

The effect of topical finasteride in treatment of idiopathic hirsutism

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Abstract

Hirsutism relatively is a common medical problem and an important influence on about 5-10% of women of reproductive age. Fifty-five female shares in the study, seventeen of them did not continue the study, therefore we evaluated 38 females, aged 18-52 years old. In our study we compared pre-treatment and post-treatment for the color of the hairs and the hair removal frequency and the pain during hair removal for four groups which are good response group and moderate response group and mild response group and no response group, by subjective evaluation of all the patients noted a diminished rate of hair growth (fewer times needed for shaving) and a decrement in the density of hairs on the chin area and change in color of the hair but there was no significant difference between groups regarding hair color and there were highly significant difference in hair removal frequency before and after treatment ($P < 0.001$) when we used finasteride cream 1% for 3 months. Six months of topically applied finasteride (0.5%) does not effect on number and thickness of facial hirsutism significantly. Despite lack of objective changes, on questioning, most patients in finasteride group perceived a decrease in hair growth with time.

Keywords: Hirsutism; 5- α - dihydrotestosterone; TSH; FH; LH

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Introduction

The term hirsutism defines as presence of coarser, thicker and terminal hair in women in a male like pattern and locations [1]. Hirsutism relatively is a common medical problem and an important influence on about 5-10% of women of reproductive age [2, 3]. The prevalence of hirsutism is dependent on the ethnic and racial origin of the population under study, an incidence of hirsutism of 8% was found in the US [4]. The androgen responsible for the change in voice and the increase in muscle mass in women is testosterone, and that responsible for hirsutism is 5- α - dihydrotestosterone (5 α -DHT) [5]. The testosterone is the key circulating androgen which is produced by the ovaries and adrenals either as testosterone or as prohormones (mainly androstenedione and dehydroepiandrosteron sulfate) which are metabolized into testosterone in the peripheral tissues such as fat [6]. Testosterone is converted into

dihydrotestosterone (DHT) in the peripheral tissue by the enzyme 5- α reductase. DHT is the most potent androgen in the body. The phenomena of increased conversion rate of DHT in the target area may help to clarify the increased sensitivity of hair follicles to androgens [3]. “Idiopathic hirsutism” (IH), also called simple or peripheral hirsutism, while IH is often referred to as “familial hirsutism,” this represents a misnomer. In fact, it is now well established that other forms of hyperandrogenism, e.g., PCOS and NCAH, also demonstrate a strong familial predisposition [7].

Material and Method

The present study was carried out in Collage of Medicine Babylon University from November 2013 – November 2014 for treatment Fifty five females were enrolled in this study. Their age was between (18-55 years) and the mean of their age was 32.26. Those females were chosen from consulting dermatologist department in Mergan medical city in Babylon. These patients complained from hirsutism and given Finasteride 1% cream and was measured TSH, FSH, LH and free Testosterone pretreatment and post-treatment and also measured the:

- Hair color
- Hair removal frequency of the patients
- Pain severity before and after treatment
- F-Gallawy score
- Visual analogue score

The follow up continue every 15 day and after 3 months (end of study) it was measured the same parameters. The patients were asked about the name, age, marital state, parity, blood group, onset of hirsutism, duration, distribution of hirsutism as it occur in the face only or other body area, hair type as dark hair or fine hair, other features of hyperandrogenism as acne and hair loss and disturbance of the menstrual cycle.

Previous treatment as some drugs may case or exacerbate hirsutism, previous hair removal, number of hair removal, and history of contraceptive, history of other disease.

Follow up with each patient every two weeks and evaluate the case by evaluating the number of the hair and the roughness of the hair by Ferriman Galway Scoring Sheet and we know the improvement the patient through this score. All the patients gave informed consent for their participation in our study after reading the protocol of this experiment. They had not used any other therapy for idiopathic hirsutism for at least the six previous months. They were told that finasteride could affect a male fetus and consequently pregnancy was contraindicated during the treatment and so effective contraceptive must be used. They were also informed that potential side effects of finasteride were unknown in women and

they should report any possible side effects during the medication. The patients were explained not to use any other drug for IH at the same time.

Moreover electrolysis, waxing and plucking were not permitted during the treatment whereas shaving was permitted for subjective evaluation of hair growth by patients. The degree of hirsutism in the chin area was determined by Ferriman-Gallaway score. The scale is from 0 (absence of terminal hairs) to 4 (extensive terminal hair growth). Then they received finasteride cream 1% on their chins once a day for 3 months.

They were explained to clean the chin area before usage and to avoid using powder, lotions, and sprays two hours after cream. The finasteride cream made as the Pure finasteride was procured from Samarra a drug industry, firstly 1 gram Finasteride powder weighted and putted beaker and dissolve it in 3 ml of alcohol and shaking it for 4 minutes until it dissolved completely and became clear after that we complete the weight to 100 gram with aquasoft cream (Ajanta company) and shake the combination for 5 minutes by spatula and then weight the finasteride cream in small plastic containers each one containing 10 grams from finasteride cream to be used by the patients.

Then the patients allocated to four groups according the visual analogue scale and the F.G score: Group (1): good response group

Group (2): moderate response group

Group (3): mild response group

Group (4): non response group The definition of each one:

1. Good response group: are the patients whom have response to the treatment more than >75%.
2. Group (2): moderate response group: are the patients whom have response to the treatment 50-75%.
3. Group (3): Mild response group: are the patients whom have response to the treatment 25-50%.
4. No response group: are the patients whom have response to the treatment less than <25%.

The patients were seen in consultation at 3 months intervals. Questions were asked about the side effects, menstrual abnormalities and also patient's selfevaluation of the clinical effects of the treatment.

After six months, the mean Caliber of three plucked hairs and the Ferriman- Gallwey score of the chin area was assessed again. Data are presented as mean \pm SD or percentage. Statistical analyses were performed using SPSS software version 20:0:0 and paired TTest for comparison of quantitative variables

was used to compare the hair caliber before and after medication. P values less than 0.05 were statistically significant.

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Results

Statistical analysis

Fifty five females shares in the study. Seventeen of them did not continue the study, therefore we evaluated 38 females, aged 18-52 years old. Data are presented as mean \pm SD.

Means of TSH ,FH, LH and Free testosterone for two groups were compared with paired student's t-test in SPSS software by using SPSS (statistical package for social sciences) version 20 in which we use paired T-test, chi square test, wilcoxon test, Freidman test according to the need. We set P value <0.05 as significant. A Pvalue less than 0.05 was considered statistically significant. Out of fifty five participants, seventeen were excluded because they stopped the medication. The thirty eight remained patients with the mean age was 32.2 ± 8.04 continued the medication throughout the 3-month study period.

None of the females reported any systemic problems with irregularity of menstrual periods, nausea, vomiting, diarrhea, abdominal pain or headache. Acne was the only problem reported in 5 patients (7.6%) on the chin area where the drug was applied. By subjective evaluation all the patients noted a diminished rate of hair growth (fewer times needed for shaving) and a decrement in the density of the hairs on the chin area. By objective evaluation, free testosterone was decreased after medication that was statistically significant $P < 0.001$.

Variable	Pretreatment	Post-treatment	P value
	Mean±SE	Mean±SE	
TSH(uIU/ml)	3.0884±0.50754	2.2243±0.29844	0.043
LH(pg/ml)	9.2077±1.49261	9.4453±1.33724	0.779
FSH(mIU/ml)	7.3907±1.20073	8.3816±1.79212	0.266
Free testosterone (pg/ml)	2.9387±0.32011	2.6127±0.41021	0.179

The Ferriman-Gallwey score of the chin area statistically decreased from 2.3421 to 1.9737 after a 3-month finasteride cream therapy (P<0.001) By Pearson correlation test.

