

EFFICACY AND SAFETY OF DIODE LASER FOR FACIAL HAIR REDUCTION IN HIRSUTISM – A CLINICAL AND TRICHOSCOPIC EVALUATION



Thesis

Submitted to

All India Institute of Medical Sciences, Jodhpur

In partial fulfilment of the requirement for the degree of

DOCTOR OF MEDICINE (MD)

(DERMATOLOGY, VENEREOLOGY AND LEPROLOGY)

JULY 2019

AIIMS, JODHPUR

DR. SAHIBA RAFI



ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR

DECLARATION

I hereby declare that the work reported in the thesis entitled **“Efficacy and safety of diode laser for facial hair reduction in hirsutism – a clinical and trichoscopic evaluation”** embodies the result of original work carried out by the undersigned in the Department of Dermatology, Venereology and Leprology, All India Institute of Medical Sciences, Jodhpur.

I further state that no part of this thesis has been submitted either in part or in full for any other degree of All India Institute of Medical Sciences, Jodhpur or any other institution.

Dr. Sahiba Rafi

Junior Resident

Department of Dermatology, Venereology and Leprology

All India Institute of Medical Sciences, Jodhpur



ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR

CERTIFICATE

This is to certify that this thesis entitled “**Efficacy and safety of diode laser for facial hair reduction in hirsutism – a clinical and trichoscopic evaluation**” is a bonafide work of **Dr. Sahiba Rafi** conducted in the Department of Dermatology, Venereology and Leprology at All India Institute of Medical Sciences, Jodhpur, under our direct supervision and guidance.

Chief Supervisor:

Dr. Anil Budania

Associate Professor

Department of Dermatology, Venereology & Leprology

All India Institute of Medical Sciences

Jodhpur

Co-supervisors:

Dr. Abhishek Bhardwaj

Additional Professor and Head

Department of Dermatology, Venereology & Leprology

All India Institute of Medical Sciences, Jodhpur

Dr. Saurabh Singh

Associate Professor

Department of Dermatology, Venereology & Leprology

All India Institute of Medical Sciences, Jodhpur

Dr. Anupama Bains

Assistant Professor

Department of Dermatology, Venereology & Leprology

All India Institute of Medical Sciences, Jodhpur

Signature



ALL INDIA INSTITUTE OF MEDICAL SCIENCES, JODHPUR

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Dr. Abhishek Bhardwaj

Additional Professor and Head

Department of Dermatology, Venereology & Leprology

All India Institute of Medical Sciences, Jodhpur

ACKNOWLEDGEMENT

First and foremost, I would like to praise and thank GOD ALMIGHTY, who has granted me the strength, knowledge, opportunity, and the ability to undertake this research study. I have finally been able to accomplish this achievement and complete it satisfactorily, I am grateful to god for this. Without the blessings of god, this work would not have been possible.

I owe a great many thanks to many people who helped me during the entire thesis.

I am profoundly indebted to my chief-supervisor Dr. Anil Budania who was very generous with his time and knowledge and assisted me in each step to complete the thesis. I am grateful to him for his creative suggestions, timely advice, and constant encouragement. It has been a tremendous experience to work under sir's guidance. I would thank him for the valuable help, suggestions, and supervision during the entire thesis. Without his support, the submission of this thesis would not have been possible. I shall always remain grateful to him.

My sincere thanks to my Co-supervisors Dr. Abhishek Bhardwaj, Dr. Saurabh Singh, Dr. Anupama Bains who helped to formulate the initial study design, recruitment of patients and offered their valuable suggestions during my entire thesis. They were a constant source of motivation for me during the entire period. I would also like to thank Dr. Suman Patra for the contribution of his ideas during the period.

I am grateful to Dr. Akhil Goel and Dr. Devi Soumya for her invaluable help and guidance in carrying out the statistical analysis of this study.

I am grateful to my immediate senior Dr. Afroz Alam for helping me in preparation of the thesis and for the valuable suggestions which have been vital during the study period. I would like to sincerely thank Dr. Bandhala Rajan, Dr. Ravi Kumar, Dr. Varun Rajagopal Dr. Utkrist Lahoria for supporting me during the thesis.

I would thank Dr. Yashdeep Pathania, Dr. Farzana Ansari, Dr. Navneet Kaur and Dr. Maninder Kaur and Dr. Rinkal who helped me in recruitment of patients.

I would also like to thank my batchmate Dr. Neelam for constant support throughout my thesis period.

I would like to acknowledge the immense help and assistance that I have received during this

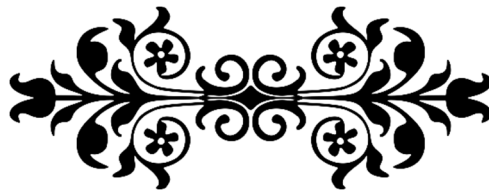
tough time from my hardworking juniors Dr.Benetta Benny, Dr.Monisha, Dr.Thoyyib, Dr. Karthick, Dr. Yamini , Dr. Akriti, , Dr. Shilpi, Dr. Priyanka, Dr. Shubhojit, Dr. Shubham, Dr. Kriti, Dr. Nazneen, and Dr. Nagbhushan. I am grateful to them for their love and support.

I thank OPD staff Mr. Rameez Raja, Mr. Praveen, Mrs. Saroj , Mr. Poonaram and Mrs. Pooja for their assistance.

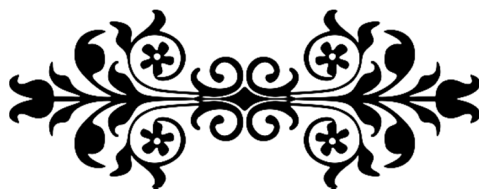
This work has been possible due to the support of a large number of people and I would like to sincerely apologise for any omissions made in listing out the name.

I would also like to thank my patients for participating in the study without whom the study was futile. I would like to thank my friends for the constant emotional support. Last but not the least in particular, I wish to thank my parents and my siblings for always giving me encouragement and support. Their constant love and support kept me going.

Dr. Sahiba Rafi



***DEDICATED TO MY PARENTS,
TEACHERS & PATIENTS***



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LIST OF ABBREVIATIONS

Abbreviations	Full forms
Nd:Yag	Neodymium-Doped Yttrium Aluminium Garnet
PCOD	Polycystic Ovarian Disease
TRT	Thermal Relaxation Time
DHEAS	Dehydroepiandrosterone Sulfate
LH	Leutinisig Hormone
FSH	Follicle Stimulating Hormone
TSH	Thyroid Stimulating Hormone
USG	Ultrasound
MFG	Modified Ferriman-Gallwey Score
OCP	Oral Contraceptive Pills
RCT	Randomized Controlled Trials
IPL	Intense Pulsed Light
LPDL	Long Pulsed Diode Laser
BMI	Body Mass Index

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SUMMARY

Background: Hirsutism is the presence of excessive terminal hair on androgen-dependent areas. Lasers like Alexandrite, diode and Neodymium-doped Yttrium aluminium garnet (Nd:Yag) lasers has been used for hair reduction with varying efficacy. Trichoscopy of hair is a simple non-invasive method for hair counting using dermoscope.

Objectives: To clinically and trichoscopically assess efficacy of diode laser in facial hair reduction in hirsutism. Also, the safety of diode lasers in Indian skin color was assessed.

Materials and Methods: It was a prospective observational study. Seventy three patients were recruited during the study period. Diode laser was done with fluence 18-20 J/cm² in first treatment. In subsequent visits, fluence was increased by 2-4 J/cm² upto a maximum of 34 J/cm² depending on subject's tolerance and presence of side effects. The treatment was repeated every 4 weekly with goal of 6 sessions. Clinical and trichoscopic evaluation along with photographs were obtained at baseline, third visit and sixth visit. Clinical parameters used were modified Ferriman-Gallwey score of face (0-4), percentage reduction (patient reported), Investigator assessment (-3 to +3), frequency of hair removal and predominant hair type. In addition, trichoscopic parameters like total hair count, terminal hair count, vellus hair count, terminal/vellus hair ratio (per field) done for 4 sites including sidelocks, chin, upper lip and submandibular area. Hair counting was done manually from prints of the photographs taken. Side effects, if any, was noted in every sitting. Statistical analysis was done using SPSS version 25.

Results: Mean age was 26.37 ± 5.82 years with a range of 18-24 years as the most commonly affected group. All patients were females of Fitzpatrick skin type III-V with mean duration of hirsutism of 4.08 years. Forty one patients out of seventy three patients fulfilled Rotterdam criteria for polycystic ovarian disease. Most commonly involved sites were chin followed by upperlip, submandibular area and side locks. All clinical parameters showed statistically significant hair reduction when compared with baseline. Trichoscopic parameters of hair reduction like total hair count, terminal hair count, and terminal/vellus hair ratio (per field) also showed reduction compared to baseline which was statistically significant.

Most common side effect noted in our study was pain followed by erythema and perifollicular edema. Also, mild superficial burns, hyperpigmentation, paradoxical hair growth, acneiform eruptions and herpes labialis were noted in few cases. All side effects were mild and transient.

Conclusions: Diode laser is an effective and safe method in the reduction of unwanted facial hair, even in darker skin type. We also wanted to emphasize that trichoscopy for the monitoring of laser hair reduction is a new, noninvasive, sensitive and underutilized investigation that is valuable in assessment of the laser hair reduction for hirsutism. No serious adverse events were noted in our study.



INTRODUCTION



INTRODUCTION

Hirsutism is the presence of excessive terminal hair on androgen-dependent areas. It affects 5–15 % of reproductive-age females. It can be caused by increased androgen production, greater skin sensitivity to androgens, or a combination of the two. It can be classified into two types: androgen-induced and non-androgen-induced. The most common cause of non-androgen-induced hirsutism is idiopathic hirsutism, while the most common cause of androgenic induced hirsutism is polycystic ovarian disease (PCOD). Idiopathic hirsutism and PCOD together constitutes 95% cases of hirsutism. Cushing's syndrome, hyperprolactinemia, ovarian or adrenal tumors are a few other important etiologies ¹. Hirsutism, regardless of its cause, can result in significant psychological distress and low self-esteem. About 20% of women use temporary hair removal treatments such as tweezing, shaving, waxing, and bleaching at least once in a week ².

Commonly used methods to treat excessive facial hair include hormonal treatment, temporary/physical methods of hair removal and permanent/curative hair removal like laser-assisted hair reduction ³. Traditional hair removal treatments have mostly been surpassed by laser and light-based therapies, which are superior in terms of achieving long-term hair reduction.

Melanin is the chromophore targeted in laser hair reduction. Melanin in the hair follicle absorbs laser radiation leading to a rise in temperature in the hair bulb and bulge, resulting in hair follicle thermal death (photothermal effect). Simultaneous cooling of the epidermis to protect it will result in selective photothermolysis, in which the chromophore absorbs selective wavelengths ⁴. People with light complexion (Fitzpatrick skin types I-IV) and dark hair are the best candidates for hair reduction. Because the absorption occurs at the level of follicular melanin rather than epidermal melanin, the risk of epidermal injury is reduced ⁵.

Lasers produce a substantial delay in hair regrowth, lasting from weeks to months. Terminal hairs are largely replaced by fine vellus hairs after laser treatment. Repeated treatment improves efficacy. Laser hair reduction is considered to be permanent when there is a stable decrease in the number of terminal hair for a duration longer than the complete hair growth cycle at a given body site after treatment. Lasers with wavelengths in the range of 600–1200 nm like ruby (694 nm), diode (810 nm), Nd: YAG (1064 nm), alexandrite (755 nm) and intense-pulsed light can achieve this.

Factors affecting the outcomes in laser hair reduction can be divided into (a) patient factors (patient skin type, hair type, site, hormonal profile, comorbidities) and (b) Laser machine related factors (fluence, pulse duration, wavelength, spot size) ⁴.

The efficacy of laser therapy can be assessed by comparing hair reduction from baseline, predominant hair type, and objective measures like hair counting, hair thickness assessment, terminal to vellus hair ratio. Patient-reported improvement can also be assessed including hair reduction and satisfaction scores⁶. Trichoscopy can be performed on the patient using dermoscope after which parameters like hair density, hair thickness and terminal to vellus hair ratio can be assessed either by direct counting or by software like trichoscan⁷.

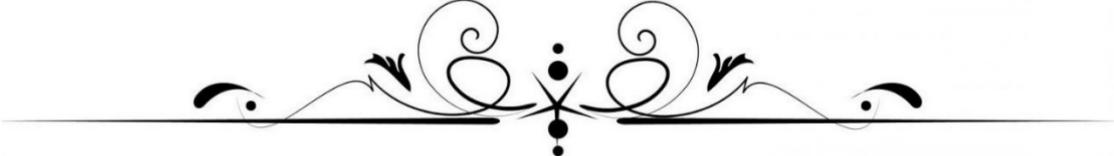
Adverse effects reported after laser-assisted hair reduction are generally mild and transient. Few of the common cutaneous side effects include pain, immediate erythema and perifollicular edema. Severe side effects like burns, blistering, dyspigmentation and permanent scarring may also occur rarely. Other rare side effects include aggravation of acne, rosacea, leucotrichia and tunneling of hair underneath the skin⁸.

Diode lasers for hair reduction were cleared to market in USA in 1997⁵. The active medium of diode laser is a solid state semiconductor made of aluminium, gallium and arsenide, which produces laser wavelengths, ranging from 810 nm to 980 nm. All diode wavelengths are absorbed primarily by melanin and hemoglobin. The hair reduction noted with 810-nm diode laser usually ranges from 22% to 59%. Lasers with longer wavelengths like the diode and the Nd: YAG lasers are preferred to treat darker skin types due to lesser side effects than lasers with shorter wavelengths like ruby laser. Efficacy in hair reduction between diode and Nd: YAG lasers are variable among studies. Most studies have shown few and short-lasting side effects using diode laser to treat patients with darker skin types⁸.

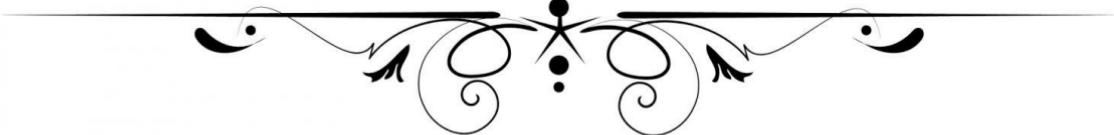
Few newer technologies in laser include -super hair removal, vacuum-assisted laser hair removal, larger spot size, and TRASER (Total Reflection Amplification of Spontaneous Emission of Radiation)⁵.

Trichoscopy is a method for hair evaluation in hair disorders like alopecia. It uses dermoscope to get magnified image of hair and the surrounding skin. Trichoscopy can be used for evaluating efficacy of lasers by assessing hair density, thickness, type of hair, etc. But studies on trichoscopic assessment of efficacy of lasers are very limited. To the best of our knowledge, this would be the first study to assess diode laser hair reduction using

trichoscopy. Also, this study may help in assessing efficacy and safety of diode laser in Indian skin color.



AIM & OBJECTIVES



AIM AND OBJECTIVES

AIM OF THE STUDY

To assess the efficacy and safety of diode laser in facial hair reduction in hirsutism

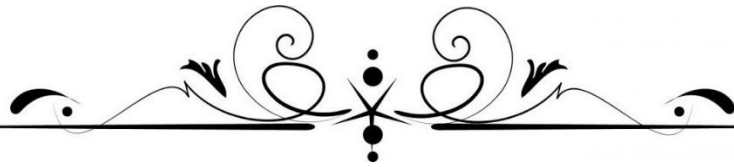
OBJECTIVES

Primary Objective:

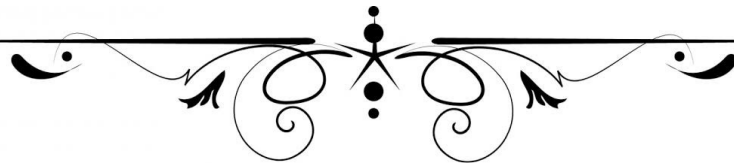
- To clinically and trichoscopically assess efficacy of diode laser in facial hair reduction in hirsutism

Secondary Objective:

- To assess safety of diode laser in Indian skin color



REVIEW OF
LITERATURE



REVIEW OF LITERATURE

HISTORY

In 1916, Einstein proposed the concept of Stimulated Emission, which said that photons stimulate the emission of other photons with the same frequency, phase, polarisation, and direction as the first one by interacting with excited atoms. The first laser, based on this idea, was created in 1960 by Theodore H. Maiman, who used ruby as the medium and high-energy light pulses to stimulate it. In 1964, the Nobel Prize in Physics was awarded to Charles H. Townes, Nikolay G. Basov, and Alexander M. Prokhorov for their research on the MASER ("Microwave Amplification by Stimulated Emission of Radiation") principle; and in 1977, Gordon Gould was recognized as the "Father of the Laser", who is also known for coining the term "Laser" ("Light Amplification by Stimulated Emission of Radiation")⁹.

Goldman and his colleagues published the first study on the effects of lasers on skin in 1963, documenting the selective destruction of pigmented skin structures, including hair follicles, with the ruby laser. They discovered very selective destruction of pigmented structures (black hair) with no discernible alteration in the white skin beneath. Since then, over 15 laser systems, including ruby (694 nm), alexandrite (755 nm), diode (800–1,000 nm) and long-pulsed neodymium: yttrium-aluminium-garnet (Nd:YAG; 1,064 nm), and intense pulsed light sources (550–1,200 nm), have been approved by the US Food and Drug Administration for use in hair reduction¹⁰.

Laser technology is commonly used in medical fields like ophthalmology, dermatology, dentistry, otorhinolaryngology, neurosurgery, and plastic surgery in the medical industry. Hair reduction, pigmented lesions, tattoo removal, skin resurfacing, and vascular lesions treatment are few common dermatological indications⁹.

LASER CHARACTERISTICS

Laser light is monochromatic, coherent and collimated

Monochromatic: Light waves of the same wavelength and energy are emitted. It allows for precision targeting within tissue while protecting other structures.

Coherence: All waves are in phase with one another in space and time.

Collimated: Photons all travel in the same direction, parallel to each other¹¹.

PARTS OF LASER MACHINE

Parts of laser machine can be divided into laser medium, pump, optically pumped laser and output (Figure 1)^{12,13}

Laser medium: A solid, liquid, or gaseous material or substance capable of creating laser light by a stimulated electron transition from an unstable high-energy orbit to a lower one, resulting in the emission of collimated, coherent, monochromatic light.

Pump: a source of energy for the laser medium that can be electrical, optical, radiofrequency, or chemical.

Optically pumped laser : is one in which electrons are stimulated by light energy absorbed from an external source.

Output

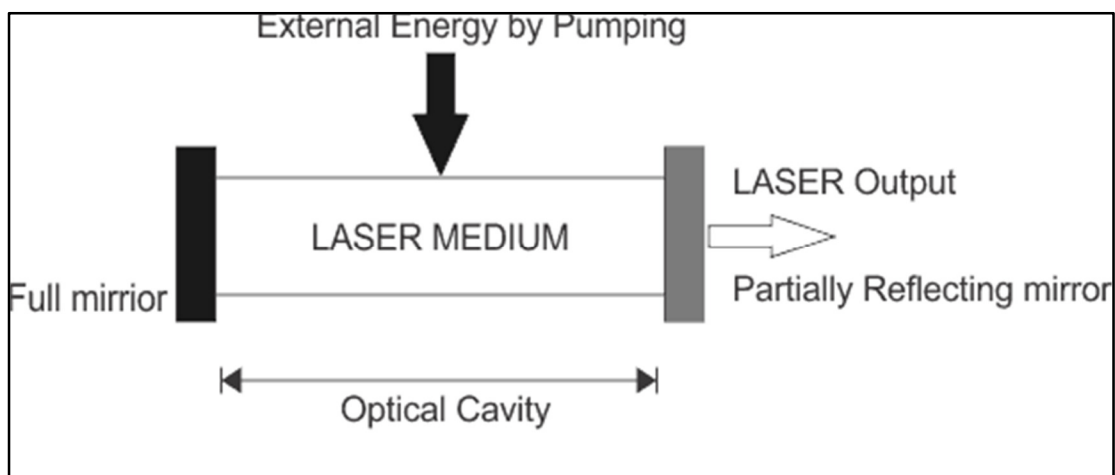


Figure.1 Components of LASER

PARAMETERS USED IN LASER APPARATUS

Measurements used routinely in laser applications include wavelength, frequency, energy, power, fluence and irradiance¹².

