

Efficacy of Sahajna (*Moringa Oleifera*) among obese women due to PCOS (IKIYAS-E-KHUSYATUR REHAM) : A Randomized Single blind study.

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ABSTRACT

Background: PCOS is a heterogeneous, multisystem endocrinopathy in reproductive age women characterized by menstrual abnormalities, oligo /anovulation and hyper androgenism. These signs and symptoms vary widely within Individuals, overtime women with this endocrine disorder also have higher rates of dyslipidemia, obesity and insulin resistance, which increase long term health risks. **Objective:** Objective was to evaluate the efficacy of Sahajna (*Moringa Oleifera*) among obese women due to PCOS. **Methodology:** This was a prospective– a randomized single blind study, to scientifically evaluate the efficacy of Sahajna in obese women. The present study was conducted in Govt.Nizamia General Hospital during the years of 2019 – 2021. 40 obese patients with the history of PCOD were registered from outpatient department of GNGH, out of which 30 patient were selected for clinical trial who has given consent for research study. A single group of 30 patients were selected for the study and patients were selected randomly. Study medicine is given to all the patients for a period of 3 months. Results were divided on the basis of subjective and objective parameters Overall results were assessed by Chi -square test. **Results:** Analysis of data shows overall therapeutic response based on the subjective and objective parameter in this study were assessed as excellent, good, satisfactory and poor. The patients were satisfied by reduction of weight and improve their personality. **Conclusion:** It is observed that the patients had good response with this medicine (sufoof–e-Sahajna) Marked reduction of weight observed by analyzing of BMI before and after completion of therapy for 3 months. It was noted that out of 30 patients 16.7% (n=5) patients were got excellent relief. 46.7% (n=14) patients showed good relief, 33.3% (n=10) patients showed satisfactory relief and 3.3% (n=1) patient showed poor response.

KEYWORDS

Polycystic Ovarian syndrome, Ikiyas-e-khusyatur reham, *Moringa Oleifera*, Sahajna, Obesity, BMI, Randomized single blind study.

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INTRODUCTION

Polycystic ovarian syndrome (PCOS) is an endocrine– metabolic disorder characterized by multiple hormonal imbalance, reflexing on a clinical presentation dominated by manifestations of hyperandrogenism which generate short and long term consequences on women health(9,12). Polycystic ovarian syndrome was originally described in 1935 by Stein and Leventhal as a syndrome manifested by amenorrhea, hirsutism and obesity associated with enlarged polycystic ovaries(11) PCOS is the most common endocrine disorder of reproductive aged women and affects approximately 4-12% in general population studies. Although symptoms of androgen excess may vary among ethnicities, PCOS appears to affect all races and nationalities equally (22, 23, 25)

It is the most common endocrine disorder in women of reproductive age. Among these infertility is one of the most alarming morbidity(28) Indeed its optimal diagnosis is often hindered, due to its apparent similarities with several other pathologies remarkably obesity as well as Cushing syndrome, ovarian and adrenal neoplasm and congenital adrenal hyperplasia. Fertility in women is highly regulated by hypothalamo–pituitary-ovarian axis (14, 17).

Anovulation is a common problem encountered in infertility which occurs in about 10% cases. This heterogeneous disorder is characterized by excessive androgen production by the ovaries. PCOS is a multifactorial and polygenic condition (11, 22,23). Deregulations of the CYP 11a gene, up regulation of enzymes in androgen biosynthetic pathway have been suggested.(17)

Insulin receptor gene on chromosome 19p 13.2 are also involved. Women afflicted by this disease show an increased prevalence of several comorbidities including obesity, dyslipidemia, hypertension (26, 27) metabolic syndrome and type-2 Diabetes mellitus in comparison with women without PCOS. The features along with other alterations such as endothelial dysfunction and a chronic low grade inflammatory state, facilitates greater risk of developing cardiovascular disease and increased all-cause mortality observed in these Patients insulin resistance is a fundamental link associating these conditions, although Insulin resistance may be present in PCOS independently of Obesity(25,36)

