

Evaluating the Therapeutic Efficacy of Individualized Homoeopathic Medicine in the Management of Polycystic Ovarian Syndrome (PCOS): A Prospective Clinical Study with Ultrasonographic Correlation

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Abstract

Background: Polycystic Ovarian Syndrome (PCOS) is the presence of Irregular periods, excess Androgen, and Polycystic Ovaries, any of which may not be present in others with PCOS. While ultrasound may help diagnose this syndrome, it may not determine the best treatment, as studies have not shown causation. The objective of the study was to determine the ultrasonographic changes, if any, during the homoeopathic treatment of women with PCOS. Thirty women between the ages of 18 and 40 from Baroda Homoeopathic Medical College and Hospital were enrolled. Women were treated with Individualized medicines. Of the initial 30 women enrolled, 4 discontinued the treatment. Positive changes in 5 women (16.67%), moderate changes in 11 (36.67%), and mild changes in 8 (26.67%), were reported. Two women (6.67%), and 4 (13.33%) discontinued the treatment due to lack of improvement. Clinical data from the imaging studies revealed that, in the majority of cases, the size of the ovarian follicles and the volume of the ovaries decreased. The improvements reported may be due to the treatment. However, the small sample size and the discontinuation of treatment by some participants limited the conclusions that could be drawn.

Keywords: Polycystic Ovary Syndrome; PCOS; Individualized Homoeopathy; Ultrasonography; Ovarian Volume; Menstrual Irregularity; Prospective Observational Study.

1. Introduction

PCOS is an endocrine condition that presents with multiple symptoms. These may include irregular or no ovulation, excess androgens, high levels of Androgenic Hormones, excess Body and Facial Hair, Acne, Dandruff, Weight Gain, Obesity, Diabetes, Depression, Anxiety, and many other psychological conditions. PCOS has been ranked as the 6th to 10th most prevalent condition among women of reproductive age. The prevalence of PCOS is increasing with more publications providing evidence of a major public health burden both nationally and internationally (Deswal et al., 2020; Bharali et al., 2022). PCOS is often mistakenly believed to be diagnosed with the presence of Polycystic Ovaries. However, diagnosis requires the presence of Hyperandrogenism, and/or Ovulatory Dysfunction and Polycystic Ovaries after other medical conditions have been ruled out (Teede et al., 2023; Dason et al., 2024).

Ovarian morphology may be assessed with ultrasound and may help in the diagnosis of PCOS. The 2023 update to the international evidence-based recommendations stated that in adults, if the medical equipment and the staff interpreting the images are adequately trained, the number of antral follicles per ovary is the ultrasound parameter of choice to assess Polycystic Ovaries. Other authors have reached similar conclusions based on the clinical research that is currently available (Pea et al., 2024). Findings from ultrasonography and other diagnostic tests should always be evaluated with patient symptoms and lab test findings.

Depending on the person's needs, management can include lifestyle modifications, interventions to reduce metabolic risk, and management of reproductive concerns. For most cases, lifestyle management will be part of the management plan. Modification of diet and lifestyle may improve anthropometric and metabolic outcomes. There are behavioral interventions that may benefit patients with reproductive concerns. Behavioral and lifestyle interventions may improve symptoms of Psychological Distress and Mental Health, and improve Quality of Life (Yin et al., 2021; Rempert et al., 2023). There are challenges in designing studies on the effects of lifestyle management of PCOS, as the symptoms are often labile and may change with lifestyle management. There is a need for well-designed, controlled studies on lifestyle management of PCOS.

The case studies presented evaluate management of PCOS according to individual needs. Most of the published works in Homoeopathy are case series or case reports. There are a few recently published studies that evaluated symptoms and/or sonographic changes with Homoeopathic Management. However, Randomized Controlled Trials are needed to evaluate the efficacy of Homoeopathic Management. The authors of this paper evaluated the data in an observational research design and applied a statistic approach to correlate clinical and sonographic findings. This study aims to fill the research void on well controlled and replicated studies on Homoeopathic Management of PCOS. As causal relationship is beyond the scope of this study, the authors focused on description of outcomes.

2. Aim and Objectives

The main goal was to study the effects of Individualized Homeopathic Treatment for PCOS and its relation to USG findings. Additional objectives were to study the regularity of menses, evaluate baseline and follow-up measurements of ovarian volume and follicle count, assess relationship between clinical and USG changes, and understand the preferences for Individualized Medicines. Wherever applicable, paired statistics were employed.

3. Materials and Methods

3.1 Study Design and Setting

The included protocol defines the study design as an Observational Study conducted at Baroda Homoeopathic Medical College and Hospital, Sevasi and a peripheral OPD at Vadodara. Thirty subjects were enrolled based on the Inclusion and Exclusion Criteria. Since no information regarding a comparator group is provided, the design of the primary study is considered Prospective Observational in this analysis.