Energy: Energy is measured in Joules (J) and proportional to the number of photons.

Power: Power is the rate of delivery of the energy. It is measured in watts (W) where 1 W = 1 J/sec.

Fluence: Fluence is the energy delivered per unit area (J/cm^2)

Irradiance (Power density): The quotient of incident laser power on a unit surface area, expressed as watts/cm^2

Pulse Duration: The amount of time a focused and scanned laser beam interacts with a specific location on the skin (typically measured in milliseconds or nanoseconds)

Wavelength: It is the distance between two subsequent peaks or troughs of a light wave. It is usually expressed in nanometers.

LASER TISSUE INTERACTION

Each layer of the skin, a laser beam can be reflected, transmitted, scattered, or absorbed. Tissue effect can only be produced by photons that have been absorbed. A chromophore is essential for photon absorption in a tissue. Endogenous light-absorbing molecules called chromophores absorb light of a given wavelength. As a result, we want to reduce photon reflectance, scattering, and transmission in order to improve photon absorption.

When a chromophore absorbs laser light, it can result in three biological reactions: photothermal, photomechanical, or photochemical^{11, 14}.

Photothermal effects: Photothermal effects arise when absorbed light energy is transformed into thermal energy within the chromophore. It is the main method through which lasers work in the skin. Various consequences, such as coagulation or vaporisation, can occur depending on the actual temperature obtained within the target.

Photomechanical effects : When exceptionally high energy are absorbed at short pulse durations, photomechanical reactions occur within the chromophore, resulting in extremely fast thermal expansion of the target and consequent photomechanical destruction.

Photochemical effects: Photochemical effects are elicited by endogenous or exogenous photosensitizers, such as those employed in photodynamic treatment. It also explains the paradoxical hair growth that occurs following laser therapy.

SELECTIVE PHOTOTHERMOLYSIS

Anderson and Parrish established the theory of selective photothermolysis in 1983 and it is one of the most fundamental concepts for explaining tissue interactions. It also explains why laser light can be employed for specific therapeutic objectives. It claims that laser energy can be absorbed by a specific target chromophore, resulting in its controlled annihilation without causing major tissue damage. It implies that we may selectively destroy cells within the skin, such as melanosomes or tattoo ink particles, without causing damage to the surrounding tissue, such as arteries or collagen.

A few principles must be followed in order for this notion to be valid. (a) The laser light's wavelength must match the absorption spectrum of the target chromophore. (b) Pulse Duration of the laser beam must be equal to or less than the target chromophore's thermal relaxation time (TRT). (TRT is defined as the time required by an object to cool down to 50% of the initial temperature achieved). As a result, smaller items cool faster than larger ones, and larger chromophores have a longer TRT than smaller ones. Hair follicles, for example, have a diameter of 200 μm and TRT -10-100ms, but tattoo ink has a diameter size 1-4 μm and TRT 10ns. (c) Fluence should be sufficient to destroy the target¹⁴.

THE CHROMOPHORES

The skin contains a variety of chromophores that may absorb light; however, the three most important endogenous chromophores in the skin are melanin, haemoglobin, and water. Each of these chromophores has its own absorption spectra and peaks, which show their relative absorption for each wavelength.

Melanin has a decreasing absorption spectrum that ranges between 400 and 750 nm. Hemoglobin has an absorption spectrum that ranges from 400 to 600nm, featuring absorption peaks that can be targeted specifically. Water shows increasing absorption, starting at mid-infrared and increasing towards the infrared portion of the electromagnetic spectrum. Thus, visible and UV light are mainly absorbed by melanin and hemoglobin, while infrared light is mainly absorbed by water. Tattoo ink is the most important exogenous chromophore in laser dermatology. Its wavelengths are determined by the color of the ink particle¹⁴.

DIODE LASER

In 1997, the FDA approved the use of diode lasers for hair reduction in the United States⁵. A solid state semiconductor consisting of aluminium, gallium, arsenide, and occasionally indium serves as the diode laser's active medium, producing laser wavelengths ranging from 810 to 980 nm. Tissue pigment (melanin) and haemoglobin absorb the majority of diode wavelengths¹⁵.

INDICATIONS OF DIODE LASER

Table 1: Indications of diode laser¹⁵

1	Hirsutism
2	Hypertrichosis
3	Pilonidal sinus
4	Hidradenitis suppurativa
5	Dissecting folliculitis
6	Pseudofolliculitis barbae
7	Peristomal hair growth
8	Flaps/Grafts with hair

TARGETS OF DIODE LASER

Infundibulum, isthmus, bulge, and bulb are the different parts of a hair follicle. With different stages of hair growth, the distance between the bulb (has melanocytes) and the skin surface changes. It is shallowest at early anagen and deepest at late anagen stage. Also, coarser the hair, deeper will be the follicle. Melanin in the hair root is a photon-absorbing chromophore that heats up when exposed to light. A coarse, dark black hair root in the anagen growth phase on a lighter skin type would be an appropriate target. In any event, no current laser can treat a target that is lighter than the epidermis. Attempts are being made, however, to improve

the absorbability of such lighter targets by introducing external pigment (For example, MeladineTM)¹¹.

The hair root is an example of a target and chromophore that are not identical. Melanin, which is found in the hair bulb and bulge, is a chromophore that absorbs photons. The follicular epithelium, which surrounds the bulb at a distance, is the target. As a result, the bulb must be heated for long enough for sufficient heat to be transferred to the target. Pulse duration should be long enough for bulb to heat up and transfer the heat. Hence, coarse hair requires a greater pulse duration than vellus hair

HAIR REDUCTION NOT REMOVAL

According to Food and Drug Administration permanent hair reduction defined as “the number of hairs re-growing must be stable over a time greater than the duration of the complete growth cycle of hair follicles, which varies from 4 to 12 months according to body location”¹⁶.

HIRSUTISM

Hirsutism is the presence of terminal coarse hairs in females that are distributed in a male-like pattern. It affects about 5-15% of women and is a prevalent cosmetic concern in dermatological outpatient departments.

Traditionally, hirsutism was thought to be a sign of elevated androgen levels in women caused by the adrenals or ovarian illness. Polycystic ovarian syndrome and ovarian tumors are two ovarian causes of hyperandrogenism. Cushing's syndrome, androgen-producing tumors, and congenital adrenal hyperplasia are all examples of adrenal causes. The hyperandrogenic-insulin-resistant-acanthosis nigricans syndrome is a less common cause (HAIR-AN). Hirsutism can be caused by hyperprolactinemia, which is caused by an increase in adrenal dehydroepiandrosterone sulphate (DHEA-S) synthesis. Hormonal medications are another common cause of hirsutism.

Idiopathic hirsutism can occur in up to 20% of people with normal testosterone levels and ovarian function. The cause of these women's excessive hair is assumed to be related to peripheral androgen activity abnormalities. Idiopathic hirsutism begins shortly after puberty

and progresses slowly. PCOD and idiopathic hirsutism account for 90% of the hirsutism in women. Some premenopausal women can develop hirsutism, which can last for a few years following menopause. This is related to a reduction in ovarian oestrogen secretion with persistent androgen synthesis¹⁷.

The European Society of Human Reproduction and Embryology/American Society for Reproductive Medicine Rotterdam consensus (ESHRE/ASRM) defines the diagnostic criteria of PCOD, requiring two of three features: anovulation or oligo-ovulation, clinical and/or biochemical hyperandrogenism, and polycystic ovarian morphology seen on ultrasound¹⁸.

EVALUATION OF PATIENTS OF HIRSUTISM

1. Detailed history includes age of onset, progression, any symptoms of virilisation (acne, deepening of voice, menstrual irregularities, clitoromegaly, increased libido), history of weight gain or diabetes and any significant drug history.
2. Complete general physical and systemic examination- including body mass index, hair assessment, palpation of abdomen.
3. In drug induced hirsutism, withdrawal of the suspected drug will resolve the symptoms.
4. Hormonal profile includes Testosterone , Dehydroepiandrosterone sulfate (DHEAS) , 17 Hydroxy progesterone , LH,FSH , Prolactin, TSH
5. Pelvic ultrasonography can be done to look for an ovarian neoplasm or a polycystic ovary¹⁷.

HAIR ASSESSMENT

A) CLINICAL ASSESSMENT

Visual scoring tools are employed in the clinical evaluation of hirsutism, with the modified Ferriman-Gallwey (mFG) score being the most extensively used. The mFG score assesses hair growth in nine androgen-sensitive body areas: the upper lip, chin, chest, upper and lower back, upper and lower belly, arms and thighs. A score of 0 indicates no terminal hair, whereas a score of 4 indicates significant growth of terminal hairs. Hirsutism is defined as a total score of 8 or higher. Hirsutism can be divided into three categories: mild (mFG score 9-16), moderate (mFG score 17-25), and severe (mFG score 26). (mFG score 26-36)^{19, 20}.

Few objective methods of hair assessment include weighing the hairs obtained by dry shaving the body region of interest; measuring the outer diameter of either plucked or clipped hairs; determining the density of terminal hairs (i.e. the number of hairs per defined surface area) either by direct counting or photography; and measuring the rate of hair growth using calibrated glass capillary tubes or photography. The vellus index, defined as the fraction of vellus (unmedullated) hairs in a sample of 100 shaved hairs, is another approach for evaluating androgenization of hairs that has been proposed. This index was found to be considerably lower in hirsute women and males when compared to healthy women. Direct methods are primarily useful for assessing the hair growth rate, terminal hair density, or changes in hair growth. They are relatively less useful, due to their complexity, cost and low patient acceptance⁶.

Leyden J et al²¹ used Investigator assessment for scalp hair assessment which used 7-point scale to answer the following question: “How would you subjectively rate the patient’s hair at this time point compared to baseline, as the investigator?” Scores are : -3 = greatly decreased, -2 = moderately decreased, -1 = slightly decreased, 0 = no change, 1 = slightly increased, 2 = moderately increased, 3 = greatly increased.

Efficacy of laser therapy can also be assessed depending on patient reported hair reduction from baseline and patient satisfaction scores (global aesthetic improvement scale). In addition, information about the change in thickness and color of persisting hair and change of growth speed²².

B) TRICHOSCOPIC ASSESSMENT

Trichoscopy can be done using dermoscope and parameters like hair density, terminal to vellus hair ratio and hair thickness can be assessed either by direct counting or by softwares like trichoscan^{2, 7}.

Nabi et al⁷ conducted study on clinicotrichoscopic response to treatment with Nd-Yag Laser. After six laser sessions, excellent response was seen in 70% of patients in idiopathic hirsutism group and in 54% of patients in PCOD group. The trichoscopic features were assessed before each laser session which showed reduction in hair shaft thickness, hair shaft colour, terminal vs. vellus hair ratio, density of hair per cm² in both groups.

Mohamed et al² conducted study on 70 females with hirsutism who received six sessions of Nd:YAG laser 4-weekly. Mean hair density/cm², percentage of terminal/vellus hair ratio, and hair thickness(mm) were assessed at baseline and monthly for six sessions using TrichoScan[®] software. At the final visit, mean hair density, terminal to vellus hair ratio, and hair thickness were significantly decreased from baseline (73.7, 72.5, 0.095 respectively) to (19.4, 21.3, 0.02 respectively).

Mittal et al²³ studied safety and efficacy of long-pulsed, 1064 nm Nd:YAG laser-assisted hair reduction in relation to multiple treatment sessions in Indian patients(n=59). At the end of the 3rd, 4th, 5th, and 6th sessions, achievers(who converted to thin vellus hair) were 5%, 15%, 25%, and 56% respectively of all the patients..

Sadick et al²⁴ conducted a study on 24 female subjects who were treated three times at monthly intervals with diode laser (810nm) A mean hair reduction efficiency of 74% and 79% was noted at 3 and 6 months.

MEDICAL TREATMENT

Non pharmacological measures including diet, exercise and weight reduction should be advised to women with hirsutism. Also multiple oral and topical drugs can be used^{25, 26}.

Somani et al²⁶ did a detailed literature review on medical treatments in hirsutism and following conclusions were drawn:

- Physical modalities (lasers), topical eflornithine, and oral contraceptive pills are first-line therapies.
- Antiandrogens (Spironolactone, cyproterone acetate, and finasteride) are indicated for moderate to severe hirsutism or when oral contraceptive pills are contraindicated.
- Combinations of OCP+ antiandrogen or of spironolactone+finasteride, further enhance efficacy.
- Topical eflornithine is indicated as monotherapy for mild hirsutism or in add on therapy with physical and pharmacologic modalities. Addition of eflornithine to laser hair reduction results in a more rapid and complete reduction of unwanted facial hair in women when the combination is used for up to 6 months.

COMPARISON OF DIFFERENT LASER AND LIGHT-BASED DEVICES

Hair reduction lasers employed initially had shorter wavelengths like Ruby 694 nm and Alexandrite 755 nm. Despite their stronger affinity for melanin, they are unable to penetrate deep into the skin. They had higher rates of side effects like epidermal burns and post-treatment hyperpigmentation in darker skin types V and VI. Longer wavelengths, such as Diode 800 nm and Nd:YAG 1064 nm, have a lower affinity for melanin than shorter wavelengths, but are proven to be more effective since they penetrate deeper into the hair follicles, which can be 3- 4 mm deep. Both of these wavelengths have been confirmed to be beneficial for hair reduction at present ^{5,11}. There are various studies comparing different lasers and their efficacy and safety in hair reduction (Table 2).

Table 2. Studies comparing efficacy and safety of different lasers for hair reduction

S.No	AUTHOR	METHOD	EFFICACY	SAFETY
1	Puri et al ²⁷	RCT comparing Diode (n-10), Nd:Yag (n-10) and IPL (n-10)	<p>Percentage of hair reduction after</p> <p>2 sessions- 40% with diode laser>35% with Nd: Yag laser > 10% with IPL .</p> <p>4 Sessions : 64% with diode laser> 62% with Nd: Yag laser > 48% with IPL</p> <p>8 sessions: 92% with diode laser> 90% with Nd: YAG >70% with IPL .</p>	Nd:Yag had lesser side effects than Diode
2	Bouzari et al ²⁸	Retrospective study comparing Nd Yag(n-11), Diode(n-30) and Alexandrite(n-29) lasers	The 755-nm alexandrite and the 800-nm diode laser have almost equal efficacy, whereas the Nd:YAG laser was the least efficacious.	The overall occurrence of side effects in patients who were treated with Nd:YAG (45%), alexandrite (40%), and diode (46%) was not different.

3	Ibrahim et al ²⁹	Comparing Nd-Yag (n-35), Alexandrite laser(n-33) and Diode laser(n-32) in skin type 4-6	Percentage hair reduction at 6 months- 50% with Nd-Yag laser, 50% with Alexandrite laser and 60% with Diode laser All three laser systems gave comparable long-term results (at 6 months and 12months)	The safest laser system for skin types IV, V, and VI was Nd-Yag laser.
4	C.S.Haak et al ³⁰	31 patients with normal testosterone levels received six sitting, split-face with IPL (525–1200 nm)and LPDL(810nm)	IPL and LPDL reduced hair counts significantly, with median reductions from baseline of 77%, 53% and 40% for IPL and 68%, 60% and 34% for LDPL at 1, 3 and 6 months, respectively.	Pain scores were consistently higher for IPL [median 6, interquartile range (IQR) 4–7] than LPDL (median 3, IQR 2–5) .
5	Safa et al ³¹	n-55 RCT comparing IPL and diode laser	Percentage hair reduction after 2 sessions 45% with diode, 30% with IPL 4 sessions-58% with diode, 37% with IPL. 6 sessions -80% with diode 42% with IPL	No dangerous or permanent damage were observed with both methods.

FACTORS AFFECTING OUTCOMES OF THE LASER THERAPY

1. **Patient Factors-** An ideal patient for laser therapy is one who has thick, dark terminal hairs, light skin, and normal hormonal status.

- **Skin Type-** Light skin (Fitzpatrick skin type I-IV) and dark hair are an ideal combination for effective hair reduction. The absorption is more at the level of follicular melanin rather than epidermal melanin, hence reducing the chances of epidermal damage. The safety of patients with type V-VI skin is a challenge for laser hair reduction because of the high density of competing chromophore in the epidermis⁵.

Adrian et al³² did study with diode laser in African-American patients and stated that diode lasers can be used safely in skin type V and VI patients. Longer pulse durations enabled the delivery of higher fluences with minor and acceptable side effects.

- **Type of Hair, Color of Hair, and Stage of Hair Cycle-**The anagen hair is more prone to laser therapy since melanin is present only in anagen hair. Terminal hair, being more pigmented, responds better than vellus hair. This is true when treating areas such as the upper lip, where chromophore in vellus hairs is less for laser wavelength absorption.
- **Hormonal Profile-** Polycystic ovarian syndrome, thyroid dysfunctions, adrenal hyperplasias, and hyperprolactinemia are hormonal dysfunctions that influence hair regrowth following laser hair reduction⁵.

Nabi et al⁷ did comparative study of the clinico-trichoscopic response to treatment of hirsutism with Nd:YAG laser (1064 nm) in idiopathic hirsutism and polycystic ovarian syndrome patients. After sixth sessions of laser therapy, more than 75% reduction was seen in 70% of patients in group A (idiopathic hirsutism) and in 54% of patients in group B (polycystic ovary disease). After 3 months of follow-up of the last laser session, it was found that the results persisted in patients with idiopathic cause than in those due to PCOD.

- **Site of Hair Removal-**Since there are differences in anagen-telogen ratios in various anatomic sites, there may be differences in response rates. Axillae and belt areas respond better than legs, arms, and chest.

Nanda et al³³ conducted a prospective study on 200 female patients (skin type IV-V) underwent treatment with Nd:YAG laser. Result in patients with lower face was less than that of chin or upper lip.

2. TYPE OF LASER, PARAMETERS, AND NUMBER OF SITTING

- Neerja et al³⁴ did a study that compared the efficacy of 3 laser devices: a mean hair reduction of 59.5%, 70.3%, and 47.4% was reported after 3 sessions with diode, alexandrite, and Nd:YAG laser respectively. (5)The Nd:YAG laser is considered safest in treating darker skin .
- Pai et al³⁵ compared the safety and efficacy of a low-fluence, high-repetition rate (Group 1) versus a high-fluence, low-repetition rate (Group 2) with 810-nm diode laser for permanent hair reduction in patients with facial hirsutism. The median reduction of hair was 90.5% and 85% in group 1 and group 2 respectively. Also, Low fluence and high repetition did show a significant reduction in hair thickness and a low pain score.
- Mittal et al²³ investigated the safety and efficacy of 1064 nm Nd:YAG laser hair reduction in relation to multiple treatment sessions and different hair types in Indian patients. At the end of the 3rd, 4th, 5th, and 6th sessions, percentage of patients whose facial hair converted to thin vellus hair were 5, 15, 25, and 56% respectively of all the patients and concluded that the effectiveness of laser sessions was directly dependent upon the number of sessions.

