

**AN EXPLORATORY STUDY OF HIRSUTISM & ITS MANAGEMENT WITH UNANI
DRUGS IN COMPARISON WITH STANDARD CONTROL DRUG IN GOVT. NIZAMIA
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Article Received on 21/02/2025

Article Revised on 11/03/2025

Article Accepted on 01/05/2025

ABSTRACT

Unani System of Medicine is bestowed with a vast literature of gynaecological and endocrine afflictions like Hirsutism. Hirsutism is characterized by Growth of terminal hair growth in women like male. Distributions various treatment modalities available such as mechanical, cosmetic and pharmacological, not a single remedy is effective competently to ameliorate it. Although many studies have been conducted on hirsutism, majority of the published work concerning management with herbs shows considerable shortcomings. Therefore, the aim of this article is to review the ancient physiological concept of hirsutism present in Unani system of Medicine in the light of available new information and to appraise the effects of herbs on hirsutism with an objective to update the current knowledge. Rigorous literature search was done to understand the physiology and management of hirsutism described in ancient Unani literature. Herbs like Shahitra Chiraita Tukhm-e-Gazar Majeeth, Darchini, Barg-e-Sudab, Afsanteen, Aftimoon, Tukhm-e-Sambhalu, Barinjasif may modulate the underlying endocrine and metabolic disturbances responsible for hirsutism directly or indirectly by anti-androgenic, estrogenic, hypolipidaemic, hypoglycemic and insulin sensitizing properties, but the evidences are weak.

KEYWORDS: Unani Medicine; Hyperandrogenism, Sue Tarkeeb Amraz e adad, Herbs like Shahitra Chiraita Tukhm-e-Gazar Majeeth, Darchini, Barg-e-Sudab, Afsanteen, Aftimoon, Tukhm-e-Sambhalu, Barinjasif.

I. INTRODUCTION OF HIRSUTISM

As World is developing, the peoples are also modifying themselves in modernization which becomes great impact on health and most of the population measures different lifestyle disorders and become a big issue for health and social life. For women to be healthy, physically and mentally the regular menstrual cycles, body weight and beauty is most important. Any disturbances in these factors results in physical, mental and social health problems. Now a day's Hirsutism (Latin Hirsutus = Shaggy, Hairy) is a common Gynaecological, Endocrinological as well as Dermatological, Cosmetic and Psychogenic disorder in women which is characterized by excessive growth of terminal hairs in women in a male distribution, specifically growth of midline hair over the upper lip, chin, chest, abdomen, back, linea alba and inner thighs.

In women, these areas normally do not have terminal hair. Isolated hirsutism is usually gradual in onset and is due to mild increase in circulating androgen or increased sensitivity of pilosebaceous units to androgen. Menstrual

irregularity and amenorrhea are common, but some woman with hirsutism may have regular menstrual cycles. Hirsutism is usually the result of an underlying endocrine imbalance, which may be adrenal, ovarian or central. Hirsutism is a commonly presenting symptom in dermatology, endocrinology, and gynecology clinics, and one that is considered to be the cause of much psychological distress, great anxiety and social difficulty. Facial hirsutism often leads to the avoidance of social situations and to symptoms of anxiety and depression.

II. Unani Concept of Hirsutism

The term for hirsutism in unani classical books as "kasarat-e-sha'r".^[22] The temperament of hair is Cold 3 & Dry 3 and it is Aza-e-Mufrada. According to Unani concept, Hirsutism comes under (Su-e-tarkeeb – Amraz-e-adad).^[21] It is a complication of prolong amenorrhoea with other male features such as hoarseness of voice, male body pattern, acne and clitoromegaly.

Buqrat (460-370BC), first mentioned the integration of excess facial and body hairs (hirsutism) in females with prolonged amenorrhea, obesity and infertility. The Similar symptoms were observed and explained by Jalinoos (130-200AD). Rabban tabri (838-870AD), who was return in his legendary book "*Firdous-ul- hikmat*" that male gonads (testes) are responsible for the appearance of beard in male and removal of testicals before puberty leads to non-significant growth of facial and body hairs. He also mentioned that specific material is being secreted from testes that cause faciail hairs in males.^[2] Rhazes (Mohd. Ibn Zakariya Razi) — (865-925AD), Combination of science associated with menstrual disturbance including hirsutism, obesity, acne, hoarseness of voice and infertility.^[1] Which are suggestive of PCOD and hyperandrogenism. He recommended regular induction of menstruation as one of the treatments of choice applied for hirsutism. He also given a line of management for hirstuism based on correction of temperament and menstrual irregularities by use of effective emmenagogue. According to Abulhasan Ali bin Abbas and Abul sahal maseehi described about the hair that "Hair comes under Aza-e-Mufrada". Allama Nafees said that "Hair is the most dried organ of the body."

The patho-physiology of hirsutism was explained by Avicenna (Ibn-e-Sina): (980-1037AD) and Zayn-Al-Din Gorgani (Ismail Jurjani) — (1041-1136AD), alteration of normal temperament of female was considered as important factor for hirsutism. It was said that persistence of amenorrhoea for a long duration causes alteration in internal environment of female body and equilibrium is significantly disturbed which results in formation of some waste and unwanted material in the body which is being excreted through skin pores and participate in the formation of thick hairs over the body.^[12] These physicians were observed that development of masculine features is more common in obese females.

Haly Abbas (Ali-Ibn-Al-Abbas-Al Majoosi) was first person who has explained the physiology of hair growth and differentiation. He stated that hairs arise from "Bukhaarat- e-Dukhanian". It is a compound made up of four components such as water, soil, air and fire. Its production rises at the time of puberty specially in males.

Burhanuddin Kirmani, explained that "Bukhaarat-e-Dukhanian" includes airy, watery, fiery and earthy part. Hair growth occurs from these four parts in such a way that "Bukhaarat-e-Dukhanian" while circulating in the blood get separated as it passes near the pores of skin and attached to specific sites at a particular temperament with utilization of fiery part (energy), the earthy part (keratin & melanin) participates in the formation of hair in the presence of air and watery part. This process occurs repeatedly and further deposition of "Bukhaarat-e-Dukhanian" takes place maintaining continuous hair growth and the cycle is going on.^[9]

The term for hirsutism in unani classical books is "kasarat-e-sha'r. It is a complication of prolong amenorrhoea with other male features such as hoarseness of voice, male body pattern, acne and clitoromegaly. Alteration of normal temperament of female was considered as important factor for hirsutism. The Ancient physicians said that persistence of amenorrhoea for a long duration causes alteration in internal environment of female body and equilibrium is significantly disturbed which results in formation of thick hairs over the body. These physicians were observed that development of masculine features is more common in obese females. After the careful study of Hirsutism its pathology and causes, the drugs were selected mostly with action of Emmenagogue, Diuretic, Demulcent, Expectorant of Phlegm, Blood purifiers, Depilators, Skin protective and hair growth controller.

The formulae were selected according to ancient unani books which have been used by ancient physicians to treat the Hirsutism.

