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A comparative study of homoeopathic treatment versus integrated approach of homoeopathy and yoga in the treatment of menstrual disorders related to PCOS in young females

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Abstract

Background: PCOS is a common clinical entity encountered in females of reproductive age group attributed to elevated androgen levels leading to ovarian cysts, irregular menstrual cycles and hirsutism.

Aim & Objective: To assess if the interventions can facilitate regular menstrual cycle and reduce hyperandrogenism associated with PCOS.

Materials and Methods: Randomized, non-controlled, clinical trial was conducted at Father Muller Homoeopathic OBG, OPD, Mangaluru in 62 females aged between 18-36 years diagnosed with PCOS according to Rotterdam criteria. 31 subjects were treated with homoeopathy and compared with 31 subjects treated with homoeopathy and yoga therapy. Hyperandrogenism was assessed by serum testosterone level and signs of Hirsutism were evaluated according to Ferriman-Gallwey scale for Hirsutism before and after treatment.

Results: According to the statistical analysis there was a significant reduction in Ferriman galley scores in both the intervention groups ($p < 0.001$). It was also observed that both interventional groups are equally effective in regularising menstrual cycle, Chi square test $P = 0.739$, NS and also proved to be equally efficient in attaining fertility among infertile females with PCOS Chi square test $P = 0.855$, NS.

Discussion: In this study *Phosphorous 200 C* proved to be effective constitutional remedy in treatment of PCOS with homoeopathy. *Natrum Muriaticum 200 C* is the most effectual constitutional remedy in the treatment of PCOS along with yoga therapy. It was observed that treatment with constitutional remedy and integrated approach of yoga with constitutional remedy are beneficial in facilitating regular menstrual cycle and reduction in hyperandrogenism associated with PCOS and enhancing fertility rate.

Keywords: Constitutional remedy, Ferriman gallwey scale, Homoeopathy, Polycystic ovarian syndrome, Yoga

Introduction

Polycystic ovary syndrome (PCOS) is a multifaceted entity that has an effect on there productive system, metabolic functions and psychological health throughout a female's life. The causes are varied and quite complex which can include a range of factors such as genetic susceptibility, hormonal imbalances, insulin resistance, and obesity-related mechanisms^[1]. Stein, Irving F and Michael L. Leventhal first described PCOS in 1935 identifying anovulation as a feature of ovarian cysts^[2]. This common female endocrine disorder affects between 2.2% to 26% of women and has been studied mostly in adult women aged 18 to 45 years old^[3]. PCOS is a complex disorder with multiple phenotypes, and there are currently four recognized types.

- Hyperandrogenism, oligo/absence of ovulation and polycystic ovaries.
- Hyperandrogenism, oligo/anovulation.
- Hyperandrogenism and polycystic ovaries.
- Oligo/anovulation and polycystic ovaries.

It is important for clinicians to accurately determine a patient's phenotype because each phenotype has different long-term implications on health and metabolism^[4]. The diagnosis can be confirmed if there is presence of any one of the four typical PCOS symptoms which include menstrual irregularities, signs of hirsutism, presence of acne, infertility due to anovulation with ultrasound suggestive of polycystic ovaries. If the ovarian morphology on ultrasound suggests no abnormalities, then diagnosis is confirmed by biochemical testing to estimate increase in Luteinizing hormone levels, fasting blood glucose/insulin ratio less than

4.5 and elevated testosterone excluding late-onset congenital adrenal hyperplasia^[5]. Most widely accepted diagnostic methodology for PCOS is Rotterdam Criteria. According to this criteria a positive diagnosis of PCOS can be made if a patient presents with any two of the three symptoms: Clinical and biochemical signs of oligo and anovulation, hyperandrogenism and ultrasound findings of polycystic ovarian morphology^[6].

Hyperandrogenism is a key factor associated with the pathophysiology of PCOS. It causes dysregulation in the Gonadotrophin releasing hormone (GnRH) secretion, which is partly due to abnormal feedback by estrogen and progesterone. This leads to the abnormality in gonadotropin secretion and excessive LH secretion, which exacerbates the dysregulation in growth of ovarian follicles, hence resulting in increased secretion of androgens from thecal cells. Insulin resistance is another important factor leading to adiposity in the viscera and dysfunction of adipocytes. These factors are responsible for the production of sex hormone-binding globulin (SHBG) by the hepatocytes, which increase the concentration of free testosterone and further exacerbates the dysfunctions related to hyperandrogenism^[7].