Diagnosis is based upon the presence of any two of the following three criteria ASRME/ESHRE oligo and anovulation, hyper androgenism (clinical and bio chemical), Polycystic ovaries (32,33) Other etiologies congenital adrenal hyperplasia, thyroid dysfunction, hyper prolactinaemia, Cushing syndromes are to be excluded. The incidence is prevalent. In young reproductive age group (20-30%). Polycystic ovary maybe seen in about 20% of normal women (29)

In unani system of medicine the polycystic ovary disease is called as „**Ikyas – e- Khusya-Ur- Reham**. Unani physicians believe that health is a state of body, in which there is equilibrium in the humours and functions of the body. When the equilibrium of the humour specially balgham is disturbed quantitatively or qualitatively or both(1,2,3,4,5,6,7) It changes the temperament of affected organ resulting disease and physiological functions are deranged due to abnormal body temperament of affected organ or system resulting in this disease(5,6,7,8)

The various treatments recommended by unani physicians are ilaj bil Ghiza, Ilaj bil Dawa, Ilaj bil Tadbeer and Ilaj bil Yad keeping in view of the ancient and Modern literature, this drug was selected with the following properties. Diuretics eminogouge, antispasmodic, cardiac tonic, laxative (13, 16, 18, 40) A randomized single blind study is designed. A sum of 30 patients has been treated with sufoof- e-sahajna (10). This study has proved the efficacy of the Sahajna for treating obese women due to PCOS.

METHODOLOGY

Study design:

A prospective, Single blind randomized, pre and post-evaluation clinical trial was conducted on 30 patients who attended the outpatient department of OBG at Govt. Nizamia General Hospital, Charminar, Hyderabad, Telangana, India with chief complaint of obesity with PCOS during the years 2019 – 2021. The study protocol was approved by the institutional ethical committee. Data collection and intervention were started after taking written informed consent from subjects. Women were included aged 18-40years, married and unmarried, with history of irregular menstruation, BMI >25kg/m², with USG finding of PCOD, and willing to undergo laboratory investigations, also willing to participate in trial and signing in consent form. Women were excluded age below 18 and above 40 years, patients having the history of renal failure, liver disorder and

autoimmune disease, patients with any serious medical illness, patients having congenital uterine abnormalities, Women with BMI > 44kg/m² and Women on HRT.

A detailed history including demographic profile of patients was noted. Following complete evaluation of history and clinical examination. Patient were subjected to baseline investigations of CBP ,CUE ,ESR ,HIV ,HbsAg, USG(abdomen& pelvis) and Specific investigations Thyroid profile ,Serum prolactin , serum FSH, LH levels. Diagnosis by Rotterdam criteria (35) hyperandrogenism, Oligo/ anovulation, Polycystic Ovaries [2 out of 3 need]

Interventions

A single group of 30 patients were selected for the study and patients were selected randomly. Study medicine is given to all the patients for a period of 3 months Patients were requested to take sahajna powder orally 5 grams with 100ml Luke warm water once in early morning empty stomach and night before bed for 3 consecutive months. Before starting the treatment all patients were investigated according to the protocol as well as measured weight, height and BMI was calculated and recorded according the age. Patients were also enquired for any improvement or changes in the menstrual cycle and recorded monthly. Results were divided on the basis of subjective and objective parameters i.e. weight reduction .Assessed by BMI and 5-10 % weight reduction improve the associate symptoms, like menstrual irregularities, Acne, Acanthosis nigricans, Hirsutism and Male pattern baldness. If any adverse effect experience by the Patient also requested to report immediately.

Table-1 Basic characteristics of patients

Parameter	Statistics
No. of patients	30
Age (Mean ±S.D.)	22.9 ±4.0 yrs.
Age (Range)	18 – 35 yrs.

