

**SUCCESSFUL MANAGEMENT OF PCOS WITH A NON-HORMONAL, COMBINATION
THERAPY OF AYURVEDIC FORMULATIONS****¹Dr. Divya C.S., ²Dr. Manu K.N. and ³Dr. Aarti Patil**

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ABSTRACT

Objective – The objective of the study was to evaluate the efficacy and safety of non-hormonal combination therapy of Ayurveda formulations in females suffering from irregular menstrual cycles due to PCOS. **Materials & Method** – The study was an open-label, non-comparative, single centre, prospective, interventional clinical study. A total of 190 female patients suffering from PCOS (diagnosed by USG) between the age group of 15-40 years having complaints of irregular menstrual cycles were recruited in the study. Participants were advised to take combination therapy of two proprietary marketed products containing ingredients like *Kanchanaar*, *Shatavari*, *Dashmool* etc. (*Myrah and Vamah Tablets*) in a dose of 2 tablets twice daily with water for 6 months. Monthly follow up of participants was done to assess frequency of menstrual cycle, no of days of bleeding, quantity of bleeding and associated symptoms while USG was repeated at the end of the study. **Results** – Female participants of average age 23.05 ± 7.78 having PCOS over a period of 6.78 ± 3.45 months were recruited. A total of 137/190 participants (72.10%) reported of regular menstrual cycles at the end of 6 months. The No. of days of bleeding increased from 1.21 ± 0.34 at baseline to 2.22 ± 1.29 at the end of three months and 3.32 ± 1.59 at the end of 6 months ($p < 0.05$). Similarly quantity of bleeding also showed significant increase over the period of 3 and 6 months. USG was performed in 121 participants of which 45 subjects (37.19%) showed complete resolution, 48 subjects (39.66%) showed partial resolution while 27 participants (22.31%) did not show any change. None of the participants showed worsening in their condition. No adverse drug reaction was observed and the study products were well tolerated. **Conclusion**- Combination therapy of Ayurvedic tablets (Myrah & Vamah) was found to be effective in regularising menstrual cycles, improving overall menstrual flow and managing PCOS.

KEYWORDS: PCOS, Myrah Tablets, Vamah Tablets.**INTRODUCTION**

Polycystic Ovary Syndrome (PCOS) is one of the commonest chronic gynaecological conditions affecting approximately 5-10% of the women in the reproductive age.^[1] Sedentary lifestyles, food habits and the use of various hormonal treatments by females in the modern day have lead to the condition being commonly observed in clinical practice.^[2] Signs and symptoms of PCOS include amenorrhoea, dysmenorrhoea, excess body and facial hair, pelvic pain, difficulty in conceiving, patches of thick, dark, velvety skin, especially around the neck.^[3] PCOS can also present with type 2 Diabetes, weight gain, disturbed sleep, and mood disorders amongst other symptoms.^[4] There is no specific cure for PCOS.^[5] Changing life style, managing weight, reducing calorie intake and doing regular exercise helps in the management of PCOS. Medical intervention includes use

of oestrogen tablets, metformin tablets and anti-androgen treatment. Other symptomatic treatment of hair removal, anti-acne is often employed. In some cases surgical intervention leading to even removal of ovaries may also be required.^[6]

Various Ayurvedic formulations and herbs have been extensively studied for their effect on the reproductive system like uterine tonics, hormone balancers, anti-inflammatory, follicle stimulators etc.^[7] Ayurvedic physicians as well as modern medicine experts use these formulations for the successful management of various uterine and ovarian conditions like PCOS. In the present study a herbal combination therapy of tablets containing ingredients like *Kanchnar* (*Bauhinia variegata*), *Varuna* (*Crataeva nurvala*), *Ashwagandha* (*Withania somnifera*), *Haridra* (*Curcuma longa*), *Shatapushpa* (*Anethum*

graveolens), Ulatkambal (*Abroma augusta*), Gajar beeja (*Daucus carota*) Jyotishmati (*Celastrus paniculatus*) currently available in market as MYRAH Tablets and VAMAH Tablets were studied for their effect on irregular menstrual cycle due to PCOS.