COMPLICATIONS OF LASER PROCEDURES

It may be classified as immediate (up to 7 days), transient (1–6 weeks) and persistent (after 6 weeks)³⁶ (Table 2)

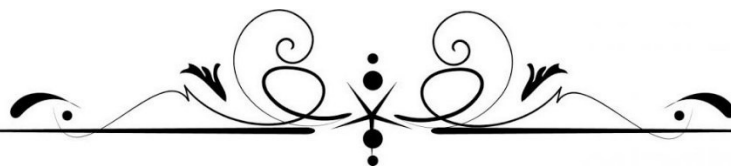
Table 3. Side effects of LASER procedure

IMMEDIATE	TRANSIENT	PERSISTENT
Pain	Acneiform eruptions	Paradoxical hypertrichosis
Erythema	Folliculitis	Undesired styling of hair
Perifollicular edema	Reticulate erythema	Ocular complications
Superficial thrombophlebitis	Postinflammatory	Leucotrichia
Cold urticaria	dyspigmentation	

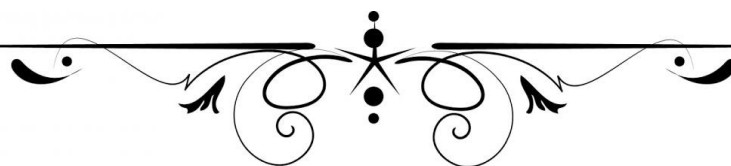
Table given below summarizes few studies on safety of diode laser for hair reduction. (Table 4).

Table 4. Studies related to diode laser induced complications
(n=sample size)

S.No	Author	Details	Parameters	Side effects
1	Ibrahim et al ²⁹	n-32	Diode Laser with Pulse duration 40ms, spot size 9mm, fluence 20-40 J/cm ²	Redness(68.7%), burn(30.3%), scarring(6.2%) hyperpigmentation(31%), hypopigmentation(5%)
2	Greppi et al ³⁷	n-8 Fitzpatrick skin type V–VI	Fluence of 10 J/cm ² , pulse duration 30 ms and averaged 7 – 10 treatment sessions every 4–6 weeks	2 patients developed blistering, crusting, and hypopigmentation that resolved within 2 months 3 patients developed hyperpigmentation, which cleared by 4 months
3	Magdalena et al ³⁸	n-217 Fitzpatrick skin type - I-VI	pulse duration between 15 and 400 ms Fluence-10-100J/cm ²	Multiple side effects were observed ten times more frequently in groups of Black and Mixed-race participants than in White and Asian groups Sensitivity (44.1%), burns (24.1%), hyperpigmentation (24.1%), and erythema (14.5%) Number of treatments had a significant impact on the incidence of erythema and burns



MATERIALS & METHODS



MATERIALS & METHODS

STUDY SETTING:

This study was conducted on patients of hirsutism who attended the Dermatology, Venereology and Leprology OPD at AIIMS Jodhpur.

STUDY DESIGN:

Prospective observational study

STUDY PARTICIPANTS:

Patients of hirsutism attending the Department of Dermatology, Venereology and Leprology OPD at AIIMS Jodhpur were recruited.

The inclusion and exclusion criteria were taken as follows:

Inclusion criteria:

Patients fulfilling all the following criteria were included in the study, after informed written consent.

1. Females with hirsutism
2. Age \geq 18 years

Exclusion criteria:

Following patient were excluded from the study.

1. Pregnancy and Lactation
2. Patients with photosensitivity or photo-aggravated skin diseases
3. History of keloid formation
4. Patients with skin malignancies
5. Treatment area with active cutaneous infections

SAMPLING

Sample size for the study was based on the results obtained by M Mohamed et al² who found that after 1 session of laser treatment, the terminal/vellus hair ratio changes from 72.5 ± 14.7 at baseline to 62 ± 13.9 .

Considering this for the effect size calculation, we estimated a sample size of **73 patients** at 95% confidence interval, 80% power and 10% contingency.

STUDY DURATION

Jan 2020 to June 2021 (18 months)

ETHICAL CONSIDERATIONS:

Thesis proposal was approved by the Institutional Ethics Committee, All India Institute of Medical Sciences, Jodhpur (Annexure 1). At the time of recruitment, a detailed explanation of the study protocol was provided to the participants, following which written informed consent was obtained before enrolment.

STUDY PROCEDURE:

Evaluation

1. Detailed history including demography, age of onset, rate of onset of symptoms, any symptoms of virilisation (acne, deepening of voice, infrequent menstruation, etc), history of weight gain or diabetes, drug history prior to onset, family history, frequency of hair reduction.
2. Complete general physical and systemic examination including body mass Index, Fitzpatrick skin type, extend of involvement along with modified Ferriman-Gallwey score and signs of hyperandrogenism (acne, cliteromegaly)
3. Hormonal profile (Testosterone , Dehydroepiandrosterone sulfate (DHEAS), LH,FSH , Prolactin, TSH) and Pelvic ultrasonography advised in all patients.

4. After informed consent, subjects will undergo treatment with 805 nm diode laser (Light Sheer Desire Light Model, Lumenis) (Figure 2) using 12 mm spot size and pulse duration of 30ms. Diode laser is done with fluence 18-20 J/cm² in first treatment. On subsequent treatments ,fluence will be increased by 2-4 J/cm² depending on subjects tolerance upto maximum of 34J/cm². Laser shots were given with an overlap of 10-20%.
5. The treatment was repeated every 4 weekly with goal of 6 sessions.
6. Clinical and trichoscopic evaluation along with photographs were obtained at baseline, third visit and sixth visit.
7. Clinical parameters used were modified Ferriman-Gallwey score of face (0-4), percentage reduction (patient reported) , Investigator assessment (-3 to +3), frequency of hair removal and predominant hair type.
8. Trichoscopy was done using Dermlite DL4 with magnification of 10x. (Figure 3).
9. Trichoscopic parameters included total hair count, terminal hair count, vellus hair count, terminal/vellus hair (per field) done for 4 fixed sites including sidelocks, chin, upper lip and submandibular area. Hair counting was done manually from prints of the photographs taken.
10. Side effects if any was noted in every sitting and treated accordingly.(Figure 4,5)

TECHNIQUE OF LASER

1. Positioning the patient comfortably.
2. Removal of hair using razor before the procedure
3. Eye protection for both the operator and the patient was used
4. Individualize the parameters to each patient's skin and hair type and the type of laser being used (Starting with a fluence of 18-20J/cm² and pulse duration of 30 ms)
5. The handpiece placed perpendicular to the skin and it is pressed down gently but firmly to bring the follicles close to the surface and temporarily decrease the blood supply to the treatment area.
6. Mild erythema considered as end-point for the procedure.

Post-Procedure Care

1. Although our machine had inbuilt cooling system, ice packs was used post-procedure to minimize pain and swelling.
2. Strict sun protection and sunscreens advised for all patients .
3. Topical steroid creams prescribed if excessive erythema, burns or swelling seen.

STATISTICAL ANALYSIS:

Data was entered in excel sheet and analysed using Statistical Package for Social Sciences (SPSS) version 25. All quantitative variables were estimated using measures of central tendency (Mean and median). Descriptive analysis was done for patient demographics and clinical variables (Polycystic ovary disease, Body mass index, hyperandrogenic features, family history) and side effects. As the data was not normally distributed, Friedman's Test was done to compare trichoscopy (total hair, terminal hair, vellus hair, terminal /vellus hair) and clinical parameters like modified Ferriman-Gallwey score. Predominant hair type assessed using Cochran Q test. Investigator assessment and percentage reduction was analysed using Wilcoxon Signed Ranks Test. P value <0.05 will be taken as significant and <0.01 taken as very significant.



Figure 2. Diode laser : Light Sherr Desire Light(805 nm)



Figure 3. Dermoscope (Dermlite DL4™)

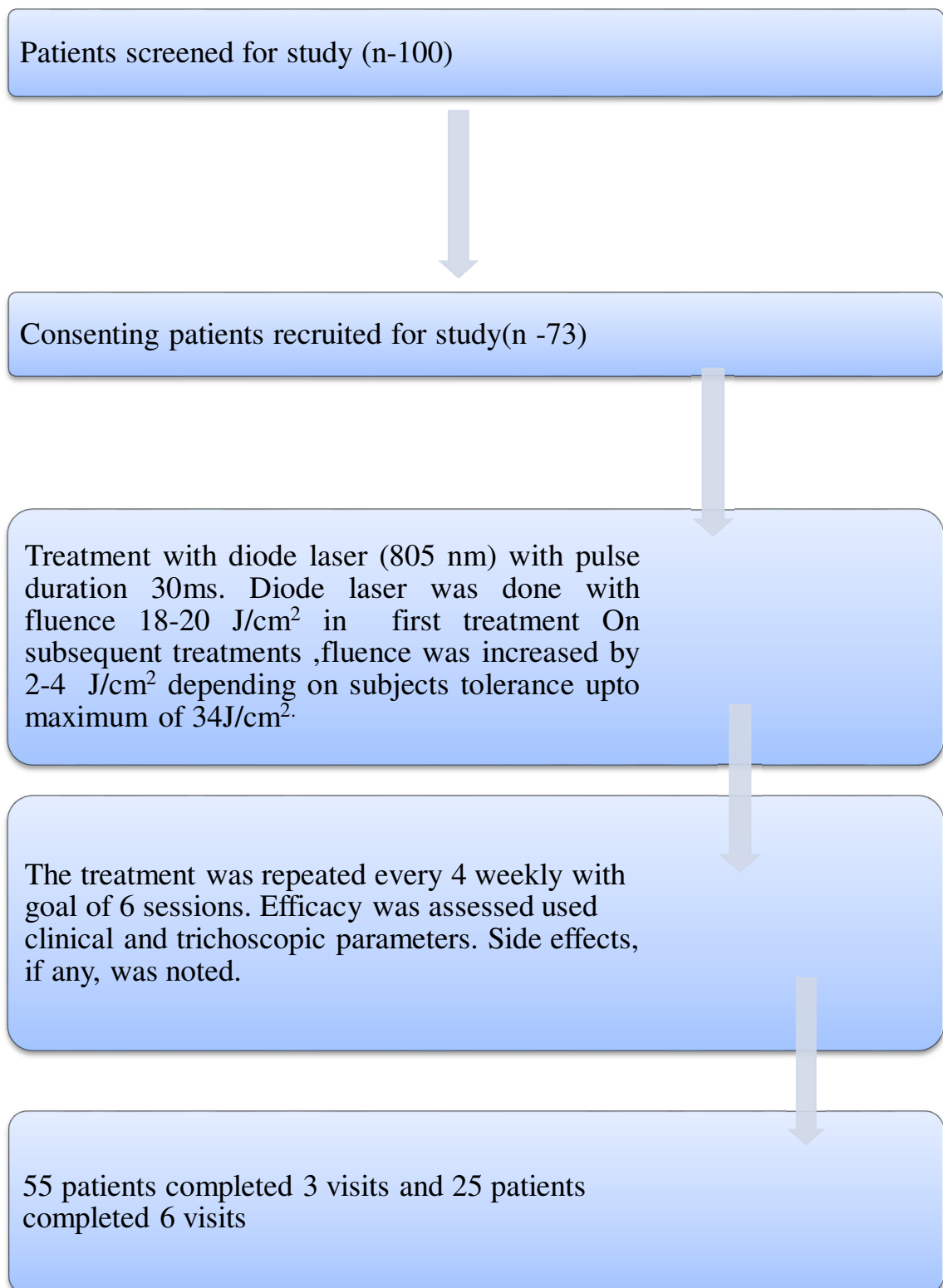


Figure 4. Study flow diagram

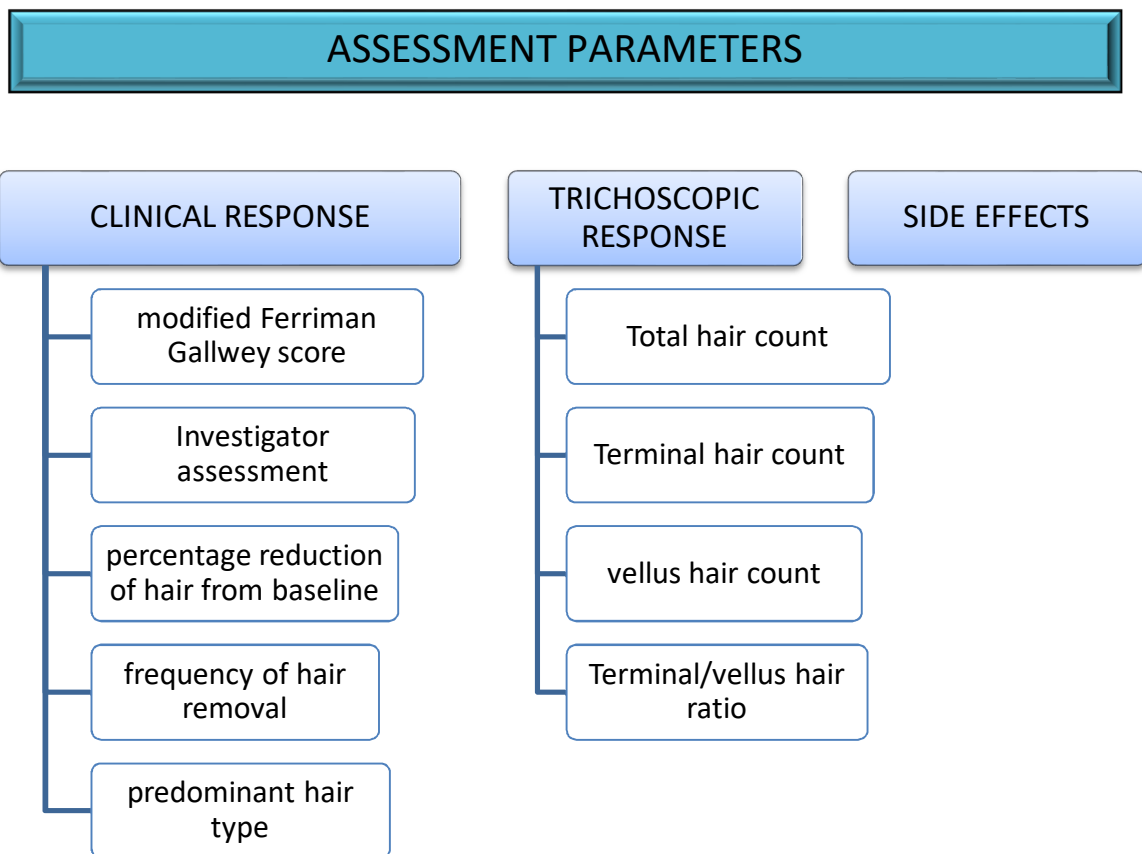
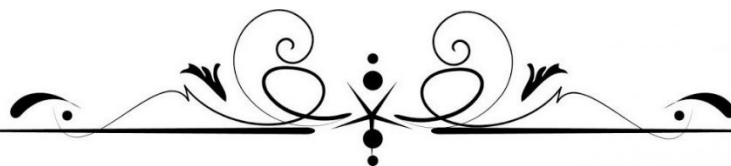
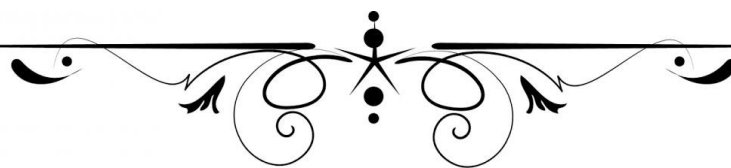


Figure 5. Assessment parameters



RESULTS



RESULTS

During the study period, a total of 100 patients of hirsutism were screened at the Dermatology, Venereology and Leprology out-patient department (OPD) at AIIMS, Jodhpur. Seventy three patients with hirsutism fulfilling the inclusion criteria gave informed written consent and were considered as participants of this study.

Demographic data

All the patients were females of age ranging from 18 years to 43 years with a mean of 26.37 \pm 5.825 years. Among all age groups, most patients were found in the age group 18-24 years [32 (43.8%)] followed by 25-31 years [27 (37%)] and 32-38years [11(15.1%)] (Figure 6). Majority of the recruited patients were students [24 (32.9%)], followed by housewife [21 (28.8%)]. (Figure 7). Majority of the patients were unmarried 45(61.6%) (Table 5).

Table 5. Distribution of demographic characteristics of study subjects (n=73)

S.No	Demographic characteristics	n	%
1	Age (years)		
	18-24	32	43.8
	25-31	27	37
	32-38	11	15.1
	39-43	3	4.1
2	Sex		
	Female	73	100
3	Occupation		
	Student	24	32.9
	Housewife	21	28.8
	Doctor	13	17.8
	Other jobs	15	20.5

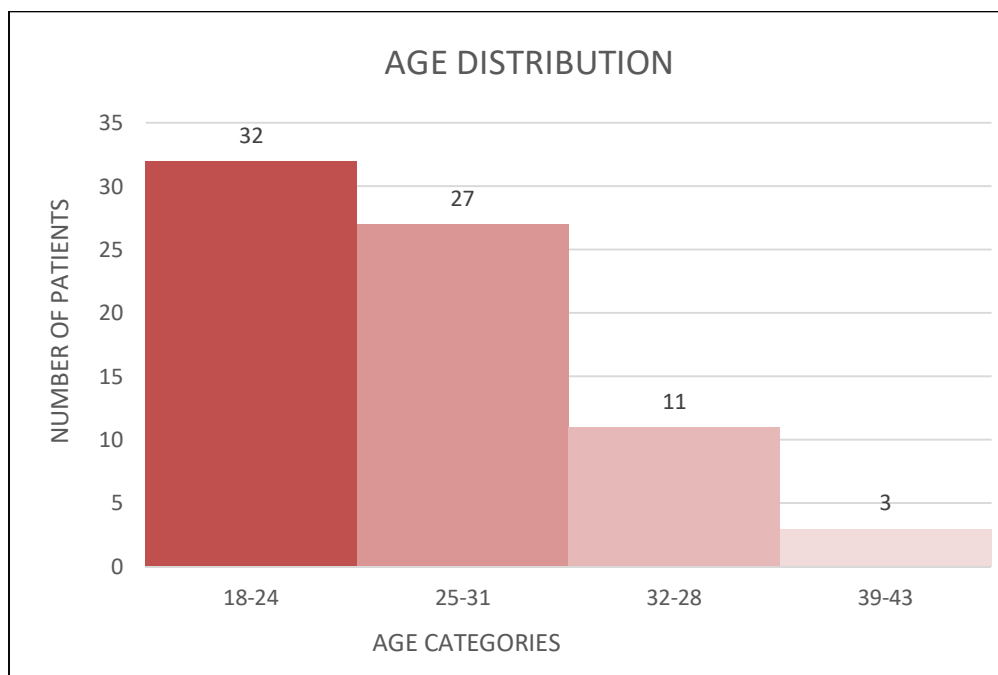


Figure 6 .Age distribution of study subjects

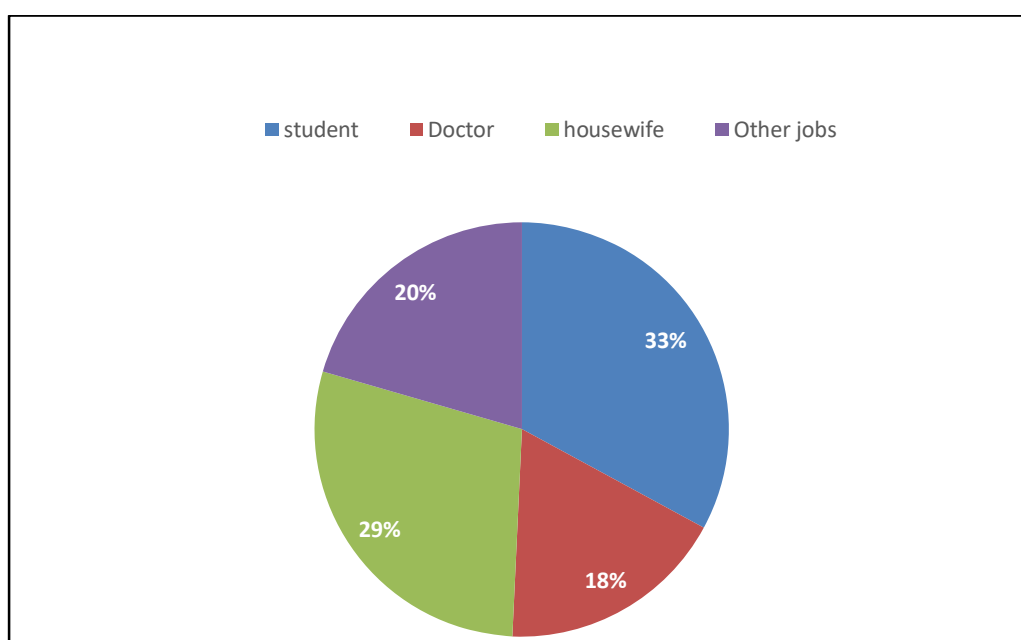


Figure 7. Distribution of occupation of study subjects

Basic clinical characteristics of patients

Menstrual cycles was irregular in 44 patients (60.3%) and was regular in 29 patients (39.7%). However criteria for PCOD was fulfilled in 41 patients (56.2%) (Figure 8). Two patients had comorbidities like diabetes (1) and hypothyroidism (1) (Figure 9). Features of hyperandrogenism like acne, seborrhea and alopecia were seen in 59 (80.8%) of patients. Family history of hirsutism was present in 19 patients (26%) (Figure 10).

