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Original Article

Effect of *Majoon Idraare Haiz* in Polycystic Ovarian Syndrome - A pilot study

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ABSTRACT

Background & Objectives: Polycystic ovarian syndrome (PCOS) is one of the commonest endocrine abnormality in women of reproductive age affecting from 4% - 21% of the reproductive women and is characterized by chronic anovulation and hyperandrogenism. The aim of the study was to evaluate the effect of *majoon idraare haiz* in menstrual regulation and morphological changes in ovaries in poly cystic ovarian syndrome.

Methods: A Pilot study was carried out in the department of *Ilmul qabalat wa amraze niswan*, National institute of unani medicine, hospital, Bengaluru. Fifteen Patients of PCOS aged 18-35 diagnosed using Rotterdam criteria were included in the study. Patients with insulin sensitizing treatment within 3 months, hormonal treatment and those with h/o diabetes mellitus, hypertension, pregnant and lactating women were excluded.*Majoon idraare haiz* was administered orally at a dose of 10 g with 20 ml *arqbed mushk* once daily from fifth day of cycle for 21 days for three consecutive cycles. Primary outcome measure was menstrual regularity while changes in USG pelvis(normal ovarian morphology) was considered as secondary outcome measure. In addition, duration of flow and changes in basal metabolic index (BMI), modified Ferriman Gallwey (mFG) score, acanthosis nigricanswere observed. Data were analyzed using, ANOVA, paired student't' test, fisher exact test.

Results: Changes in duration of cycle, duration and amount of flow was achieved in 93.3% patients with $p<0.0001$ and 46.6% patients showed normal findings on pelvic ultrasonography with $p=0.006$. In addition, significant changes were also observed in BMI, hirsutism and acanthosis nigricans with p value of 0.0001, $p=0.003$ and $p=0.009$ respectively

Conclusion: *Majoonidraare haiz* can be used as an effective alternative in management of PCOS patients. It has significant effect on menstrual regulation and changes in polycystic ovarian morphology to normal.

KeywordsPolycystic ovarian syndrome, Unani formulation, *Majoon idraare haiz, Arq bedmushk,* Pelvic ultrasonography

INTRODUCTION

Polycystic ovarian syndrome is the most common endocrine disorder (Kamboj, 2017) which starts appearing at 15-25 years of age and it may take years for its clinical presentation to appear (Bhat, 2015). It can significantly impact women's quality of life as they express a collection of symptoms which include menstrual dysfunction and androgen excess. (Naeimi, 2018).

The prevalence of PCOD ranges from 4% - 21% (Gainder, 2019). A more recent joint consensus statement between the European Society for Human Reproduction and Embryology and the American Society for Reproductive Medicine (ESHRE/ASRM) has revised the criteria for diagnosis of PCOD to include two from three of the following criteria: i) oligomenorrhoea/anovulation; ii) clinical or biochemical evidence of hyperandrogenism; iii) polycystic ovaries, with the exclusion of other etiologies. The hallmark clinical features of PCOD are menstrual irregularities (amenorrhea, oligomenorrhoea, or other signs of irregular uterine bleeding), signs of androgen excess, and obesity (Firdose, 2016). The goals of management are to restore normal menstrual pattern, (Hoffman, 2016 and Pal, 2017) correct ovarian morphology of polycystic ovaries, hirsutism, and acanthosis nigricans (Pal, 2017).

Combined oral contraceptive pills (Hoffman, 2016 & Nd efo, 2013) metformi (Bashtian, 2013) and clomiphene citrate (Hoffman, 2016 & Kashani, 2016) are often used for menstr u a l regulation and ovulation. Even though these treatment options are effective to some extent, they have their own side effects such as irregular menstruation, gastrointestinal

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symptoms, weight gain, and increased insulin resistance (Bieber, 2006). Therefore, there is a need to develop a safe and effective treatment for this disease (Lai, 2017).

According to WHO, there is a new trend, and a significant move towards complementary medicine (Naeimi SA, *et al.,* 2018) hence the present study is the first step towards addressing the unani management in PCOS associated menstrual irregularities, changed ovarian morphology and features of androgen excess like can, hirsutism, acne etc using renowned unani formulation "*majoon idraare haiz* with *arq bed mushk*" (Amrohi, 2004); which is commonly used treatment for symptoms associated with menstrual irregularities and features of androgen excess.