Table-2 Showing distribution of patients according to age

Age (in years)	No. of patients	Percentage
18 – 22	17	56.7
23 – 27	8	26.7
28 – 32	4	13.3
33 – 37	1	3.3
Total	30	100.0

Table-3 Showing distribution of patients according to menarche

Age (in years)	No. of patients	Percentage
10	2	6.7
11	3	10.0
12	14	46.7
13	9	30.0
14	2	6.7
Total	30	100.1

Table-4 Showing distribution of patients according to marital status

Marital status	No. of patients	Percentage
Unmarried	10	33.3
Married	20	66.7
Total	30	100.0

Table-5 Showing distribution of patients according to family history of PCOD

Family history of PCOD	No. of patients	Percentage
Present	20	66.66
Absent	10	33.33
Total	30	100.0

Table-6 Showing distribution of patients according to mizaj (temperament)

Mizaj (temperament)	No. of patients	Percentage
Damwi	0	0.0
Balghami	25	83.3
Safrawi	0	0.0
Saudawi	5	16.7
Total	30	100.0

Table-7 Showing distribution of patients according to Socio-economic status (SES)

Socio-economic status	No. of patients	Percentage
Upper group	4	13.3

Upper middle group	15	50.0
Middle group	8	26.7

Lower middle group	3	10.0
Total	30	100.0

Table-8 Showing remission in signs and symptoms after treatment

Parameter	Unit	Before treatment	After treatment	χ^2 -test	P <0.05
Menstrual irregularities	Present	29	8	30.848	H.Sig.
	Absent	-	21		
Acne	Present	20	9	12.539	Sig.
	Absent	-	11		
Hirsutism	Present	8	8	0.000	Not sig.
	Absent	-	0		
Acanthosis nigricans	Present	9	9	0.000	Not sig.
	Absent	-	0		
Male pattern Baldness	Present	3	3	0.000	Not sig.

Table-9 Showing reduction in BMI after treatment

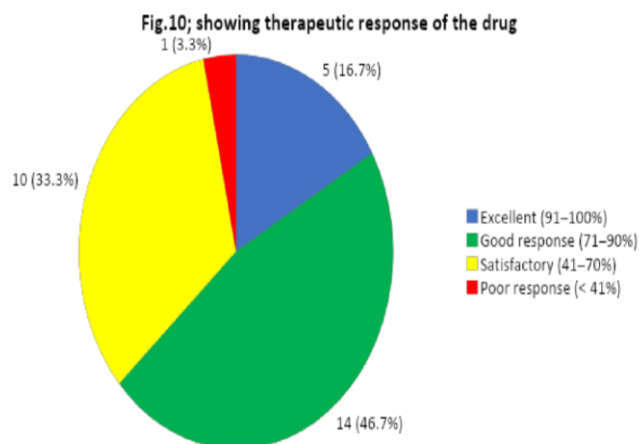
Parameter	Before treatment (mean±S.D.)	After treatment (mean±S.D.)	t-test	P <0.05
BMI	31.46 ±1.94	28.26 ±2.15	27.10	H.Sig.

Table-10 Therapeutic response of drug

Response	Test Group	
	No. of patients	Percentage
Excellent (91 - 100)	5	16.7
Good (71 - 90)	14	46.7
Satisfactory (41-70)	10	33.3
Poor (<41)	1	3.3
Total	30	100.0

Table-11 Showing mean (±S.D.) therapeutic response of the drug

Parameter	Response (mean±S.D.)	t-test	p-value
Response	72.80 ±20.71	19.25	< 0.001



Assessment

A total 40 patients were selected for the study, out of which (n=3) patients denied and 37 were evaluated through investigation. (n=4) were excluded as they doesn't comes under inclusion criteria and (n=33) patients were enrolled in Overall results were assessed by Chi-square test as excellent, good, satisfactory and poor.

In the present study it was observed that among 30 patients (n= 5) has excellent Response to the drug and (n=14) patients have shown good response to the drug. 33.3% patients have shown satisfactory and one patient, that is 3.3% shown poor response to the study medicine. Excellent response that is (n= 5) patients have shown of marked reduction (91-100%) in BMI and associate symptoms. (n=14) patients out of 30 have shown good response, moderate reduction (71- 90%) of BMI and associate symptoms. Satisfactory responses have shown 33.3 % of patients' mild reduction (41-70%) of BMI and associate symptoms. Finally one patient reduced 2kg weight only (<41%), that is considered as poor response.