Total duration of hirsutism ranged from 0.5 to 15 years with a mean of 4.08 ± 2.83 years. Frequency of hair removal (variable hair removal methods like shaving, tweezing, threading) ranged from 0-60days with a mean of 14.85 ± 13.33 days. Few patients received treatments [23(31.5%)] including oral medications (15(20.5), and lasers [12(16.4)] (Figure 11). Some of them had to continue oral drugs (like OCP and spironolactone) in addition to laser [16(21.9%)] (Table 6).

Table 6: Baseline clinical characteristics (n=73)

S. No	Clinical characteristics	n	%
1	Menstrual history		
	Irregular	44	60.3
	Regular	29	39.7
2	PCOD		
	Present	41	56.2
	Absent	32	43.8
3	Comorbidities		
	Diabetes	1	1.4
	Hypothyroidism	1	1.4
	Absent	71	97.2
4	Previous treatments	23	31.5
	Oral drugs	15	20.5
	Laser	12	16.4
5	Family history of hirsutism		
	Present	19	26
	Absent	54	74

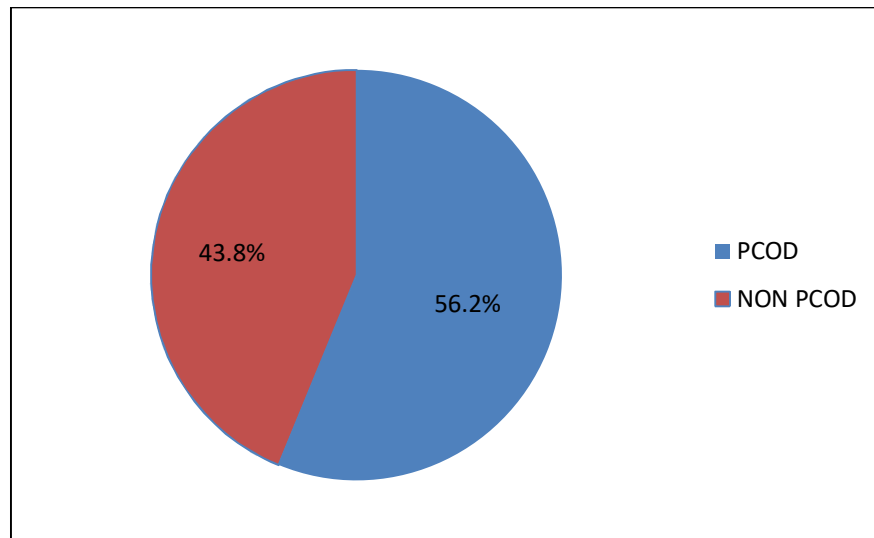


Figure 8. Distribution of PCOD patients

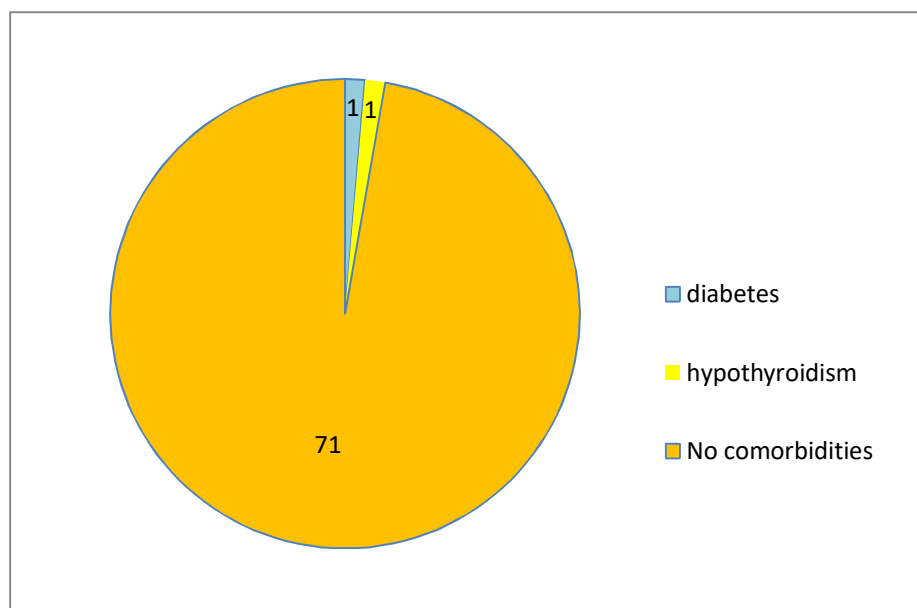


Figure 9. Distribution of comorbidities in patients

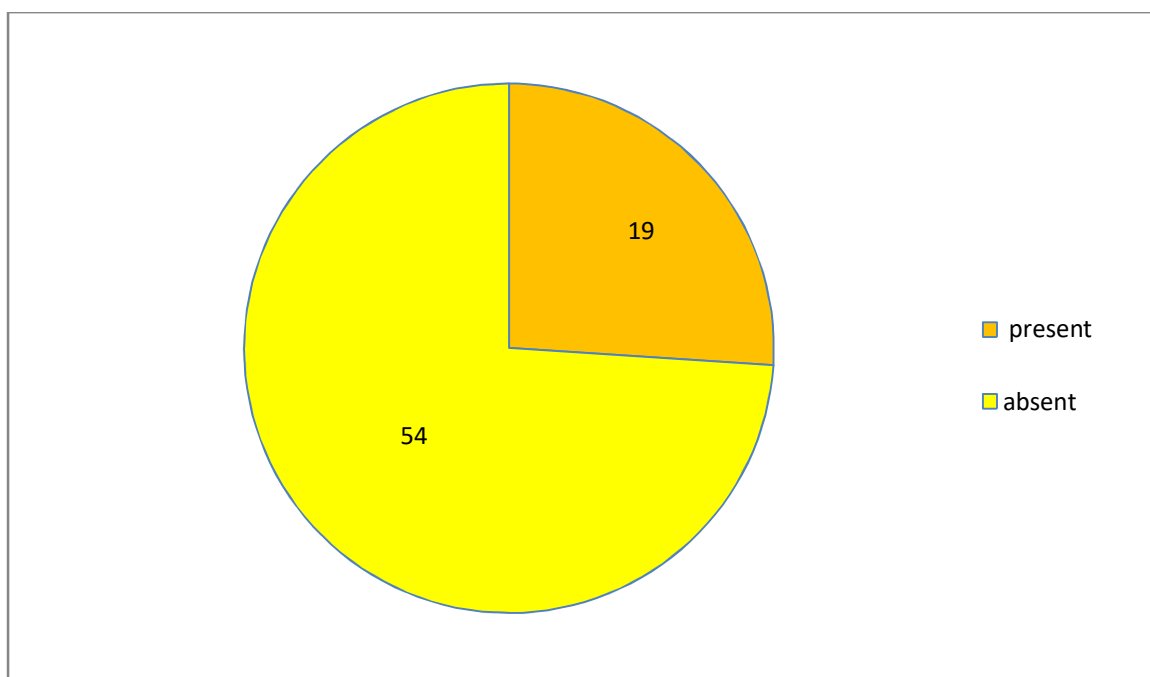


Figure 10 :Family history

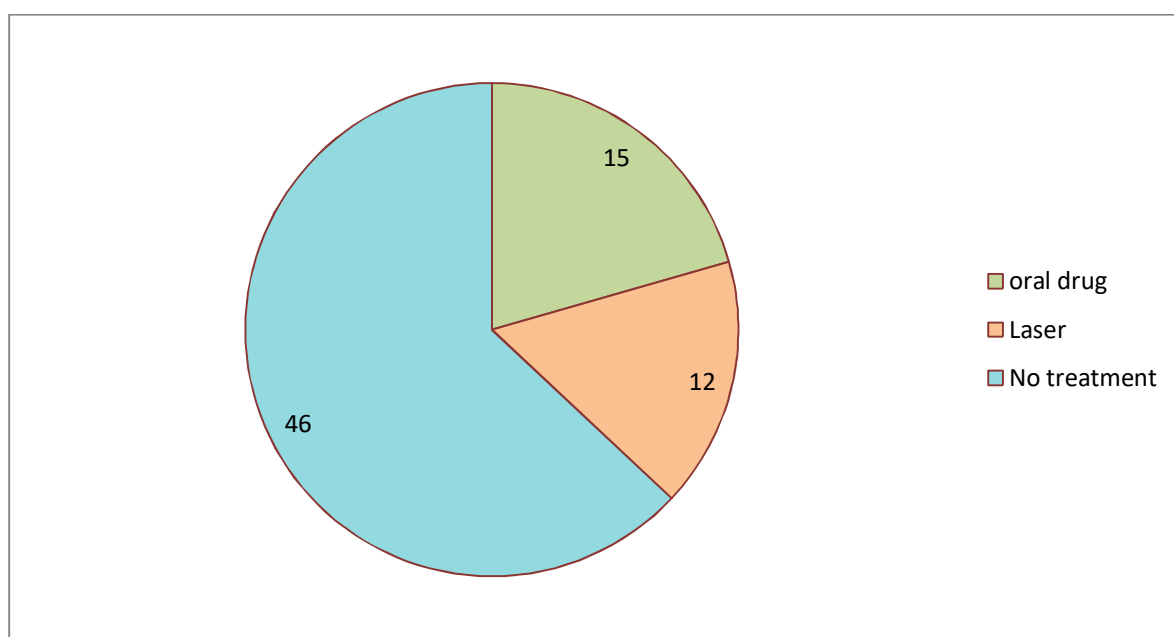


Figure 11 : Previous treatments

Baseline clinical assessment of patients

A) Majority of the patients were of Fitzpatrick skin type 4 [45(61.6%)], followed by type 3 [19 (26%)] and type 5 [8 (11%)] (Table 7) (Figure 12).

Table7: Fitzpatrick skin type (n=73)

Fitzpatrick skin type	n	%
1	0	0
2	1	1.4
3	19	26
4	45	61.6
5	8	11
6	0	0

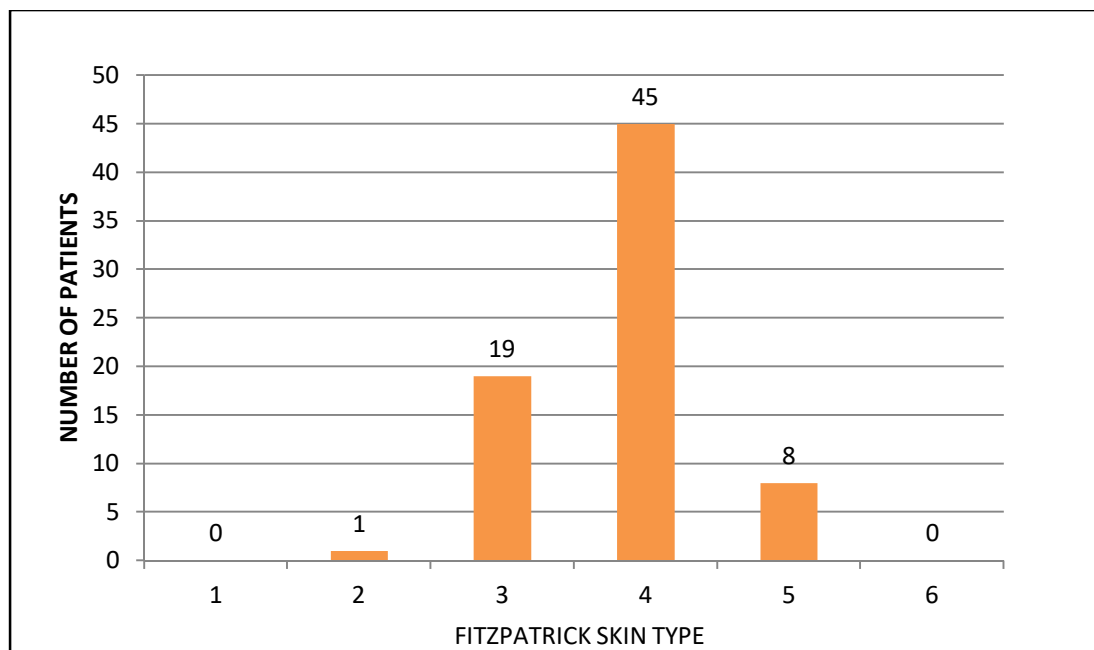


Figure 12. Distribution Fitzpatrick skin type of patients

B) Body mass index of patients ranged from 17.7 kg/m² to 33 kg/m² with mean being 23.24 kg/m². Most patients fell in BMI category 18.5-22.9 kg/m² [34 (46.6%)] followed by more than 25 kg/m² [21(28.8%)]. (Figure 13)(Table 8)

Table 8. Distribution of body mass index of patients (n=73)

BMI (in kg/m ²)	n	%
Under 18.5	1	1.4
18.5-22.9	34	46.6
23-24.9	17	23.3
25 and more	21	28.8

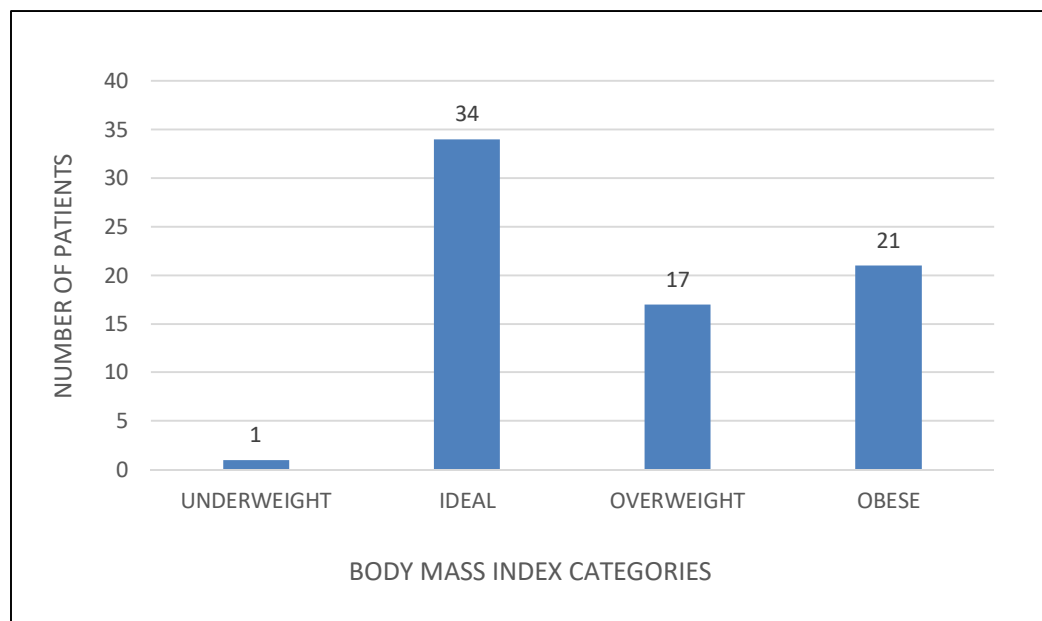


Figure 13 . Distribution of body mass index of patients

C) Baseline hair assessment of patient was done with modified Ferriman-Gallwey score which ranged from 6 to 20 with maximum people in group of mild hirsutism [60(82.2%)], followed by moderate hirsutism [11(15.1%)] (Table 9) (Figure 14).

Table 9. Distribution of modified Ferriman-Gallwey score of patients (n=73)

MFG	N	%
Less than 8	2	2.7
8-16	60	82.2
17-25	11	15.1
26-36	0	0

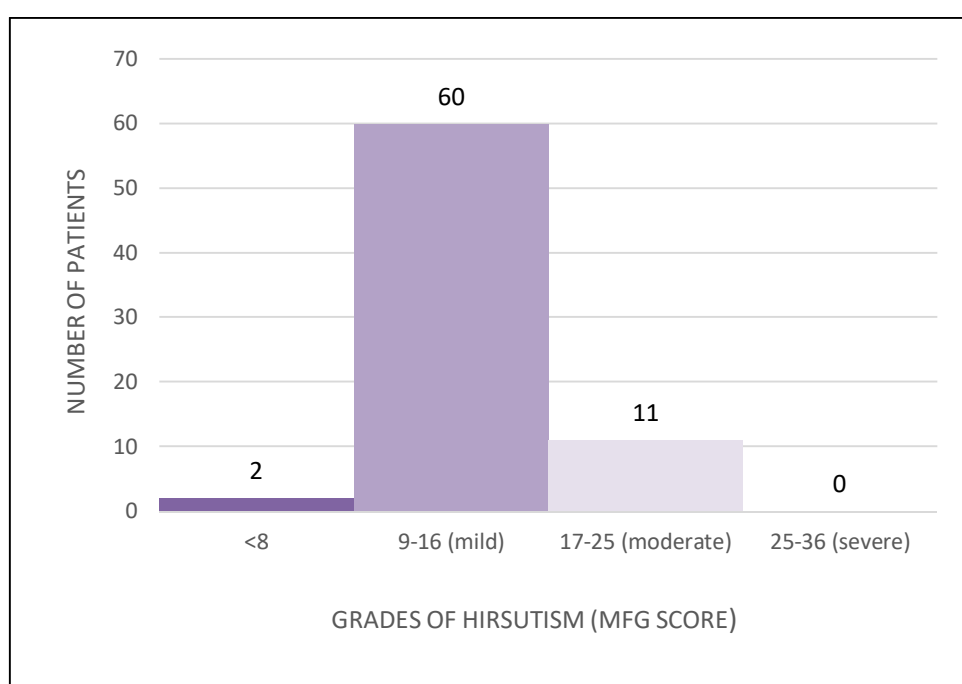


Figure 14: Distribution of modified Ferriman-Gallwey score of patients

D) Most commonly involved sites were chin [68(93.2%)] followed by upper lip [61(83.6%)], submandibular area [49(67.1%)] side-locks [27(37%)] (Table 10)(Figure 15).

