically significant *p*-value of 0.00.

Conclusion: The combination of intense pulse light and topical eflornithine therapy is more efficacious than intense pulse light therapy alone in the treatment of idiopathic facial hirsutism.

Keywords: Idiopathic facial hirsutism, terminal hair, average number of terminal hair, percentage hair reduction. (JPMA 69: 930; 2019)

Introduction

Hirsutism is characterized by excessive terminal hair that appears in females with male pattern distribution. It may result either from increase in the sensitivity of hair follicles to normal levels of androgen or from increase in the circulating androgen levels.[1] In this condition, increased growth of terminal hair occurs in those body regions that are sensitive to circulating androgens.[2] Hirsutism is important because it is a common clinical problem in premenopausal women and is associated with adverse psychological effects and reduced quality of life.[2-4] Overall actual prevalence of hirsutism ranges from 4.3% to 10.8%, in blacks and whites, with prevalence of 10.5% in Chinese women.[5,6]

Idiopathic hirsutism is the term used when hirsute patient has normal circulating androgen levels and ovulatory functions.[7] It may also be due to endocrine abnormalities or drug induced. Among endocrine pathologies, polycystic ovarian syndrome being the most common cause, adrenal and central endocrine abnormalities have also been found.[8]

Various methods are available for the removal of unwanted hair. Eflornithine shows some reduction in hair growth when used as a cream. It inhibits the activity of ornithine decarboxylase, delaying the anagen initiation and leaving the follicle in telogen phase.[9] It is applied topically, twice daily.[10,11] Intense Pulse Light devices are the source of high energy light, like lasers, in which the filtered light causes mechanical and or thermal damage to the hair follicle by targeting the pigment in hair.[1] Patients on intense pulse light treatment are treated at an interval of 4-6 weeks and with six treatment sessions excellent results are obtained.[1]

The objective of the study was to compare the efficacy of Intense Pulse Light Therapy and topical eflornithine

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combination versus Intense Pulse Light therapy alone in treating patients with idiopathic facial hirsutism.

Methodology

A randomized controlled trial was conducted in the Dermatology Department of Lady Reading Hospital, Peshawar, for the duration of 6 months (May 2014 to Nov 2014). Total sample size was 78 patients i.e, 39 Patients in each group using 93.5% efficacy of combination of Intense Pulse light and topical eflornithine therapy and 67.9% efficacy of Intense Pulse Light therapy alone, 90% power of test and 5% level of significance, using WHO software for sample size determination.[12]

The study was conducted after getting approval from hospital ethical and research committee. All patients meeting the inclusion criteria i.e. female patients with idiopathic facial hirsutism were included in the study through OPD. The purpose and benefits of the study were explained to the patients and they were assured that the study was done purely for data publication and research purpose and a written informed consent was obtained. All patients were subjected to detailed history, clinical examination and laboratory investigations. All patients were randomly allocated in two groups by lottery method. Patients in Group A were subjected to combination therapy of Intense Pulse Light and topical eflornithine, while patients in Group B were subjected to Intense Pulse Light therapy alone. Over six months, a total of six sessions of Intense Pulse Light treatment were received by each patient in the study at an interval of 4 weeks while in those of Group A topical eflornithine twice daily was applied over six months duration. Fluence range of 18-22 J/cm^2 was used in the first session and later was increased according to the patients response in the subsequent sessions to the maximum of 42 J/cm^2, pulse duration of 3 milliseconds remained constant. Total number of terminal hair in an area of 2.5 X 2.5cm^2 was counted at two different anatomical landmark areas and then its average value was calculated and labelled as average number of terminal hair at first session and then after the total of six sessions was again calculated and percentage hair reduction from the baseline was calculated at the end of six sessions to determine the efficacy.

All the observations, average number of terminal hair, percentage of hair reduction calculation and Intense pulse Light therapy procedure was conducted under supervision of a single expert dermatologist having minimum of five years experience. All of the above information including name, age were recorded in a pre-designed performa. Exclusion criteria was followed to control confounders and bias in the study results.

Data was analysed in SPSS version 16. Mean±SD was calculated for numerical variables like age, average number of terminal hair and percentage hair reduction at first presentation and at each session for total of six sessions. Frequencies and percentages were calculated for categorical variables efficacy. Chi-square test was applied to compare the efficacy. Efficacy was stratified among age, average number of terminal hair at baseline to see the effect modification. Results were presented in form of tables, graphs and charts.

Results

A total of 78 patients were included in the study. The average number of terminal hair at baseline in group A was minimum of 46, and maximum of 316, with total mean of 144.26±61.82, as shown in table 1. On follow up after receiving combination therapy for six months, the average number of terminal hair in group A turned out to be minimum of 2, and maximum of 32, with total mean of 14.46±7.84. Percentage hair reduction in group A after six months was 90.44±2.89 as shown in table 1. The average number of terminal hair in group B at baseline was minimum of 39 and maximum of 339, with total mean value of 176.64±71.23 as shown in table 1. On follow up after six months, the average number of terminal hair was

Table-1: Average number of terminal hair at baseline and after six months with percentage reduction.