Methodology

Study design: A pilot study

Sample size: 15 patients

Duration of study: One and half year

Ethical Clearance: The study was started after obtaining approval from Institutional Ethical Committee, NIUM, Bangalore under IEC No. NIUM/IEC/2016- 17/036/IMR/04 and CTRI registration no: **CTRI/2018/10/015900**

Method of collection of Data

- History taking and clinical examination
- Laboratory Investigations

Study Site: Dept. of Ilmul Qabalat wa Amraze Niswan (OBGYN), National institute of unani medicine, Bengaluru-91.

Criteria for selection of subjects

Inclusion criteria

1. Patients aged 18-35
2. Oligomenorrhoea or amenorrhoea
3. Clinical evidence of hyperandrogenism (Hirsutism / Acne)
4. USG findings of PCO

Exclusion Criteria

1. Patients with Insulin sensitizing treatment within 3 months
2. Patients with Hormonal treatment
3. Patients with H/o DM, Hypertension
4. Pregnant and lactating women.

Initial Screening of patients

Patients in the age group of 18-35 years with polycystic ovaries on USG Pelvis presenting with complaints of irregular periods like oligomenorrhoea or amenorrhea along with weight gain, features of hirsutism, acne and acanthosis nigricans were evaluated at gynecology OPD of NIUM Hospital, Bengaluru. In each patient, thorough clinical examination was performed and FBS, Sr. prolactin and TSH were done to rule out diabetes mellitus, hyper prolactinemia and thyroid dysfunction respectively. Patients who fulfilled the inclusion criteria were given the information sheet and only those who agreed to participate in the study, were asked to sign the informed consent form.

Procedure of the study

Patients complaining of menstrual irregularities like oligomenorrhea or amenorrhea, weight gain and presenting with excessive hair growth particularly on face, acne, hyper pigmented thick velvety patches in the body folds and creases especially in the nape of the neck, were evaluated and diagnosed as PCOS based on the presence of any 2 of 3.

Rotterdam criteria

1. Oligo/anovulation (oligo/amenorrhea) and
2. Clinical e/o of Hyperandrogenism (hirsutism) or
3. Polycystic ovaries on ultrasound (Barbosa, 2016),

Fifteen diagnosed cases of PCOD were selected and written informed consent was obtained from them. Details of menstrual history including pattern of menstrual cycle (nature of cycle, duration of cycle), and history of weight gain were inquired. On physical examination, breast was examined for galactorrhoea and pelvic examination (in married subjects) were performed to rule out any pathological conditions. Nutritional Status, BMI, hirsutism score, acanthosis nigricans score and vitals were recorded; *Mizāj* of each subject was assessed according to the parameters mentioned in Unani literature. SES was assessed by Kuppuswamy's socioeconomic status scale. Following evaluation, patients were advised for necessary investigations.

Investigations

- **Pre-test** (for exclusion):FBS, TSH, Sr. prolactin
- **Pre & post-test:** USG Pelvis, LFT (AST, ALT, alkaline phosphatase) & RFT (Blood Urea, Serum Creatinine).

Criteria for selection of test drug

The constituents of *majoon idraare haiz* possesses properties like *muḥallil-i-aurām*, *mufattiḥ*, (Baghdadi, 2007 & Kabiruddin, 2007), *mudirr-i-bawl wa hayḍ* (Kabiruddin, 2007 & Anonymous, 1992), *mulaṭṭif*, *musakkin-i-dard*, *muqawwī-i-mi'da*) (Baghdadi, 2007 & Anonymous, 1992), *muqawwi jigar wa bah* (Kabiruddin, 2007), properties. Therefore, it can be used in the treatment of PCOS. Moreover, Unani literature mentions *majoon idraare haiz* to be a time tested formulation in oligo- & amenorrhoea (Amrohi, 2004). The constituents of *majoon idraare haiz* are also reported to contain phytoestrogens (anisoon, raziyana, darchini), phyto progestrogens and anti-infertility properties thus aiding in normalizing the menstrual cycle (Firdose, 2020; Firdose F, 2020; Al- Asmari, 2017; Al-Snafi, 2014; Kooti, 2015; Michl, 2017; Kumar, 2019; Brahmi, 2017; Balakrishnan, 2015 and Khatoon, 2019). Thus, *majoon idraare haiz* was selected for the present study.