PCOS can present with a variety of symptoms which include amenorrhea and infertility with signs of hyperandrogenemia (HA) associated with disturbances in metabolism involving resistance to insulin and dyslipidemia^[8]. It is observed that women suffering from PCOS have reduced fertility and also likely to have increased risk of hypertension during pregnancy, pre-eclampsia, and diabetes mellitus. They also have a higher prevalence of mood disorders which include depression and anxiety and are at elevated risk of developing endometrial cancer in comparison to females without PCOS especially in premenopausal period^[9].

The management focuses on symptomatic treat to prevent long-term complications. Effective lifestyle changes have to be implemented including adoption of active lifestyle, maintaining a balanced and healthy diet, avoiding unhealthy eating habits, weight reduction in overweight individuals and practising stress management techniques.^[10] Homoeopathy is a drug therapy system that follows the "Law of Similar". Individualization is based on the response of an individual to an unfavourable environment observed through the derangement of life force as signs and symptoms in the emotional sphere, intellectual and physical levels^[11]. The founder of homoeopathy Dr Samuel Hahnemann, emphasised that human being is an integrated whole comprising of reason gifted mind, healthy body and spirit like vital force which are interconnected and free to act without hindrance when the vital force is in balance. Equilibrium of healthy state is disrupted by the derangement of the vital force. Polycystic homoeopathic remedies selected according to the "Law of Similar" will contribute significantly in the treatment of endocrine disorders^[12].

Practice of yoga is an ancient 3,000 years old tradition. In modern times the western world recognizes practice of yoga contributes to holistic health and is classified by the National Institutes of Health as Complementary and Alternative Medicine. Term "Yoga" originated from Sanskrit root "Yuj" attributing to union and concentration of attention. Practice of yoga produces a stress-free physiological state. When stress response is interrupted the balance and unity between mind and body is accomplished.

Firstly, the most important Yogic Principal states that human body is regarded as holistic entity comprising of various dimensions that are interrelated and inseparable from each other. Health or illness in any individual dimensions adversely affects others. Secondly it highlights uniqueness of individual needs hence the practice of Yoga must be tailored to acknowledge the individuality^[13]. Yoga combined with medicines has proved to be effective in treating symptoms of PCOS^[14]. The Holistic approach of Homoeopathy and practice of yoga can efficiently treat the complex symptoms of PCOS.

Materials and Methods

Study Design

It is a randomized, non-controlled, clinical trial with an open-label trail. Randomization was done by sealed envelope method. The trial was registered under Clinical Trial Registry, India on 24/05/2019. Institutional ethical clearance was obtained prior to commencement of the project. Study was conducted at Father Muller Homoeopathic Medical College Hospital, OBG-OPD over a duration of 2 years. The data was collected from Females in the age group between 18-36 years, consulting for treatment of menstrual irregularities associated with PCOS. Relevant data through detailed case taking was recorded in the case format after obtaining informed consent from the subjects.

Sample size calculation

Assuming that effect size = 0.6 at 98% C.I and 90% power, the required sample size was 62 cases, 31 in each group.

Inclusion criteria

- Females between the age group of 18-36years.
- Rotterdam criteria was used to diagnose PCOS.
- Subjects opting to lead a healthy life style and willing to practice yoga regularly (5 days in a week for minimum duration of 30 minutes).

Exclusion criteria

- Subjects diagnosed with Diabetes mellitus, Cushing's disease and increased prolactin levels.
- Subjects with thyroid disorders.
- Subjects suffering from adrenal tumours.

31 subjects received homoeopathic medicines and 31 subjects were enrolled to receive homoeopathic medicines in combination with yoga therapy by a professional trainer. Sealed envelope method was used to recruit subjects to receive the treatment modality. Subjects were scheduled follow up for 9 months at a regular interval of one month to analyse the treatment outcome. Hyperandrogenism was evaluated before and after treatment through laboratory investigations of serum testosterone levels. The assessment of hirsutism was based on Ferriman-Gallwey scale for hirsutism^[15] before and after treatment.

Assessment of Hirsutism according to Ferriman-Gallwey scale: Nine areas of the body are evaluated for hirsutism and a score of a 1-4 specified.

- Normal score-Total scoring < 8.
- Mild hirsutism-Score within range of 8-15.
- Moderate to Severe hirsutism-Score > 15.

Absence of terminal hair 0 Score.