III. AIMS AND OBJECTIVES

- ❖ To evaluate the efficacy of Unani drugs in the management of Hirsutism.
- ❖ To give safe, effective and economical drugs with close temperament of remedy.
- ❖ To popularize the unani medicines in the management of Hirsutism.
- ❖ To eradicate the psychological effect of Hirsutism like significant degree of depression and interpersonal conflicts.
- ❖ To compare the efficacy of Test drugs with standard control drugs.
- ❖ To reduce the uses of painful techniques of hair removal like threading, bleaching, plucking and shaving.
- ❖ To avoid the complications of Laser therapy. To reduce the risk of Virilism.

IV. Management of Hirsutism

Management of Hirsutism includes weight reduction, diet therapy, medical and cosmetic measures.

- Weight reduction: - In obese patients' weight reduction is first line of treatment.
- BMI < 25 is improves menstrual disorders, hyperandrogenemia (Hirsutism, acne).
- Diet therapy: - low carbohydrate diet can help in weight reduction which results in regular menstrual cycles.
- Medical management: - To suppress or neutralize the excess androgen action and regular menstrual cycles. The useful drugs in Hirsutism are combined oral contraceptive pills (norgestimate, desogestrel, gestodine), anti-androgens i.e. cyproterone acetate, spironolactone, flutamide, ketoconazole. In OCPs progestin suppresses LH and oestrogen improves SHBG and reduce free testosterone.
- Removal of Hair: - The excess hair is to be

removed by bleaching, twitching, epilation, waxing, laser, shaving or electrolysis.

V. PATIENTS AND METHODS

The study was conducted during the period between 2016 -18 in the Post Graduate Dept. of Ilmul Qabalat Wa Amraz-E-Niswan, in Govt. Nizamia Tibbi College and Govt. Nizamia General Hospital from OPD and IPD. Total 100 patients were evaluated for the study. 30 patients did not meet the inclusion criteria and 10 patients denied participation. 20 patients had irregular follow ups and left in between and hence were excluded. 40 patients taken for the study with 20 patients in each Group i.e. (Group A & Group B) and treated OPD and IPD basis in Govt. Nizamia General Hospital, Charminar, Hyd.

SAMPLE SIZE: 40 Patients of clinically diagnosed Hirsutism and divided 20 Patients in Group - A and 20 Patients in Group – B.

Duration of Treatment: 4 Cycles, Each cycle with 20 days of duration of treatment in each month.

Patients were selected on the basis of detailed history especially regarding Excessive and thick hair growth and menstrual irregularities, obesity, OCP consumptions, investigations and by special case sheet proforma. Family history and Infertility also evaluated. Complete physical and systemic examination were performed and recorded in the case sheet proforma. Hormonal i.e. Sr. Testosterone, DHEAs, E2, TSH, FSH, LH, Prolactin and Ultrasound of Abdomen & Pelvis, evaluation done to rule out the cause of Hirsutism. Other routine biochemical investigations like CBC, CUE, RBS, HIV I&II, HBsAg, VDRL were also done.

Inclusion Criteria

- Age : - 15 to 50 years
- With complaints of thick & excessive hair growth
- Polycystic Ovarian Syndrome.
- Hyperandrogenism.
- Drug induced.
- Familial.
- Idiopathic.
- Patients who are willing to participate in the study with regular follow up cycles.

Exclusion Criteria

- Tumours of ovaries and Adrenal glands.
- Adrenal hyperplasia (Congenital or late onset)
- Cushing's syndrome.
- HAIR-AN syndrome.
- Patients with positive HBsAg, HIV and VDRL
- Known cases of tropical and infectious diseases

Criteria for Selection of Research Drugs

After the careful study of hirsutism keeping in view the detail pathology and causes, the drugs were selected mostly with action of Emmenagogue, Diuretic, Demulcent, Expectorant of Phlegm, Blood purifiers, Depilators, Skin protective and hair growth controller. The formulae were selected according to ancient Unani books and the drugs which are easily available, most effective and having less side effects were selected for the trial in Group - A and in Group - B well known standard drugs were selected according to modern literature.

VI. Pharmacognosy of Drugs used in Formulation

GROUP - A (MEDICINES): - It consist of Joshanda, Sufoof, Noura and Zimad.

SUFOOF (POWDER).

S.NO	DRUG	Botanical Names	DOSAGE
1	TUKHM-E-ANISOON	Pimpinella anisum	3gram
2	IRSA	Iris germanica	3gram
3	TUKHM-E-SAMBHALU	Vitex negundo Linn.	3gram
4	BARINJASIF	Achilla mellifolium	3gram
5	BARG-E-GAUZABAN	Borage officinalis Linn	3gram

JOSHANDA (DECOCTION)

S.NO	DRUG	BOTANICAL NAME	DOSAGE
1	SHAHITRA	Fumaria indica	5gram
2	CHIRAITA	Swertia chirata	5gram
3	TUKHM-E-GAZAR	Daucus carota	5gram
4	MAJEETH	Rubia cardifolia	5gram
5	DARCHEENI	Cinnamomum zeylanicum	3gram
6	BARG-E-SUDAB	Ruta graveolens	5gram
7	AFSANTEEN	Artemisia absinthium	5gram
8	AFTIMOON	Cuscuta reflexa	5gram
9	TUKHM ETURB	Raphanus Sativus	5gram

NOURA (DEPILATORY CREAM)

S.NO	DRUG	Scientific Names	DOSAGE
1	ZARNEEKH	Arsenic trisulphide	1gram
2	CHUNA	Calcium oxide	2gram
3	SIBR ZARD	Aloe barbadensis Mill	3mg
4	KAF-E-DARIYA	Os sepia	1gram

ZIMAAD (PASTE FOR LOCAL APPLICATION)

S.NO	DRUG		DOSAGE
1	JUND-E-BEDASTAR	Castoreum	10gms
2	ASL	Honey Mel.	250gms

Preparation of Decoction: -Soak all the dried drugs overnight i.e. Shahtra, Chirayata, Tukhm-e-Gazar, Majeeth, Barg-e-Sudab, Afsanteen, Aftimoon, Tukhm-e-Turb each drug 5 grams and Dar chini 3 grams in 400ml of water and boiled in the morning until it reduce to half and used into two divided doses in empty stomach in morning and evening for 20 days, per 4 cycles from 5th day of menstrual cycle.

Preparation of Powder: -All the dried drugs i.e. Tukhm-e-Anisoon, Irsa, Tukhm-e-Sambhalu, Barinjasif, Barg-e-Gauzaban each drug 3 grams are grinded into fine powder and sieved to separate remnants from the powder and is used as 5 grams thrice daily after food for 20 days, per 4 cycles from 5th day of menstrual cycle.

Preparation of Depilatory Paste: -The dried drugs i.e. Zarneekh and Kaf-e-Dariya grinded into fine powder and sieved by use of muslin (malmal) cloth to reduce the risk of skin irritation and the lime washed three times with water and sibr zard grinded and make powder. All these drugs mixed together and added rose water to make paste and applied on the hair region. Noura is common for Group - A & Group — B.

Preparation of Paste for Local Application: -Jund-e-Bedastar 10grams grinded into fine powder and mixed in 250grams of Honey and boiled for few minutes till it becomes paste. And applied morning and evening regularly for 4 months.