Method of preparation, dosage and route of administration

Research Formulation:*Majoon Idraare Haiz*

- *Anisoon (Pimpinella anisum* L.*)* 35gms
- *Tukhme karafs (Apium graveolens* Linn.*)* 35gms
- *Raziyana (Foeniculum Vulgare* Mill.*)* 35gms
- *Pudina (Mentha Piperita* L.*)* 35gms
- *Mushktramashi (Mentha Pulegium* L.) 35gms
- *Darchini (Cinnamomum zeylanicum* L.*)* 24.5gms
- *Asaroon (Asarum europaeum* L.*)* 24.5gms
- *Abhal (Juniperus Communis* L.*)* 24.5gms
- *Asl (*Honey*)* 745.5ml

Method of Preparation:*Majoon* is prepared according to the standard method of preparation in National institute of unani medicine pharmacy.

Route of Administration and Dosage: 10gms *majoon* with Arq Bedmushk 20 ml(Amrohawi HJ, 2004)once daily from 5th day of cycle for 21 days.

Duration of protocol therapy: 3 months

Assessment cum follow up during treatment

- **During trial:** Every cycle for 3 cycles
- **After trial**: One subsequent cycle

Improvements in duration of cycle and duration of flow were assessed at every cycle during the treatment. Patients were inquired for any adverse effect of the test drug during the trial. USG Pelvis (objective parameters), LFT and RFT were performed after completion of trial. Pre and post treatment values of subjective and objective parameters were analyzed statistically to evaluate the efficacy of the drugs.

Assessment criteria Subjective parameters

- Duration of cycle > 35 days and duration of flow.
- **BMI: BMI = Weight (kg) / (Height in m)^2**

Body Mass Index was calculated before and after treatment (Purnell, 2018)

- **Modified Ferriman Gallwey scale (mFG) for Hirsutism:**

Hirsutism was measured by modified Ferriman Gallwey scoring system in which the presence of androgen dependant male pattern hair growth in nine areas of the body was noted. Improvement in score was noted during the trial. (Khan, 2019)

- **Acanthosis Nigricans scale**

Neck was examined for acanthosis nigricans and the score was recorded. Hyper pigmented thick velvety patches in the creases in the nape were noted as.

- **Absent**: not detectable on close inspection.
- **Present**: when seen on nape of neck and lateral margins

Objective Parameter

- **USG pelvis:**

The imaging in PCOS is advised to properly identify and document the presence of polycystic ovaries. However, because PCOS is a syndrome, the presence of polycystic ovaries alone is insufficient for diagnosis.

Polycystic ovaries are present when (a) one or both ovaries demonstrate 12 or more follicles measuring 2–9 mm in diameter. Only one ovary meeting either of these criteria is sufficient to establish the presence of polycystic ovaries.

Changes in pelvic scan were considered when ovaries are normal without PCO on post treatment scan.

Assessment of efficacy: Effectiveness of the trial was assessed by the following parameters.

Primary outcome measures: Changes in duration of cycle

Secondary outcome measures: Changes in USG pelvis (Ovarian Morphology)

Withdrawal criteria:

- Failure to follow the protocol therapy
- The cases in which adverse drug reactions are noticed

Assessment of safety:

- Clinical sign and symptoms
- Laboratory Investigations (LFT & RFT)
- Adverse drug reaction.

Adverse effect documentation: No adverse reaction of the drug was noted during the trial.

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.

Statistical software: The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data.

RESULT

The present study entitled "Effect of *majoon idrare haiz* in polycystic ovarian syndrome- a pilot study" was conducted in the Department of *Ilmul Qabalat Wa Amraze Niswan,* National Institute of Unani Medicine Hospital, Bengaluru.

Total 27 patients were assessed for eligibility, 5 denied participating and 7 patients were excluded for not meeting the inclusion Criteria and 15 were enrolled in the study.

Main findings: In this study, it was observed that changes in duration of cycle and duration of flow was achieved in 93.3%, patients. Change in BMI was achieved in 100 % and 46.7 % PCOD patients showed normal findings in USG pelvis.

Demographic data

- **Age:** Majority of patients (53.3%) were in the age group of 26-35 years and remaining 46.7% were in 18-25 years of age. The Mean ±SD of age was 27±5.43.
- **Marital status:** Majority of patients, 53.3% were married and 46.7% were single.
- **Socio-economic status:** Maximum patients, 40% belonged to Upper middle class, 33.3% from lower middle and 26.7 from upper class respectively.
- **Diet:** All the patients in the present study had mixed dietary habits.
- ***Mizāj*:** Maximum patients (46.7%) had *Balghamī mizāj, 33.3% had damvi mizaj* and 20% had *safrawi mizāj*.
- **Family h/o PCOD:** Most of the patients, 60% had a family h/o PCOD (Table1).