AIM OF THE STUDY

The objective of the study was to evaluate the effect of a combination therapy of two proprietary Ayurveda medicines (MYRAH Tablets and VAMAH Tablets) in subjects suffering from irregular menstrual cycle due to PCOS.

MATERIALS AND METHODS

Patients attending to the regular OPD of Ayurmithra Healing Clinic, Palakkad, Kerala, from the period of January 2021 to September 2021 were screened for their possible inclusion in the study. Non Pregnant female patients in the age group of 15 to 40 years with complains of irregular menstrual cycle and having a confirmed diagnosis of PCOD diagnosed by USG for more than 6 months were included in the study. Subjects who were ready to provide consent and follow the study related procedures were included. Patients with known history of hyper or hypothyroidism and those with excess and prolonged bleeding were excluded from the study.

A total of 190 eligible patients were given a combination therapy of Ayurvedic formulations which were already available in the market viz. MYRAH Tablets and VAMAH Tablets. These tablets were recommended in a dose of 2 tablets each two times a day after meals for a period of 6 months. Subjects who achieved normalization of menstruation of menstrual cycle were asked to stop the study medication. The minimum treatment duration was 3 months. Patients were followed up on monthly basis for assessment of menstrual related frequency, duration of menstrual bleeding, quantity of bleeding (assessed by the no of sanitary pads to be changed on daily basis). Other associated symptoms like abdominal pain, backache, weakness etc. were also assessed. Those subjects who were ready to undergo USG were asked to do the same after resolution of their symptoms.

Investigational products

The investigational products are a combination of two tablets viz. MYRAH Tablets and VAMAH Tablets. These Tablets are formulated, developed and marketed by Gynoveda, and are manufactured in GMP certified facility.

Composition Of Myrha Tablets: Extracts- Kanchnar (*Bauhinia variegata*) 200 mg, Varuna (*Crataeva nurvala*) 40 mg, Ashwagandha (*Withania somnifera*) 40 mg, Haridra (*Curcuma longa*) 40 mg, Amalaki (*Phyllanthus emblica*) 40 mg, Methika (*Trigonella foenum-graecum*) 30 mg, Vijaysar (*Pterocarpus marsupium*) 20 mg, Avartaki (*Cassia auriculata*) 20 mg, Jambu (*Eugenia jambolana*) 20 mg, Meshashringi (*Gymnema sylvestre*) 20 mg, Mamejava (*Enicostemma littorale*) 20 mg, Saptarangi (*Casearia esculenta*) 20 mg, Guduchi (*Tinospora cordifolia*) 20 mg, Bilvapatra (*Aegle marmelos*) 20 mg, Neem (*Melia azadirachta*) 10 mg, Karela (*Momordica charantia*) 10 mg. **Powders-** Kutaja (*Holarrhena antidysenterica*) 80 mg, Patol (*Trichosanthes dioica*) 80 mg, Kutki (*Picrorhiza kurroa*) 80 mg, Trikatu (*Piper longum*, *Piper nigrum*, *Zingiber officinale*) 30 mg, Trijata (*Elettaria cardamomum*, *Cinnamomum verum*, *Abies webbiana*) 30 mg, Shuddha shilajit (*Asphaltum*) 80 mg, Yashada Bhasma (*Generic preparation*) 20 mg.

