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Original Article

Effect of *Saleekha* and *Majeeth* in Polycystic Ovarian Disease: An Open Observational Study

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ABSTRACT

Introduction: PCOD is a common, complex reproductive endocrinopathy characterized by menstrual irregularities, hyperandrogenism, polycystic ovaries, metabolic and psychological disorders and affects up to 18% of reproductive-aged women. **Objectives:** To evaluate the effect of *Saleekha* and *Majeeth* in PCOD. **Materials and Methods:** Clinically diagnosed Patients (n=30) with PCOD in age 18-35 years with oligomenorrhea or amenorrhoea were included in the study. Patients with thyroid dysfunction, systemic diseases, endometrial tuberculosis, malignancies on hormonal treatment in the last 3 months, pregnancy, and lactation were excluded. The research drug was administered orally in a dose of 3.5 gm B.D *safūf* (powder) of *Saleekha* with *Joshānda* (decoction) of *Majeeth* 7 gm BD for 14 days/ cycle for three consecutive cycles. Outcome measures were changes in subjective parameters (nature of bleeding, duration of cycles, duration of flow, amount of flow, weight reduction) and objective parameters, pictorial blood loss assessment chart (PBAC) score, basal metabolic index (BMI), modified Ferriman Gallwey (mFG) score, acanthosis nigricans scale and pelvic ultrasonography. Data were analyzed using the paired Student *t*-test. **Results:** Marked improvement was observed in menstrual irregularity and PBAC score with $p<0.001$ which is highly significant after the intervention. Significant change is seen in BMI, Ovarian volume, and SF-12 with $p<0.001$ after treatment. Safety parameters were within the normal range. **Interpretation and Conclusion:** Research drugs (*Saleekha* and *Majeeth*) can be used as an alternate remedy in PCOD patients, as it significant effect to regularize menstruation by reduction of BMI and probably by improving insulin resistance in PCOD. No adverse effect of the research drug was noted during the trial.

Keywords: BMI, *Majeeth*, mFG, PBAC score, PCOD, *Saleekha*.

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INTRODUCTION

Polycystic ovary syndrome (PCOS) is a complex condition in reproductive age, characterized by elevated androgen level, menstrual irregularities and / small cysts on one or both ovaries,[1-2] It affects around 6% to 8% of women of reproductive age.[1-4]

The exact cause of PCOD is unknown but it has certainly been linked to a variety of aetiological factors; genetic, environmental, lifestyle etc,[1,4,] contribute to the development of PCOD. Women may present with a number of reproductive, endocrine, metabolic and psychosocial symptoms.[1,2,4,5]

Long-standing PCOD can lead to long term consequences including Type 2 DM, hypertension, cardiovascular disease,[5,1,2] endometrial cancer.[1,2,5,6] Early diagnosis and treatment can help control the symptoms and prevent long-term problems.[2]

In Unani text book, disease has been described under the headings of *Ihtibās Al- Tamth (*amenorrhea*)* is mainly caused by dominance of *khilt-i-balghm* which increases the viscosity of *khūn-i-hayd* and from *sudda* as a result menstrual blood is unable to expelled out of the uterus.[7]

The principle of treatment is *Ilaj biz zid*; the temperament of the disease being *bārid ratab*, the drugs having *garm wa khushk mizāj*; possessing the properties like *muddir-i-hayd, mulattif balgham, mufattīh* are used in the management of *Ihtibās Al- Tamth;* Also they transform the *akhlāt* towards hot temperament, facilitating the metabolism of *balgham* to *dam.*[8]

Several single drugs and compound formulations are enlisted in the management in PCOD patients. Drugs such as *Majeeth, Saleekha* is selected as research drugs to induce menstruation in PCOD patients, as they exhibit the properties of *mudirr-i-bawl wa hayd, mufattih-i-sudad, munaqqi-i-jiger, munáffith-i-balgham, mu'arriq, musakhkhin, muhallil-i-awrām.*[9,10] In this study *Majeeth,* and *Saleekha* has been selected based on its ingredients and as per the indications and hypothesized, which probably may regularize the menstruation by reduction in BMI and improving

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insulin resistance. Hence, an open observational clinical study was envisaged.