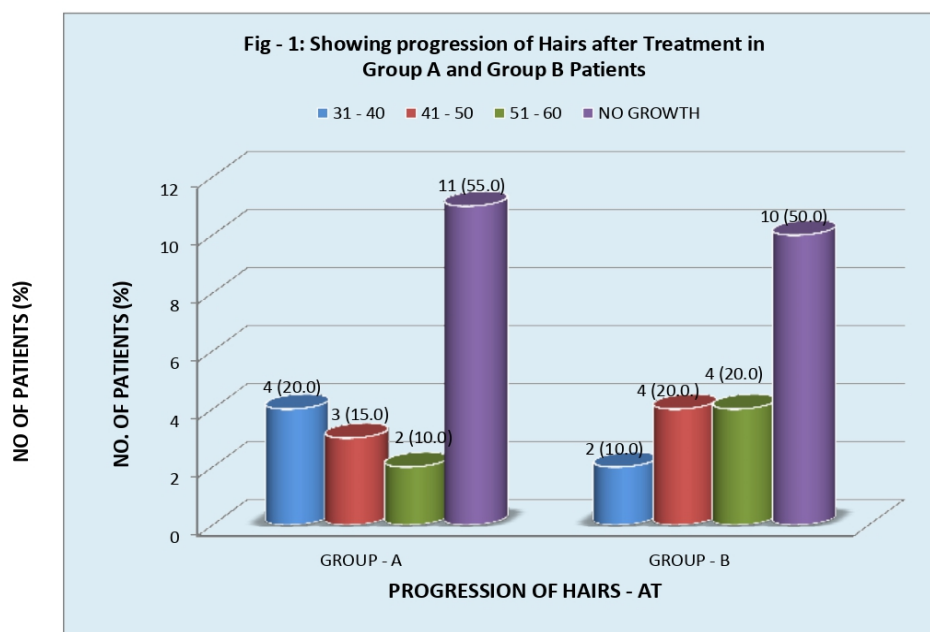
OBSERVATION AND REUSLTS

Table No: 1: Showing Progression of Hairs after Treatment in Group A and Group B Patients.

S. No	NO. OF DAYS	Group – A		Group – B	
		No. of Patients	%	No. of Patients	%
1	31 - 40	04	20.0	02	10.0
2	41 - 50	03	15.0	04	20.0
3	51 - 60	02	10.0	04	20.0
4	No Growth	11	55.0	10	50.0
	TOTAL	20	100	20	100

Table 2: Showing Hair Growth status of Patients before and after Treatment in Group A and Group B.

S. No	TERMINAL HAIRS	BT	AT	Subsided (%)	χ^2 - test	P Value
1	Group A	20	09	11 (55.0)	12.539	< 0.0004
2	Group B	20	10	10 (50.0)	10.800	<0.0010

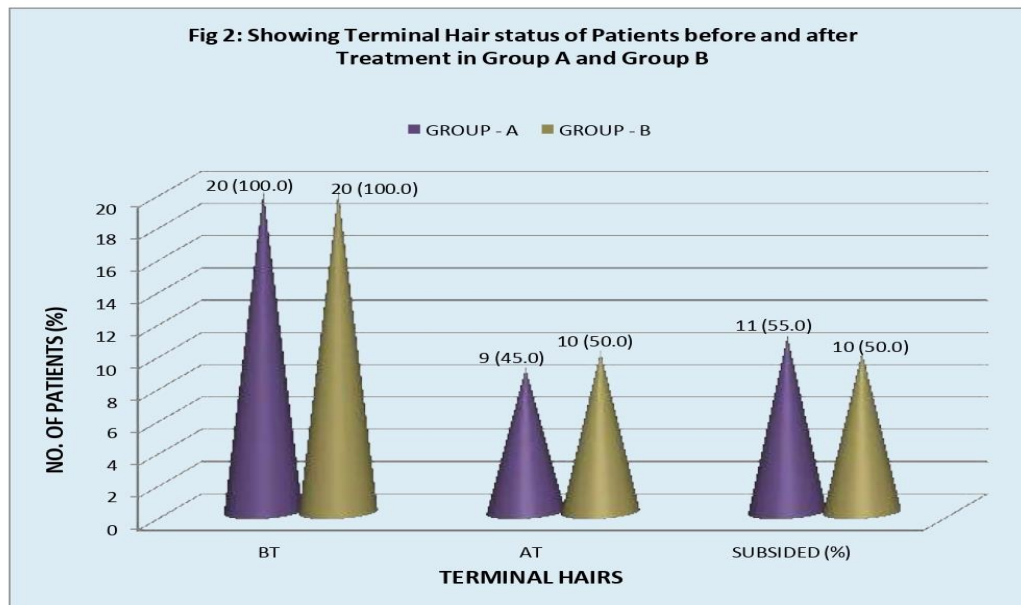


Table No. 3: Showing changes in Laboratory investigations after treatment in Group – A patients.

S. No	Bio-chemical Parameters	No. of Patients	Base line (Mean \pm SD)	After Treatment (Mean \pm SD)	P Value	P < 0.05
1	TSTR	20	49.75 \pm 26.22	28.51 \pm 26.51	< 0.0001	Significant
2	DHEAS	20	224.10 \pm 162.24	296.4 \pm 158.45	< 0.0074	Significant
3	TSH	20	3.11 \pm 1.62	3.00 \pm 1.05	< 0.6011	NS
4	E2	20	73.73 \pm 39.09	73.80 \pm 42.68	< 0.9918	NS
5	FSH	20	5.84 \pm 1.20	5.25 \pm 1.49	< 0.0604	NS
6	LH	20	9.19 \pm 5.74	8.44 \pm 5.04	< 0.4321	NS
7	PRL	20	12.72 \pm 4.35	10.65 \pm 2.60	< 0.0288	Significant