GROUP		Minimum	Maximum	Mean	Percentage hair reduction
A: n=39 (SD 2.891)	Average number of terminal hair at baseline	46	316	144.26(SD61.817)	90.44
	Average number of terminal hair after 6 sessions	2	32	14.46(SD7.837)	
B: n=39 (SD 10.594)	Average number of terminal hair at baseline	39	339	176.64(SD 71.232)	59.23
	Average number of terminal hair after 6 sessions	12	153	71.28(SD 34.586)	
Total: n=78 (SD17.497)	Average number of terminal hair at baseline	39	339	160.45(SD 68.231)	74.83
	Average number of terminal hair after 6 sessions	2	153	42.87(SD 37.925)	

Table-2: Efficacy of treatment.

	Yes n (%)	No n (%)
Group A	39 (100)	-
Group B	19 (48.7)	20 (51.3)
Total	58 (74.4)	20 (25.6)

minimum of 12, maximum of 153, with total mean of 71.28±34.58. Percentage hair reduction in group B after six months was found to be 59.23±10.59 as shown in table 1. Efficacy of therapy in group A was observed in all 39 patients (100%) included in group A, where as it was observed in 19 (48.7%) of patients in group B, as shown in table 2. Chi square was applied to results. The p-value was 0.000, which was significant. Age wise efficacy in patients, with age in the range of 20-29 was found to be in 31(73.8%) patients among 42 patients. Patients with age in the range of 30-39, efficacy was found in 23 (74.2%) among 31 patients. While, patients with age of more than 39, treatment was found to be efficacious in 4 (80%) among 5 patients. Chi square was applied to these results and the p-value was 0.956, which was insignificant. Efficacy was also stratified for the average number of terminal hair at baseline, and the p value on applying chi square test was 0.477 which was again insignificant. Efficacy was stratified for Fizpatrick skin type, and it was found that the response to treatment was more in patients with Fitzpatrick skin type III and IV, but p value was found again to be insignificant, that is 0.345.

Discussion

Hirsutism is a very common clinical problem encountered in dermatology and causes both psychological and social distress to women who suffer from this condition. Nowadays, multiple physical and pharmacological therapies, both topical and systemic, are available for the treatment of hirsutism.[12] Till date, still no single preferred treatment modality is known to be satisfactory enough for both patients as well as the physician.The primary objective of this study was to explore whether a combination of physical (laser) and pharmacological (topical eflornithine) therapy for the treatment of idiopathic facial hirsutism was more effective than laser therapy alone, and to establish practical guidelines for the effective reduction of hair in patients with hirsutism. The result of this study, has shown that the combination of Intense Pulse Light and topical eflornithine is superior and very effective in the treatment of idiopathic hirsutism than Intense Pulse Light therapy alone.

As far as demographical features are concerned, patients in study by Asad et al[1] were selected with age above 18 years with no hormonal imbalance, and this was consistent with our study, as all women of reproductive age were included with no underlying hormonal abnormality.[1] All patients in Hamzavi et al[12] were of the age range between 22-65 years with the mean age of 40.5, while in our study patients had age range of 22-42 years with mean age of 29.59±5.29. The age range of patients in Asad et al[1] was 18 to 36 years, with mean age of 24.5 years.[1] In Hamzavi et al,[12] the difference of outcome of two treatment modalities on basis of objective assessment was 17%, being 67.9% in group on laser therapy alone, and 93.7% in group on combination therapy. In the study by Smith et al,[13] significant and persistent hair reduction was observe more with combination treatment as compared to laser therapy alone. In our study, same findings were also observed, that with significant reduction in the number of hair, the regrowth of hair was also delayed, and the newer growing hair were weak and could be plucked easily.[13] Another study in 2008 showed superiority of synergy of eflornithine cream and laser over laser therapy alone in treatment of facial hirsutism.[10]

Weir and Woo showed 42% and 37% reduction in hair density using single treatment session of laser therapy in patients with Fitzpatrick skin type IV and V, respectively.[14] In our study, response to treatment was more in patients with Fitzpatrick skin type II, III and IV. In Asad et al's study all patients included were of Fitzpatrick skin type III and IV.[1] Hamzavi et al had maximum number of patients were of Fitzpatrick skin type IV, while in our study maximum number of patients had Fitzpatrick skin type III and IV.[12]

Hamazavi et al also mentioned that reduction of hair was faster, leaving patients hair free for longer duration of time in between the sessions with fewer hair growth and with reduced need of further treatment sessions.[12] Similar findings were also seen in this study aswell. In his study,[5] patients on combination therapy, did not need any further sessions after receiving 5 treatment sessions.[12] In our study one patient did not need any treatment session after receiving 2 treatment sessions of laser in combination with regular twice a day use of topical eflornithine, and 4 other patients on combination therapy did not need any treatment sessions after receiving 5 treatment sessions. It was also seen that the effect of therapies, both combined

and IPL alone was more on darkly pigmented thick hair, and these findings were consistent with Hamzavi et al.[12]

In the referral studies, it is also stated that IPL can be used effectively in the conditions like hirsutism that are responsive to other laser therapies, and is cheaper and more cost effective in comparison to other treatment options.[1] As female patients who present to our hospital belong to families with lower socioeconomic status, who cannot afford high costs of other laser therapies, these treatment options can prove helpul in relieving their condition of hirsutism that is causing them great social and mental distress.

Conclusion

The combination of intense pulse light and topical eflornithine therapy is more effective than intense pulse light therapy alone in the treatment of idiopathic facial hirsutism.

Disclaimer: This study was part of a post-graduate dissertation.

Conflict of Interest: None to declare.

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