MATERIALS AND METHODS

Study design

An observational clinical study.

Study duration

One and half year from December 2020-February 2022.

Sample size

30 patients.

Ethical clearance

Ethical clearance is obtained by Institutional Ethical Committee vide No: NIUM/IEC/2019-20/009/ANQ/01. CTRI registration done vide no. CTRI/2021/02/031070. Informed consent all the participants gave written informed consent before the study starts. Drug identification was done at FRLH Bengaluru with an a/c no.03711450000072.

Selection criteria

Patient both unmarried and married between 18-35 year of age, H/o irregular periods like oligomenorrhoea or amenorrhoea with PCOD. Presence of PCO on USG pelvis, obesity was included. Patients with systemic and endocrine diseases like HTN, DM, and thyroid dysfunction pregnancy and lactating women and on contraceptives, malignancies, endometrial tuberculosis were excluded.

The procedure of study

The Inclusion criteria fulfilled patients were included in study. Participants were asked to provide details on their demographic data. Menstruation cycle with the medical history. In each patient, history is evaluated and a complete physical examination was performed including gynecological examination, investigations, were recorded in case record form structured for the study.

Criteria for selection of test drug

Majeeth, Saleekha is selected to evaluate its efficacy in the management of *Ihtibase–i-tamth* as this formulation has pharmacological activities such *as Musakhkhin, Mulaṭṭiff, Muhallil-i- Awrām, Mudirr-i-Bawl wa Hayd, Mufattih-i-sudad, Muqawwī-i-Miʿda wa jiger,Kāsire-i-Riyāh, Munaqiye-i- rhim, Munnaqiye-i-jiger, Munáffith-i-balgham, Mu'arriq*, *Muwalid-i-sheer*[9,11,12]

Method of preparation, dosage and route of administration

The purest form of *Saleekha* was provided by the pharmacy of NIUM and was further authenticated by FRLHT, Bengaluru. With an A/c no. 03711450000072. The drug was finely powdered as per standard preparation and weighed 7 gm powder of *Saleekha* another drug *Majeeth* was coarse grinded and weighed 14 gm decoction of *Majeeth* was administered orally twice a day for 15 days and observed for commencement of menstruation for next 15 days and patient were asked to come back after 30 days for follow up and collect the drug for next cycle.

Initial screening of patients

Baseline laboratory investigations like Hb% UPT, RBS and TSH were done to rule out anemia, pregnancy, diabetes mellitus and thyroid dysfunction, and pelvic ultrasound was done to exclude pelvic pathology. Safety profile Blood Urea, Serum Creatinine, AST, ALT and Alkaline Phosphatase, was done before and after the intervention for the safety of test drug.

Subjective parameters

Nature of cycle, duration of cycle, duration of flow, amount of flow, Clinical sign of hyper-androgenism, obesity.

Objective parameters

PBAC, SF-12 survey to assess QOL, BMI, Waist circumference, ovarian volume.

Outcome measures

It is assessed by change in subjective and objective parameters.

Statistical Methods

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in number (%). Significance is assessed at 5% level of significance.[13-15]