Table 1. Baseline characteristics of patients studied

Age in years	No. of Patients	(%)
• 18-25	7	46.7

• 26-35	8	53.3
Marital status		
• Married	8	53.3
• Single	7	46.7
Socio economic status		
• Upper Middle	6	40
• Upper	4	26.7
• Lower Middle	5	33.3
Diet		
• Mixed	15	100
Life style		
• Sedentary	2	13.3
• Average	13	86.7
Family history		
• Present	9	60
• Absent	6	40
Mizaj		
• Damvi	5	33.3
• Balghami	7	46.7
• Safravi	3	20

Menstrual History: 14 93.3% of the patients had irregular cycles, of whom 60% had a cycle duration of 35-60 days while in 40 % of patients the cycle duration was 61-90 days; duration of flow was 1-4 days in majority 73.3 % and 5-8 days in 26.7% of patients (Table 2).

Table 2. Menstrual history of patients studied

Regularity	No. of Patients	(%)
• Irregular	14	93.3
• Regular	1	6.7
Duration of cycle (days)		
• 35-60	9	60
• 61-90	6	40
Duration of flow (days)		
• 1-4	11	73.3
• 5-8	4	26.7

Clinical signs of hyperandrogenism: Hirsutism was present in 66.7% while acne and acanthosis nigricans were distinctly seen in 60 % of patients. 80% of patients were obese and overweight, while 13.3% had normal weight and 6.7 % had underweight respectively (Table 3).

Table 3. Significant history of patients studied

Acne	No. of Patients	(%)
• Present	9	60
• Absent	6	40
Hirsutism		
• Present	10	66.7
• Absent	5	33.3
Acanthosis nigricans		
• Present	9	60
• Absent	6	40
BMI		
• UW	1	6.7
• NW	2	13.3
• OW	6	40
• OB	6	40

Subjective parameters

Duration of Cycle: Mean ± SD of duration of cycle Before treatment, in 1st , 2nd and 3rd cycle during treatment and after treatment were was 62.5±19.8, 41.5±9.7, 34.6±5.3, 31.6±2.5 and 31.4±4.5 respectively, with p=0.001 considered strongly significant at each follow up. Significant improvement in duration of cycle was observed during the trial. (Table 4)

Table 4. Clinical assessment of duration of cycle (in days) in patients studied

DOC	Mean ± SD	Difference	P Value
BT	62.5±19.8	-	-
C1	41.5±9.7	21	<0.001***
C2	34.6±5.3	27.9	<0.001***
C3	31.6±2.5	30.9	<0.001***
AT	31.4±4.5	31.1	<0.001***

Test used: ANOVA

Duration of Flow: Mean ± SD of duration of flow before treatment, after 1st, 2nd and 3rd cycle of treatment and after treatment were 3.6±2.2, 3.7±2, 4.5±2.1, 5±2 and 4.7±1.7 respectively, p<0.05, in first cycle, p<0.01 in 2nd cycle and p<0.001 in 3rd cycle and after treatment. (Table5)

Table 5. Clinical assessment of duration of flow (in days) in patients studied

DOF	Mean ± SD	Difference	P Value
BT	3.6±2.2	-	-
C1	3.7±2	-0.1	<0.05
C2	4.5±2.1	-0.9	<0.01**
C3	5±2	-1.4	<0.001***
AT	4.7±1.7	-1.1	<0.001***

Test used: ANOVA

mFG score: The Mean ± SD of mFG score before and after treatment were 13±6.4 and 10.2±5.1 respectively with p=0.003, considered significant reduction in mFG score. (Table 6).

Table 6. Clinical assessment of hirsutism in patients' studies

Hirsutism	Mean ± SD	Difference	P Value
BT	13±6.4	-	-
AT	10.2±5.1	2.8	0.003

Test used: Student t test (paired)

Body weight: Mean ± SD of body weight before treatment and after treatment were 28.7±5.0 and 26.5±5.5 respectively with p<0.001 considered highly significant. (Table 7)

Table 7. Clinical assessment of BMI in patients' studies

BMI	Mean ± SD	Difference	P Value
BT	28.7±5.9	-	-
AT	26.5±5.5	2.2	<0.0001

Test used: Student t test (paired)

Acanthosis Nigricans scale: The acanthosis nigricans was present before and after treatment in 12 (80%) and 3(20%) respectively with p=0.009, considered significant reduction in acanthosis nigricans. (Table 8)