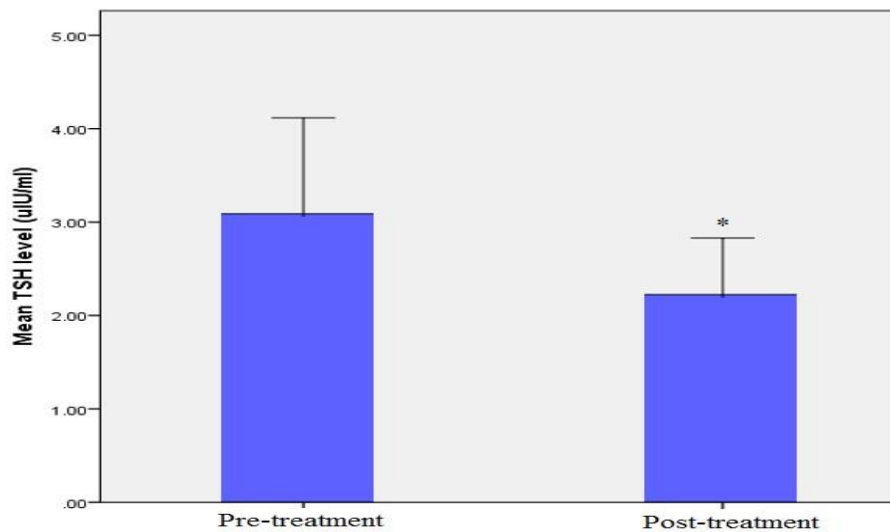


Figure 1.

TSH level before and after treatment for all patients. The TSH level decreased after treatment with topical finasteride cream as some patients also have changes in TSH. There are cases where the Post-Finasteride Syndrome induced hypothyroidism. However, it is not most cases.

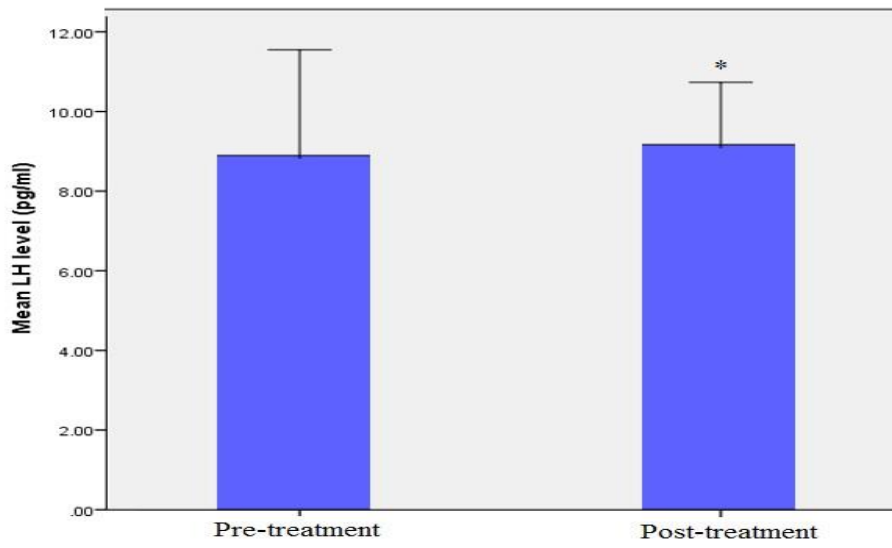


Figure 2.

LH level before and after treatment for all patients

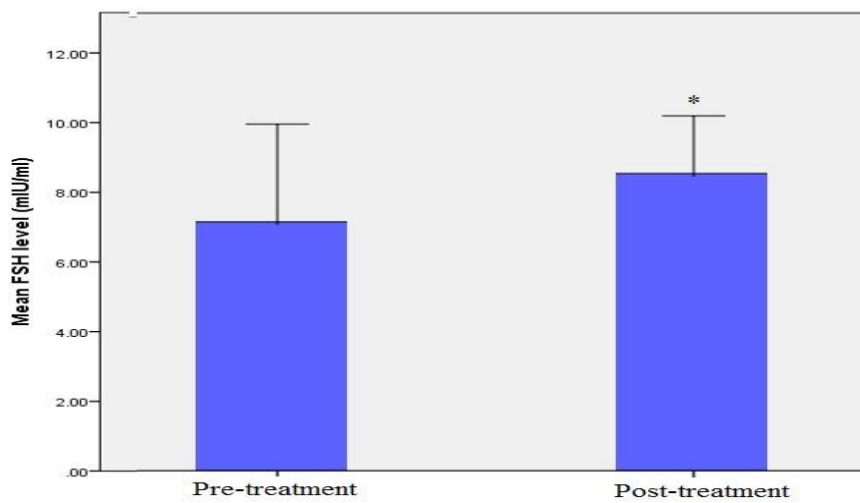


Figure 3.

FSH level before and after treatment for all patients, and demonstrated no significant difference of FSH level after treatment of all the patients.

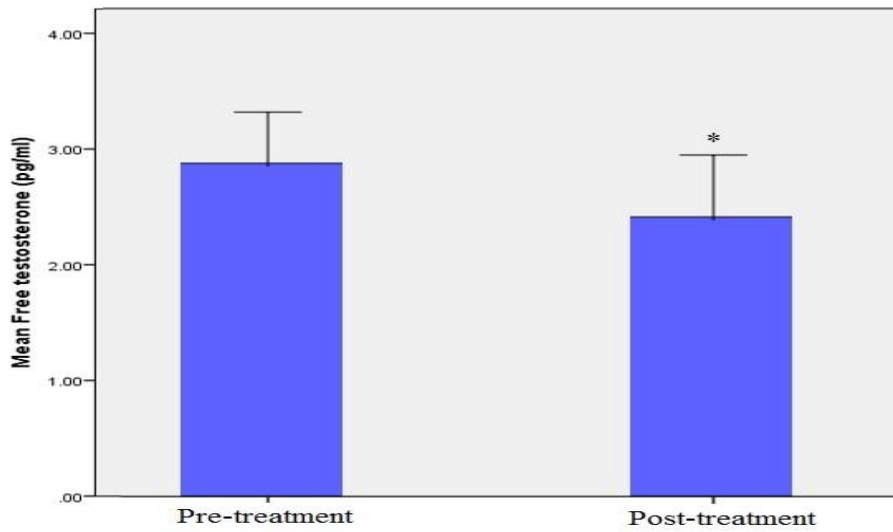


Figure 4.

Free testosterone level before and after treatment, and demonstrated no significant difference in free testosterone level after treatment of all the patients.

Table 2.

Hormonal assessment before and after treatment among good response group.