Table 10. Sites of involvement *

Sites	n	%
Sidelocks	27	37
Chin	68	93.2
Upperlip	61	83.6
Submandibular area	49	67.1

*The values are not exclusive (Percentage (%) do not add up to 100%)

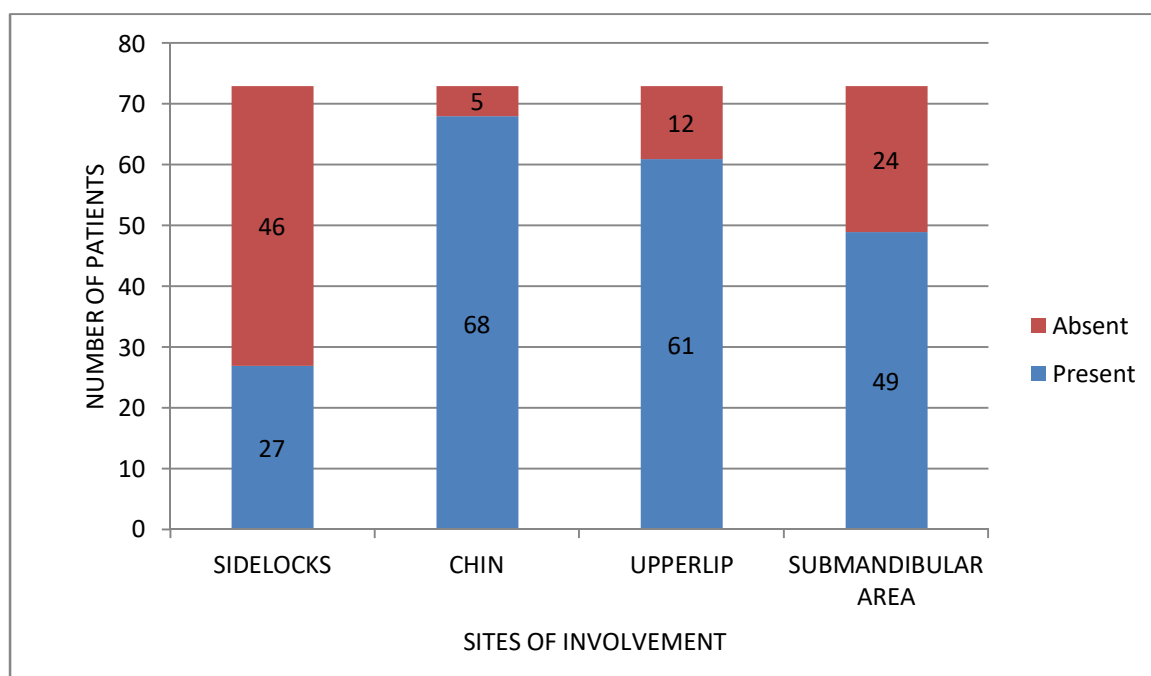


Figure 15: Distribution of sites of involvement

E) Hormonal Profile revealed high testosterone levels in 8 patients (11%) (Figure 16) whereas USG Pelvis showed features of PCOD in 23 patients (31.5%) (Figure 17)

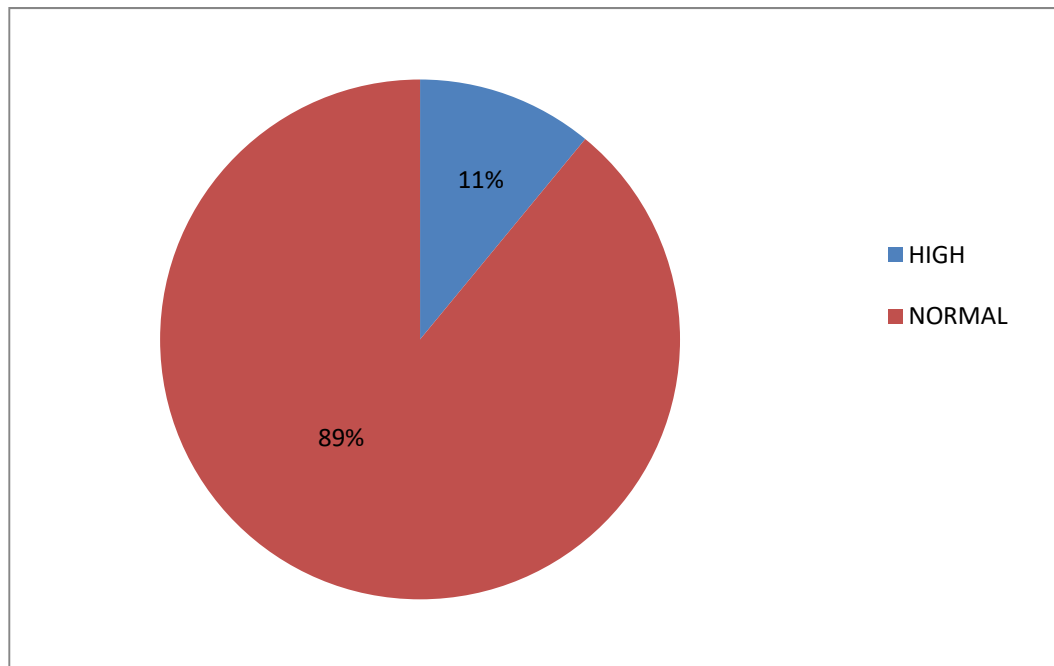


Figure 16. Testosterone levels

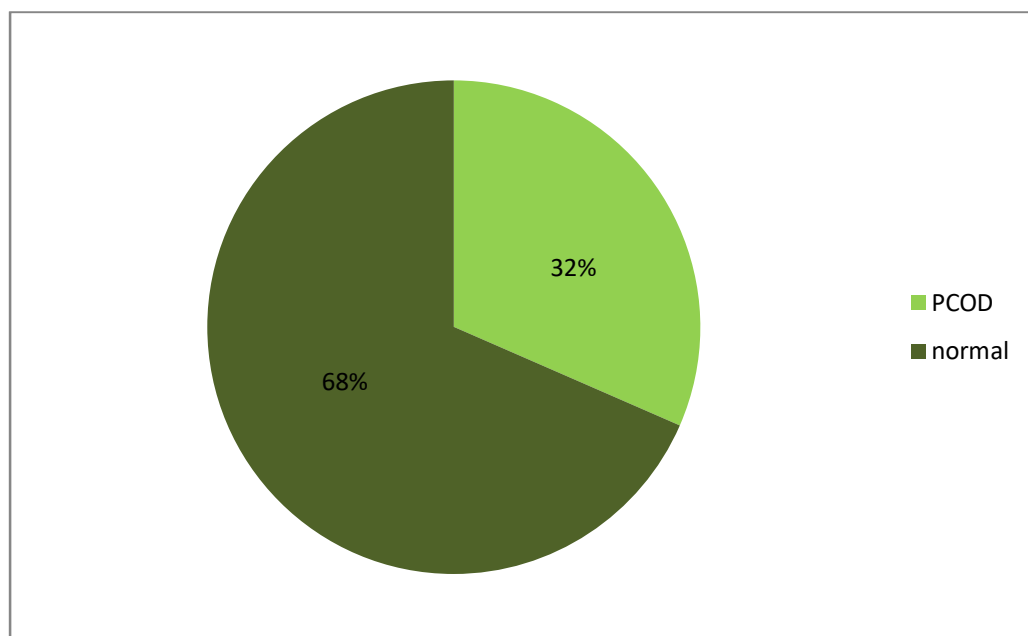


Figure 17. Ultrasound Pelvis

F) Though 6 visits were planned, not all patients were able to complete follow up. 55 patients completed 3 visits and 25 patients completed all 6 visits. (Table 11),(Figure 18)

Table 11: Number of treatments received by patients*

Number of treatment	n
1	73
2	62
3	55
4	53
5	26
6	25

The values are not exclusive (Percentage (%) do not add up to 100%)

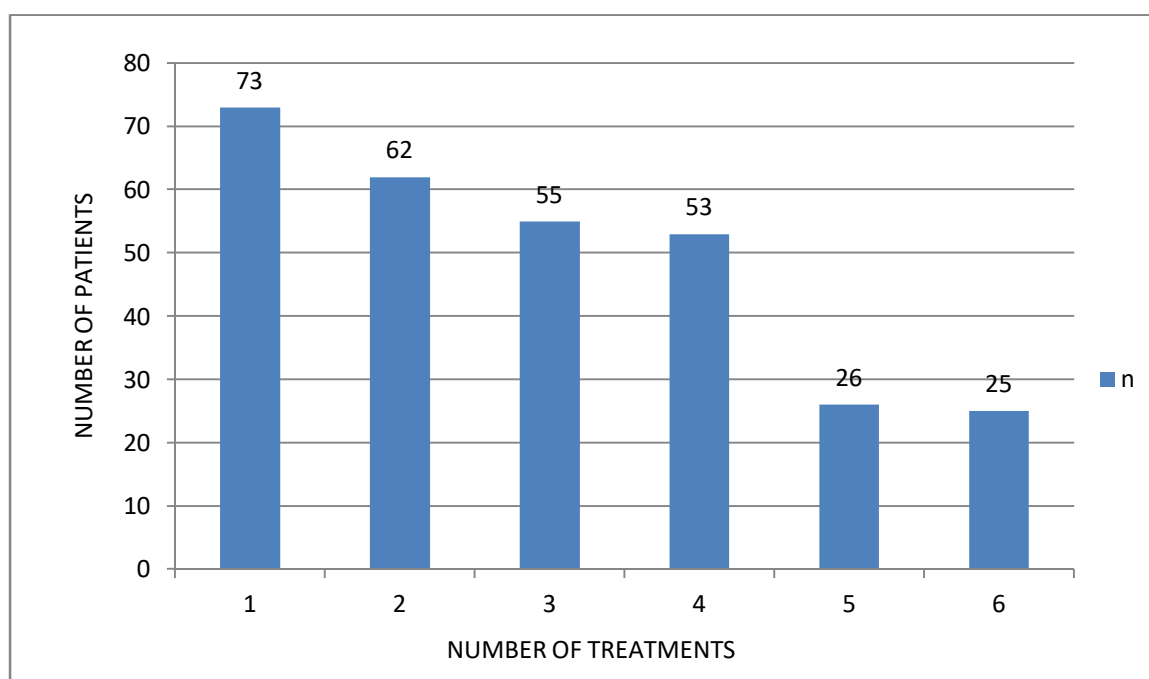


Figure 18. Number of treatment sessions received by patients

CLINICAL RESPONSE

Clinical parameters used for assessment included

1. Facial Modified Ferriman-Gallwey score
2. Predominant hair type
3. Investigators assessment tool
4. Patient reported hair reduction (in percentage)
5. Patient reported reduction in frequency of hair removal

1. FACIAL MODIFIED FERRIMAN-GALLWEY SCORE

Modified Ferriman-Gallwey score on face reduced with repeated sessions. Median at first, third and sixth sitting are 3, 2 and 1 respectively. Reduction of facial MFG score from baseline was statistically very significant. ($P < 0.01$ using Friedman test) (Figure 19) (Table 12)

Table 12: Comparison of medians of Facial MFG score between baseline and follow up visits

	Median	Percentile 25	Percentile 75
MFG1	3	2	3
MFG3	2	1	2
MFG6	1	1	2

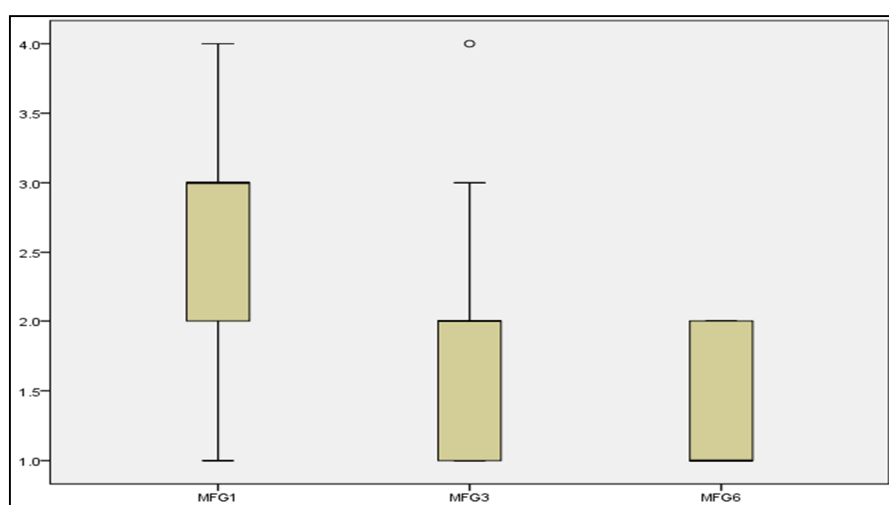


Figure 19: Comparison of Facial MFG score using boxplot

2. PREDOMINANT HAIR TYPE

Proportion of patients having terminal hair as the predominant hair type reduced with repeated sessions. Proportion of patients having predominantly terminal hair was 86.3 %, 69.1% and 48 % at first, third and sixth visit respectively (Table 13)(Figure 20).Reduction in proportion of patients having terminal hairs compared to baseline was statistically very significant. (P value- 0.002 using Cochran Q test)

Table 13: Comparison of predominant hair type between baseline and follow up visits

Predominant hair	First visit		Third visit		Sixth visit	
	n-73	%	n-55	%	n-25	%
Terminal hair	63	86.3	38	69.1	12	48
Vellus hair	10	13.7	17	30.9	13	52

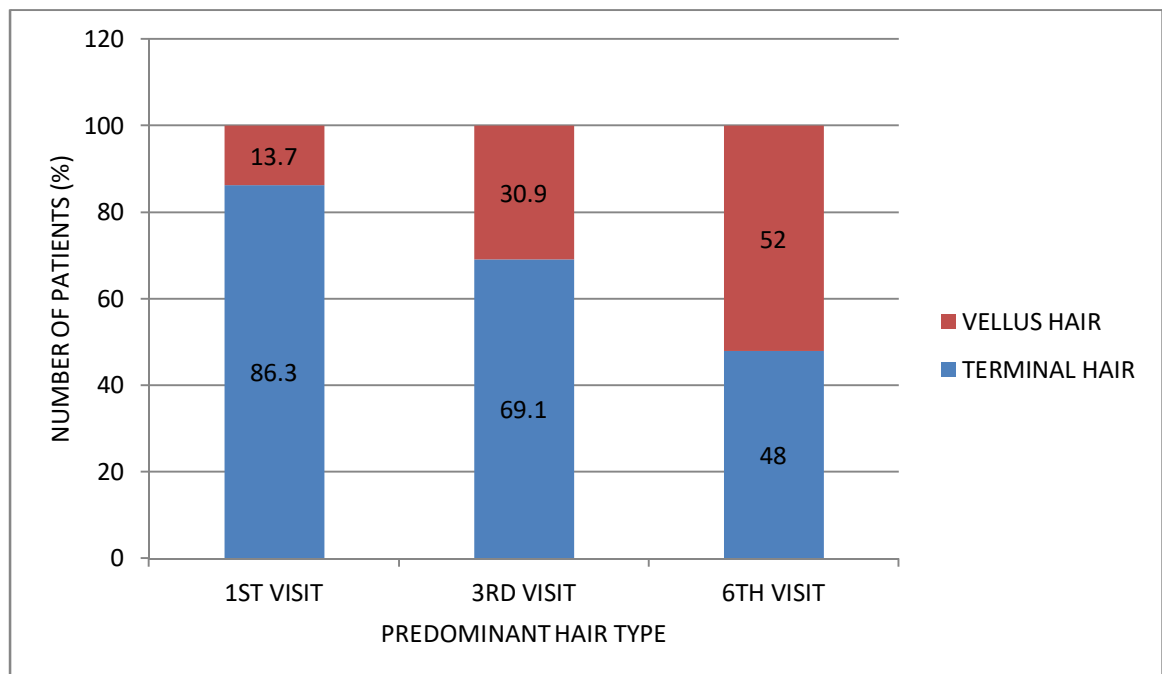


Figure 20: Comparison of predominant hair type between baseline and follow up visits

1. INVESTIGATOR ASSESSMENT

Median of Investigator assessment score at third and sixth visit is -2(moderately decreased) and -3(greatly decreased) respectively(Table 14), (Figure 21). Investigator assessment showed very significant hair reduction compared to baseline (p value- 0.008) (Wilcoxon signed Rank Test).

Table 14: Comparison of medians of Investigator Assessment at 3 months and 6 months

	Median	Percentile 25	Percentile 75
IA3	-2	-2	-1
IA6	-3	-3	-2

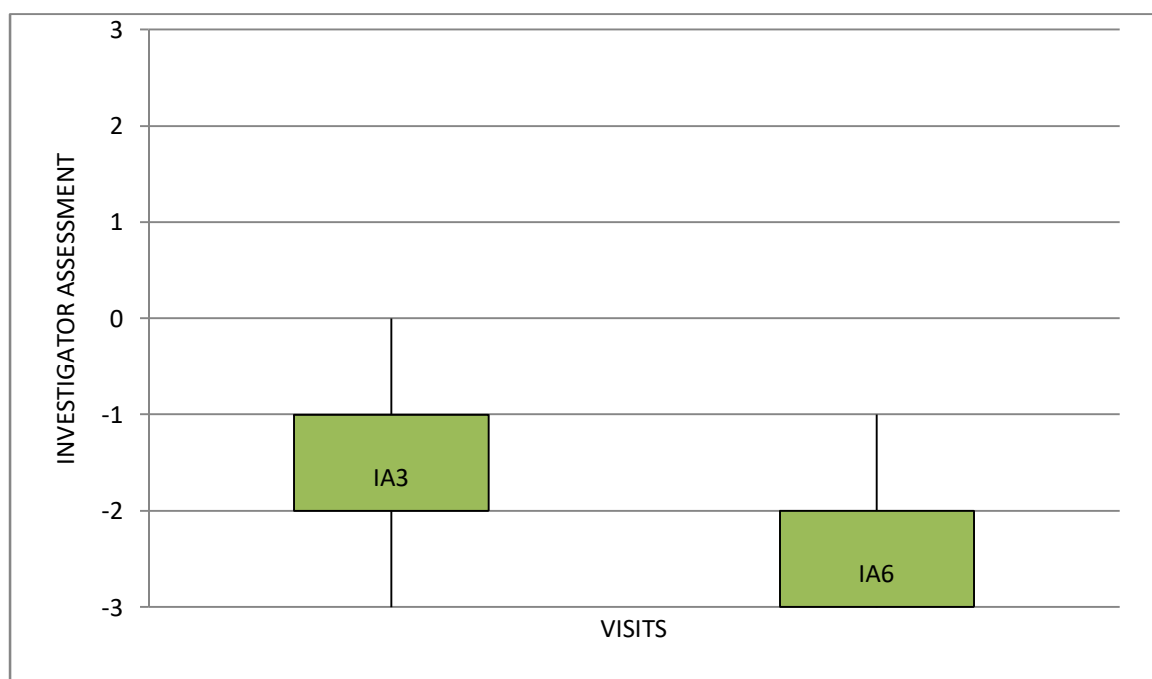


Figure 21: comparison of investigator assessment using boxplot

2. PERCENTAGE REDUCTION

- The mean percentage of patient reported hair reduction at third visit was 46.36% and at sixth visit was 66.80% which was statistically very significant when compared to baseline. (p value <0.01 using Wilcoxon signed Rank Test)
- No significant difference in hair reduction noted between PCOD group and Idiopathic hirsutism at third visit (p value- 0.423) or at sixth visit (p value- 0.152) (Mann Whitney Test)
- Also, no significant difference in hair reduction between patients receiving systemic treatment with laser and patients receiving laser alone (p value-0.724 at third visit and p value -0.303 at sixth visit) (Mann Whitney Test)

5. FREQUENCY OF HAIR REMOVAL

Hair removal frequency also reduced from once in 13.16 days at baseline to once in 69.8 days at sixth visit. (Table 15).(Figure 22). Hair removal frequency reduction from baseline was statistically very significantly at third visit (p value <0.01) and sixth visit (p value < 0.01) (Friedman test).