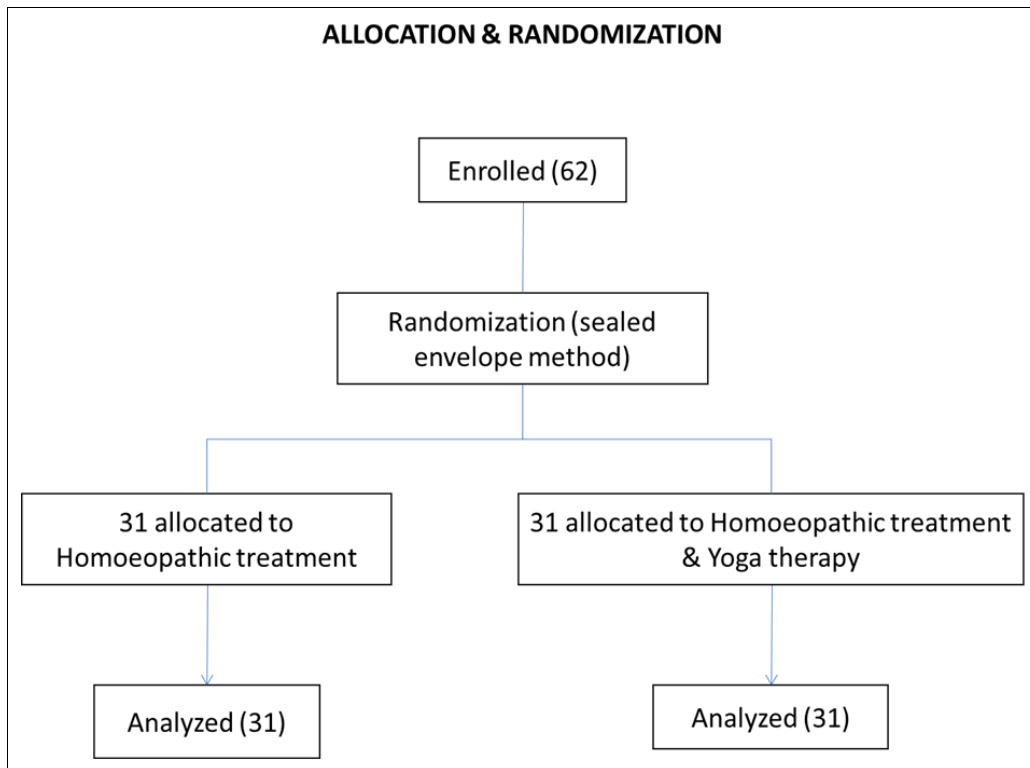


Table 1: Statistical analysis-paired t-test

								To compare before and after		To compare between the groups	
	Group		Mean	Std. Deviation	Mean Difference	S.D of Difference	Change (%)	T-Value	P	T-Value	P
Ferriman Gallwey score	PCOD with homoeopathy & Yoga	Before	15.58	6.08	6.097	4.742	39.13	7.16	0.000, HS	0.89	0.378, NS
		After	9.48	4.73							
	PCOD with Homoeopathy	Before	12.90	7.13	4.833	6.182	37.46	4.28	0.000, HS		
		After	8.07	4.78							

According to statistical analysis in the research study, we observed a significant reduction in Ferriman-Gallwey scores in both the interventional groups ($p < 0.001$). However, we

did not observe any significant change of the score among the interventional groups ($p = 0.378$) NS (Reference Table No 1).

Table 2: Chi square test

		Group			
		PCOD with Homoeopathy & Yoga		PCOD with Homoeopathy	
		Count	Column N%	Count	Column N%
Menstrual cycle	Regular	20	64.52	19	61.29
	Irregular	11	35.48	12	38.71

It was observed that both interventional groups are equally effective in regularising, menstrual cycle. Chi square test $p = 0.739$, NS PCOS patients treated for menstrual irregularity with homoeopathy and yoga 64.52% achieved

regular menses. PCOS patients treated for menstrual irregularity with homoeopathy 61.29% achieved regular menses (Reference Table No 2).

Table 3: Chi square

		Group					
		PCOD with homoeopathy & Yoga		PCOD with homoeopathy		Total	
		Count	Column N%	Count	Column N%	Count	Column N%
Conceived	Yes	3	21.43	3	18.75	6	20.00
	No	11	78.57	13	81.25	24	80.00

It is observed that both interventional groups are equally effective in attaining fertility among infertile females suffering from PCOS. Chi square test $p = 0.855$, NS (Reference Table No 3).

This study has enhanced the fertility rate in infertile females suffering from PCOS. During course of treatment 3 patients out of 13 infertile patients receiving homoeopathic treatment conceived and out of 11 infertile patients 3 conceived receiving homoeopathic treatment and yoga therapy.