Variable	Pretreatment	Post-treatment	P value
	Mean±SE	Mean±SE	
TSH(uIU/ml)	2.9792±0.85394	2.4800±0.60835	0.133
LH(pg/ml)	6.8577±1.92950	7.9977±2.34525	0.310
FSH(mIU/ml)	7.8346±2.78310	10.4385±4.82816	0.253
Free testosterone(pg/ml)	2.6823±0.33680	1.4847±0.28468	0.006

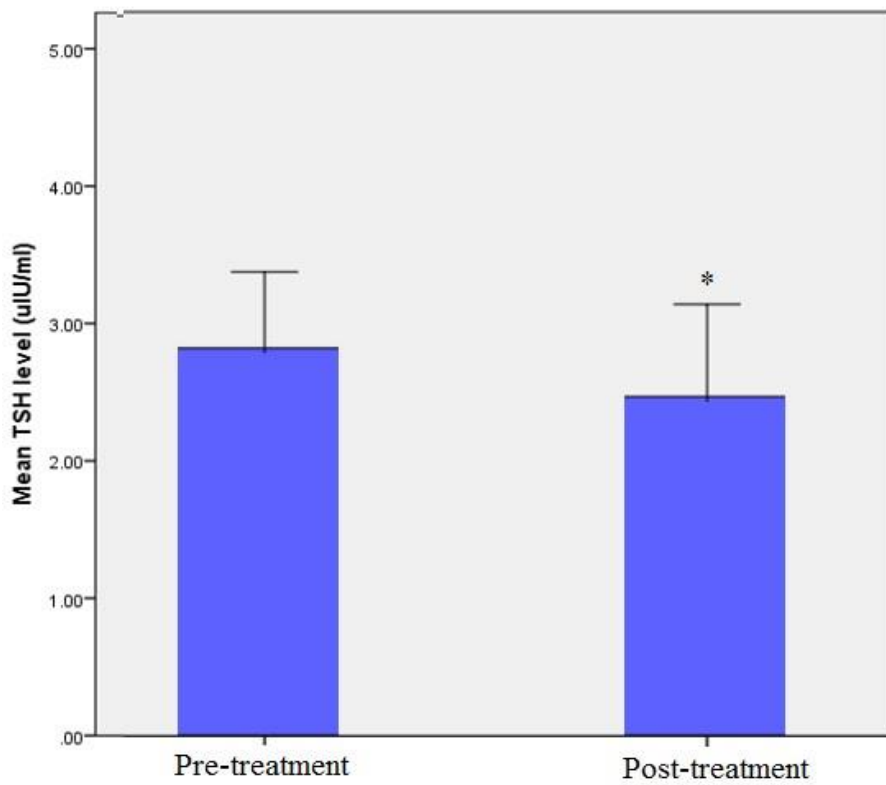


Figure 5.

TSH level before and after treatment among good response group. The TSH level decreased after treatment with topical finasteride cream as some patients also have changes in TSH.

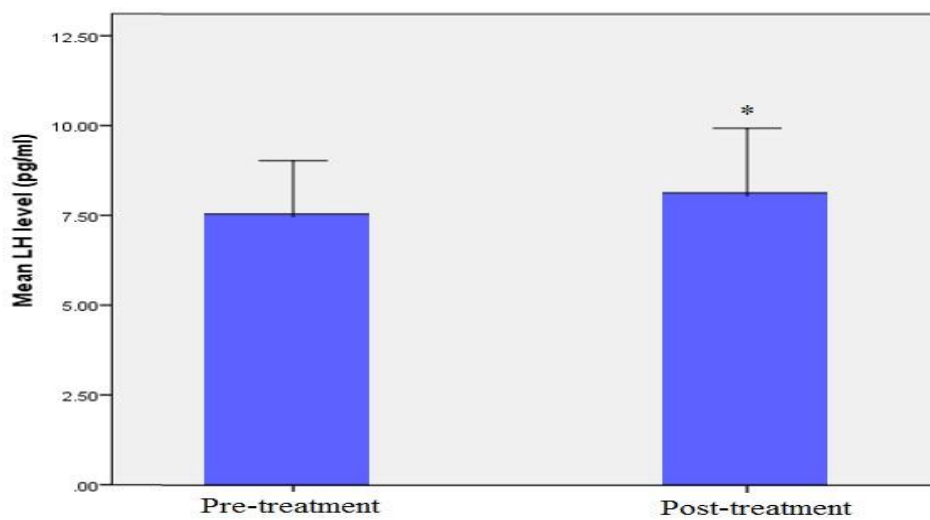


Figure 6.

LH level before and after treatment among good response group, without significant difference of LH level after treatment for good response group patients.

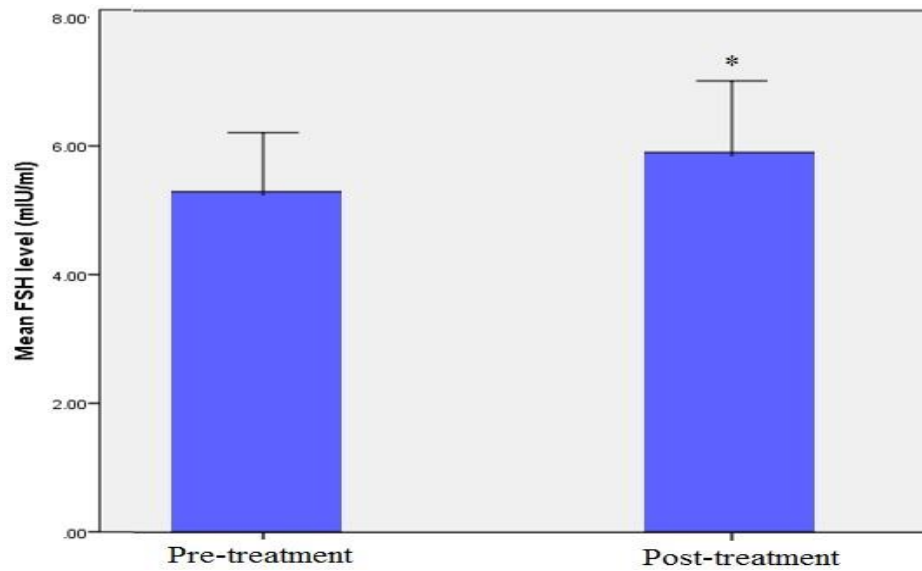


Figure 7.

FSH level before and after treatment among good response group, there is no significant difference of FST level after treatment for good response group patients.

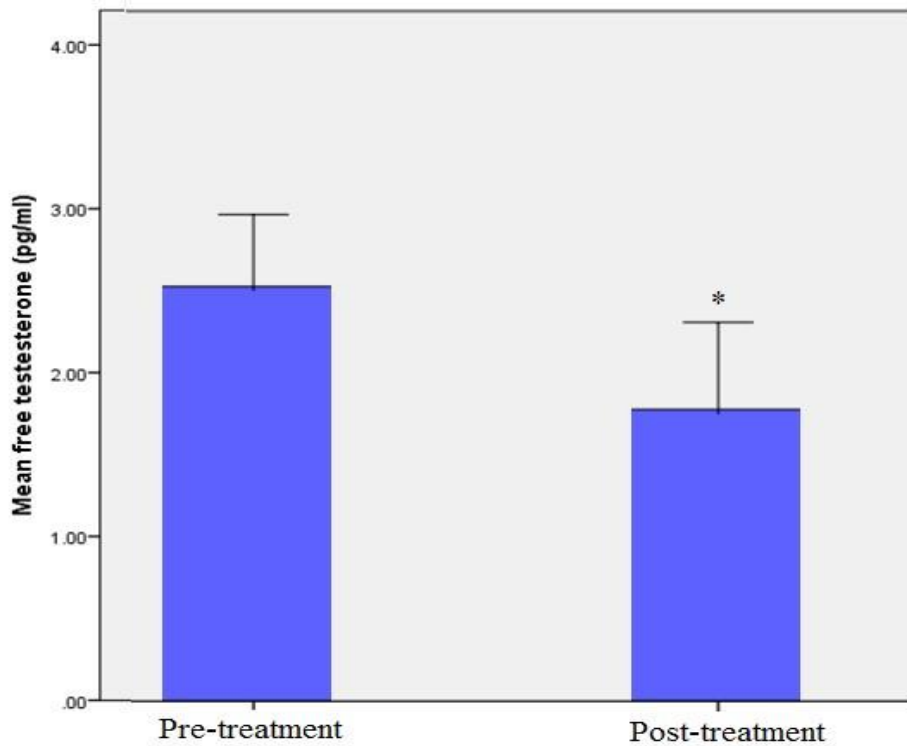


Figure 8.