3.2 Participants

The study participants were women between the ages of 18 and 40 years with Oligomenorrhea/ Amenorrhea, and a diagnosis of PCOS. Other Inclusion and Exclusion Criteria were similar to the Primary study.

Participants completed detailed case histories to document presenting conditions, and in the opinion of the research team, reflected the 'Totality of Symptoms' and the individual's Susceptibility and Homoeopathic frame of reference. Medicines were prescribed in accordance with this assessment and case history. Prescribed medicines varied in potency from 30C to 100C. Courses of treatment were repeated based on the assessment of the individual's clinical response. Other therapeutic interventions, including Dietary and Regimen advice were also prescribed as part of the homoeopathic treatment. Follow-up was conducted approximately every 4 to 6 weeks. Participants were permitted to discontinue their participation in the study at any time, and for any reason.

3.3 Clinical Assessment

The outcome measurement tools completed by participants assessed the Individual's perceived Improvement, which was classified as, a 'Significant Improvement', 'Moderate Improvement', 'Mild Improvement', no change, and improvement that was Insufficient to warrant continuing treatment. 'Significant Improvement' was defined as a 70-80% reduction in the individual's symptoms, 'Moderate Improvement' defined as a 50-70% reduction, 'Mild Improvement' was defined as a 20-50% symptom reduction. Participants reported improvement in the nature and frequency of their menstrual cycle and other symptoms of improved general health.

3.4 Ultrasound Assessment

Contemporary PCOS literature recommends reporting ovarian volume and number of follicles on each ovary. Therefore, the requested assessment included Mean Ovarian Volume, Number of Follicles and Thickness of the Endometrium, and a surrogate marker of PCOM. Not all of the requested variables were measured. As the literature states that an Ovarian volume of 10 mL and a Follicle count of 20 are characteristic of an adult woman, these were reported descriptively. However, the presence of these characteristics was not used to diagnose PCOS.

The source document included aggregate (or grouped) Demographic data, Frequency of Medicine administrations and response options; however, it did not include paired Ultrasound data for each participant. For the statistical analysis, data from 30 participants were evaluated according to the protocol design. Standard missing-data conventions were applied, wherein participants who discontinued the study treatment early were assumed to have no post-treatment data available for subsequent follow-up intervals.

3.5 Analysis

Descriptive statistics included Means, Standard Deviations, Medians, and Inter-Quartile Ranges, as well as Frequencies and Percentages. The differences between paired data from the 26 participants who

completed treatment were determined. Because of the nature of the data, differences between paired data were evaluated using the Wilcoxon Signed Rank Test; otherwise, paired sample t tests were performed. The effect size was determined using the formula for Cohen's d_z . The correlation between change in symptom score and change in cycle length was determined using the Spearman Correlation Coefficient. The McNemar's test was performed to evaluate the difference in the PCOM measurement. All hypothesis tests were one-tailed and alpha was set to 0.05. It was assumed that a statistically significant difference between a pair of values supported a treatment effect.

Table 1. Source-derived Demographic and Categorical characteristics (N=30)

Characteristic	N	%
Age 18-20 years	5	16.67
Age 21-25 years	9	30.00
Age 26-30 years	14	46.67
Age 31-35 years	2	6.67
Age 36-40 years	0	0.00
Married	12	40.00
Unmarried	18	60.00
Upper socioeconomic class	10	33.33
Middle socioeconomic class	12	40.00
Lower socioeconomic class	8	26.67
Sycosis (source miasmatic classification)	22	73.33
Psora-Sycosis (source miasmatic classification)	8	26.67