Composition of VAMAH Tablets - Extracts - Kumari (*Aloe vera*) 50 mg, Shatavari (*Asparagus racemosus*) 200 mg, Shatapushpa (*Anethum graveolens*) 50 mg, Deodar (*Cedrus deodara*) 50 mg, Ulatkambal (*Abroma augusta*) 20 mg, Dashmoola (*Group of 10 herbs*) 50 mg, Haritaki (*Terminalia chebula*) 50 mg, Kulattha (*Macrotyloma uniflorum*) 40 mg, Krishna Jeeraka (*Carum carvi*) 20 mg, Gajar beeja (*Daucus carota*) 20 mg, Karpas beeja (*Gossypium herbaceum*) 20 mg, Methika (*Trigonella foenum-graecum*) 20 mg, Rason (*Allium sativum*) 20 mg, Jyotishmati (*Celastrus paniculatus*) 20 mg, Chitraka (*Plumbago zeylanica*) 20 mg, Chandrashoor (*Lepidium sativum*) 20 mg. **Powders-** Shatapushpa (*Anethum graveolens*) 50 mg, Shatavari (*Asparagus racemosus*) 50 mg, Deodar (*Cedrus deodara*) 20 mg, Manjistha (*Rubia cordifolia*) 50 mg, Pippali (*Piper longum*) 50 mg, Hing (*Asafoetida*), 50 mg, Kasis Bhasma (*Generic preparation*) 50 mg, Loha Bhasma (*Generic preparation*) 10 mg.

RESULTS

A total of 190 patients were recruited in the study. The mean age of the subjects in the study was 23.05 ± 7.78 years. The average weight and BMI of the subjects in the study was 67.30 ± 10.56 kg and 23.84 ± 4.60 respectively. There were a total of 113 (59.47%) married females and 77 (40.52%) unmarried females in the study. The mean frequency of the menstrual cycle in the subjects were 44.67 ± 24.14 months. The details are presented in table 1.

Table 1: Baseline demography.

No. of Subjects	190
Age (Mean SD)	23.05 ± 7.78
Weight in Kg	67.30 ± 10.56
BMI (Kg/m ²)	23.84 ± 4.60
Married Participants	113 (59.47%)
Unmarried Participants	77 (40.52%)
No. of Subject having PCOD	190

No. of Subjects having Irregular Menstrual Cycle	190
Duration of Menstrual Periods (in months)	44.67 ±24.14
	Median 66 (22-110)
No of Subjects with Diabetes	
No of subjects with Hypothyroidism	

Assessment of number of subjects achieving regular menstruation:

At baseline visit, all the 190 subjects had irregular menstrual cycles. A total of 137 (72.10%) subjects achieved regular menstruation at the end of the study. Of these 49 (25.78%) subjects achieved regular

menstrual cycle at the end of 3 months while 88 (46.31%) subjects achieved normal menstrual cycle at the end of 6 months. The remaining 53 (27.89%) subjects continued to have regularities in their cycle even at the end of the study.

Table 2: Assessment of number of subjects achieving regular menstruation.

Time point	No and % Percentage of subjects with Regular Menstrual cycle	No and % Percentage of subjects with Irregular Menstrual cycle
Baseline	190 (100%)	0
3 Months	49 (25.78%)	141 (74.21%)
6 Months	88 (46.31%)	53 (27.89%)
End of the study	137 (72.10%)	53 (27.89%)

Assessment of number of bleedings in days per cycle

The average no of bleeding days per cycle at the baseline visit was 1.21 ± 0.34 which increased to 2.22 ± 1.29 at the end of 3 months and further to 3.32 ± 1.59 at the end

of 6 months. On statistical analysis the increase in the no of bleeding days was found to be statistically significant from baseline to 3 months and further to 6 months. Refer table 3.

Table 3: Assessment of number of bleedings in days per cycle.

No. of Bleedings days per cycle	Baseline	3 months	6 months
Mean ± SD	1.21 ± 0.34	2.22 ± 1.29	3.32 ± 1.59
p Value		p<0.05	p<0.05

Assessment of quantity of bleedings per cycle

The average quantity of bleeding per cycle at the baseline visit, 3 months and 6 months was 0.89 ± 0.34 , 2.87 ± 0.58 and 3.95 ± 0.54 respectively. There was a statistically significant increase in the quantity of bleeding per cycle as compared to baseline visit. (The average number pad(s) changed per day were calculated

by dividing the total number of pads used with number of bleeding days per cycle. The amount of menstrual bleeding then graded as per annexure-I viz. 0=spotting (no pad used), 1=scanty (up to 1 pad used/day), 2=moderate (for 1-2 pads used/day), and 3=excessive (for 2-4 pads used/day). Details are presented in table 4.

Table 4: Assessment of quantity of bleedings per cycle.