RESULTS

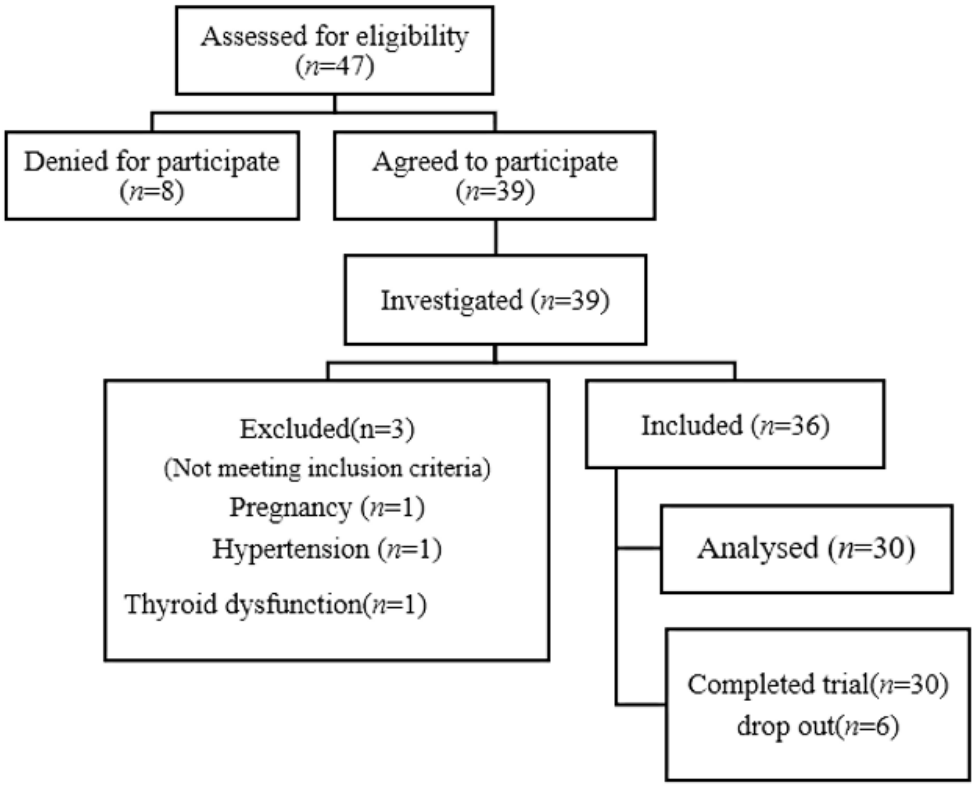
Marked improvement was observed in menstural irregularity and PBAC score with $p<0.001$ which is highly significant after the intervention. Significant change is seen in BMI, Ovarian volume, and SF-12 with $p<0.001$ after treatment. Safety parameters were with in normal range. Baseline data has been represented in (Table 1)

Age

A similar study conducted by Kouser *et al.*[16] reported 46.66% in the age group 20-30 years. Ghavi F *et al.*[17] reported 23.60 ± 2.32 and 23.14 ± 2.7 in two groups, hence, in the present study most of the patients were young adults.

Age of menarche

Deswal R. *et al.*[18] reported 12.7± 0.9 and 13.1 ± 1.4 in two groups.



Flow diagram.

Marital status

The majority of patients, 53.3% were married 46.7% were single. This is in consonance with Jzani AM *et al.*[19] reported 55.56%as married and 44.4% as in single.

Socioeconomic status

This finding accordance with the study of Firdose KF *et al.*[16] reported 53.3%, 26.7%, 20% in test group and 53.3%, 20%, 26.7% in control group belong to upper lower, lower middle, upper middle class respectively.

Family H/O PCOS

Similar study conducted by Bhat SA *et al.*[20] reported 82.5% and 17.5% patient had negative and positive family h/o PCOD in test group and 83.34% and 16.66% patient had negative and positive family h/o PCOD in control group respectively.

Mizāj

Saman *et al.*[21] reported 53.33%, 30% and 16.5% in *Balghamī, Damvi*, and *safrawī mizāj* respectively. These finding confirm the writing of ancient unani scholars quoted that this disease is more common in dominance of *Khilt-i- Balgham*.