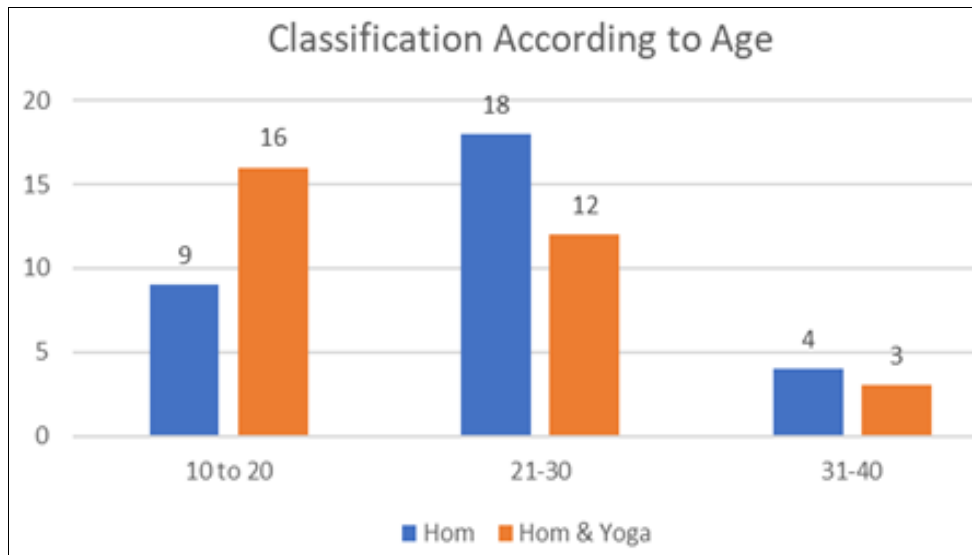


Fig 1: Classification according to age

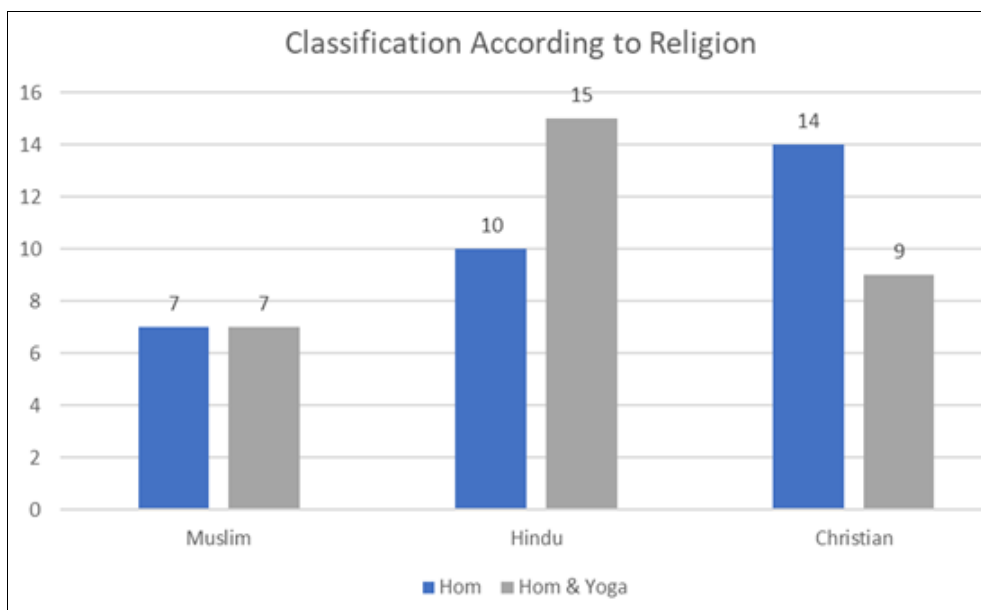


Fig 2: Classification according to religion

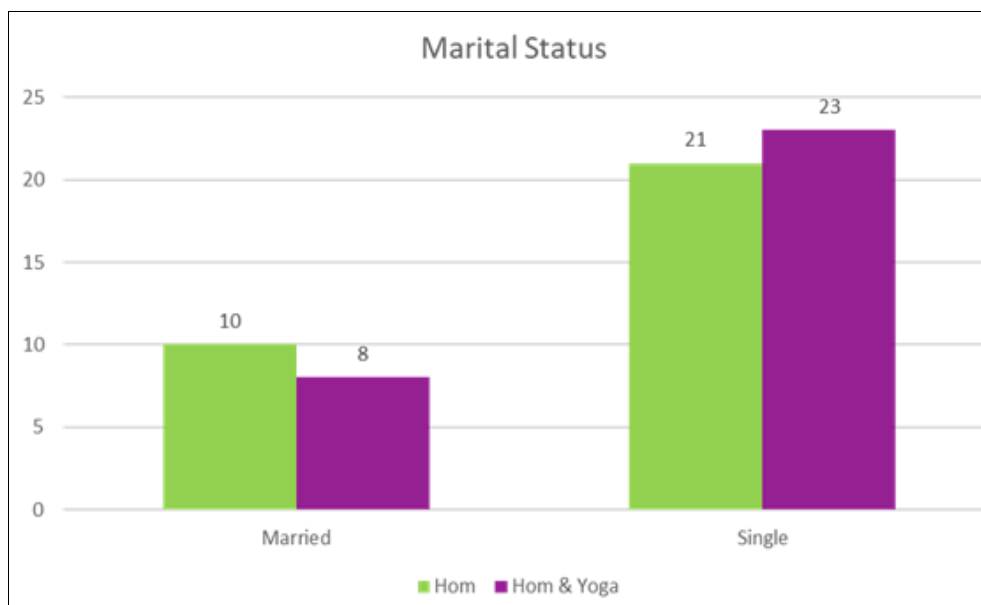