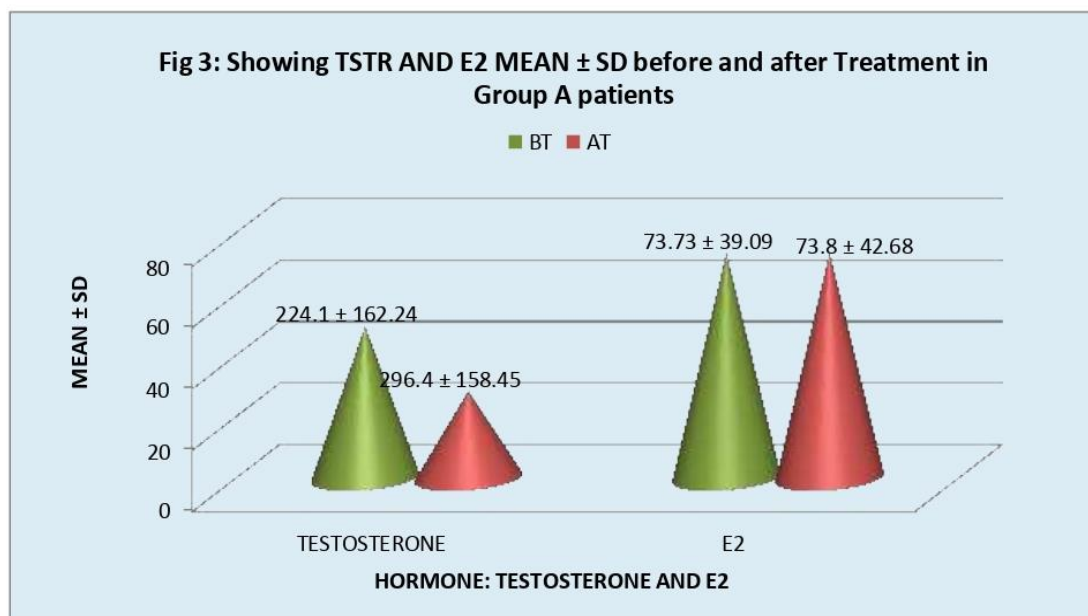


Fig 4: Showing DHEAS MEAN \pm SD before and after Treatment in Group A patients

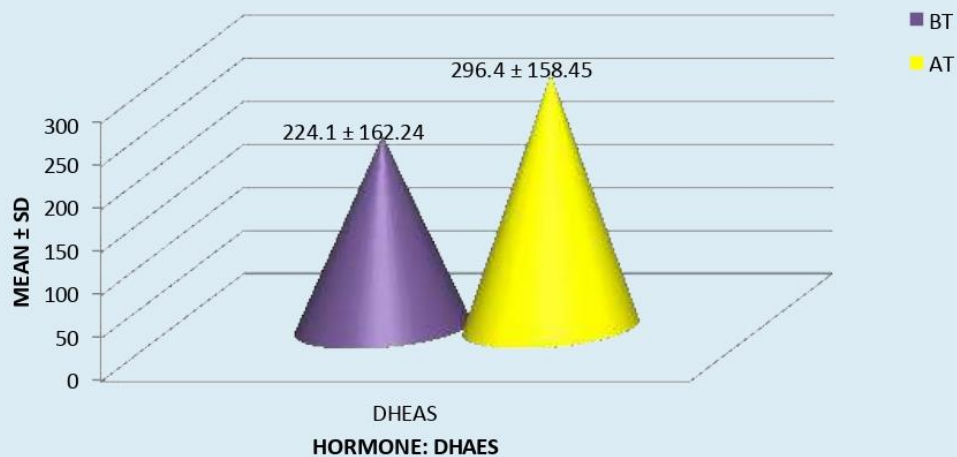


Fig 5: Showing TSH, FSH, LH, PRL MEAN \pm SD before and after Treatment in Group A patients

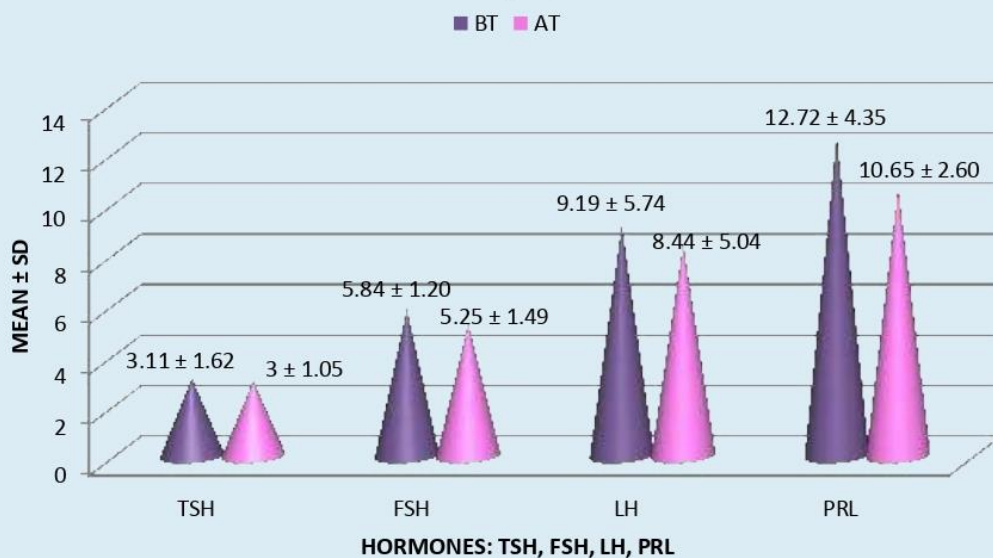


Table No. 4: Showing changes in Laboratory investigations after treatment in Group – B patients.

S. No	Bio-chemical Parameters	No. of Patients	Base line (Mean \pm SD)	AT (Mean \pm SD)	P Value	P < 0.05
1	TSTR	20	47.39 \pm 20.81	21.93 \pm 18.00	< 0.0001	Significant
2	DHEA	20	171.36 \pm 89.60	258.18 \pm 115.93	< 0.0125	Significant
3	TSH	20	2.36 \pm 1.09	2.45 \pm 0.95	< 0.5850	NS
4	E2	20	63.35 \pm 57.66	74.45 \pm 69.02	< 0.1006	NS
5	FSH	20	6.06 \pm 2.88	5.60 \pm 2.24	< 0.2006	NS
6	LH	20	11.30 \pm 12.19	8.60 \pm 7.40	< 0.0443	Significant
7	PRL	20	12.07 \pm 4.63	10.88 \pm 3.11	< 0.1510	NS

Fig 6: Showing TSTR AND E2 MEAN \pm SD before and after Treatment in Group B patients

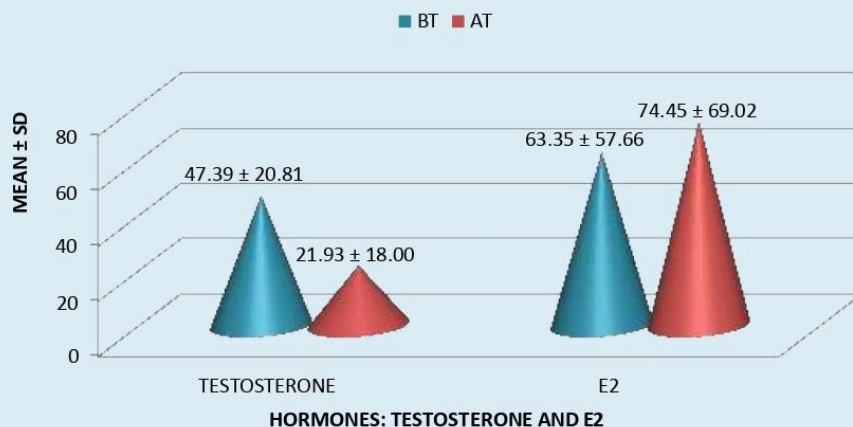


Fig 7: Showing DHEAS MEAN \pm SD before and after Treatment in Group B patients

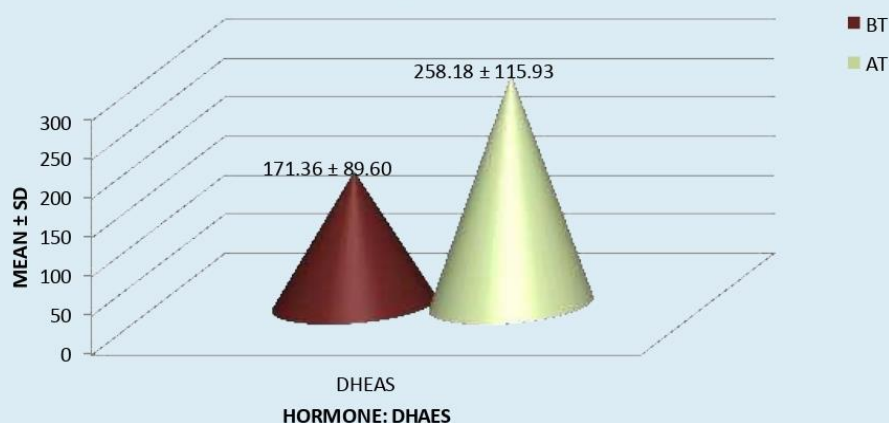


Fig 8: Showing TSH, FSH, LH, PRL MEAN \pm SD before and after Treatment in Group B patients