Table 15: Mean of frequency of hair removal and baseline and follow up visit

Visit	Frequency (in days)
1 ST	13.16+11.11
3 RD	52.8+37.28
6 TH	69.8+31.83

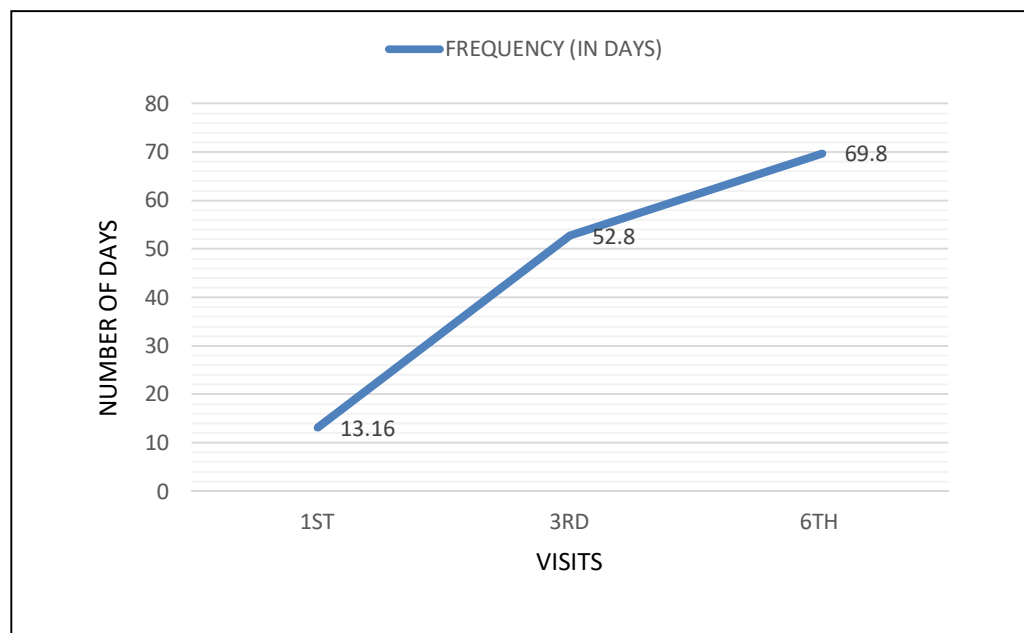


Figure 22: Comparison of frequency of hair removal at baseline and follow up visit

TRICHOSCOPIC ASSESSMENT

Trichoscopic parameters assessed were

1. Total hair count
2. Terminal hair count
3. Vellus hair count
4. Terminal/vellus hair ratio

They were assessed at 4 sites including: sidelocks , chin, upper lip and submandibular area

1. TOTAL HAIR COUNT

Total hair count reduced with repeated laser sittings. Reduction was statistically very significant compared to baseline in all four areas. The mean total hair count at sidelocks at baseline, third and sixth visit was 39.5, 28.79 and 25.45 respectively. The mean total hair count at chin at baseline, third and sixth visit was 38.16, 25.68 and 23.68 respectively. The mean total hair count at upperlip at baseline, third and sixth visit was 39.92, 30.16 and 23.56 respectively. The mean total hair count at submandibular area at baseline , third and sixth visit was 29.16, 18.84 and 16.88 respectively (Table 16),(Figure23)

Table 16: Comparing total hair count at baseline and at follow up visits

Sites	Mean(1 st)	Mean (3 rd)	Mean(6 th)	P-Value
Sidelocks	39.5	28.79	25.45	< 0.01
Chin	38.16	25.68	23.68	< 0.01
Upperlip	39.92	30.16	23.56	< 0.01
Submandibular area	29.16	18.84	16.88	< 0.01

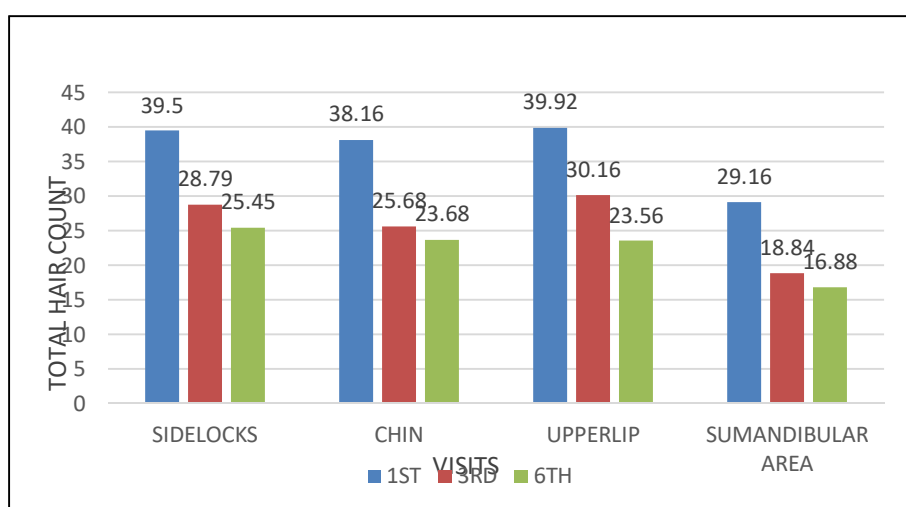


Figure 23: Comparing total hair count at baseline and at follow up visits

2. TERMINAL HAIR COUNT

Terminal hair count reduced with repeated laser sittings. Reduction was statistically very significant when compared to baseline in all four areas . The mean terminal hair count at sidelocks at baseline , third and sixth visit was 12.92, 9.36 and 4.16 respectively. The mean terminal hair count at chin at baseline , third and sixth visit was 17.48, 9.2 and 5.56 respectively. The mean terminal hair count at upperlip at baseline , third and sixth visit was 18.56, 11.96 and 5.84 respectively. The mean terminal hair count at submandibular area at baseline, third and sixth visit was 11.2, 4.52 and 3.48 respectively.(Table17),(Figure 24)

Table 17: Comparing terminal hair count at baseline and at follow up visits

Sites	Mean(1 st)	Mean (3 rd)	Mean(6 th)	P-Value
Sidelocks	12.92	9.36	4.16	< 0.01
Chin	17.48	9.2	5.56	< 0.01
Upperlip	18.56	11.96	5.84	< 0.01
Submandibular area	11.2	4.52	3.48	< 0.01

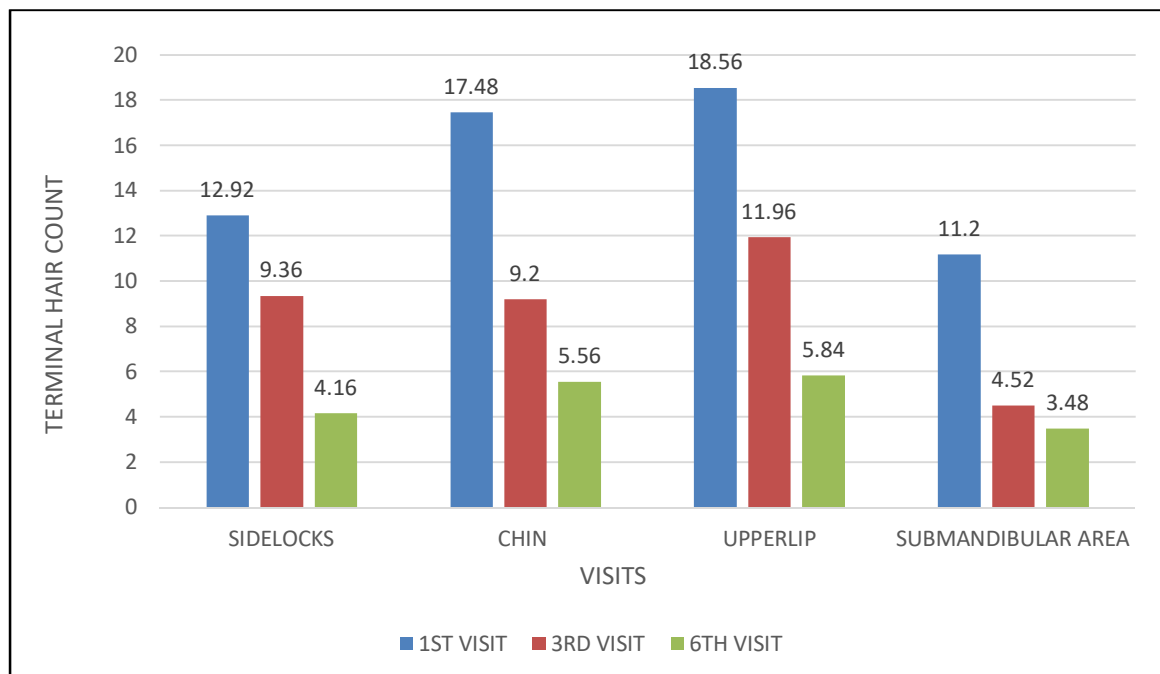


Figure 24 : Comparing terminal hair count at baseline and at follow up visits

3. VELLUS HAIR COUNT

Vellus hair count reduced with repeated laser sittings. Reduction was statistically very significant only in sidelocks. The mean vellus hair count at sidelocks at baseline, third and sixth visit was 25.48, 20.12 and 21.12 respectively. . The mean vellus hair count at chin at baseline, third and sixth visit was 20.68, 16.48 and 17.04 respectively. The mean vellus hair count at upperlip at baseline , third and sixth visit was 21.36,18.20 and 17.72 respectively. The mean vellus hair count at submandibular area at baseline, third and sixth visit was 17.96,14.32 and 13.44 respectively (Table 18)(Figure 25).

Table 18 : Comparing vellus hair count at baseline and at follow up visits

Sites	Mean(1 st)	Mean (3 rd)	Mean(6 th)	P-Value
Sidelocks	25.48	20.12	21.12	< 0.01
Chin	20.68	16.48	17.04	0.331
Upperlip	21.36	18.2	17.72	0.057
Submandibular area	17.96	14.32	13.44	0.224

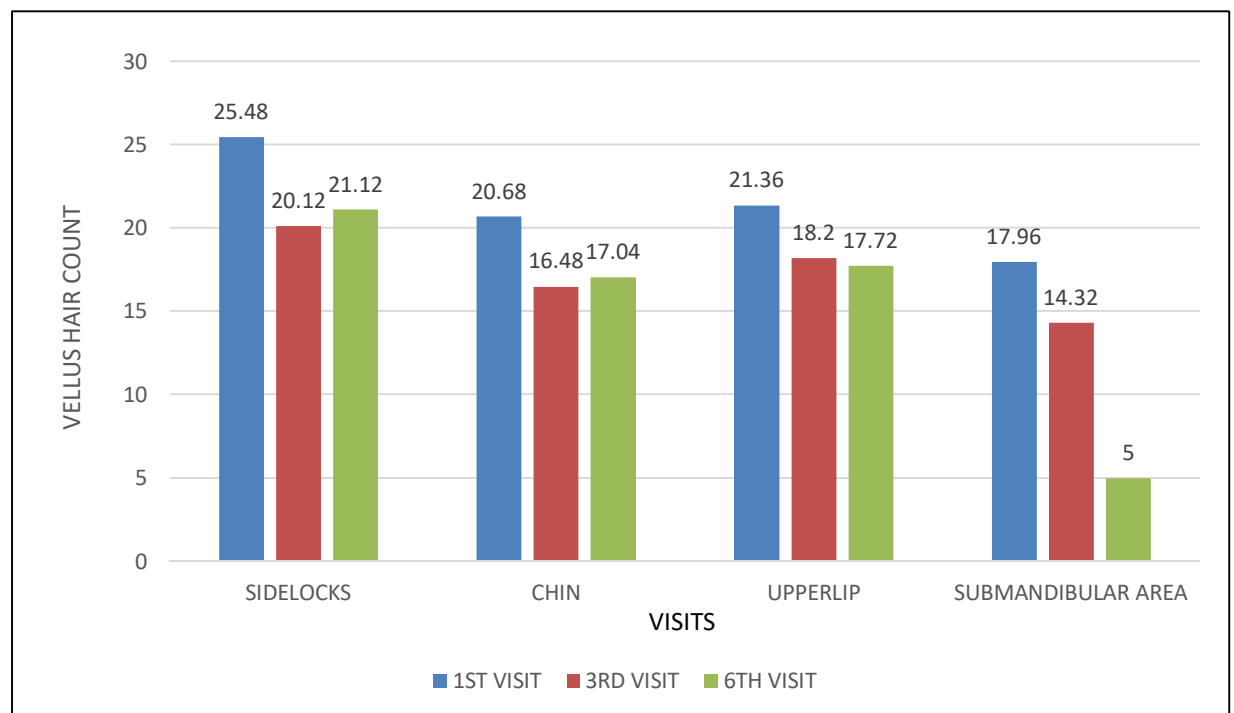


Figure 25: Comparing vellus hair count at baseline and at follow up visits

4. TERMINAL/VELLUS HAIR RATIO

Terminal/vellus hair ratio reduced with repeated laser sittings. Reduction was statistically significant in all four areas. The mean terminal/vellus hair ratio at sidelocks at baseline , third and sixth visit was 0.47,0.47 and 0.61 respectively. The mean terminal/vellus hair ratio at chin at baseline , third and sixth visit was 0.98,0.62 and 0.39 respectively The mean terminal/vellus hair ratio at upperlip at baseline , third and sixth visit was 0.98,0.64 and 0.29 respectively The mean terminal/vellus hair ratio at submandibular area at baseline , third and sixth visit was 0.76, 0.44 and 0.29 respectively. (Table 19),(Figure 26)

Table 19 : Comparing terminal /vellus hair count at baseline and at follow up visits

Sites	Mean(1 st)	Mean (3 rd)	Mean(6 th)	P-Value
Sidelocks	0.47	0.47	0.61	0.012
Chin	0.98	0.62	0.39	< 0.01
Upperlip	0.98	0.64	0.29	< 0.01
Submandibular area	0.76	0.44	0.29	< 0.01

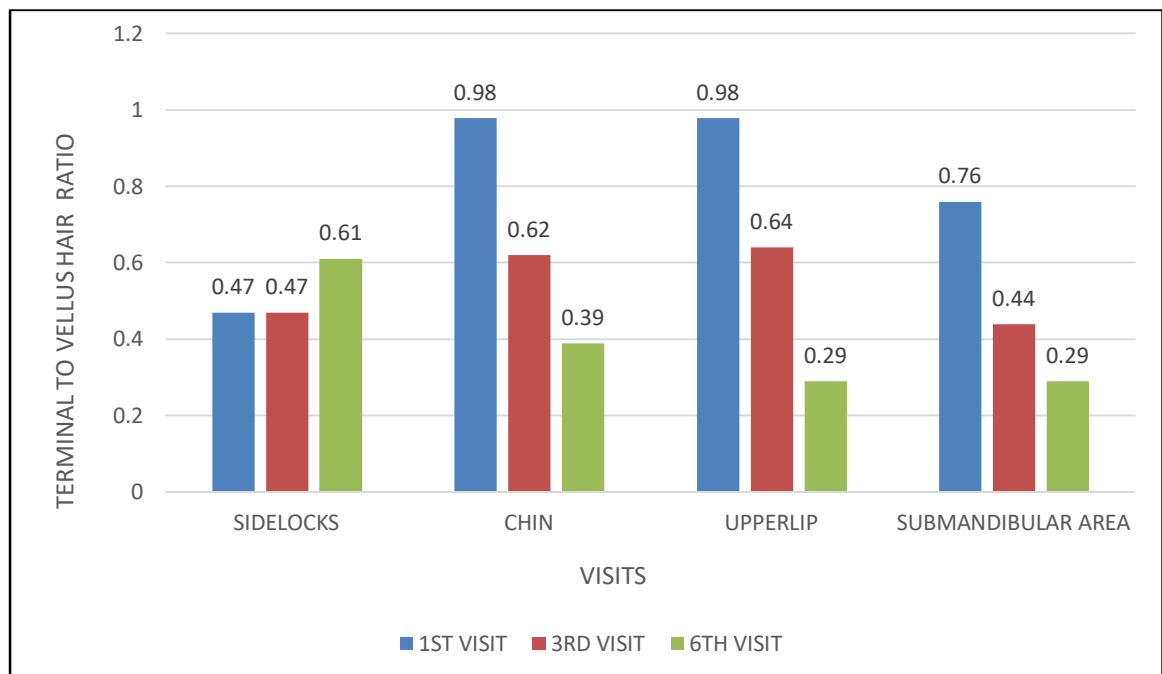


Figure 26: Comparing terminal /vellus hair count at baseline and at follow up visits

SIDE EFFECTS

Most common side effect noted in our study was pain [71(97.3%)] followed by erythema [65(89%)] and perifollicular edema [61(83.6%)]. Pain was mild and very transient resolved immediately after the procedure. Erythema and perifollicular edema mostly resolved in minutes to hours. Patients were advised application of mid potent steroid along with strict sunprotection if erythema persisted.

Mild superficial burns[8(11%)] followed by hyperpigmentation[5(6.8%)] noted in few patients mostly in Fitzpatrick 4,5. Ice application along with midpotent steroids for 2 days was advised in case of burns. Pigmentary changes resolved spontaneously or with mild depigmenting agents in 1-2 months in all patients. Paradoxical hair growth in form of multiple small vellus hair seen in 2 patients. Acneform eruptions and herpes labialis seen in 1 patient each.(Table 20)(Figure 27)

Table 20 : Frequency of side effects

Side effects	n*	%
Pain	71	97.3
Erythema	65	89
Perifollicular edema	61	83.6
Burns	8	11
Dyspigmentation	5	6.8
Paradoxical hair growth	2	2.7
Acneform eruption	1	1.4
Herpes labialis	1	1.4

*The values are not exclusive (Percentage (%) do not add up to 100%)

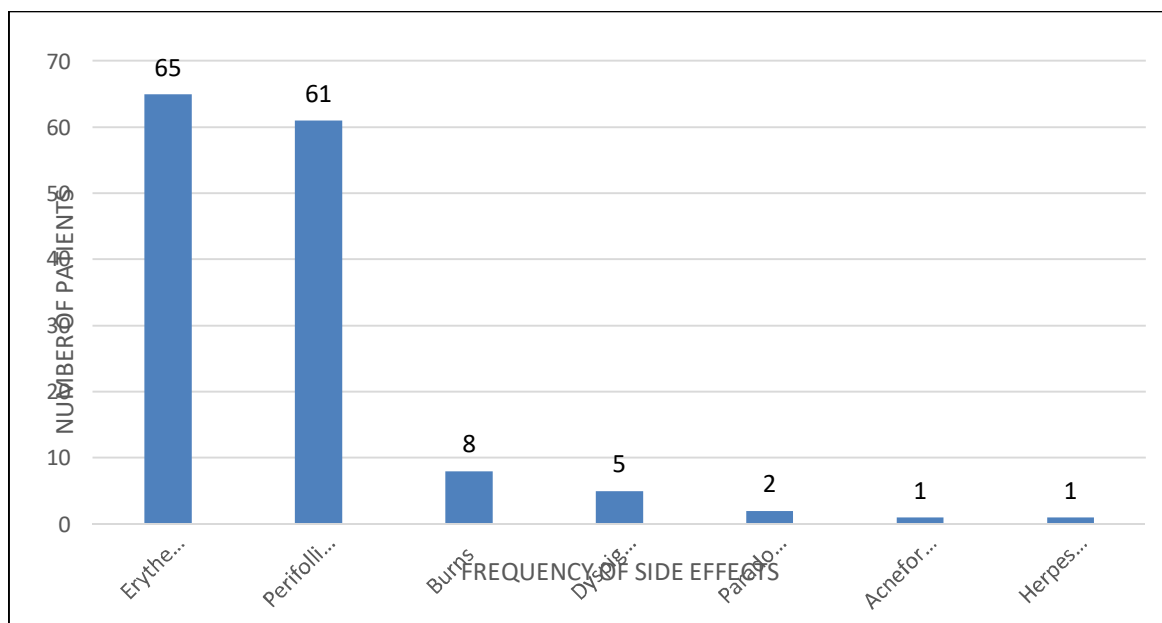


Figure 27 : Frequency of side effects



Figure 28: Clinical images of chin and sumandibular area at baseline (mFG score-3) ,3rd visit (mFG score-2) and at 6th visit(mFG score-1)



Figure 29: Clinical images of chin and sumandibular area at baseline (mFG score-4) ,3rd visit (mFG score-2) and at 6th visit(mFG score-2)

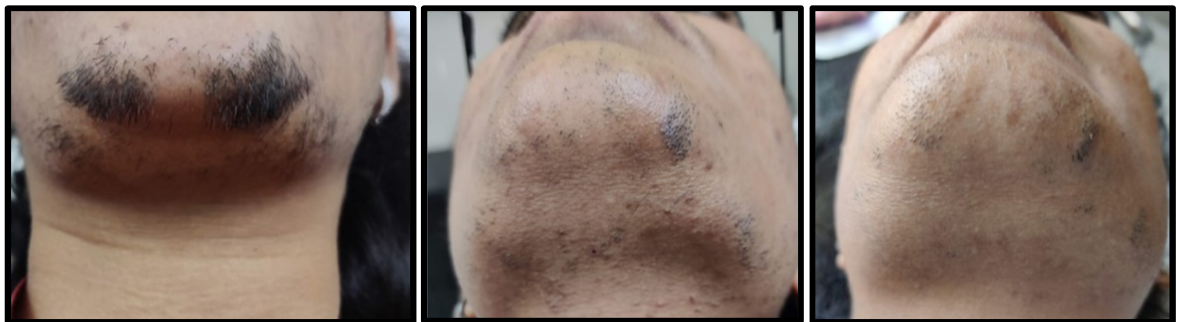


Figure 30: Clinical images of chin and sumandibular area at baseline (mFG score-4) ,3rd visit (mFG score-2) and at 6th visit(mFG score-1)