SUBJECTIVE PARAMETERS

Duration of cycle

Study by Khan AA *et al.*[22] reported 62.50 ±17.88 and 32.45 ±9.84 before and after treatment in test group. 56.25 ±12.55 and 35.50±10.37 in control group. Khatoon R. *et al.*[8] reported 49.17±32.71, 90.17±30.82, 64.45±47.14, 55.43±50.14 and 45.07±43.62 respectively before treatment 1st, 2nd, 3rd cycle during treatment and after treatment. Anjum F *et al.*[23] reported 35.15±8.31, 31.30±5.08, 30.74±4.54, 30.68±2.38 in test group, 60.95±6.20, 29.30±2.05 29.00±1.17, 28.65±1.18, 28.65±3.42 in control group respectively before treatment 1st, 2nd, 3rd cycle during treatment and after treatment (Table 2).

Duration of flow

The study conducted by Khatoon R. *et al.*[22] reported 4.37±1.54, 2.79±2.53, 4.52±2.00, 4.11±1.45 and 4.73±2.51 respectively before treatment 1st, 2nd, 3rd cycle during treatment and after treatment. Anjum F *et al.*[23] reported 3.4±1.64, 3.9±1.17, 3.85±0.93, 4.32±0.95, 3.79±1.03 in test group, 3.75±1.21, 4.3±0.66, 4.45±0.51, 4.25±0.64, 4.45±0.6 in control group respectively before treatment 1st, 2nd, 3rd cycle during treatment and after treatment (Table 3).

Amount of flow

Nasreen *et al.*[24] reported Mean ± SD of amount of flow before treatment 1st,2nd,3rd cycle during treatment and after treatment

were 3.50 ±1.80, 6.53 ±2.98, 7.37 ±2.59, 9.17 ±3.46. with $p<0.001$ respectively (Table 4).

Body weight

Fatemeh *et al.*[25] reported 41.5% weight reduction in her study. Firdose KF *et al.*[16] reported 66.67% weight reduction in her study which is correlating with present study (Table 5).

Table 1: Demographic data of PCOD patients studied.

Characteristics	No. of patients	%
Age in years: (mean±SD:22.66±3.98)		
<20	9	30.0
20-30	20	66.7
31-40	1	3.3
Age of menarche: (mean±SD:12.8±1.34)		
11-13	25	82.4
14-15	3	10.0
16-17	2	6.6
Marital Status		
Married	16	53.3
Unmarried	14	46.7
Socio-economic Status		
Lower Middle	12	40.0
Upper Lower	16	53.3
Upper Middle	2	6.7
Education		
Illiterate	1	3.3
Primary	2	6.7
High School	14	46.7
Graduate	13	43.3
F/H of PCOD		
No	23	76.7
Yes	7	23.3
Mizaj		
Balgami	19	63.3
Damvi	11	36.7

Objective Parameters

PBAC score

Khatoon R. *et al.*[8] reported 94.03±63.65, 50.53±59.38, 87.90±82.06, 87.40±57.43, and 103.97±79.99 respectively before treatment 1st, 2nd, 3rd cycle during treatment and after treatment. Obvious improvement in menstrual cyclicity may be due to *mudirr-i-bawl wa hayḍ, mufattih sudad, mulaṭṭif* and *jālī* properties (Table 6).[9,10]

BMI

Anjum F *et al.*[23] reported change in BMI from 30.76±4.57 to 29.58±4.82 and 28.61±5.95 to 27.57±5.55 in two groups in 3 months. Khatoon R. *et al.*[8] reported change from 29.71±3.87 to 28.89±3.75 in 3 months Jazani AM. *et al.*[18] reported change from 26.37 to 25.80 and 26.52 to 25.75 in two groups in 3 months. Khan AA. *et al.*[21] reported change from 26.50±5.22 to 26.31±4.99 and 25.43±5.93 to 25.27±5.88. Bhat SA *et al.*[19] reported change from 28.41±0.74 to 27.55±0.6847. Esmaeilinezhad Z *et al.*[26] reported change from 25.75±2.45 to 26.25±2.93 and 26.29±1.70 to 26.77±1.70 (Table 6).

mFG Score

Khatoon R *et al.*[8] reported 5.93±5.93 and 6.03±3.43. Bhat SA *et al.*[19] reported 5.55±3.59 and 4.95±3.412 (Table 6).