Free testosterone level before and after treatment among good response group. Finasteride is considered to be a potent non-steroidal antiandrogen that acts by inhibiting the type 2-5 α -reductase isoenzyme, blocking the conversion of testosterone to 5- α -DHT, with a significant reduction of serum 5 α -DHT levels and no prominent side-effects.

Table 3.

Hormonal assessment before and after treatment among moderate response group

Variable	Pretreatment	Post-treatment	P value
	Mean \pm SE	Mean \pm SE	
TSH(uIU/ml)	2.9479 \pm 0.68128	2.4300 \pm 0.54213	0.094
LH(pg/ml)	11.4036 \pm 3.11762	9.8929 \pm 2.47450	0.375
FSH(mIU/ml)	7.9464 \pm 1.95649	7.1471 \pm 1.94245	0.145
Free testosterone(pg/ml)	2.4264 \pm 0.54332	2.5743 \pm 0.84006	0.737

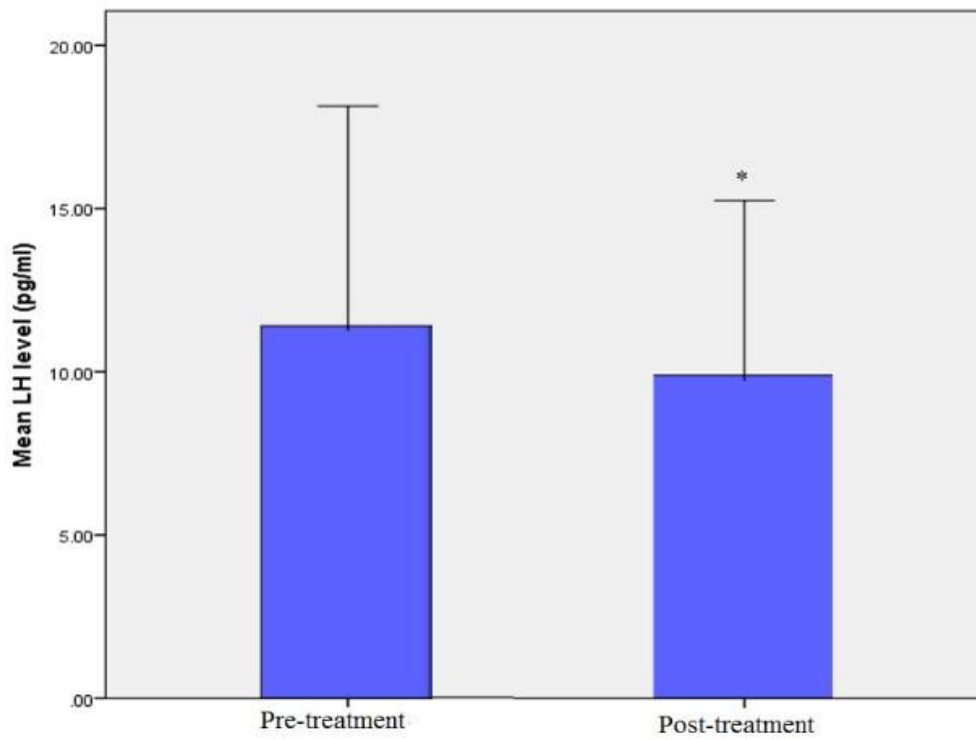


Figure 10.

LH level before and after treatment among moderate response group, in moderate response group we have slightly decrease in the LH levels.

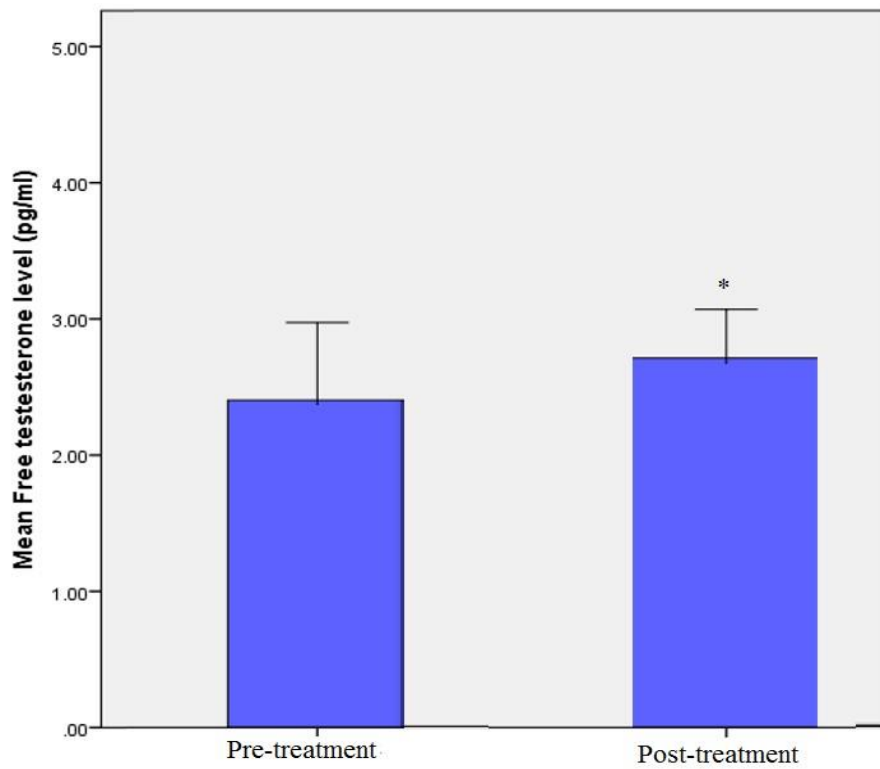


Figure 12.

Free test level before and after treatment among moderate response group, in moderate response group we have slightly increase in the free testosterone levels.

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Table 4.
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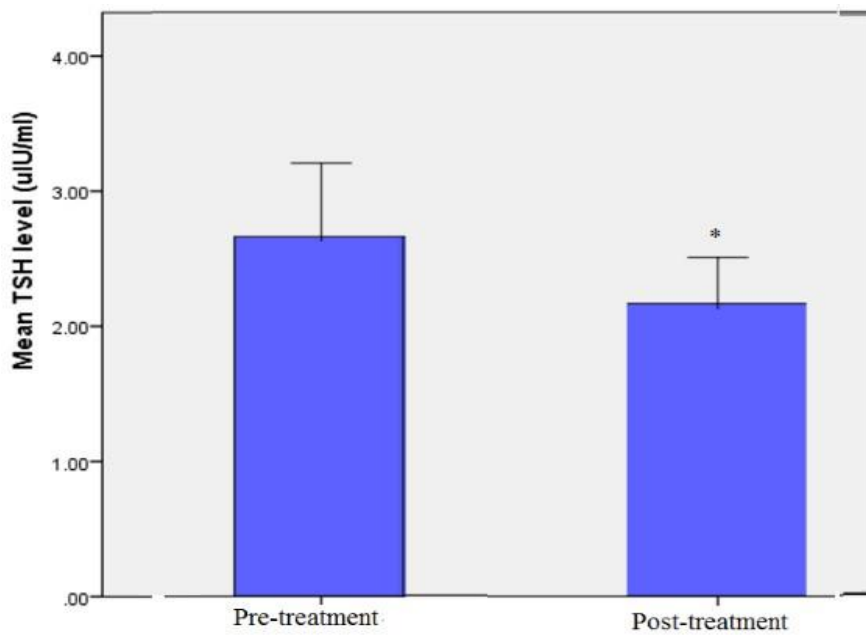


Figure 13.
 TSH level before and after treatment among mild response group, in mild response group we have slightly decrease in the TSH levels.