Quantity of Bleedings per cycle	Baseline	Day 90	Day 180
Mean ± SD	0.89 ± 0.34	2.87 ± 0.58	3.95 ± 0.54
p Value		p<0.05	p<0.05

Assessment of change in polycystic ovary as observed in the USG

All subjects at baseline visit had PCOD as observed in the USG. USG could be performed in 121 participants of which 45 subjects (37.19%) showed complete resolution, 48 subjects (39.66%) showed partial resolution while 27 participants (22.31%) did not show any change.

Assessment of safety

Safety assessment was done by evaluating the occurrence of adverse events. It was observed that none of the study participants showed evidence of any adverse drug reaction. The study products were well tolerated.

Also none of the participants showed worsening in their condition.

DISCUSSION

Modern medical science understands PCOS as a syndrome characterized by ovarian hyper-androgenism and chronic anovulation.^[8] Features also include insulin resistance with compensatory hyper-insulinemia, obesity, oligomenorrhoea, anovulation and hyperandrogenism. Hormonal imbalance including those of follicle stimulating hormone (FSH), luteinizing hormone (LH) from the anterior pituitary gland and oestrogen and androgens are attributed to be the factors causing PCOS.^[9]

Ayurveda texts describe various gynaecological problems related to menstruation under the topics of Artava rogas. PCOS in the Ayurveda can be understood as *Arthava kshaya* (deficiency or loss or scanty menstruation), *Animayat Artava* (irregular or delayed) associated with systemic conditions like obesity (*Medoroga*) and Diabetes (*Prameha*). Ayurveda management targets to improve digestion & metabolism through medicines and methods like *Amapachan* and *Amashodhan*. Along with this local action on the ovaries to stimulate follicles (*Beejaposhan*) and Uterus to improve endometrial health (*Arthavjanan*) are very critical to the successful management of conditions like PCOS through Ayurveda.

Ayurveda management of any disease condition aims to correct the underlying pathophysiology.^[10] Various treatment methods and modalities including procedures like *Panchakarma* and internal medicines are recommended. The Ayurvedic combination used in the current study viz. MYRAH TABLETS and VAMAH TABLETS contain ingredients like *Triphala*, *Trijataka*, *Jeeraka* and *Hingu*, which help to improve digestion and enhance metabolism at cellular level.^[11,12] Herbs like *Kanchanara*, *Varuna* have cyst dissolving properties (*Granthihar*) can help in eliminating immature multiple follicles.^[13] Other ingredients in the composition like *Methi*, *Neem*, *Karela*, *Jamun*, *Triphala* etc. helps in reducing the peripheral insulin resistance which is one of the most important pathological component of PCOS affecting ovarian functions & weight gain.^[14] Herbs like *Ashoka*, *Shatavari*, *Ashwagandha*, *Kumari*, *Krishna Jeeraka*, *Shatapushpa* help to support normal hormonal functions and thus promote maturation of ovum.^[14] These herbs also help to improve overall endometrial functions.^[16]

Modern scientific literature also supports the use of various herbs through their phytoestrogenic activity. Scientific evidence on herbs like *Kanchanaar*, *Shatavati*, *Ashoka* have proven their uterine tonic, endometrial health promoting activities.^[17,18] Anti-inflammatory activities of herbs like *Dashmool*, *Triphala* and anti-oxidant effect of herbs like *Daruharidra*, *Ashwagandha* have also been reported.^[19] Also herbs like *Jeerak*, *Gajar*, *Beej*, are known to stimulate ovulation and also regulate menstrual cycles.^[20] The combined synergistic effect of these herbs helps to regularize menstrual cycles, improve the menstrual flow and increase the chances of ovulation and thus helps treat infertility.

CONCLUSION

The combination therapy of Ayurvedic formulation (*Myrah Tablets* and *Vamah Tablets*) helps in regularizing menstrual cycles and improving the quantity of menstrual flow in patients of PCOS. Also reduction in incidence PCOS was observed with the use of this combination. Further randomized. Controlled trials are recommended to establish and validate the outcome of the study.

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