Fig 3: Classification according to marital status

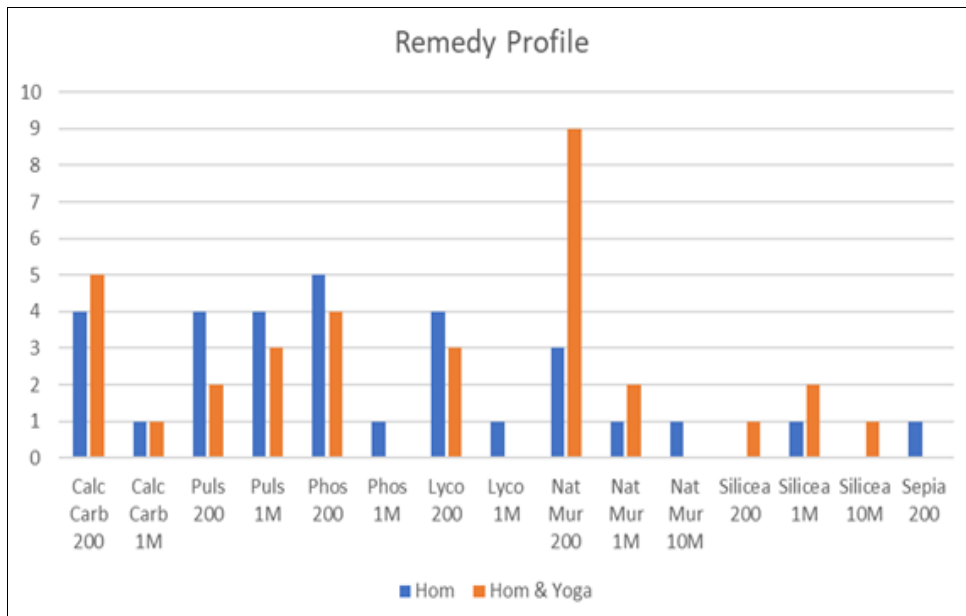


Fig 4: Remedy Profile

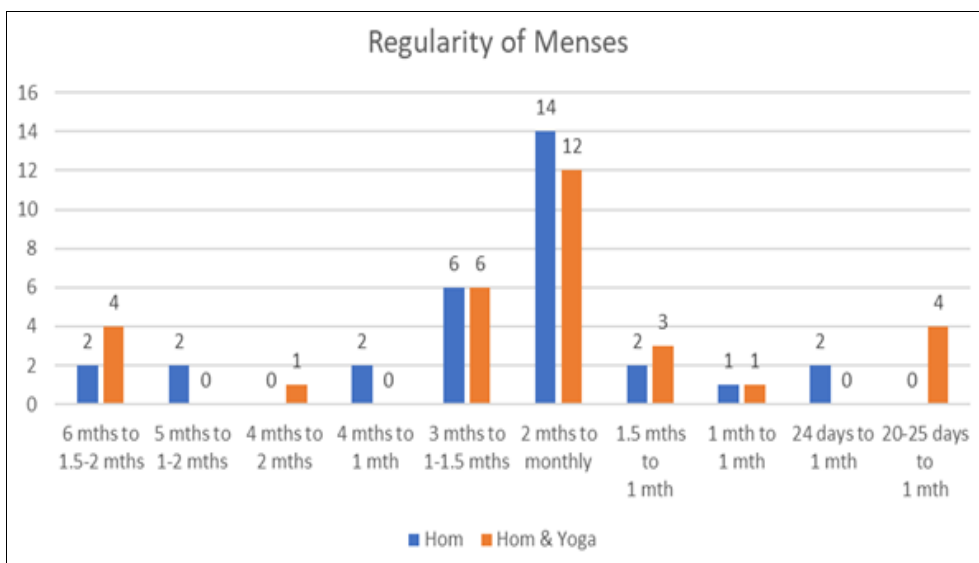


Fig 5: Regularity of menses attained (Based on duration of the cycle)