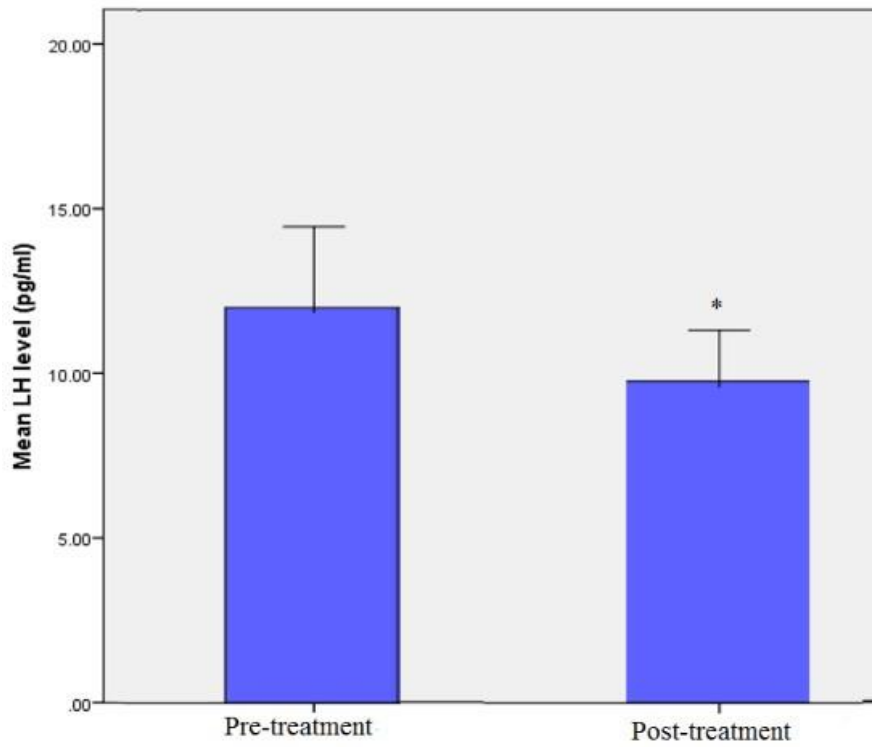


Figure 14.

LH level before and after treatment among mild response group, in mild response group we have slightly decrease in the LH levels.

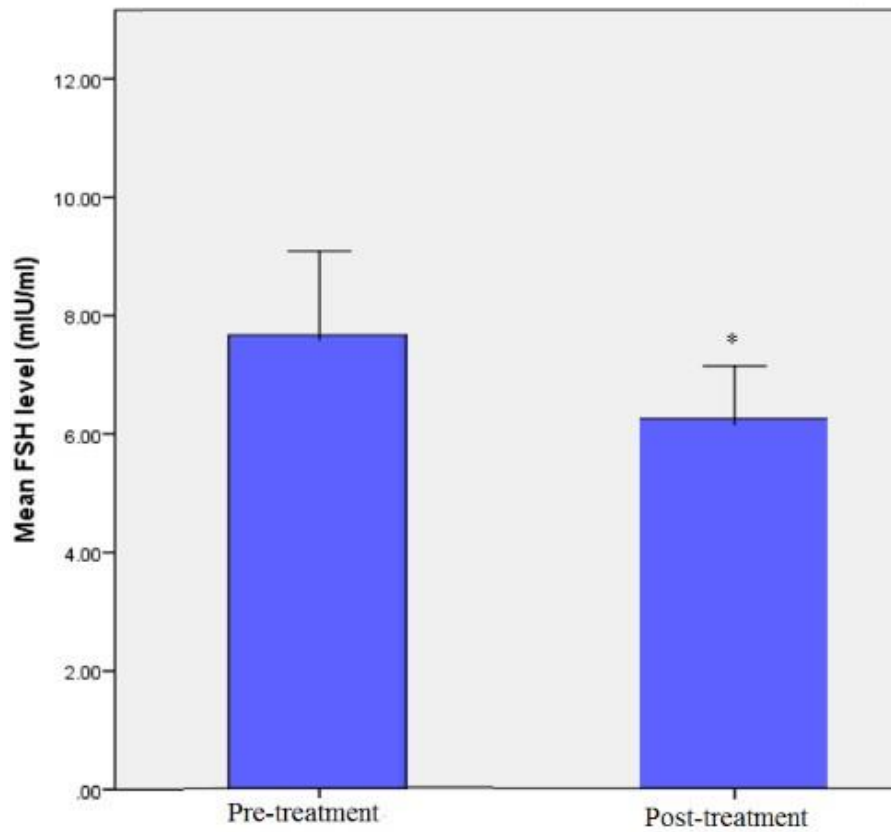


Figure 15.

FSH level before and after treatment among mild response group.

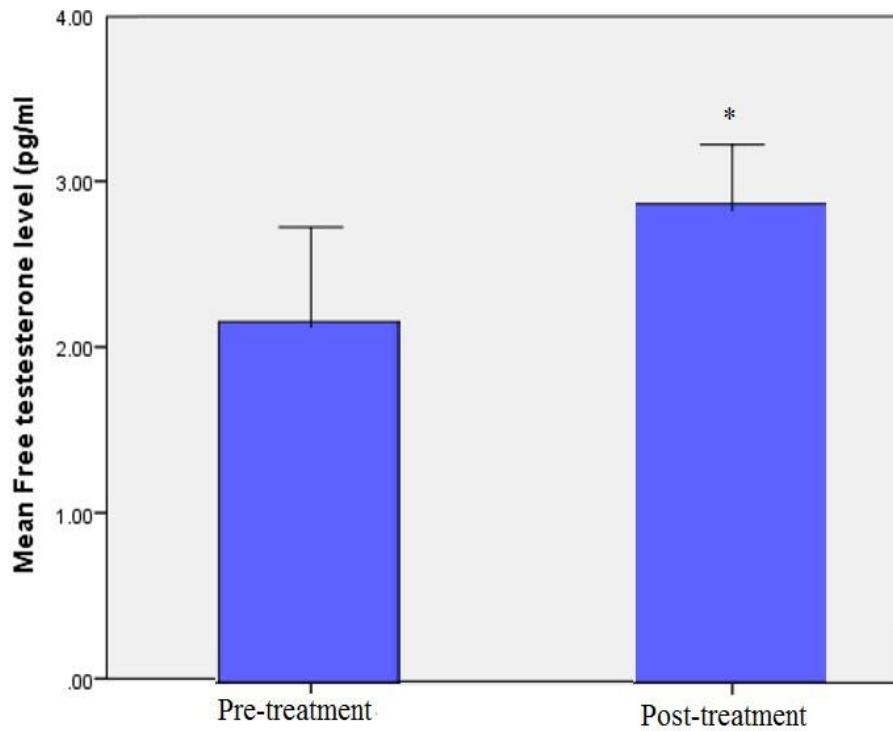


Figure 16.

Free test level before and after treatment among mild response group, in mild response group we have slightly increase in the free testosterone levels.