12 Item Short Form Survey

Mean ± SD SF12 of before and after treatment were 664.20±161.69 and 820.93±148.00 respectively and *p* value is <0.001** considered suggestive strong significant (Table 6).

Waist circumference

Khatoon R. *et al.*[8] reported change in waist circumference from 96.10±6.05 to 95.43±6.40 in 3 months. Angik. R *et al.*[27] reported change 73.43 ± 9.23 to 76.14 ± 7.41 and 72.10 ± 9.18 to 71.36 ± 8.86 in two group in 6 months. Esmaeilinezhad Z. *et al.*[26] reported change from 94.21 ±7.60, 95.30 ± 7.30, 93.65 ± 5.59, 96.13 ± 5.40 to 91.59 ± 5.15, 95.04±5.73, 91.47 ± 5.69, 96.85 ± 5.03 respectively in four groups. Tang T *et al.*[28] reported change from 111.9±13.7 to 108.8±18.2 in 6 months (Table 7).

Table 2: Duration of Cycle (Days) in PCOD patients studied.

Duration of Cycle (Days)	Min-Max	Mean ± SD	Difference	*t* value	*P* value
BT	30.00-120.00	63.23±17.97	-	-	-
C_1	0.00-90.00	40.40±23.53	22.833	3.850	0.001**
C_2	0.00-116.00	28.50±26.73	34.733	6.068	<0.001**
C_3	0.00-77.00	36.20±18.98	27.033	4.996	<0.001**
AT	0.00-183.00	42.53±35.41	20.700	3.451	0.002**

Table 3: Duration of Flow in PCOD patients studied.

Duration of Flow	Min-Max	Mean ± SD	Difference	t value	P value
BT	1.00-10.00	4.43±1.83	-	-	-
C_1	0.00-8.00	4.60±2.57	-0.167	-0.418	0.679
C_2	0.00-8.00	3.63±2.89	0.800	1.309	0.201
C_3	0.00-9.00	5.53±2.78	-1.100	-2.387	0.024*
AT	0.00-10.00	4.97±2.79	-0.533	-0.867	0.393

Table 4: Amount of flow in PCOD patients studied.

Amount of flow	Min-Max	Mean ± SD	Difference	*t* value	p-value
BT	1.00-3.00	2.30±0.65	-	-	-
C_1	0.00-4.00	2.60±1.25	-0.300	-1.179	0.248
C_2	0.00-4.00	2.13±1.61	0.167	0.507	0.616
C_3	0.00-4.00	2.97±1.27	-0.667	-2.819	0.009**
AT	0.00-4.00	2.57±1.25	-0.267	-0.928	0.361

Table 5: PBAC score in PCOD patients studied.

PBAC score	Min-Max	Mean ± SD	Difference	*t* value	*p* value
BT	4.00-81.00	40.07±25.35	-	-	-
C_1	0.00-121.00	55.97±35.29	-15.900	-3.257	0.003**
C_2	0.00-116.00	48.60±41.10	-8.533	-1.030	0.311
C_3	0.00-150.00	66.57±35.85	-26.500	-4.684	<0.001**
AT	0.00-100.0	56.20±35.32	-16.133	-1.934	0.063+

Acanthosis nigricans scale

Bhat SA *et al.*[19] reported 1.07±0.99 and ±0.95± 1.011 (Table 6).

Pelvic Scan

Polycystic ovaries

On USG of pelvic,100% patient had PCOD at baseline which persist in 46.7% patients after treatment while, 53.3% reduction in PCO in 3 months Khatoon R. *et al.*[8] reported 23.34% reduction in PCO on USG in 3 months. Anjum F. *et al.*[23] reported 70% and 80% patients had no PCO on USG after treatment in two groups.