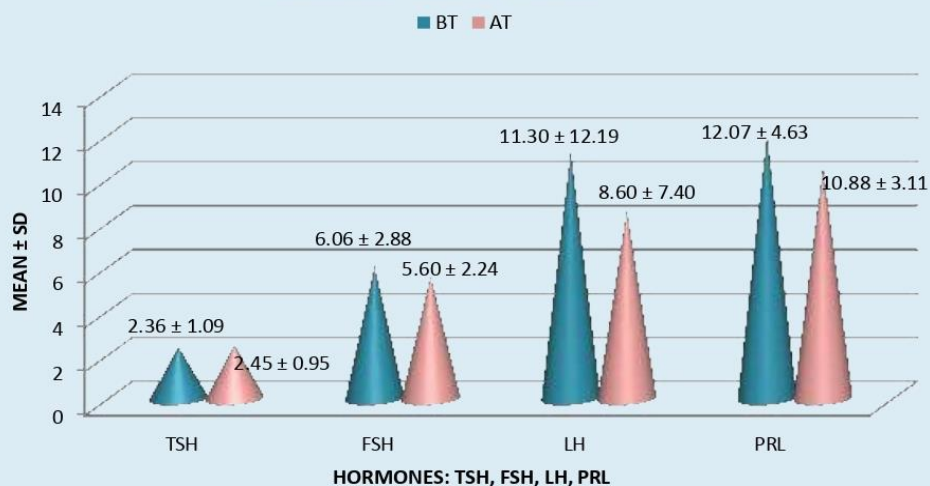


Table No. 5: Showing Result of Ferriman Galwey's Score applied in Group A and Group B patients.

S. No	FG'S App	BT	AT	Subsided (%)	χ^2 -test	P Value
1	Group A	20	03	17 (85%)	26.189	<0.0001
2	Group B	20	04	16 (80%)	23.438	<0.0001

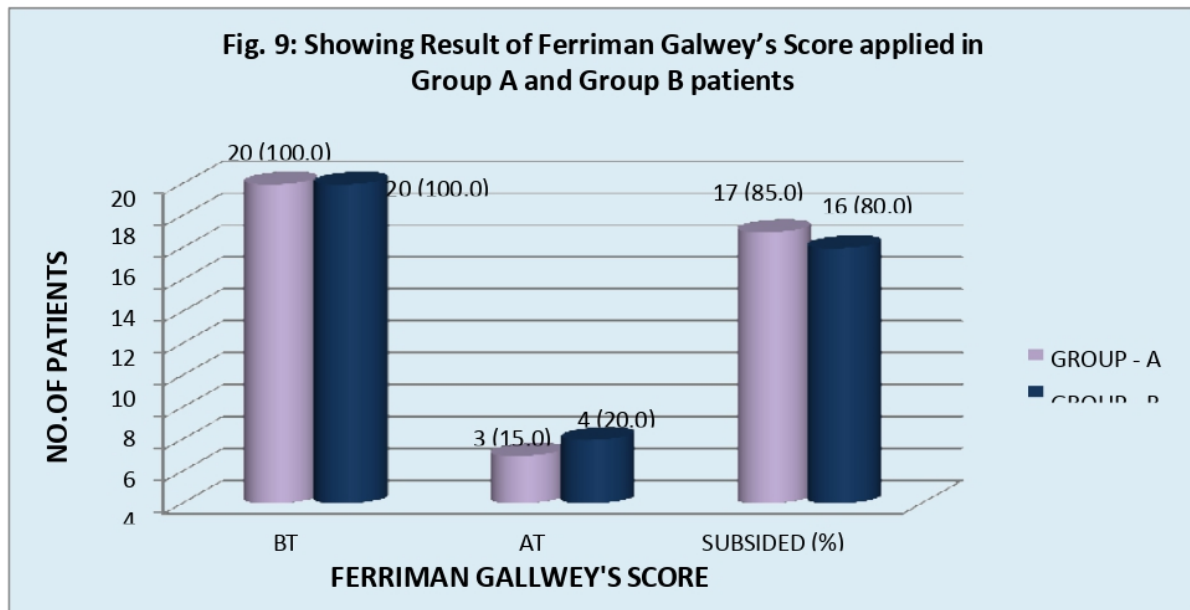


Table No. 6: Showing Drug Response in Irregular Menstruation of Group A and Group B patients.

S. No	Irregular Menses	Before Treatment	After Treatment	Subsided (%)	χ^2 -test
1	Group - A	18	02	16 (88.88%)	0.250
2	Group - B	20	03	17 (85.00%)	0.450