Table 8. Clinical assessment of acanthosis nigricans in patients' studies

Acanthosis nigricans	Present No. (%)	Absent No. (%)	Total (%)
BT	12 (80)	3 (20)	15 (100)
AT	4 (26.7)	11 (73.3)	15 (100)
P value: 0.009 (Fisher exact test)			

USG Pelvis: PCO on Usg pelvis were present before and after treatment in 15 (100%) and 8(53.3%) respectively with p=0.006, considered significant changes in ovarian morphology on ultrasound pelvis. (Table 9)

Table 9. Assessment of USG findings in patients' studies

USG findings	PCODNo. (%)	Normal No. (%)	Total (%)
BT	15 (100)	0 (0)	15 (100)
AT	8 (53.3)	7 (46.7)	15 (100)
P value: 0.006 (Fisher exact test)			

Safety profile: Research drug was safe as all safety parameters were within normal limits. Also, no adverse effect of research drug was noted during the trial. This validates the safety of the research drug. (Table10)

Table 10. Assessment of safety parameters in patients' studies

Safety parameters	Mean ± SD		Difference	P Value
	BT	AT		
ALT	15.1±5.2	16.2±4.9	-1.1	0.155
AST	15.6±4.3	17.8±3.9	-2.2	0.002
ALK. Phos.	116.4±26.3	119.1±24.4	-2.7	0.339
Bld. urea	20.8±6	24.2±4.6	-3.4	0.10
Sr. creat.	1.23±1.5	0.84±0.1	0.39	0.321

Test used: Student t test (paired)

Outcome measures

Primary outcome measures: Changes in duration of cycle, duration of flow and amount of flow was achieved in 14 (93.3) patients and weight reduction was noted in all 15(100%) patients. (Table 11)

Table 11. Treatment outcome

Treatment outcome	Achieved No. (%)	Not achieved No. (%)	Total (%)
Primary outcome measures (POM)	14 (93.3)	1 (6.7)	15 (100)
Secondary outcome measures (SOM)	8 (53.3)	7 (46.7)	15 (100)

Secondary outcome measures: 46.7% PCO patients showed normal findings on USG pelvis. Khatoon R et al reported 20% (Khatoon, 2017) and Zainub *et al.* reported 30% patients had no PCO on pelvic ultrasonography after treatment. (Zubair, 2020) (Table 11)

DISCUSSION

Demographic data

Age: The Mean ±SD of age was 27±5.43. This is in accordance with Khatoon R. *et al.* reported 27.53±4.83 (Khatoon, 2017), Khomami MB. *et al.* reported 28.02±6.02, (Khomami, 2015) Lai L. *et al.* reported 28.5±6.0, (Lai, 2017) Arentz S. *et al.* reported 29.2±5.6 and 28.9±5.6 in two groups respectively (Arentz, 2017).

Marital status: 53.3% of patients were married. This is in consonance with Bhat. *et al.*reported 55% and 45% in test group and 53.34% and 46.66% in control group(Bhat, 2015), Farzana *et al* reported 43.3% and 56.7% (Farzana, 2015)and Choudhary A. *et al.*reported 40% and 60% as married and single patients respectively. (Choudhary, 2017)

Diet: All the patients in the present study had mixed dietary habits.

***Mizāj*:** 46.7% patients had *balghamī mizāj, 33.3% had damvi mizaj* and 20% had *safrawi mizāj*. Bhat. *et al.*reported *balghamī mizāj* in 80% each and *damwī mizāj* 20% each in both groups (Bhat, 2015). Khatoon R.*et al* reported 46.7%, 33.3%, 16.7% and 3.3% patients as *balghamī, damwī, ṣafrāwī* and *sawdāwī mizāj* respectively. (Khatoon, 2017) Saman A.et al. reported 53.33%, 30% and 16.5%, in *balghamī, damwī* and *ṣafrāwī mizāj* respectively. (Saman, 2015) This coincides with the theory proposed by Unani Scholars that PCOD is caused by accumulation of abnormal *balgham* secondary to *ḍu'f al jigar.* (Firdose, 2016; Baghdadi, 2007; Khan, 2019 & Iqbal, 2018)