Variable	Pretreatment	Post-treatment	P value
	Mean±SE	Mean±SE	
TSH(uIU/ml)	3.3964±1.21531	1.6603±0.28699	0.224
LH(pg/ml)	9.1904±2.41841	10.5864±2.12646	0.376
FSH(mIU/ml)	6.1587±0.94639	7.5218±0.99069	0.357
Free testosterone(pg/ml)	3.8936±0.72674	3.9945±0.72578	0.746

Table 5.

Hormonal assessment before and after treatment among no response group.

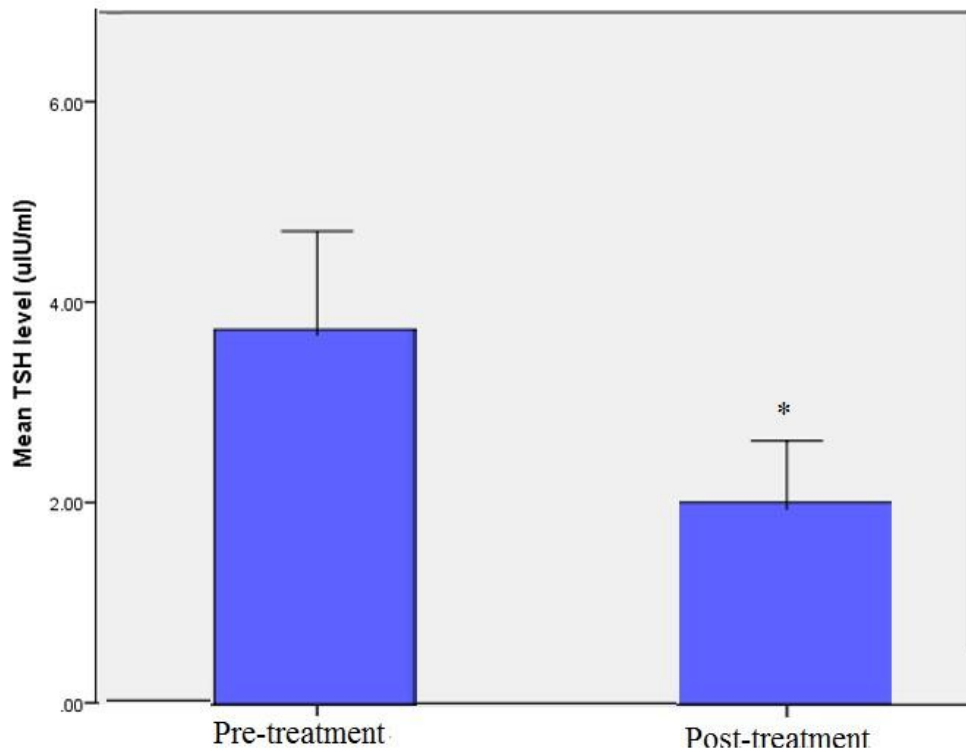


Figure 17.
TSH level before and after treatment among no response group.

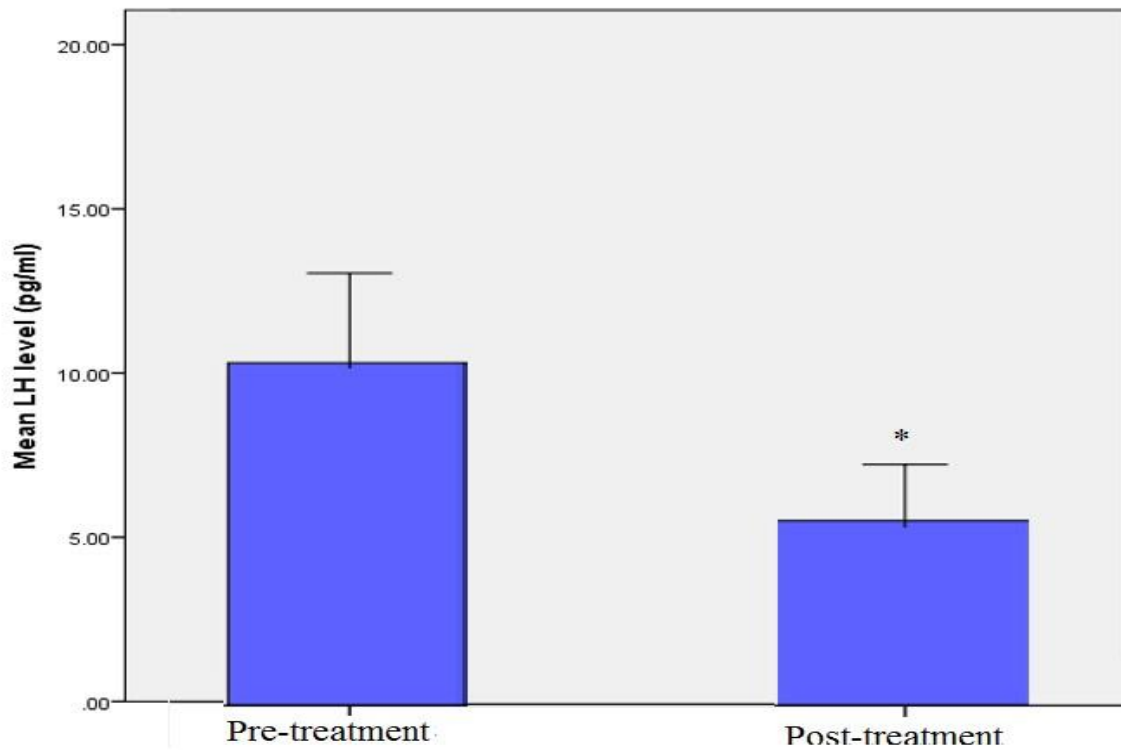


Figure 18.
LH level before and after treatment among no response group.

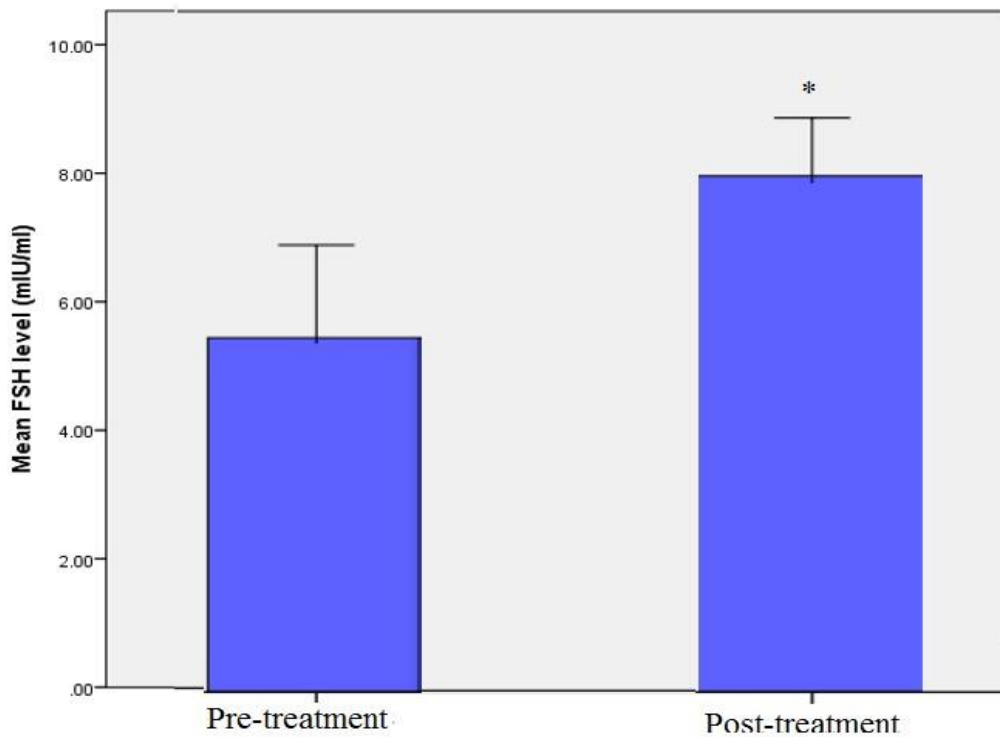


Figure 19.