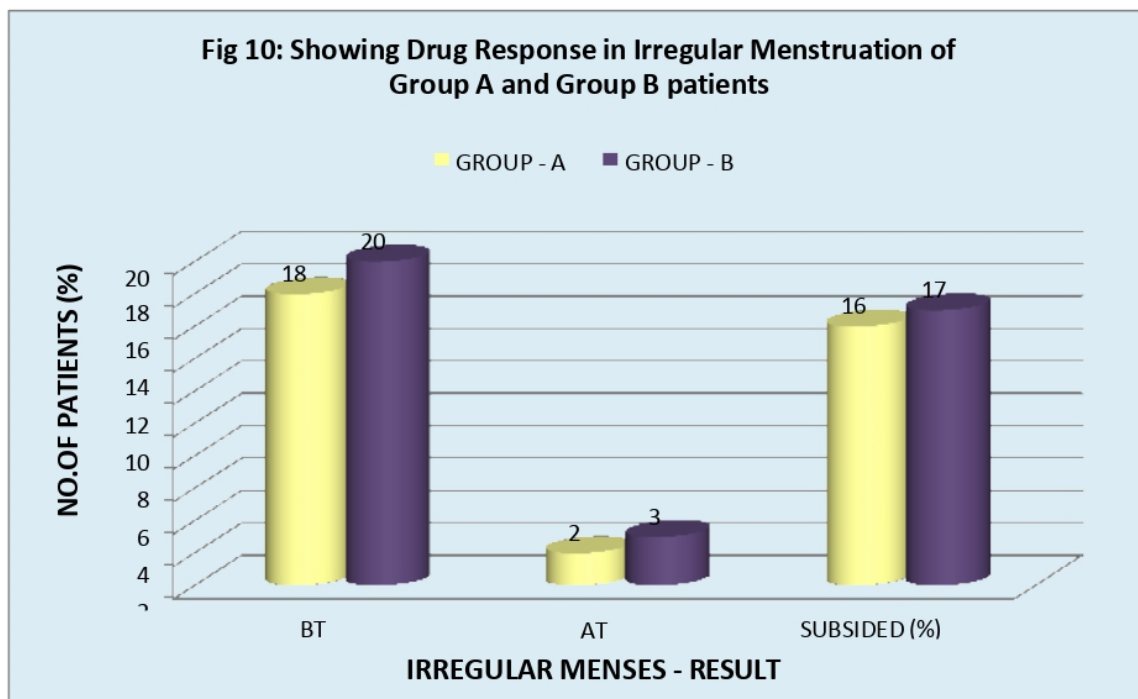
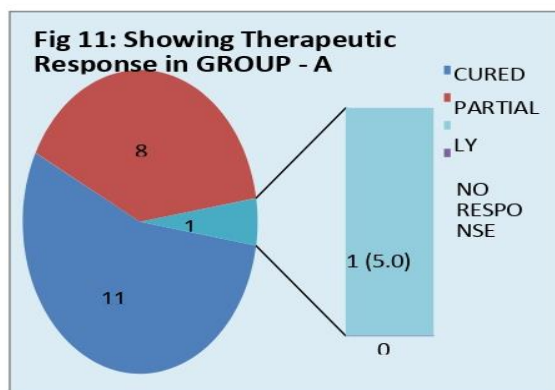
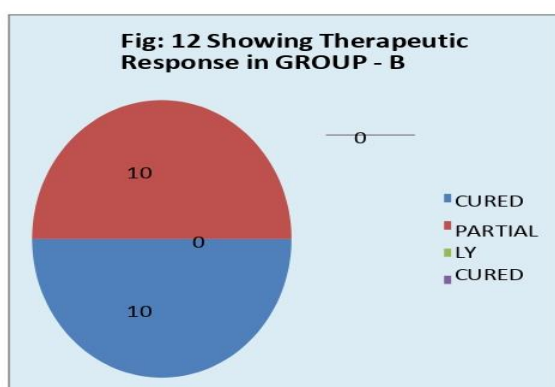


Table No. 7: Showing Therapeutic Response in Group A.

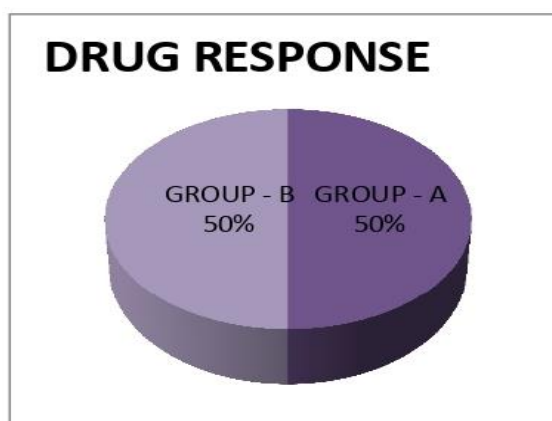
No	Drug Response	No. of Patients	Percentage (%)
1	Cured	11	55.0
2	Partially Cured	8	40.0
3	Poor Response	1	5.0
4	No Response	-	-
	TOTAL	20	100.0

**Table No. 8: Showing Therapeutic Response in Group B.**

No	Drug Response	No. of Patients	Percentage (%)
1	Cured	10	50.0
2	Partially Cured	10	50.0
3	Poor Response	-	-
4	No Response	-	-
	TOTAL	20	100.0

**Table No. 9: Showing Therapeutic Response of Group A in Comparison with Group B.**

S. No	Therapeutic Response	Group A	Group B	P Value
1	Mean \pm SD	87.5 \pm 15.17	87.5 \pm 12.82	< 0.0001



DISCUSSION

Hirsutism is a common gynaecological, endocrinological as well as dermatological and cosmetic, psychogenic disorder in women which is characterized by excessive growth of terminal hairs in women in a male distribution, specifically growth of midline hair over the upper lip, chin, chest, abdomen, back, linea alba and inner thighs. In women, these areas normally do not have terminal hair. It is due to increase in circulating androgen or increased sensitivity of pilosebaceous units to androgen. Menstrual irregularity and amenorrhea are common.

Prevalence: - In India 2.2 % to 26 % and in PCOD 17 % to 83%, most reports in adult women with age ranged from 18-45 years. Hirsutism affects between 5–15% of all women across all ethnic backgrounds. Depending on the definition and the underlying data, approximately 40% of women have some degree of unwanted facial hair.

According to unani concept Hirsutism (Su-e-tarkeeb — Amraz-e-adad). It is a complication of prolong amenorrhea with other male features such as hoarseness of voice, male body pattern, acne and clitoromegaly. Due to amenorrhea body's equilibrium becomes disturbed, and the mizaj becomes su- e-mizaj. According to Ancient physicians Hirsutism is due to Amenorrhea for a long time and alteration in internal environment of female body which results in formation of some waste and unwanted material in the body which is being excreted through skin pores and participates in the formation of thick hairs over the body. These physicians were observed that development of masculine features is more common in obese females. Those waste materials of body which have important role in formation of thick hairs are known as "Bukhaarat-e-Dukhanian". It is a compound made up of four components such as water, soil, air and fire. As per the physiology of unani system all organs of body have four powers from which the normal power of elimination becomes weaker and power of retention and absorption become stronger then there is a more tendency of four components such as water, soil, air and fire to absorb (in the skin and hair follicles) more and more morbid material.

According to modern concept the cause of Hirsutism is purely of hormonal, common causes of Hirsutism are polycystic ovarian syndrome and Increase concentration of serum androgen especially of testosterone or Decreased level of SHBG (sex hormone binding - globulin) or Increased responsiveness of the target organ (skin) to the normal circulating androgens or Increased activity of 5 α -reductase which converts testosterone to DHT (Dihydrotestosterone) in the skin and hair follicles. In some patients it is due to Hyper Androgenism, Insulin Resistance, Acanthosis Nigricans (RHAIR-AN) syndrome, Androgen producing Tumours of ovaries such as Sertoli – ley ding cell tumor, Hilus cell tumor, Lipoid cell tumor and Luteoma of pregnancy. In some patients it is caused by Adrenal hyperplasia (Congenital or late onset), Cushing's syndrome and Adrenal tumours. In some Hirsute patients the causes are Iatrogenic such as Anabolic steroids i.e. Danazol, Cortisone or Anti epileptics i.e. Phenytoin, Valproic acid, Other medications such as Methyl dopa, Metoprolamide. In some Patients Hirsutism is of Genetic origin which can be seen in Androgen sensitivity syndrome, whereas some patients have Familial, and some are Idiopathic. Now a day's one more cause of Hirsutism is Cosmetics and other facial techniques i.e. waxing, bleaching, threading, plucking, shaving.