Subjective parameters

Duration of Cycle: Significant improvement in duration of cycle was observed during the trial. This may be due to the uterine stimulant, (Firdose, 2016; Firdose F, 2020; Al- Asmari, 2017; Al-Snafi, 2014; Khan, 2019) emmenogogue (Khare, 2007) properties of the unani formulation *(majoon Idraare haiz and arq bedmushk*). Khan AA. *et al.*reported 62.50 ± 17.88 and 32.45 ± 9.84 before and after treatment in test group and 56.25±12.55 and 35.50±10.37 in control group. (Khan, 2019) Khatoon R. *et al.*reported 49.17±32.71, 90.17±30.82, 64.45±47.14, 55.43±50.14 and45.07±43.62 respectively before treatment, 1st, 2nd, 3rd cycles of treatment and after treatment. (Khatoon, 2017)

Duration of Flow: Significant improvement in duration of flow was observed. The findings are similar to the study of Shayan A. *et al.*3.66±0.54, 5.26±1.2, 6.28±1.04 and 6.66±0.628 in test group and 3.56±0.59, 5.45±1.26, 6.28±1.02 and 6.65±0.633 in control group. (Shayan, 2016). Khatoon R. *et al.*reported 4.37±1.54, 2.79±2.53, 4.52±2.00, 4.11±1.45 and 4.73±2.51 respectively. (Khatoon, 2017)

mFG score: Significant reduction in mFG score was observed. Khatoon R. *et al* reported 5.93±3.42 and 6.03±3.43 (Khatoon, 2017) and Bhat SA. *et al.*reported 5.55±3.59 and 4.95±3.412 before and after treatment respectively. (Bhat, 2015)

Body weight: Highly significant change in BMI was observed, indicating a strong significant reduction in body weight which may be due to *Mudirr-i*-Bawl (Kabiruddin, 2007 & Anonymous, 1992) *mudirr-i-Hayḍ, (*Kabiruddin, 2007*)Mufattiḥ-i-Sudad,* (Kabiruddin, 2007 & Anonymous,

1992) *Muḥallil, (*Kabiruddin, 2007*)* antihyperlipidemic, hypoglycaemic properties of Unani formulation.

USG Pelvis: PCO on ultrasound pelvis were present before and after treatment in 15 (100%) and 8(53.3%) respectively with p=0.006, considered significant changes in ovarian morphology on ultrasound pelvis.

Safety profile: No adverse effect of research drug was noted during the trial. This validates the safety of the research drug.

Outcome measures

Primary outcome measures was achieved in 14 (93.3) patients except for weight reduction which was noted in all 15(100%) patients.

Secondary outcome measures was achieved in 46.7%. Khatoon R *et al.*reported 20% and Zainub *et al.* reported 30% treatment outcome. (Khatoon, 2017 & Zubair, 2020). Improvement in outcome measures are attributed to *mudirr-i-hayḍ* (emmenogogue) (Khare, 2007),*mufattiḥ-i- sudad* (deobstruent), (Kabiruddin, 2007 & Anonymous, 1992) *muḥallil* (anti-inflammatory), *musakkin-i-dard* (analgesic), *muqawwī-i-dimāgh wa jigar* (brain tonic and liver tonic),(Kabiruddin, 2007). uterine stimulant, hepatoprotective, antidiabetic, antioxidant, (Firdose, 2020; Firdose F, 2020; Al-Asmari, 2017; Al-Snafi, 2014; Kooti, 2015; Michl, 2017; Kumar, 2019; Brahmi, 2017) CNS stimulant, antispasmodic, anticoagulant, antihyperlipedemic, immunity enhancer and tonic properties of research formulation. (Firdose, 2020; Al-Asmari, 2017; Al-Snafi, 2014; Kooti, 2015; Michl, 2017; Kumar, 2019) Moreover, research drug contains estrogenic flavonoids (eriodictyol and apigenin) flavonoids, phenols, glycosides,tannins and saponins, (Anonymous, 1992) coumarins, sesquiterpene lactones, volatile oils etc. (Firdose, 2020; Firdose F, 2020; Al- Asmari, 2017; Al-Snafi, 2014; Kooti, 2015; Balakrishnan, 2015; Khatoon, 2019).

CONCLUSION

Majoon idraare haiz with arq bed mushk can be used as an alternate therapy in PCOS patients as it has significant effect to regularize the menstruation by reduction in BMI and probably by rectifying ovarian changes, however further studies on larger sample size and RCT's with standard preparations are required to further validate the efficacy of this unani formulation.

Strength of the study: This is the preliminary study conducted to assess the effect of *majoon idraare haiz with arq bed mushk* inwomen with PCOS.

Limitations of the study: Small sample size and only one cycle of follow up.

Future recommendations: Future trial on large sample size, higher dose and for longer duration with follow up for longer period is imperative.

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CONFLICT OF INTEREST

The authors have no conflicting financial interests.

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