TRICHOSCOPIC IMAGES

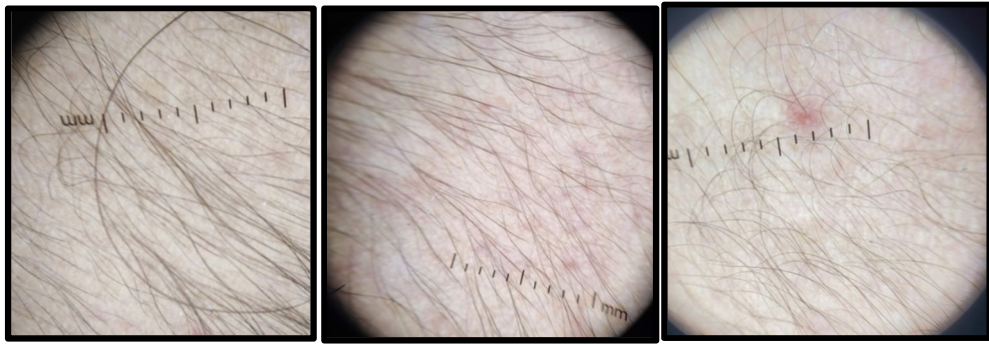


Figure 31: Trichoscopic images of sidelocks at baseline, 3rd visit and at 6th visit showing reduction in total hair, terminal hair and terminal/vellus hair ratio



Figure 32: Trichoscopic images of chin at baseline, 3rd visit and at 6th visit showing reduction in total hair, terminal hair,vellus hair and terminal/vellus hair ratio



Figure 33: Trichoscopic images of upperlips at baseline, 3rd visit and at 6th visit showing reduction in total hair, terminal hair,vellus hair, terminal/vellus hair ratio

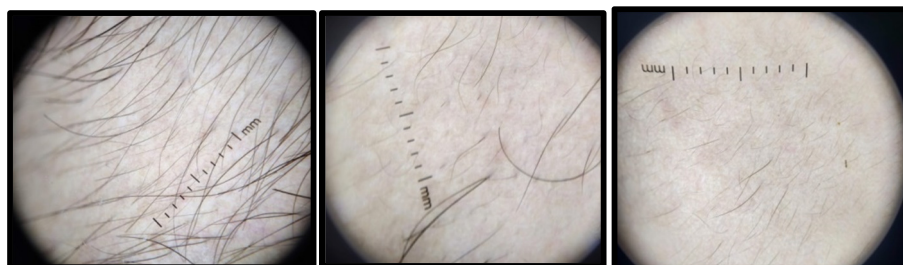


Figure 34: Trichoscopic images of submandibular area at baseline, 3rd visit and at 6th visit showing reduction in total hair, terminal hair, vellus hair and terminal/vellus hair ratio

IMAGES OF SIDE EFFECTS



Figure 35: Perifollicular edema

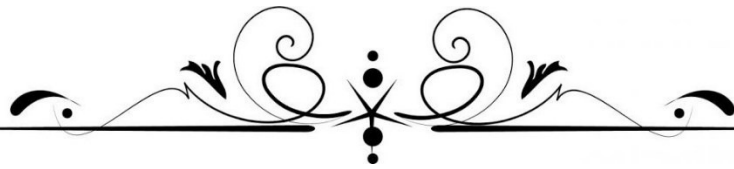


Figure 36: Clinical and dermoscopic images of hyperpigmentation

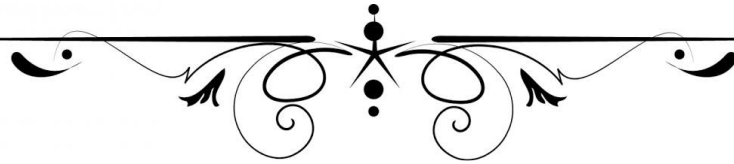


Figure 37: Acneiform eruption

Figure 38: Herpes labialis



DISCUSSION



DISCUSSION

About 5–15% of all women develop some degree of hirsutism¹. Increased hair growth has strong negative psychological effect on the well-being of the women. For this reason, various methods of hair removal have been practiced. Multiple lasers and light-based technologies are available for hair removal. Most studies conducted using lasers present decreased efficacy and an increase in side effects in darker skinned patients^{5, 38}. Out of the various laser systems used for hair reduction, longer wavelength lasers like diode laser penetrate deep into dermis, thus causing less epidermal absorption and sufficient hair follicle damage.

In our study, seventy three patients were recruited for diode laser hair reduction from the Dermatology, Venereology and Leprology OPD at AIIMS, Jodhpur over a period of 18 months. The age of patients ranged from 18 years to 43 years with a mean of 26.37 ± 5.82 years. This was concordant with the study done by Mohamed et al² where mean age was 25 years. Among all age groups, most patients were found in the younger age group 18-24 years (43.8%) followed by 25-31 years (37%). Most of the hyperandrogenic disorders begin to clinically manifest in peripubertal age group which can explain the high prevalence in this age group. Out of 73 patients, 45 patients were unmarried. The cosmetic concern and matrimonial prospects can be a possible reason for more unmarried women seeking treatment.

In our study, menstrual history was irregular in 44 (60.3%) patients, however only 41 (52.6%) patients fulfilled the Rotterdam criteria for polycystic ovary disease. It is similar to study of Roche et al in which 44 patients (70%) out of 63 patients were fulfilling criteria for PCOD³⁹. Also, only two patients had concomitant comorbidities. One patient had diabetes and the other had hypothyroidism. Family history of hirsutism was present in 19 patients (26%). It was higher compared to the study of Sharma et al⁴⁰ in which family history was positive in 9(18%) out of 50 patients but lower compared to study of Mohamed et al² in which 36 patients (51.4%) out of seventy had positive family history.

The mean duration of hirsutism in our study was 4.08 years (range - 0.5 to 15 years). It was similar to study of Mohamed et al² in which mean duration of hirsutism was 3.5 ± 1.9 years (range 1– 9 years). The cause of delayed presentation to doctor maybe due to use of other methods of hair removal (shaving and waxing) and stigma and lack of awareness regarding hirsutism. 16 patients received additional treatments like oral contraceptive pills and

spironolactone. Most patients were given oral drugs due to their concurrent menstrual irregularities or hormonal acne.

Among the 73 patients recruited, most patients had Fitzpatrick skin type 4 (61.6%), followed by type 3 (26%). Due to increased risk of incidence of adverse effects, there are lesser number of studies of laser on darker skin types. Few studies like Agarwal et al⁴¹, Adrian et al³², Mustafa et al⁴², have studied effect of laser on darker skin type and concluded that lasers can be safely used in darker phenotypes. Body mass index of patients ranged from 17.7 kg/m² to 33 kg/m² with mean being 23.24 kg/m². BMI was more than 25 kg/m² in 21 patients (28.8%). This is concordant with an Indian study done by Sharma et al⁴⁰ which showed 36% of patients having a BMI more than 25. Increased incidence of overweight in hirsutism may be due to the concurrent higher incidence of polycystic ovary disease.

Baseline body hair assessment of patient was done using modified Ferriman-Gallwey score, which ranged in our study from 6 to 20. Out of 73 patients, 60 patients had mild hirsutism while 11 patients had moderate hirsutism and no patient had severe hirsutism. It is concordant with the study of Sharma et al⁴⁰ in which out of 50 patients, 40 patients had mild hirsutism score while 10 patients had moderate hirsutism and no patient had severe hirsutism. Most commonly involved sites on face were chin (93.2%) followed by upperlip (83.6%), submandibular area (67.1%) sidelocks (37%). This was similar to the study of Mittal et al²³ (n=59) in which most common sites were chin (35.6%) followed by upper lip (28.8%) and sidelocks (18.6%).

In our study, USG Pelvis showed features of PCOD in 23 patients (31.5%) whereas hormonal profile revealed high testosterone levels in 8 patients (11%). Similarly, in a study conducted by Mukta et al⁴³, out of 51 patients, only 5 patients had evidence of polycystic ovarian disease on USG, out of which only one female had abnormal hormonal workup.

Though 6 visits were planned, not all patients were able to complete follow up. 55 patients completed 3 visits and 25 patients completed all 6 visits. Patients lost to follow up in our study were relatively higher than previous studies. This was mainly due to the COVID pandemic and related curfew. Other reasons included complete remission, inadequate response and difficulty to follow up with frequent visits.

Modified Ferriman-Gallwey score on face reduced with repeated sessions. Median at first, third and sixth sitting are 3, 2 and 1 respectively. Reduction of facial modified Ferriman-

Gallwey score compared to baseline was statistically very significant (p value <0.01). Similarly, in the study done by Francesca et al⁴⁴, the mode of facial MFG in group A (BMI < 29.9) pretreatment and 2 years post treatment with IPL was 2 and 1 respectively whereas in group B (BMI>29.9) was 4 and 1 respectively. Proportion of patients having terminal hair as the predominant hair type reduced with repeated sessions. Predominant hair type was terminal hair in 86.3 % patients at first visit but later at third and sixth visit, only 69.1% and 48 % patients respectively had terminal hairs. The change in the predominant hair type compared to baseline was statistically very significant. Similarly, in study of the Mittal et al²³, 59 patients had coarse hairs . At the end of the study (six weeks after the sixth laser session), the number of patients who converted to vellus hairs were 33 (56%).(23)

Investigator assessment was a hair assessment tool used by Dhurat et al⁴⁵ in her study on androgenetic alopecia. Paired baseline and post-treatment photographs were reviewed with the use of the standardized 7-point rating scale (−3 = greatly decreased, −2 = moderately decreased, −1 = slightly decreased, 0 = no change, +1 = slightly increased, +2 = moderately increased, +3 = greatly increased). In our study, this score was used to assess the hair reduction with laser therapy. Median of Investigator assessment score at third and sixth visit is -2 (moderately decreased) and −3 (greatly decreased) respectively. Reduction of hair from baseline using this score was statistically very significantly (p value <0.01). The mean percentage reduction at third and sixth visit was 46.36% and 66.80% respectively, which was statistically very significant. This was comparable to the study done by Sadick et al²⁴ with diode laser in skin types II-IV, 3 times at monthly intervals and showed mean hair removal efficiency of 74% and 79% at 3 and 6 months, respectively.

No significant difference in hair reduction noted between PCOD group and idiopathic hirsutism at third visit or at sixth visit. This was contrary to the study of Nabi et al⁷ who did comparative study of the clinico-trichoscopic response to treatment of hirsutism with Nd:YAG laser in idiopathic hirsutism and polycystic ovarian syndrome patients. In that study, after six laser sessions, excellent response (> 75% reduction) was seen in 70% of patients in idiopathic hirsutism group and 54% of patients in PCOD group. Dorgham et al⁴⁶ concluded in his study that combining hormonal treatment with laser hair removal can achieve greater hair reduction, significant improvements in patients' QOL, and better maintenance as compared to metformin with laser or laser alone. But our study showed that

there was no significant difference in hair reduction between systemic treatment (OCP or spironolactone) combined with laser and laser alone at third visit and sixth visit.

Hair removal frequency also reduced from once in 13.16 days at baseline to once in 69.8 days at sixth visit. Hair removal frequency reduced statistically very significantly at third visit and sixth visit. Therefore, our study showed a good clinical response with diode laser therapy. When compared to previous studies, which used percentage hair reduction as the primary efficacy parameter, our study used multiple clinical efficacy parameters like facial modified Ferriman-Gallwey score, investigator assessment, percentage hair reduction, predominant hair type, frequency of hair removal. This helps in better quantification of clinical response and more objective assessment.

Our study also assessed trichoscopic parameters like total hair count, terminal hair count, vellus hair count and terminal/vellus hair ratio. They were assessed at four sites including sidelocks, chin, upperlip and submandibular area. Studies like Mohamed et al² and Nabi et al⁷ used trichoscopic parameters to assess laser hair reduction. Mohamed et al² studied trichoscopic changes in hair during treatment of hirsutism with Nd:Yag laser using trichoscan software. Trichoscopy was done over chin showed that total hair count per cm² at baseline, third and sixth visit was 73.7, 48.3 and 27.1 respectively. Also terminal to vellus hair ratio at baseline, third and sixth visit was 72.5, 55.1 and 31.8 respectively. Similarly, Nabi et al⁷ did a comparative study of the clinico-trichoscopic response to treatment of hirsutism with Nd:YAG laser in idiopathic hirsutism and polycystic ovarian syndrome patients. The trichoscopic features were assessed before each laser session which showed decreased hair shaft thickness, decreased hair shaft colour, decreased terminal vs. vellus hair ratio, decreased density of hair per cm² at chin in both groups with successive sessions.

In our study, all trichoscopic parameters like total hair count, terminal hair count, vellus hair count, terminal/vellus hair ratio reduced with repeated laser sittings. The mean total hair count per cm² at chin at baseline, third and sixth visit was 38.16, 25.68 and 23.68 respectively. The mean total hair count per cm² at sidelocks, upperlip and submandibular area also showed decreasing trend with repeated visits which was statistically very significant. Similarly, the mean terminal hair count at chin at baseline, third and sixth visit was 17.48, 9.2 and 5.56 respectively. Reduction in terminal hair count from baseline was statistically very significant in all four areas. Vellus hair count assessed trichoscopically reduced with repeated laser sittings but reduction was statistically significant only in sidelocks. Terminal/vellus hair

ratio assessed trichoscopically reduced with repeated laser sittings and was statistically significant in all four areas.

Our study showed significant trichoscopic reduction of hair in treated areas which can be used as an additional tool for assessing efficacy of lasers. Multiple trichoscopic parameters were used like total hair count, terminal hair count, vellus hair count, terminal/vellus hair count helping in objective assessment of the response.

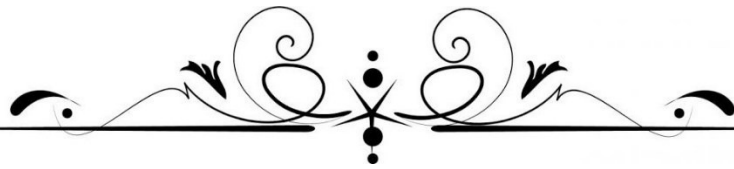
Most common side effect noted in our study was pain (97.3%) followed by erythema (89%) and perifollicular edema (83.6%). They were mild and very transient resolved immediately after the procedure. This was similar to studies of Jo et al⁴⁷, Greppi et al⁴⁸ and Royo et al⁴⁹. Also, mild superficial burns were seen in 8 patients, which later became hyperpigmented in 5 patients. Ice application along with midpotent steroids for 2 days was advised in case of burns. Pigmentary changes resolved spontaneously or with mild depigmenting agents in 1-2 months in all patients. Paradoxical hair growth in form of multiple small vellus hair seen in 2 patients, out of which one had PCOD and another had idiopathic hirsutism. Acneiform eruptions and herpes labialis seen in one patient each. Similar side effects were noted in studies of Nabi et al⁷ and Royo et al⁴⁹. Although larger number of side effects are reported with lasers in darker skin types, our study showed that laser therapy can be done safely in Indian population. Minimal side effects were noted, most of which were mild and transient. Fewer side effects in our study maybe due to using appropriate laser parameters (fluence and pulse duration), effective cooling and immediate intervention after adverse events.

A combined analysis of these results shows that all clinical parameters of hair reduction was statistically significant when compared to the baseline. Our study included multiple clinical parameters like facial modified Ferriman-Gallwey score, predominant hair type, investigator tool, percentage hair reduction and frequency of hair removal. Additionally including trichoscopy helped in better hair assessment. Dermoscopy of hair is a new, noninvasive, sensitive, specific and underutilized investigation that can be used for assessing response of hirsutism to laser hair reduction. The hand held dermoscope with 10-fold magnification may give easy and quick evaluation of hair. Compared to previous studies, more trichoscopic parameters and more facial sites were assessed. Trichoscopic parameters included in study were total hair count, terminal hair count, vellus hair count and terminal to vellus hair ratio. Sites included was sidelocks, chin, upperlip and submandibular area. Results showed that

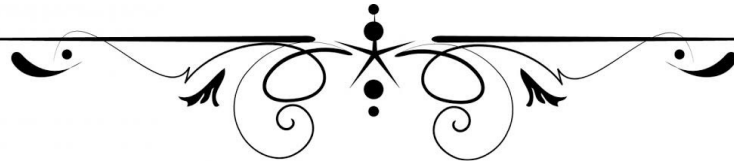
total hair count, terminal hair count and terminal to vellus hair ratio had statistically significant reduction in all four sites compared to baseline.

Although various previous studies tried to assess efficacy of diode laser, our study was unique due to multiple analysis parameters and inclusion of trichoscopic assessment. This may have increased the effectiveness of our study results. We have also concluded that diode laser therapy is safe in Indian skin color even at higher fluences (upto 34 J/cm²). Side effects were mostly mild and transient and there were no persistent side effects. Studies on safety of diode laser in Indian skin color were limited and have mostly used lower fluences (less than 25J/cm²). Procedural errors were minimized by the standard intervention delivery by a single care provider.

Although our study was designed keeping in mind the limitations of the design of previous studies, there were still some limitations in our study. Although we used fixed anatomical landmarks for photography, it was difficult at times to accurately locate the sites. Another important limitation was the relatively higher lost to follow-up (65.7%). The reasons for lost to follow up may be lockdowns due to COVID pandemic, multiple follow-up visits, lack of clinical response and progressive hirsutism requiring aggressive systemic therapy. We assessed the trichoscopic hair assessment through manual counting. Incorporation of automated hair counting software might have increased the objectivity of our assessment. Due to financial constraints, we limited our study to manual assessment.



CONCLUSION



CONCLUSION

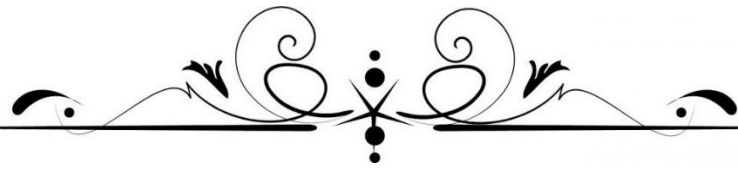
A prospective observational study was conducted on 73 patients of hirsutism attending Dermatology, Venereology and Leprology OPD of AIIMS Jodhpur. After informed consent, subjects underwent treatment with diode laser (805 nm). Diode laser is done with fluence 18-20 J/cm² in first treatment. On subsequent treatments, fluence was increased by 2-4 J/cm² depending on subjects tolerance and presence of side effects. The treatment was repeated every 4 weekly with goal of 6 sessions. Clinical and trichoscopic evaluation along with photographs were obtained at baseline, third visit and sixth visit. Clinical parameters used were modified Ferriman-Gallwey score of face (0-4), percentage reduction (patient reported), Investigator assessment (-3 to +3), frequency of hair removal and predominant hair type. In addition, trichoscopic parameters like total hair count, terminal hair count, vellus hair count, terminal/vellus hair (per field) done for 4 sites including sidelocks, chin, upper lip and submandibular area. Hair counting was done manually from prints of the photographs taken. Side effects if any was noted in every sitting and treated accordingly.

The results led us towards the following key interpretations.