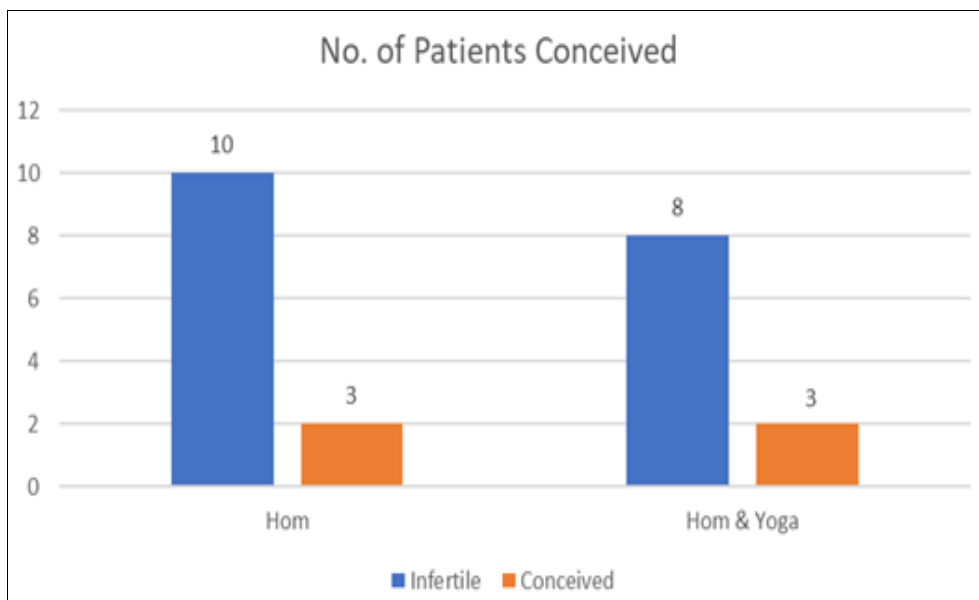


Fig 6: Infertile patients conceived

Discussion

The objectives of the study was to assess if menstrual cycle could be regularised and hyperandrogenism reduced by interventions in females suffering from PCOS. The data was collected from the patients visiting the Homoeopathic OBG OPD for treatment of menstrual irregularities diagnosed with polycystic ovarian syndrome (PCOS) in females aged between 18-36 years. All the subjects of PCOS were diagnosed as per Rotterdam criteria.

31 subjects were administered constitutional homoeopathic remedy and 31 received constitutional homoeopathic remedy along with regular practice of yoga. Each subject was followed up for 9 months at a regular interval of 1 month to evaluate treatment outcome.

It was observed that both interventional groups are equally effective in regularising menstrual cycle. PCOS patients treated for menstrual irregularity with constitutional homoeopathic remedy and yoga therapy 64.52% achieved regular menses while patients treated for menstrual irregularity with constitutional homoeopathic remedy 61.29% achieved regular menses. Chi Square Test $P=0.793$, NS (Reference Table No 2, Fig No 5).

Hyperandrogenism was assessed before and after treatment by laboratory investigation of serum testosterone levels. Around 61 subjects suffering from PCOS did not show elevation in serum testosterone levels normal range being 0.06-0.82ng/dl except one with significant reduction from 0.937ng/dl to 0.536ng/dl in the interventional group treated with constitutional homoeopathic remedy and yoga therapy (Reference Table No 4)

Signs of hirsutism were assessed according to Ferriman-Gallwey scale for hirsutism before and after treatment. Significant reduction in scores were observed in both the interventional groups. According to statistical analysis in the research study, we observed a significant reduction in Ferriman Gallwey scores in both the intervention groups ($p<0.001$). However, any significant change of the score was not observed among the intervention groups ($P=0.378$) NS (Reference Table No 1).

This study has enhanced the fertility rate in infertile females suffering from PCOS. During course of treatment 3 infertile subjects among 13 receiving constitutional homoeopathic remedy conceived. 3 infertile subjects among 11 conceived receiving constitutional homoeopathic remedy and yoga therapy. This suggests that both the interventional groups are significantly efficacious in achieving a significant fertility outcome among the infertile females suffering from PCOS. It is observed that both interventional groups are equally effective in attaining fertility among infertile females suffering from PCOS. Chi Square Test $P=0.855$, NS (Reference Table No 3, Fig No 6).