Statistical Analysis

Statistical analysis was used for analysis of data. Descriptive and inferential stastical analysis has been carried out in the present study. Reasults on continuous measurements were presented on Mean = SD and results were presented in number (%) significance. Students t- test, Chi-square has been used to find the significance of study parameters.

RESULTS

Results were divided on the basis of subjective and objective parameters i.e. weight reduction assessed by BMI and 5-10 % weight reduction improve the associate symptoms like menstrual irregularities, Acne, Acanthosis nigricans,

Hirsutism and Male pattern baldness. Overall results were assessed by Chi-square test. Results were assessed as excellent relief, good relief, satisfactory relief and poor relief. Our study showed that remission in signs and symptoms after treatment, out of 30 patients 29 had menstrual irregularity, among 29 (n=21) were relieved after treatment and (n=8) were unrelieved.

This is highly significant. n=20 patients had acne out of 20, n=11 were relived and n=9 were unrelieved this is significant n =8 patients came with hirsutism, 9 patients came with acanthosis nigricans and 3 had male pattern boldness all of these symptoms were not relieved. These symptoms are not significant.

Table 9 showing reduction in BMI after treatment, it was 31.461 ± 0.94 before treatment which was significantly improved after treatment as 28.26 ± 2.15 which was calculated by t -test with a p value of <0.05 which was significantly improved after treatment.

DISCUSSION

A detailed analysis revealed that the mean age group of patients was 22.9 years with standard deviation of ± 4.0 years (Table-1) According to menarche it is observed that 46.7% patients were in the age of 12 years (Table -3). It was observed that 66.7% patients were married (Table-4). Distribution of patients according to family history of PCOD 66.66% had history of PCOD and 33.33 % don't have family history of PCOD (Table-5) (9,11). Majority of patients were Balghami mizaj 83.3% and 16.7% were sawdawi mizaj patients (Table- 6)(1,2,3,4,5)

According to SES 50% (n=15) of patients belongs to upper middle class group, 26.7% patients belongs to middle class group (n=8), 13.3% (n=4) middle class group and 10% (n=3) belongs to lower middle class group shown in table -7 (9, 12, 38) This finding is correlated with the statement of national health portal of India and general population studies.

Our study showed that remission in signs and symptoms after treatment, out of 30 patients 29 had menstrual irregularity, among 29 (n=21) were relieved after treatment and (n=8) were unrelieved. This is highly significant. n=20 patients had acne out of 20, n=11 were relived and n=9 were unrelieved this is significant. n= 8 patients came with hirsutism, 9 patients came with acanthosis nigricans and 3 had male pattern boldness all of these symptoms were not relieved. These symptoms are not significant.

Table -9 showing reduction in BMI after treatment, it was 31.461 ± 94 before treatment which was significantly improved after treatment as 28.262 ± 15 which was calculated by t-test with a p value of <0.05 which was significantly improved after treatment.

Table- 10 shows therapeutic response of moringa oleifera, it was noted out of 30 patients 16.7% (n=5) patients were got excellent relief. 46.7% (n=14) patients showed good relief, 33.3% (n=10) patients showed satisfactory relief and 3.3% (n=1) patient only showed poor response. According to table -11 mean therapeutic response of the drug in this study was 72.80 with standard deviation ± 20.71 which is calculated by t-test with a p value of <0.001

No adverse effect of test drug was observed during the trial and the safety profile investigations were within normal limits, hence Moringa oleifera was found as a safe drug. The limitation of study was small sample size causing statistical error, therefore further trial can be carried out to confirm the efficacy and potency of drug on large number of patients.

CONCLUSION

It may be concluded that powder of sahajna (moringa oleifera) was found to be beneficial in patients of obesity due to PCOS due to its diuretics, emingouge anti spasmodic, cardiac tonic, laxative, anti-anemic, anti-hypertensive, anti-lipidemic, and anti-diabetic and antioxidant effects. It can serve as an alternate remedy for diabetes patients. This study confirms the efficacy and safety of Sahajna (Moringa oleifera) in the management of obese women due to PCOS.

CONFLICT OF INTEREST

None

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