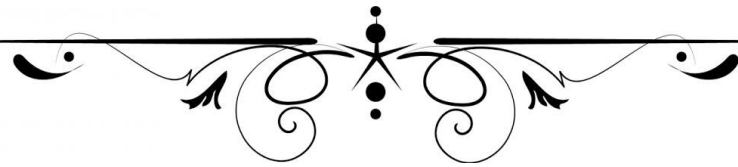
- All the hair assessment parameters showed a progressively decreasing trend in most patients.
- All clinical parameters showed statistically significant hair reduction when compared with baseline.
- Clinical parameters like facial modified Ferriman-Gallwey score, investigator tool and percentage hair reduction were showing significant change when compared to baseline.
- Predominant hair type changed from terminal to vellus hair (p value < 0.01)
- Frequency of hair removal reduced significantly (p value < 0.01)
- Trichoscopic parameters of hair reduction like total hair count, terminal hair count, and terminal/vellus hair ratio (per field) also showed reduction compared to baseline which was statistically significant.
- We were able to use higher fluences (upto 34J/cm²) with minimal adverse effects.
- Most common side effect noted in our study was pain followed by erythema and perifollicular edema. Also, mild superficial burns, hyperpigmentation, paradoxical hair growth, acneiform eruptions and herpes labialis were noted in few cases. All side effects were mild and transient.

Thus we concluded that diode laser is an effective and safe method in the reduction of unwanted facial hair, even in darker skin type. We also wanted to emphasize that trichoscopy of hair for monitoring of the laser hair reduction is a new, noninvasive, sensitive and underutilized investigation that is valuable in assessment of the laser hair reduction for hirsutism. No serious adverse events were noted in our study.

Further, more studies with longer follow-up, larger sample size, systematic reviews and meta-analyses are required in more population subsets to establish the trichoscopic efficacy for hair reduction and safety in darker skin types.



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BIBLIOGRAPHY

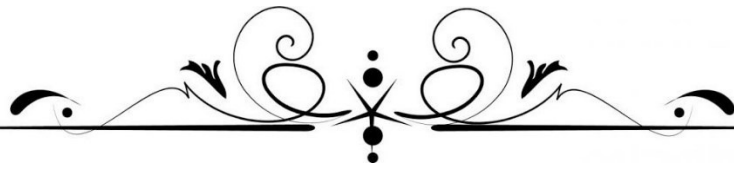
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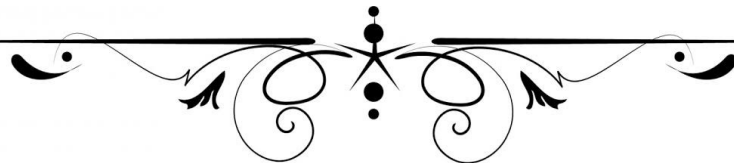
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


ANNEXURES



ANNEXURES

Appendix- I. Institutional Ethics Committee certificate

	<p>अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर All India Institute of Medical Sciences, Jodhpur संस्थागत नैतिकता समिति Institutional Ethics Committee</p>
No. AIIMS/IEC/2020/2058	Date: 01/01/2020
<p><u>ETHICAL CLEARANCE CERTIFICATE</u></p>	
Certificate Reference Number: AIIMS/IEC/2019-20/962	
Project title: "Efficacy and safety of diode laser for facial hair reduction in hirsutism--A clinical and trichoscopic evaluation"	
Nature of Project:	Research Project
Submitted as:	M.D. Dissertation
Student Name:	Dr.Sahiba Rafi
Guide:	Dr.Anil Budania
Co-Guide:	Dr.Abhishek Bhardwaj, Dr.Saurabh Singh & Dr.Anupama Bains
<p>This is to inform that members of Institutional Ethics Committee (Annexure attached) met on 23-12-2019 and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.</p>	
<p>The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.</p>	
<p>Please note that the AIIMS IEC must be informed immediately of:</p> <ul style="list-style-type: none">• Any material change in the conditions or undertakings mentioned in the document.• Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.	
<p>The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.</p>	
<p>AIIMS IEC retains the right to withdraw or amend this if:</p> <ul style="list-style-type: none">• Any unethical principle or practices are revealed or suspected• Relevant information has been withheld or misrepresented	
<p>AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.</p>	
<p>On behalf of Ethics Committee, I wish you success in your research.</p>	
Enclose:	<p>1. Annexure 1</p> <p> Dr. Pravara Sharma Member secretary Institutional Ethics Committee AIIMS, Jodhpur</p>
Page 1 of 2	
<p>Basni Phase-2, Jodhpur, Rajasthan-342005, Website: www.aiimsjodhpur.edu.in, Phone: 0291-2740741 Extn. 3109 Email: ethicscommittee@aiimsjodhpur.edu.in</p>	

Annexure 1



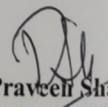
Institutional Ethics Committee

All India Institute of Medical Sciences, Jodhpur

Meeting of Institutional Ethics committee held on **23-12-2019 at 10:00 AM** at Committee Room,
Admin Block AIIMS Jodhpur.

Following members were participated in the meeting:-

S/No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1.	Dr. F.S.K Barar	MBBS, MD (Pharmacology)	Chairman
2.	Justice N.N Mathur	LLB	Legal Expert
3.	Dr. Varsha Sharma	M.A (Sociology)	Social Scientist
4.	Mr. B.S.Yadav	B.Sc., M.Sc. (Physics), B.Ed.	Lay Person
5.	Dr. K.R.Haldiya	MD (General Medicine)	Clinician
6.	Dr. Arvind Mathur	MBBS, MS (General Medicine)	Clinician
7.	Dr. Surajit Ghatak	MBBS, MS (Anatomy)	Basic Medical Scientist
8.	Dr. Vijaya Lakshmi Nag	MBBS, MD (Microbiology)	Basic Medical Scientist
9.	Dr. Sneha Ambwani	MBBS, MD (Pharmacology)	Basic Medical Scientist
10.	Dr. Kuldeep Singh	MBBS, MD (Paediatric), DM (General Medicine)	Clinician
11.	Dr. Abhinav Dixit	MBBS, MD (Physiology), DNB (Physiology)	Basic Medical Scientist
12.	Dr. Pradeep Kumar Bhatia	MBBS, MD (Anaesthesiology)	Clinician
13.	Dr. Tanuj Kanchan	MBBS, MD (Forensic Medicine)	Basic Medical Scientist
14.	Dr. Pankaj Bhardwaj	MBBS, MD (CM&FM)	Clinician
15.	Dr. Praveen Sharma	M.Sc., Ph.D. (Biochemistry)	Member Secretary


Dr. Praveen Sharma
Member Secretary
 Institutional Ethics Committee
 AIIMS, Jodhpur

Appendix- II. Case sheet proforma

Patient Name:

AIIMS ID:

Age/ Sex:

Address :.....

Father's name:

Occupation:

History:

Presenting complaints:

Systemic complaints :

Menstrual history: 1.regular 2.amenorrhoe 3.oligomenorrhoe 4

Marital and obstetric history:

Significant drug history:

Family history: hirsutism/PCOS/

Previous treatment for hirsutism:

Frequency of hair removal:..... Hair free interval:

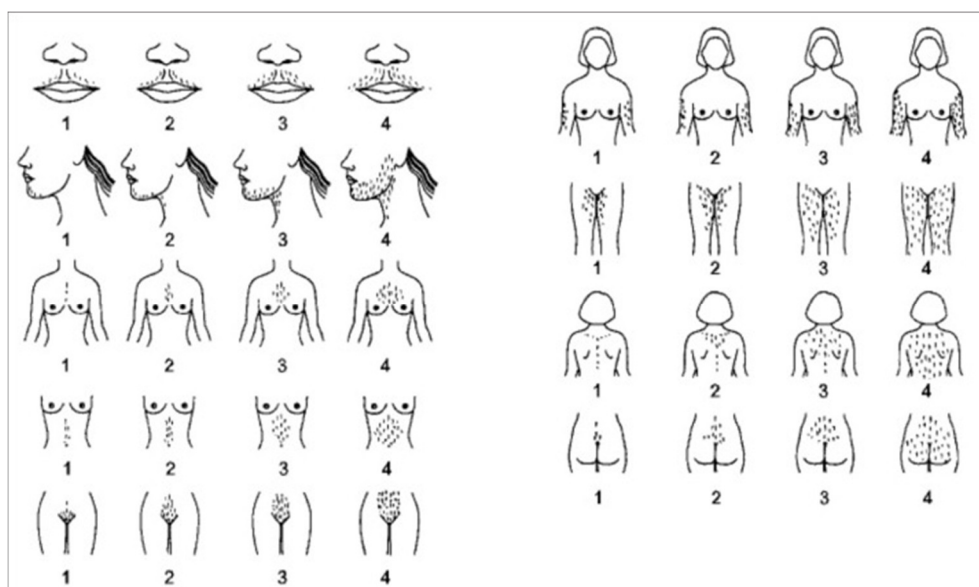
EXAMINATION

Fitzpatrick skin type: Site involved:

Modified Ferriman-Gallwey score:

BMI: S/O hyperandrogenism: acne / alopecia / acanthosis nigricans / seborrhea

S/O defeminization: clitoromegaly / breast atrophy / deepening of voice



INVESTIGATIONS:

Testosterone level:.....

USG Pelvis PCOS: Yes / No

Metabolic

syndrome:

.....

Other

investigations:

.....

Medical treatment if given : OCP / antiandrogen / metformin / eflornithine / others

RESPONSE

Areas treated

Treatment session/date	Fluence	Facial MFG	Investigator assessment	Frequency of shaving	%hair reduction	Predominant hair type	Side effects

Treatment session	TRICHOSCOPY			
	Total hair count	Terminal hair count	Vellus hair count	Terminal/vellus ratio

Appendix- III. Informed consent form (English & Hindi)

I.....age/sex.....

.....D/S/W of.....,R/O.....ID.....

Laser clinic file number ,contact number.....Hereby

declare that I authorize the doctor of Department of Dermatology, AIIMS , Jodhpur to perform treatment with diode laser machine on me.

I give my written consent for laser treatment with

for(medications) on my body

- I understand I will have to wear protective eyeglasses during the course of treatment to protect my eyes from the laser light.
- I am aware that the laser treatment can produce, but is not limited to the following common side effects: redness, swelling, itching, tingling and dry skin. I understand that these side effects can last for couple of days. I understand that there are some risks and complications that can occur from a laser treatment that can interrupt my daily life, work routine or social life. These may include but are not limited to- burning scab formation, heat rash, bruising, scarring, infection, hypopigmentation(lighter skin) and hyperpigmentation(darker skin). If any of these were to occur I understand it is my responsibility to inform treating doctor and they are available to see me and provide post treatment guidelines to speed my recovery time
- For best results, I have been informed that multiple treatments will be needed. I understand results are not guaranteed.
- When undergoing diode laser treatment, I have been informed that some of the factors can trigger new hair growth like hormonal imbalance, pregnancy medications, menopause, tweezing or waxing.
- I understand post treatment care is very important and I will adhere to all the instructions given to me. Improper care to the treated area may increase the chances of any complications.
- I give consent for my photographs taken during the course of my laser treatments. Photos will be retained as a part of my file and used for future scientific publications , under seal of my anonymity

I have read and understood all information presented to me before signing this consent .i have had ample opportunity to ask question regarding laser treatment , side effects and after care. I hereby and forever discharge my treating doctor and technicians from all claims, demands, actions, and cause of action arising out of the performance of said treatment

Signed
(patient or person legally authorized
to consent for the patient)

Witness
(to patient's sign)

Full name:
Date:

Full name.....
Date.....

रोगी सहमति पत्र

मैं, उम्र / लिंग

.....

पुत्र/पुत्री/ पत्नी श्री....., निवासी ID

.....। लेज़र क्लिनिक फ़ाइल नंबर, संपर्क नंबर

.....। मैं यह घोषित करता/करती हूँ कि मैं त्वचाविज्ञान विभाग, एम्स, जोधपुर के डॉक्टर को अधिकृत करता/ करती हूँ कि वे मुझे पर डायोड लेजर मशीन से उपचार करें। मैं डायोड लेजर से अपने शरीर के अनचाहे बालों के उपचार के लिए अपनी लिखित में सहमति देता/ देती हूँ।

• मैं समझता/समझती हूँ कि मुझे अपनी आंखों को लेजर लाइट से बचाने के लिए उपचार के दौरान सुरक्षात्मक चश्मा पहनना होगा।

• मुझे पता है कि लेजर उपचार के दुष्प्रभाव हो सकते हैं, जो निम्नलिखित आम दुष्प्रभावों तक सीमित नहीं हैं: लालिमा, सूजन, खुजली, झुनझुनी और शुष्क त्वचा आदि। मैं समझता/ समझती हूँ कि ये दुष्प्रभाव कुछ दिनों तक रह सकते हैं। मैं समझता/ समझती हूँ कि लेजर उपचार से कुछ जोखिम और जटिलताएं हो सकती हैं जो मेरे दैनिक जीवन, काम की दिनचर्या या सामाजिक जीवन को प्रभावित कर सकती हैं। इनमें निम्नलिखित जोखिम और जटिलताएं शामिल हैं, लेकिन इन तक सीमित नहीं - पपड़ी बनना, हीट रैश, नील पड़ना, निशान पड़ना, दाग, संक्रमण, त्वचा के रंग का हल्का या गहरा पड़ना। अगर इनमें से कोई भी दुष्प्रभाव हुआ तो यह मेरी जिम्मेदारी होगी कि मैं इसके बारे में डॉक्टर को सूचित करूँ और वे मुझे देखने के लिए उपलब्ध होंगे और मुझे जल्दी ठीक होने के दिशानिर्देश प्रदान करेंगे।

• सर्वोत्तम परिणामों के लिए, मुझे सूचित किया गया है कि कई बैठकों की आवश्यकता होगी। मैं समझता/ समझती हूँ कि परिणाम की गारंटी नहीं है।

• डायोड लेजर उपचार से गुजरने के दौरान, मुझे सूचित किया गया है कि कुछ कारक हार्मोनल असंतुलन, गर्भावस्था की दवाएं, रजोनिवृत्ति, चिमटी या वैक्सिंग से बाल हटाना आदि बालों के विकास को गति प्रदान कर सकते हैं।

• मैं समझता/ समझती हूं कि उपचार के बाद देखभाल बहुत महत्वपूर्ण है और मैं मुझे दिए गए सभी निर्देशों का पालन करूंगा/करूंगी। उपचारित क्षेत्र की अनुचित देखभाल किसी भी जटिलता की संभावना को बढ़ा सकती है।

• मैं अपने लेजर उपचार के दौरान अपनी तस्वीरें लेने की अनुमति देता/ देती हूं। मेरी पहचान का खुलासा किए बिना मेरी तस्वीरों को मेरी फ़ाइल के एक हिस्से के रूप में रखा जाएगा और भविष्य के वैज्ञानिक प्रकाशनों के लिए उपयोग किया जा सकता है।

मैंने इस सहमति पत्र पर हस्ताक्षर करने से पहले मेरे सामने प्रस्तुत सभी सूचनाओं को पढ़ा और समझा है। मुझे लेजर उपचार, दुष्प्रभावों और उपचार के बाद की सावधानियों के बारे में सवाल पूछने का पर्याप्त अवसर मिला है।

मैं एतद्वारा और हमेशा के लिए अपने उपचार करने वाले डॉक्टर और तकनीशियनों को सभी दावों, मांगों, उक्त उपचार से उत्पन्न होने वाली क्रिया और प्रतिक्रिया से मुक्त करता/ करती हूं

हस्ताक्षरित

साक्षी

(रोगी या व्यक्ति कानूनी रूप से अधिकृत है (रोगी के संकेत के लिए) रोगी के लिए सहमति)

पूरा नाम:

पूरा नाम:

.....

दिनांक:

दिनांक:

.....

Appendix- IV. Patient information sheet (English & Hindi)

All India Institute of Medical Sciences, Jodhpur, Rajasthan

PATIENT INFORMATION SHEET (PIS)

This document has been given to provide more information about the disease and this research is related to laser effects on facial hair in hirsutism

The current research project is titled - **efficacy and safety of diode lasers in facial hair reduction in hirsutism- a clinical and trichoscopic evaluation**

Hirsutism is the presence of terminal coarse hairs in females in a male-like distribution. Hirsutism can be caused by either an increased level of androgens, the male hormones, or an oversensitivity of hair follicles to androgens. Lasers can achieve permanent reduction of hair (not removal). They work on the principle of selective photothermolysis where the laser energy acts specifically to destroy the target (melanin). Lasers are proven to be very safe . Multiple treatment sessions are required to get a significant reduction.

The basic goal of this research is to study efficacy and safety of diode lasers in Indian skin colour, thereby playing a role in guiding laser therapy for Indian population.

The patient is also informed that all the information given by him will be kept confidential. The patient also reserves the right that during this research, patient can withdraw the consent & can be out of this research without explaining the reasons.

Principal investigator: Dr. Sahiba Rafi

Contact number: 9968066667

अखिल भारतीय आयुर्विज्ञान संस्थान जोधपुर, राजस्थान

रोगी सूचना पत्रक (पीआईएस)

यह दस्तावेज़ रोग के बारे में अधिक जानकारी प्रदान करने के लिए दिया गया है और यह अनुसंधान हिर्मुटिज़्म चेहरे के बालों पर लेजर प्रभाव से संबंधित है

वर्तमान अनुसंधान परियोजना का शीर्षक है - हिर्मुटिज़्म के साथ महिलाओं में चेहरे के बालों के झड़ने में डायोड लेजर की प्रभावकारिता और सुरक्षा- एक नैदानिक और ट्राइकोस्कोपिक मूल्यांकन

हिर्मुटिज़्म एक पुरुष जैसे वितरण में महिलाओं में टर्मिनल मोटे बालों की उपस्थिति है। हिर्मुटिज़्म या तो एण्ड्रोजन के बढ़े हुए स्तर, पुरुष हार्मोन, या एण्ड्रोजन के लिए बालों के रोम की ओवरसाइज़िंग के कारण हो सकता है। लेज़र बालों की स्थायी कमी (निष्कासन नहीं) प्राप्त कर सकते हैं। वे चयनात्मक फोटोथर्मोलिसिस के सिद्धांत पर काम करते हैं जहां लेजर ऊर्जा विशेष रूप से लक्ष्य (मेलेनिन) को नष्ट करने के लिए कार्य करती है। लेज़र बहुत सुरक्षित साबित होते हैं। एक महत्वपूर्ण कमी प्राप्त करने के लिए कई उपचार सत्रों की आवश्यकता होती है।

इस शोध का मूल लक्ष्य भारतीय त्वचा के रंग में डायोड लेजर की प्रभावकारिता और सुरक्षा का अध्ययन करना है, जिससे भारतीय आबादी के लिए लेजर थेरेपी का मार्गदर्शन करने में भूमिका निभाई जा सके।

रोगी को यह भी सूचित किया जाता है कि उसके द्वारा दी गई सभी जानकारी को गोपनीय रखा जाएगा। रोगी को यह अधिकार भी है कि इस शोध के दौरान, रोगी बिना कारण बताए सहमति को वापस ले सकता है और इस शोध से बाहर हो सकता है।

सिद्धांत अन्वेषक: डॉ। सा

हिबा रफ़ी

संपर्क नंबर: 9968066667

Appendix- V. Master chart with important key words

S.No	Variable	Coding
1	Age category	18-24-1 25-31-2 32-38-3 39-45-4
2	Occupation	Student-1 Doctor-2 Housewife-3 Others-4
3	PCOD	Yes-1 No-2
4	Marital history	Unmarried-1 Married-2
5	Menstrual history	Irregular-1 Regular-2
6	Family history	Present-1 Absent-2
7	Previous treatment	Taken-1 Not taken-2
8	Previous treatment method	Oral-1 Laser-2
9	Current treatment(other than laser)	Yes-1 No-2
10	Sites involved (sidelocks, chin, upperlip, submandibular area)	Yes-1 No-2
11	BMI category	<18.5-0 18.5-22.9-1 23-24.9-2 25 and above-3
12	Features suggestive of hyperandrogenism	Yes-1 No-2

13	Modified Ferriman-Gallwey score category	<8 -0 9-16-1 17-25-2 26-36-3
14	Testosterone level	Normal-1 Raised-2 Not available-3
15	USG	PCOD-1 Normal-2 Not available-3
16	Side effects(erythema, pain, perifollicular edema, dyspigmentation, paradoxical hair growth, acneiform eruption, others)	Yes-1 No-2
17	Missing data	99

[illegible]