In current study of Hirsutism, Serum Testosterone, DHEAS, FSH, LH, Prolactin, TSH, E2 is ruled out and its treatment with unani drugs in comparison with standard control drug is carried out in outpatient and inpatient department of Nizamia General Hospital. Out of 100 registered patients who were clinically diagnosed as Hirsutism, 40 patients were selected for Clinical trials. On the basis of selection criteria of study those patients were divided into two groups, Group A and Group B. 20 patients were selected in each group.

Selection criteria of Patients: - The patients were selected in each group with the complaints of excessive and thick hairs on upper lip, chin, chest and abdomen, menstrual disorders include amenorrhoea, oligomenorrhoea, weight gain, acne and scalp hair fall and clinical examination of thickness and distribution of hair pattern the cases were scored on the basis of Ferriman Gallwey's scoring system.

History of onset and hair removal by threading, shaving, waxing or other techniques and history of progression of hairs after removal also obtained from each patient.

The current study included inclusion and exclusion criteria.

Inclusion criteria: - It includes age 15 to 50 years with the complaints of thick and excess hair growth on face, upper lip, chin, chest and abdomen, inner thighs and back, with PCOD, menstrual disorders include amenorrhoea, oligomenorrhoea, weight gain, familial, Drug induced, and idiopathic Hirsutism. And those

Patients who are willing to participate in the study with regular follow up cycles.

Exclusion criteria: - It includes Tumours of ovaries and Adrenal glands, Adrenal hyperplasia (Congenital or late onset), Cushing's syndrome, HAIR-AN syndrome, Patients with HBsAg, HIV and VDRL positive, Known cases of tropical and infectious diseases, patients with known systemic diseases like cardiac, respiratory, renal disorders.

Laboratory Investigations: - It includes the routine investigations such as CBP to rule out Hb%, CUE to rule out any urine infection, RBS to rule out Diabetes, HIV I & II, Hbs Ag, VDRL to ruled out any of these infection and special investigations to estimate hormonal changes in Hirsutiam before and after study. It includes Serum Testosterone, DHEA'S, Estradiol (E2), TSH, FSH, LH, Prolactin and Ultra sonography of Abdomen and Pelvis to ruled out the cause of Hirsutism.

The research studies show that there are elevated levels of testosterone and DHEA'S are associated with Hirsutism.

Clinical Trial Medicines: - After the careful study of Hirsutism and keeping in view the cause and pathology, research medicines were selected, formulated in Group A and in Group B standard control drugs were selected. Treatment was given as OP and IP basis. In Group A coded medicines were prepared in decoction and powder form and given to the patients for 20 days from 5th day of menstrual cycle to 25th day in each cycle and has been repeated for next four consecutive cycles, and depilatory paste was prepared for hair removal when hair growth is present followed by hair growth inhibitor paste (zimad) is prepared and advised for regular application on hair removal areas for two times in each day regularly for 4 months.

In Group B the standard control drugs were selected in the form of tablet and cream, and given to patients tablet orally once in a day from 5th day of menstrual cycle to 25th day in each cycle and has been repeated for next four consecutive cycles, and cream is for local application on hair removal area for two times in a day for four months regularly. After four cycles of treatment with pre and post evaluation results were analyzed statistically for significant improvement of symptoms and signs and investigations. The results were analyzed by T-test, Chi Square test, Mean \pm SD (Standard Deviation) and Clinical based and tabulated in the form of tables and figures which are as follows.

Progression of Hairs (After Treatment): - In the present study, in patient's hair progression after treatment is observed that, Out of 20 patients in Group - A, 11 patients 55% were completely subsided terminal hairs, 4 patients i.e. 20% were has delayed hair progression as in 31- 40 days, 3 patients i.e. 15% were

has delayed hair progression as in 41- 50 days, 2 patient i.e. 10% has delayed hair progression as in 51- 60 days. Out of 20 patients in Group - B, 10 patients i.e. 50% were completely subsided terminal hairs, 2 patients i.e. 10% were has delayed hair progression as in 31- 40 days, 4 patients i.e. 20% were has delayed hair progression as in 41- 50 days, 4 patient i.e. 20% has delayed hair progression as in 51- 60 days. Via vide Table 1.

Terminal Hair Status: - In present study, in Group — A, 20 (100%) patients were having terminal hairs on their body. After 4 months of Unani treatment, it is observed that 11 patients i.e. 55% were completely subsided terminal hairs. Chi-Square (χ^2) – 12.539, $P < 0.0004$ In Group — B, 20 (100%) patients were having terminal hairs on their body. After 4 months of Modern treatment, it is observed that 10 patients i.e. 50% were completely subsided terminal hairs. Chi-Square (χ^2) – 10.800, $P < 0.0010$. From the above data it's observed that the response of Group — A medicines is more significant in comparison to Group - B medicines. Via vide Table 2.

Laboratory Investigations: - In present study in Group A and Group B, biochemical parameters are observed before and after treatment. After statistical analysis, the results expressed as arithmetic Mean \pm SD, Student T-test is performed for P Value.

In Group – A, Testosterone at Base line was 49.75 ± 26.22 and after treatment it observed 28.51 ± 26.51 and is extremely Significant i.e. $P < 0.0001$. The DHEAS at base line was 224.10 ± 162.24 and after treatment the value is found to be 296.4 ± 158.45 and is significant i.e. $P < 0.0074$.

The TSH at base line was 3.11 ± 1.62 and after treatment the value is found to be 3.00 ± 1.05 and is not significant i.e. $P < 0.6011$. The E2 at base line was 73.73 ± 39.09 and after treatment the value is 73.80 ± 42.68 and is not significant i.e. $P < 0.9918$. The FSH at base line was 5.84 ± 1.20 and after treatment the value is 5.25 ± 1.49 and is not significant i.e. $P < 0.0604$. The LH at base line was 9.19 ± 5.74 and after treatment the value is 8.44 ± 5.04 and is not significant i.e. $P < 0.4321$. The PRL base line was 12.72 ± 4.35 and after treatment the value is 10.65 ± 2.60 and is significant i.e. $P < 0.0288$. Via vide Table 3.

In Group – B, Testosterone at Base line was 47.39 ± 20.81 and after treatment it observed 21.93 ± 18.00 and is extremely Significant i.e. $P < 0.0001$. The DHEAS at base line was 171.36 ± 89.60 and after treatment the value is found to be 258.18 ± 115.93 and is significant i.e. $P < 0.0125$. The TSH at base line was 2.36 ± 1.09 and after treatment the value is found to be 2.45 ± 0.95 and is not significant i.e. $P < 0.5850$. The E2 at base line was 63.35 ± 57.66 and after treatment the value is 74.45 ± 69.02 and is not significant i.e. $P < 0.1006$. The FSH at base line was 6.06 ± 2.88 and after treatment the value is 5.60 ± 2.24 and is not significant i.e. $P < 0.2006$. The LH

at base line was 11.30 ± 12.19 and after treatment the value is 8.60 ± 7.40 and is significant i.e. $P < 0.0443$. The PRL base line was 12.07 ± 4.63 and after treatment the value is 10.88 ± 3.11 and is not significant i.e. $P < 0.1515$.