Ovarian volume

Khatoon R. *et al.*[8] reported before and after treatment 11.85±4.13 and 10.80±3.77, 12.79±4.39 and 10.66±4.47in right and left ovaries respectively in 3 months Angik. R *et al.*[27] reported change in mean ovarian volume from 14.45 ± 3.8 to 12.35 ± 2.83 and 14.53 ± 3.44 to 12.24 ± 2.83 in two group in 6 months. Swaroop A. *et al.*[29] reported change from 14.00 ± 6.27 to 10.00 ± 4.19 in right ovary, from 12.23 ± 5.13 to 10.05 ± 4.19 in left ovary in 3 months. Significant reduction in ovarian volume. Israni DA *et al.*[30] reported reduction in mean ovarian volume from 13.19 ± 0.53 to 7.04 ± 0.73 in married women and from 14.58 ± 0.66 to 11.4 ± 0.93 (Table 7).

Hemoglobin level

Mean ± SD before and after treatment was 12.55±1.20 and 12.70±0.84 respectively with *p* value 0.335 no significant changes was observed after treatment.

Safety profile: No significant change was observed in safety profile during the trial values are within normal limits. Moreover, the ingredients of research drugs are hepatoprotective,[31-33] and act as liver tonic (Table 8).[12]

Outcome Measures

Primary Outcome Measures

Changes in duration of cycle, duration of flow and amount of flow was achieved in 66.7%, 96.7%, 86.7% patients respectively, and weight reduction in 60% patients (Table 7).

Secondary Outcome Measures

PBAC score, BMI, W.C, 12 Item Short Form Survey, Modified Ferriman Gallwey score, USG pelvis 100%, 60%, 20%, 73.3%, 13.3%, 36.7% Improvement in menstrual menstrual cycle in 3 group in 6 months. The result of present study is compatible with most of above studies. Improvement in outcome measures are attributed to *mudirr-i-bawl wa hayd, mufattih-i-sudad, munnaqiye-i-jiger, munáffith-i-balgham, mu'arriq, musakhkhin, muhallil-i- awrām*,[9,10] hypoglycemic, hypolipidemic,

Table 6: Clinical Variables in PCOD patients studied.

Clinical variables	BT	A T	Difference	*t* value	*p* value
BMI (kg/m^2)	27.63±6.03	27.15±5.99	0.475	5.524	<0.001**
Modified Ferriman Gallwey score	6.63±5.93	6.00±5.58	0.633	3.357	0.002**
Acanthosis Nigricans scale	1.60±1.38	1.47±1.36	0.133	2.112	0.043*
12 Item Short Form Survey	664.20±161.69	820.93±148.00	-156.733	-6.195	<0.001**

Table 7: Outcome Measures PCOD patients studied.

Outcome Measures	No. of patients (*n*=30)	%	Mean ± SD		*p*-value
			BT	AT	
Primary outcome					
Duration of Cycle	20	66.7	63.23±17.97	42.53±35.41	0.002**
Duration of Flow	29	96.7	4.43±1.83	5.53±2.78	0.024*
Amount of Flow	26	86.7	2.30±0.65	2.97±1.27	0.009**
Weight Reduction	18	60.0	27.63±6.03	27.15±5.99	<0.001**
Secondary outcome					
PBAC score	30	100.0	40.07±25.35	66.57±35.85	<0.001**
BMI	18	60.0	27.63±6.03	27.15±5.99	<0.001**
W.C.	6	20.0	92.15±7.63	92.05±7.56	>0.958
12 Item Short Form Survey	22	73.3	664.20±161.69	820.93±148.00	<0.001**
Acanthosis Nigricans scale	4	13.3	1.60±1.38	1.47±1.36	0.043*
Modified Ferriman Gallwey score	11	36.7	6.63±5.93	6.00±5.58	0.002**
USG Pelvis	23	76.7	12.82±2.03	10.27±4.24	<0.0048
Rt. ovary volum.			11.68±2.13	9.56±3.08	<0.0033
Lt. ovary volum.					