Phosphorous 200 C has proven efficacious constitutional remedy in treatment of PCOS in the interventional group treated with homoeopathy. *Natrum muriaticum* 200C has proven to be the most efficacious constitutional remedy in the treatment of PCOS along with yoga therapy. (Reference Fig No 5, Table No 4, 5).

The modality of treatment adopted was simple, safe, reliable and cost effective thus made affordable to patients of low socioeconomic status.

Conclusions

This research project is novel integrating 2 systems of treatment homoeopathy and yoga. In both the interventional

groups, patients suffering from PCOS with menstrual irregularity after treatment showed improvement in terms of attaining regular menstrual cycle and there was significant reduction in Ferriman gallwey scores for hirsutism. The serum testosterone levels were not significantly reduced.

This study also has enhanced the fertility rate in infertile females with PCOS in both the interventional groups. *Phosphorous* 200 C has proven effective constitutional remedy, while *Natrum muriaticum* 200C is effectual constitutional remedy along with yoga therapy in the treatment of PCOS. This study ensures safe treatment without any adverse effects on the health of patients suffering from PCOS thus enhancing their quality of life. It is recommended to conduct this study exclusively in infertile patients suffering from PCOS.

Conflict of Interest: None declared

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Appendices

Table 4: Treatment of PCOS with Homoeopathy

SL. No.	Patient code	Age	Serum testosterone before treatment	Serum testosterone after treatment	Ferriman galloway score before treatment	Ferriman galloway score after treatment	Remedy	Menstrual cycle before treatment	Menstrual cycle After treatment
1	AL012	23	0.059	Conceived	13	9 (Conceived)	<i>Puls 200 C</i>	Profuse	Normal cycle & Normal flow
2	AL013	23	0.676	0.654	9	5	<i>Phos 200 C</i>	24 days	Monthly
3	AL016	18	0.122	0.089	26	7	<i>Lyc 1M</i>	1.5mths	Monthly
4	AL018	23	0.343	0.165	8	6	<i>Phos 1M</i>	2 mths	Monthly
5	AL021	22	0.181	0.308	12	7	<i>Natrum Mur 200 C</i>	6mths	Monthly
6	AL024	28	0.044	0.164	9	6	<i>Lyc 200 C</i>	2 mths	Monthly
7	AL026	23	0.543	0.5	21	9	<i>Puls 1M</i>	2 mths	Monthly
8	AL035	29	0.083	0.194	9	2	<i>Lyc 200 C</i>	3 mths	Monthly
9	AL048	18	0.428	0.469	7	14	<i>Puls 1M</i>	3 mths	2 Monthly
10	AL049	22	0.543	0.447	8	14	<i>Calc carb 200 C</i>	5mths	Monthly
11	AL045	20	0.696	0.407	20	19	<i>Lyc 200</i>	2 mths	Monthly
12	AL050	23	0.537	0.252	8	13	<i>Phos 200</i>	3 mths	Monthly
13	AL046	22	0.258	0.332	18	9	<i>Phos 200</i>	1.5mths	Monthly
14	AL038	19	0.425	0.519	15	8	<i>Calc carb 200</i>	2 mths	Monthly
15	AL061	31	0.16	0.56	15	8 (Conceived)	<i>Silicea 1M</i>	2 mths	Monthly
16	AL054	34	0.11	0.261	11	11	<i>Lycopodium 200 C</i>	2-3 mths	Monthly
17	AL068	20	0.608	0.573	6	4	<i>Calc Carb 200 C</i>	2 mths	Monthly
18	AL084	22	0.768	0.517	0	0	<i>Natrum mur 200 C</i>	6mths	2 Monthly
19	AL028	19	0.391	0.453	15	11	<i>Natrum mur 200 C</i>	4mths	Monthly
20	AL087	22	0.55	0.251	18	18	<i>Natrum Mur 1M</i>	2 mths	Monthly
21	AL081	19	0.271	0.176	0	0	<i>Puls 200 C</i>	4mths	Monthly
22	AL053	32	0.78	0.481	18	6	<i>Puls 1M</i>	2 mths	No improvement
23	AL073	22	0.236	0.407	14	8	<i>Natrum Mur 10M</i>	3mths	Monthly
24	AL096	23	0.193	0.133	12	7	<i>Phos 200 C</i>	2mths	Monthly
25	AL085	25	0.431	0.641	29	15	<i>Puls 200 C</i>	3mths	1.5mths
26	AL109	18	0.681	0.33	28	10	<i>Puls 200 C</i>	2mths	Monthly
27	AL033	28	0.286	0.305	14	6	<i>Sepia 200 C</i>	24days	Monthly
28	AL082	21	0.245	0.323	7	1	<i>Puls 1M</i>	2 mths	Monthly
29	AL034	28	0.123	Conceived	8	7 (Conceived)	<i>Calc carb 200 C</i>	2 mths	Monthly, Conceived
30	AL080	35	0.724	0.21	10	6	<i>Calc carb 1M</i>	5mths	2mths
31	AL101	20	0.145	0.448	12	5	<i>Phosphorous 200 C</i>	2 mths	Monthly