Application of Ferriman Gallwey Score: - In present study, in Group A and Group B, Ferriman Gallwey scoring system applied before and after treatment and result observed as follow, out of 20 (100%) patients in Group — A, on 17 (85%) patients the Ferriman Gallwey scoring cannot apply it means these patients have none or very minimal hairs, whereas 3 (15%) patients were have scoring less than “8”. Chi-Square (χ^2) - 26.189, and is extremely significant i.e. $P < 0.0001$ Out of 20 (100%) patients in Group — B, on 16 (80%) patients the Ferriman Gallwey scoring cannot apply it means these patients have none or very minimal hairs, whereas 4 (20%) patients were have scoring less than “8”. Chi-Square (χ^2) – 23.438, and is extremely significant $P < 0.0001$. Via vide Table 5.

Therapeutic Response of Drugs

Randomized single blind clinical trial with 2 parallel groups for comparison study. The formulae in Group A, selected from ancient unani books after careful study of the disease and its causes, pathology. In Group B, standard control drug were selected. Treatment was given as OP and IP basis. In Group — A, unani coded drugs has been formulated, prepared and given to the patients for 20 days from 5th day of menstrual cycle to 25th day in each cycle and has been repeated for next four consecutive cycles, and depilatory paste was prepared for hair removal when hair growth is present followed by hair growth inhibitor paste (zimad) is prepared and advised for regular application on hair removal areas for two times in each day regularly for 4 months. After administration of the drug it observed that there improvement in subjective and objective parameters like Irregular menses, weight reduction, constipation, mood swings towards social interaction and psychogenic effects of depression. Very minimal side effect was observed in two patients who were using threading for last 6 to 7 years, that they got minimal irritation after applying depilatory cream, whereas the effect of depilatory paste were found effective and painless and progression of hairs become delayed.

In Group B the standard control drugs were selected in the form of tablet and cream, and given to patients, tablet orally once in a day from 5th day of menstrual cycle to 25th day in each cycle and has been repeated for next four consecutive cycles, and cream is for local application on hair removal area for two times in a day for four months regularly. After administration of the drug, it observed that their improvement in subjective and objective parameters and very minimal side effect observed in one patient that is breast tenderness.

After 4 cycles of treatment with pre and post evaluation

were analyzed statistically for significant improvement of subjective and objective parameters. The results expressed as arithmetic Mean \pm SD, Student T-test is performed for P Value and tabulated. Out of 20 patients in group A, 11 patients (55%) cured, 8 patients (40%) partially cured, 1 patients (05%) poor response. Where as in group B, 10 patients (50%) cured, 10 patients (50%) partially cured. Via vide table 7 & 8.

Mean Therapeutic response in Group A and Group B.

In present study after the selection of patients in Group A and Group B, by careful study of parameters of subject in each group and as per the causes and pathology drugs were selected from authentic books for clinical trials. After four months of treatment with pre and post evaluation were analysed statistically for significant improvement of subjective and objective parameters. The mean Therapeutic response was observed in Group A is 87.5 ± 15.17 (SD) and the mean Therapeutic response was observed in Group B is 87.5 ± 12.82 (SD), and the P value is extremely significant that is $P < 0.0001$. Both the groups have almost equal efficacy in the treatment of hirsutism. Both group A and Group B medicines are safe and patients well responded to therapy.

SUMMARY

As World is developing, the peoples are also modifying themselves in modernization which becomes great impact on health and most of the population measures different lifestyle disorders and become a big issue for health and social life. The term for hirsutism in unani classical books is "kasarat-e-sha'r. It is a complication of prolong amenorrhoea with other male features such as hoarseness of voice, male body pattern, acne and clitoromegaly. It is not only a gynaecological disorder but also a challenge in endocrinology, dermatology, cosmetics and psychology. The aim of present clinical study is to evaluate the efficacy of Unani drugs and to popularize the unani medicines in the management of Hirsutism and to prevent the complications of virilism. After the careful study of Hirsutism and keeping in view the cause and pathology, research medicines were selected, formulated in Group A and in Group B standard control drugs were selected. Treatment was given as OP and IP basis. In Group A coded medicines were prepared in decoction and powder form and given to the patients for 20 days from 5th day of menstrual cycle to 25th day in each cycle and has been repeated for next four consecutive cycles, and depilatory paste was prepared for hair removal when hair growth is present followed by hair growth inhibitor paste (zimad) is prepared and advised for regular application on hair removal areas for two times in each day regularly for 4 months. In Group B the standard control drugs were selected in the form of tablet and cream, and given to patients tablet orally once in a day from 5th day of menstrual cycle to 25th day in each cycle and has been repeated for next four consecutive cycles, and cream is for local application on hair removal area for two times in a day for four months regularly. After four cycles of treatment with pre and

post evaluation results were analyzed statistically for significant improvement of symptoms and signs and investigations. The results were analyzed by T-test, Chi Square test, Mean \pm SD (Standard Deviation) and Clinical based and tabulated in the form of tables and figures which are as follows.

After 4 cycles of treatment with pre and post evaluation were analysed statistically for significant improvement of subjective and objective parameters. The results expressed as arithmetic Mean \pm SD, Student T-test is performed for P Value and tabulated. Out of 20 patients in group A, 11 patients (55%) cured, 8 patients (40%) partially cured, 1 patients (05%) poor response. Where as in group B, 10 patients (50%) cured, 10 patients (50%) partially cured. Via vide table 7 & 8.

The mean Therapeutic response was observed in Group A is 87.5 ± 15.17 (SD) and the mean Therapeutic response was observed in Group B is 87.5 ± 12.82 (SD), and the P value is extremely significant that is $P < 0.0001$. Both the groups have almost equal efficacy in the treatment of hirsutism. Both group A and Group B medicines are safe and patients well responded to therapy. The present clinical study on Hirsutism evident that the similar efficacy of Compound Unani formulations in comparing to standard drug and shows significant results $P < 0.0001$.

CONCLUSION

Hirsutism is a common gynecological, endocrinological as well as dermatological and cosmetic, psychogenic disorder in women which is characterized by excessive growth of terminal hairs in women in a male distribution, specifically growth of midline hair over the upper lip, chin, chest, abdomen, back, linea alba and inner thighs. The present study was aimed to reduce the risk of Laser therapy for hair removal and to reduce the complication of Virilism. The selected drugs for the treatment of hirsutism shown excellent results with safe and very minimal side effects. Biochemical parameters were studied before and after treatment and it shows significant results. In this study the compound unani formulations which have actions like emmenagogue, diuretics, blood purifiers, depilatory, skin protective, hair growth inhibitor and Expectorant of Phlegmatic humor, were compared with standard control drugs and the result of compound Unani formulation shows close to standard control drugs. After the study the subjective and objective parameters were assessed in comparing to before study and the results were drawn statistically to prove the efficacy of Unani medicines in comparison with standard control drugs. The mean Therapeutic response was observed in Group A is 87.5 ± 15.17 (SD) and the mean Therapeutic response was observed in Group B is 87.5 ± 12.82 (SD), and the P value is extremely significant that is $P < 0.0001$. Both the groups have almost equal efficacy in the treatment of hirsutism. Both group A and Group B medicines are safe and patients well responded to therapy. The present clinical

study on Hirsutism concluded that the similar efficacy of Compound unani formulations in comparing to standard drug and shows significant results $P < 0.0001$.

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