Table 8: Safety profile in PCOD patients studied.

Safety profile	Before Treatment	After Treatment	Difference	*t* value	*p* value
AST	20.77±6.55	21.80±6.03	-1.033	-0.753	0.458
ALT	29.93±16.10	38.20±9.83	-8.267	-2.513	0.018*
AP	93.33±19.48	92.50±16.71	0.833	0.276	0.785
Blood Urea	19.90±4.01	18.93±3.49	0.967	1.114	0.274
Serum Creatinine	0.84±0.11	0.69±0.07	0.147	6.416	<0.001**

hepato-protective activity, anti-cancer, antioxidant, anti-inflammatory, insulin sensitizer and stimulating effect on uterine muscle fibres due to presence of active ingredient such as cinnamic acid, cinamaldehyde, eugenol, essential oil, tanins, rubiadin, methanol extract[34-36] alloxan, triterpenoids, rubimalin saponins, Anthraquinone and their glycosoids, quinone and flavonoids,[37] Finally, it can be concluded that the research drug formulation studied can be used as alternate remedy in PCOD patients, as it has significant effect in menstrual cyclicity by reduction of weight and probably by improving the insulin resistance in PCOD.

Strength of the study

This is the initial study conducted to assess the effect of *Saleekha* and *Majeeth* in Polycystic Ovarian Disease women. Even though it was a trial of short duration was observed in menstrual cyclicity, BMI, mFG, SF12, AN scale with no adverse effects.

Limitation of Study

The effectiveness of the research drug formulation on menstrual cyclicity was demonstrated in small sample size, short duration of treatment, short period of 3 months only. Further investigation (hormonal profile) was not done due to funding limitation. Moreover, follow up period was relatively short.

Future Recommendations

Future research trials are recommended for a longer duration with long term follow up for better assessment, and larger sample size Moreover, the mechanism of action of each research drug needs to be studied.

CONCLUSION

30 diagnosed patients were enrolled in the study, 7 gm powder *Saleekha* and *Majeeth* 14 gm as decoction administered orally twice a day for 15 days for 3 consecutive cycles. Changes in menstrual cyclicity was achieved in duration of cycle, duration of flow and amount of flow was 66.7%, 96.7%, 86.7% respectively, weight reduction in 60%. Waist circumference, SF12, AN, mFG, ovarian volum 20%, 73.3%, 13.3%, 36.7%, 76.7% respectively. Improvement in outcome measures is attributed due to *mudirr-i-bawl wa hayd, mufattih-i-sudad, munnaqiye-i-jigger, munáffith-i-balgham,* hypoglycemic, hypolipidemic, hepato-protective, anti- antioxidant, insulin sensitizer due to the presence of active ingredients such as cinnamic acid, cinnamaldehyde, alloxan, triterpenoids, rubimalin saponins, Anthraquinone and their glycosides, quinone and flavonoids etc. in *saleekha* and *majeeth*. Research drug was well tolerated safety profiles within normal limits. Finally, drugs can be used as an alternative remedy in the treatment of PCOD, menstruation regulation by a reduction in weight and improving the insulin resistance in PCOD.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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National Institute of Unani Medicine, Bengaluru, Karnataka, India.

ABBREVIATIONS

PCOD: Polycystic Ovarian Disease; **Hb%:** Heamoglobin; **UPT:** Urine pregnancy Test; **RBS:** Randome blood suger; **TSH:** Thyroid stimulating hormone; **AST:** Aspartate transaminase; **ALT:** Alanine transaminase; **AP:** Alkaline Phosphatase; **SF-12:** 12-Item short form Health survey; **QOL:** Quality of life; **WC:** Waist circumference; **AN:** Acanthosis Nigricans; **PBAC:** Pictorial blood loss assessment chart score; **BMI:** Basal metabolic index; **mFG:** Modified Ferriman Gallwey score; **BT:** Before treatment; **AT:** After treatment; **C1:** Cycle 1; **C2:** Cycle 2; **C3:** Cycle 3.