FSH level before and after treatment among no response group.

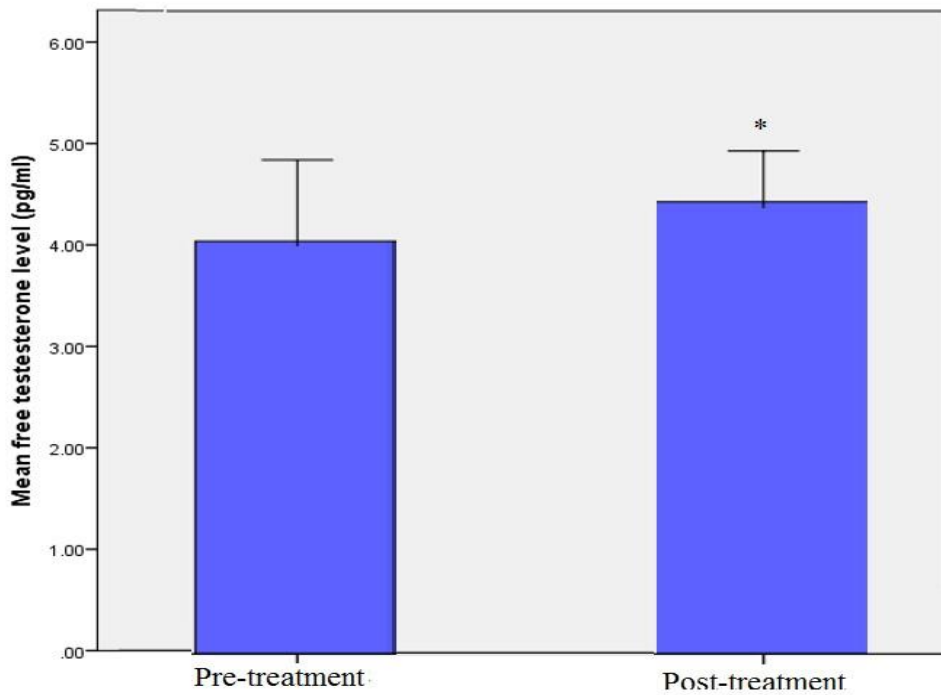


Figure 20.

Free test level before and after treatment among no response group.

Table 6.

Hair color (for all Patients).

		Hair color post		Total
		dark hair	light hair	
Good response	Dark hair(13)	2	11	13
		15.4%	84.6%	100.0%
Moderate response	Dark hair(14)	2	12	14
		14.3%	85.7%	100.0%
Mild response	Dark hair(3)	0	3	3
		0.0%	100.0%	100.0%
No response	Dark hair(8)	4	4	8
		50.0%	50.0%	100.0%
Total		8	30	38
		21.1%	78.9%	100.0%

Table 7.
 Hair color for each group

	Mean±SD	P value
Hair removal frequency pretreatment	4.50±3.311	<0.001
Hair removal frequency post-treatment	2.789±2.623	

Table 8.
 Hair removal frequency of the patients.

	Mean	Std. Deviation	P value
Hair removal frequency pre	2.85	0.987	<0.001
Hair removal frequency post	1.3077	0.48038	

Table 9.
 Hair removal- good response.

		Hair color post		P value
		dark hair	light hair	
No response	Dark hair (8)	4	4	0.024
		50.0%	50.0%	
Response	Dark hair(30)	4	26	
		13.3%	86.7%	
Total		8	30	
		21.1%	78.9%	

Table 10.
 Hair removal-moderate response.

	Mean	Std. Deviation	P value
Hair removal frequency pre	8.00	6.928	0.251
Hair removal frequency post	5.3333	4.04145	

Table 11
 Hair removal mild response

	Mean	Std. Deviation	P value
Hair removal frequency pre	7.00	4.000	0.04
Hair removal frequency post	5.5000	4.47214	

	Time	Mean	Std. Deviation	P value
Pair 1	Pretreatment	3.3158	0.66191	<0.001
	1month	2.3421	0.96636	
Pair 2	1 month	2.3421	0.96636	0.058
	2month	2.1316	0.93494	
Pair 3	2month	2.1316	0.93494	0.057
	Third month	1.9737	0.91495	
Pair 4	Pretreatment	3.3158	0.66191	<0.001
	Third month	1.9737	0.91495	

Table 12.

Hair removal-no response. Follow up with F-Gallawy score, there is a significant difference in the

	Sever Pain	Moderate pain	No pain	P value
Good response	0	6	7	0.001
	0.0%	46.2%	53.8%	
Moderate response	1	10	3	
	7.1%	71.4%	21.4%	
Mild response	0	3	0	
	0.0%	100.0%	0.0%	
No response		3	0	
		37.5%	0.0%	
Total		22	10	
		57.9%	26.3%	

Table 14.

score with time so the score is higher in the first 2 weeks while it is lower in the sixth 2 weeks, (Friedman test).

		Mean	Std. Deviation	P value
Pair 1	Pretreatment	3.4615	0.51887	<0.001
	1month	1.7692	0.92681	
Pair 2	1 month	1.7692	0.92681	0.502
	2month	1.6154	0.65044	
Pair 3	2month	1.6154	0.65044	0.337
	Third month	1.6923	0.63043	
Pair 4	Pretreatment	3.4615	0.51887	<0.001
	Third month	1.6923	0.63043	

Table 13.

Pain severity before and after treatment. pre-treatment and first month and between pretreatment

Table 15.

F-Gallawy good response, in good response group they had significant differences between pre-treatment and first month and between pretreatment and third month.

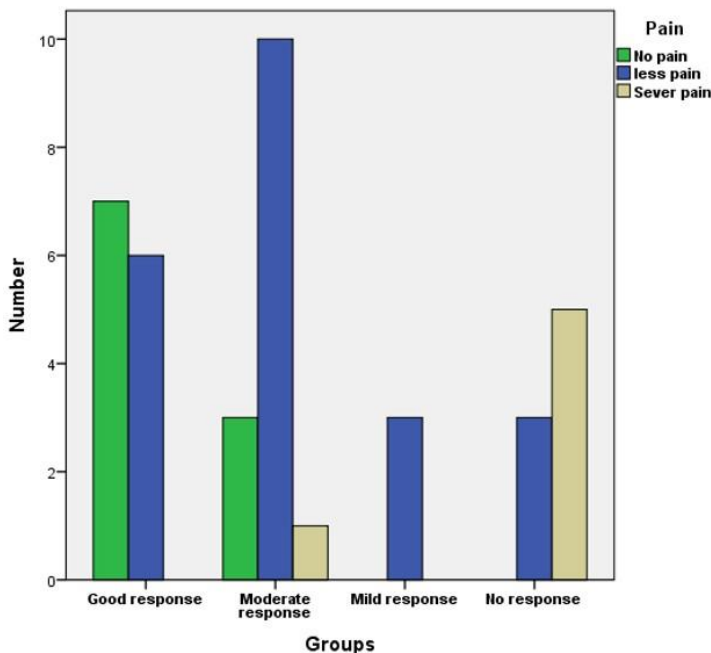


Figure 21.