Table 5: Treatment of PCOS with homoeopathy and yoga therapy

SL No	Patient code	Age	Serum testosterone before treatment	Serum testosterone after treatment	Ferriman galloway score before treatment	Ferriman galloway score after treatment	Remedy	Menstrual cycle before treatment	Menstrual cycle After treatment
1	AL002	20	0.527	0.433	8	6	<i>Natrum Mur 1M</i>	Monthly	Monthly
2	AL003	24	0.262	0.322	12	7	<i>Silicea 10M</i>	1.5mths	Monthly
3	AL004	36	0.384	0.349	15	10	<i>Lycopodium 200 C</i>	2mths	1.5 Monthly
4	AL005	23	0.419	0.309	8	2	<i>Silicea 1M</i>	22days	Monthly
5	AL007	25	0.725	Conceived	9	8 (Conceived)	<i>Natrum Mur 200 C</i>	3mths	Monthly, Conceived
6	AL008	26	0.369	Conceived	8	8 (Conceived)	<i>Pulsatilla 200 C</i>	1.5mths	1.5mths, Conceived
7	AL010	18	0.426	0.241	15	9	<i>Calc Carb 200 C</i>	1.5mths	Monthly
8	AL011	29	0.359	0.224	13	3	<i>Natrum Mur 200 C</i>	2mths	Monthly
9	AL014	35	0.212	0.28	11	4	<i>Natrum Mur 200 C</i>	20days	Monthly

10	AL015	24	0.937	0.536	19	6	<i>Silicea</i> 200 C	3mths	Monthly
11	AL017	20	0.239	0.337	13	8	<i>Calc Carb</i> 200 C	20days	Monthly
12	AL029	19	0.456	0.395	18	10	<i>Lycopodium</i> 200 C	2mths	Monthly
13	AL040	18	0.025	0.191	8	9	<i>Phosphorous</i> 200 C	2mths	Monthly
14	AL041	19	0.436	0.708	14	7	<i>Natrum Mur</i> 200 C	2mths	Monthly
15	AL052	31	0.621	0.346	19	13	<i>Calc Carb</i> 200 C	25days	Monthly
16	AL060	23	0.474	0.538	21	19	<i>Natrum Mur</i> 1M	2mths	Monthly
17	AL059	18	0.587	0.22	20	13	<i>Natrum Mur</i> 200 C	3mths	2mths
18	AL070	19	0.258	0.393	15	13	<i>Natrum Mur</i> 200 C	2mths	Monthly
19	AL089	25	0.218	0.365	24	15	<i>Silicea</i> 1M	6mths	2mths
20	AL071	19	0.319	0.56	21	14	<i>Pulsatilla</i> 1M	2mths	1.5mths
21	AL090	18	0.302	0.525	14	7	<i>Phosphorus</i> 200 C	2mths	Monthly
22	AL075	22	0.592	0.487	24	11	<i>Natrum Mur</i> 200 C	6mths	2mths
23	AL088	18	0.254	0.204	11	13	<i>Pulsatilla</i> 1M	2mths	Monthly
24	AL092	20	0.1	0.139	14	9	<i>Natrum Mur</i> 200 C	6mths	1.5mths
25	AL097	22	0.364	0.358	15	5	<i>Natrum Mur</i> 200	2mths	Monthly
26	AL117	18	0.399	0.77	4	8	<i>Pulsatilla</i> 1M	2mths	Monthly
27	AL078	28	0.578	Conceived	28	10 (Conceived)	<i>Lycopodium</i> 200 C	6mths	2mths, Conceived
28	AL082	19	0.236	0.158	18	10	<i>Natrum Mur</i> 200C	3mths	1.5mths
29	AL100	18	0.586	0.483	16	2	<i>Calc Carb</i> 200 C	3mths	Monthly
30	AL095	18	0.581	0.519	30	24	<i>Calc Carb</i> 1M	4mths	2mths
31	AL042	25	0.242	0.171	18	12	<i>Calc Carb</i> 200 C	3mths	Monthly

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