SUMMARY

Polycystic ovary syndrome (PCOS) is a complex condition in reproductive age, characterized by elevated androgen levels, menstrual irregularities, and / small cysts on one or both ovaries. Globally, prevalence estimates of PCOS are highly variable, ranging from 2.2% to as high as 26% It affects about 6-8% of reproductive age. The exact cause of PCOD is unknown. Women may present with a number of reproductive (menstrual dysfunction, infertility, and pregnancy complications), endocrine (hyperandrogenism, hirsutism, and acne), metabolic (insulin resistance, diabetes, weight gain, and obesity), and psychosocial (anxiety, depression, and poor quality of life) symptoms. The available treatment in conventional medicine is hormonal therapy all medicines have mild to severe side effects hence due to side effects, contraindications, and complications, there is an increasing demand for herbal therapy which is to be safe, effective, and easily available

The objective of the study was to evaluate the efficacy of *Saleekha* and *Majeeth* in Polycystic Ovarian Disease. An open observational study was conducted in the Department of *Ilmul qabalat wa amrāz-i-niswan,* NIUM, Bengaluru. 30 diagnosed patients were enrolled in the study. 7 gm *safūf* of *Saleekha* and *joshānda Majeeth* (*Rubia cordifolia*) 14 gm was administered orally twice a day for 15 days for 3 consecutive cycles. The outcome measures the effect of *Saleekha* and *Majeeth* in Polycystic Ovarian Disease patients during the trial.

Demographic profile: Majority of patients (66.7%) were in the age group 20-30 years with 22.8±3.98 mean age, *Balghamī mizāj*, married, belongs to upper lower class, 46.7%, had completed high school education without family history of PCOS with 12.8±1.349 as mean age of menarche.

Subjective parameters: Before and after treatment Mean ± SD duration of Cycle 63.23±17.97 and 42.53±35.41 with p value 0.002**. duration of flow was 4.43±1.83 and 4.97±2.79 respectively body weight 68.27±16.53 and 67.17±16.60 respectively with p value <0.001** was observed during trial.

Objective parameters: Strong significant improvement in PBAC score (p =<0.001**), Strong significant reduction in BMI

(p =<0.001**) suggestive significant changes in mFG score (p =0.002**) and AN scale (p =0.043*) No significant changes in waist circumference >0.958(non-significant). In right ovarian volume <0.0048 and in left ovarian volume <0.0033 were observed during trial.

Outcome measures: Changes in the duration of the cycle, duration of flow, and amount of flow were achieved in 66.7%, 96.7%, 86.7% patients respectively, and weight reduction in 60% of patients. Changes in PBAC score BMI, waist circumference,12 Item Short Form Survey, acanthosis nigricans, Modified Ferriman Gallwey score, ovarian volume 100%, 60%, 20%, 73.3%, 13.3%, 36.7%, 76.7% patients respectively, after intervention. Improvement in outcome measures are attributed to *mudirr-i-bawl wa hayd, mufattih-i-sudad, munnaqiye-i-jiger, munáffith-i-balgham, mu'arriq, musakhkhin,, muhallil-i- awrām* hypoglycemic, hypolipidemic, hepato-protective activity, anti-cancer, antioxidant, anti-inflammatory, insulin sensitizer and stimulating effect on uterine muscle fibers due to presence of active ingredient such as cinnamic acid, cinnamaldehyde, eugenol, essential oil, tanins, alloxan, triterpenoids, rubimalin saponins, anthraquinone and their glycosides, quinone and flavonoids, etc. The research drug was safe as safety parameters were normal and no adverse effect was noted during the trial. This validates the safety of the research drug as it is proved to be hepato-protective.

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