Pain severity among different groups.

		Mean	Std. Deviation	P value
Pair 1	Pretreatment	3.2143	0.69929	0.001
	1month	2.3571	0.74495	
Pair 2	1 month	2.3571	0.74495	0.165
	2month	2.0714	0.61573	
Pair 3	2month	2.0714	0.61573	0.055
	Third month	1.7143	0.61125	
Pair 4	Pretreatment	3.2143	0.69929	<0.001
	Third month	1.7143	0.61125	

Table 6

F- G moderate response good response group they had significant differences between treatment and third month.

		Mean	Std. Deviation	P value
Pair 1	Pretreatment	3.3750	0.74402	0.170
	1month	3.1250	0.99103	
Pair 2	1 month	3.1250	0.99103	0.351
	2month	3.0000	1.19523	
Pair 3	2month	3.0000	1.19523	1
	Third month	3.0000	1.19523	
Pair 4	Pretreatment	3.3750	0.74402	0.197
	Third month	3.0000	1.19523	

Table 17.

F-G no response, in non-response group they had no significant differences between pre-treatment and all months.

		Time	Mean	Std. Deviation	P value
Pair 1	Pretreatment	3.0000	1.00000	0.423	
	1month	2.6667	0.57735		
Pair 2	1 month	2.6667	0.57735	0.423	
	2month	2.3333	1.15470		
Pair 3	2month	2.3333	1.15470	0.184	
	Third month	1.6667	0.57735		
Pair 4	Pretreatment	3.0000	1.00000	0.057	
	Third month	1.6667	0.57735		

Table 18.

F-G mild response, in mild response group they had also no significant differences between pretreatment and all months.

	Mean	Std. Deviation	P value
Pre-treatment	9.5263	0.55687	<0.001
First month	5.5526	2.29803	
Second month	5.0789	2.63430	
Third month	4.9211	2.64454	

Table 19.

Visual analogue score, There was highly significant difference in visual analogue score in different months which is higher pre-treatment and lowest in third month (Friedman test).

	Mean	Std. Deviation	P value
pretreatment	9.5385	0.51887	<0.001
First month	3.0000	1.08012	
Second month	2.1538	0.89872	
Third month	2.1538	0.89872	

Table 20.

Visual analogue-good response, There was significant difference between pre-treatment with all other periods and significant difference between first month and second and third month but no significant difference between second and third month.

Table 21.

Visual analogue-moderate response, The significant difference is only between pretreatment and other periods while between the first, second, and third months no significant difference.

	Mean	Std. Deviation	P value
pretreatment	9.3571	0.63332	<0.001
First month	5.8571	0.77033	
Second month	5.4286	1.22250	
Third month	5.0000	1.46760	

Table 22.

Visual analogue-no response, the significant difference is only between pre-treatment and other periods while between the first, second, and third months no significant difference

	Mean	Std. Deviation	P value
Pretreatment	9.7500	0.46291	<0.001
First month	8.3750	1.18773	
Second month	8.3750	1.18773	
Third month	8.3750	0.91613	

Discussion

Many of antiandrogen drugs such as spironolactone, finasteride, cyproterone acetate, flutamide have been used in the treatment of hirsutism as a single drug or in combination [8, 9]. Long period of treatment is always required to improve hirsutism and to prevent or to delay its relapse, increased 5 α -reductase activity has been shown on the skin of the women with idiopathic hirsutism [10]. The use of finasteride for treatment of hirsutism is logical because of its specific effect on 5 α -reductase, the enzyme responsible for sensitizing the hair to testosterone. In other studies, finasteride administered orally has been successfully used in the treatment of hirsutism [11, 12]. Its contraindications in women due to its effect on the developing male fetus.

It inhibits development of normal male genitalia [11]. In our study we compared pretreatment and post treatment for the color of the hairs and the hair removal frequency and the pain during hair removal for four groups which are good response group and moderate response group and mild response group and no response group and by subjective evaluation of all the patients noted a diminished rate of hair growth (fewer times needed for shaving) and a decrement in the density of hairs on the chin area and change in color of the hair but there was no significant difference between groups regarding hair color and there were highly significant difference in hair removal frequency before and after treatment ($P<0.001$) when we used finasteride cream 1% for 3 months.

For other studies by subjective evaluation, Six months of topically applied finasteride (0.5%) does not effect on number and thickness of facial hirsutism significantly. Despite lack of objective changes, on questioning, most patients in finasteride group perceived a decrease in hair growth with time. As they taken 25 patients noted a considerable diminished rate of hair growth on both sides of the face, especially on the one side that they had guessed that side is medication. In comparison with baseline, hair counts in both finasteride- applied and placebo treated areas decreased significantly ($P<0.0001$) and respectively. The hair density also have significant diminished at both sides, as compared finasteride and placebo treated groups with together [15], as I agree with the decreasing the hair growth but disagree with lack of the objective changes. For other previous studies, Finasteride cream is an effective and harmless drug in patients with idiopathic hirsutism as they enrolled 40 hirsute idiopathic women, taking finasteride cream 0.25% twice daily for 6 months on their chins. Ferriman– Gallwey

score of the chin area was measured and result of them was Mean Ferriman – Gallwey score was decreased from 3.2 ± 0.41 to 2.2 ± 0.76 ($P < 0.001$). Acne also appeared by 8 patients (20%) during the treatment. And there is no other side effects [16].

Finasteride have good result when administered orally in the treatment of hirsutism [8]. Reported that FerrimanGallwey scores in 14 women with idiopathic hirsutism have significant decreasing during a 1-year course of finasteride therapy. In addition, Faloia and colleagues [17] observed the hirsute patients have 33% reduction in clinical scores after six months from usage of finasteride. Notably there have been fewer investigations about topical application of finasteride. In fact its effects as a topical drug in the treatment of hirsutism are still debated. Leopoldo Falsetti, et al. 1999 [18] showed that Both antiandrogens (finasteride and flutamide) are effective in the treatment of hirsutism; but flutamide effective significantly more than finasteride and flutamide have no change in the hormone profile; and also both antiandrogen drugs do not have any change in the menstrual cycles in women with idiopathic hirsutism or its irregularity in women with PCOS; and flutamide also has a high risk/benefit ratio and its chronic administration need a repeated liver function tests.

Flutamide reduced the Ferriman–Gallwey score with idiopathic hirsutism by 47.7–56.5%, whereas finasteride reduced the score by 29.6–37.9% in idiopathic hirsutism. Keles F 2004 [19] showed that free testosterone levels slightly decreased in women when treated with spironolactone. This confirms that the anti-androgenic effect of spironolactone is primarily related to its peripheral effect. 1 year of treatment with a combination of spironolactone and finasteride will result in significant decreasing in free testosterone levels.

In this study the hormone profile of the patients with idiopathic hirsutism present significant difference in level of free testosterone in good response group compared with the other groups. While in other study, the hormone profile of the patients with idiopathic hirsutism did not present any significant difference compared with the control group [18]. In the present study, no significant differences in the FSH, LH, and TSH levels were found in either group with agreement (Fahri Bayram 2002) [20].

Conflict of Interest

No conflicts of interest were declared by the authors.

Financial Disclosure

The authors declared that this study has received no financial support.

Ethics Statement

Approved by local committee.

Authors' contributions

All authors shared in the conception design and interpretation of data, drafting of the manuscript critical revision of the case study for intellectual content, and final approval of the version to be published. All authors read and approved the final manuscript.

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