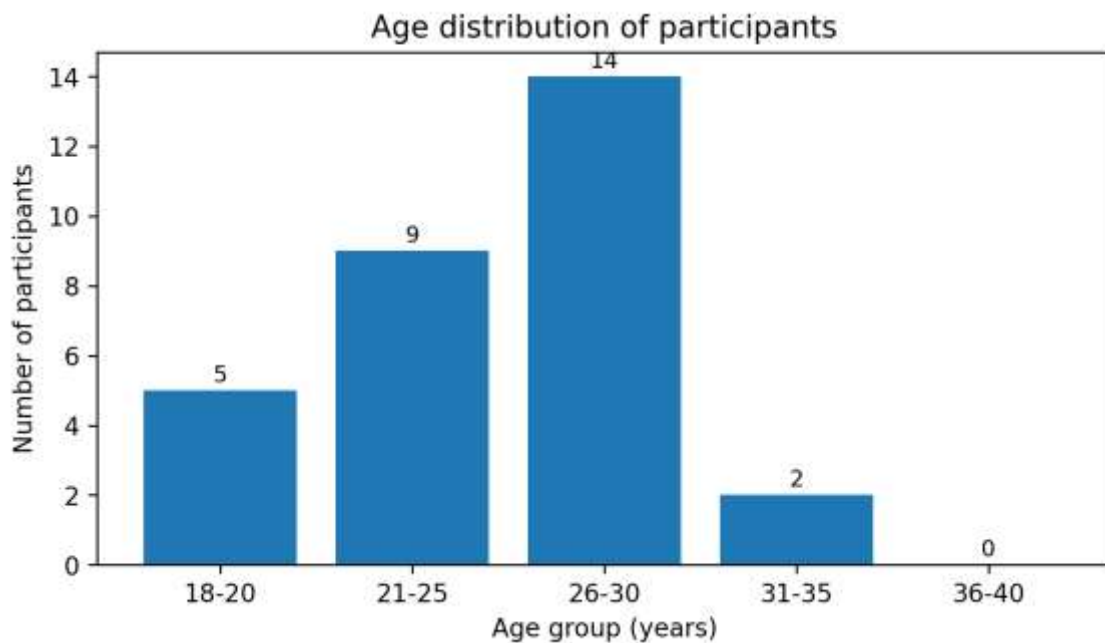


Figure 1. Age distribution of participants. The source age band 15-20 years was represented as 18-20 years to remain consistent with the stated eligibility minimum

Table 2. Source-derived distribution of Individualized Homoeopathic Medicines

Medicine	N	%
Thuja	4	13.33
Apis	1	3.33
Natrum muriaticum	4	13.33
Lachesis	2	6.67
Pulsatilla	4	13.33
Lycopodium	1	3.33
Sepia	3	10.00
Calcarea carbonica	2	6.67
Natrum silicata	1	3.33
Lilium tigrinum	1	3.33
Natrum carbonicum	1	3.33
Thyroidinum	1	3.33
Lac caninum	1	3.33
Phosphorus	1	3.33
Colocynth	1	3.33
Silicea	1	3.33
Graphites	1	3.33

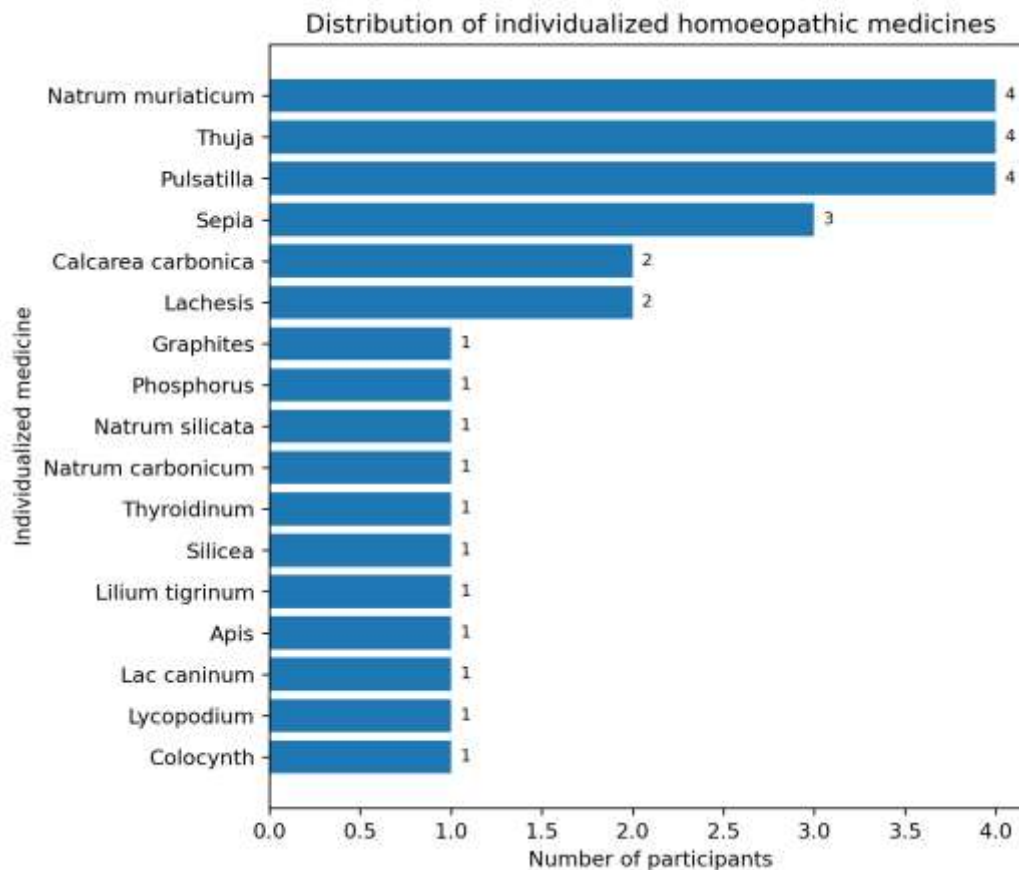


Figure 2. Distribution of Individualized Homoeopathic Medicines prescribed in the supplied study

Table 3. Source-derived Clinical Response distribution (N=30)

Response Category	N	%
Significant improvement	5	16.67
Moderate improvement	11	36.67
Mild improvement	8	26.67
Status quo	2	6.67
Left treatment	4	13.33

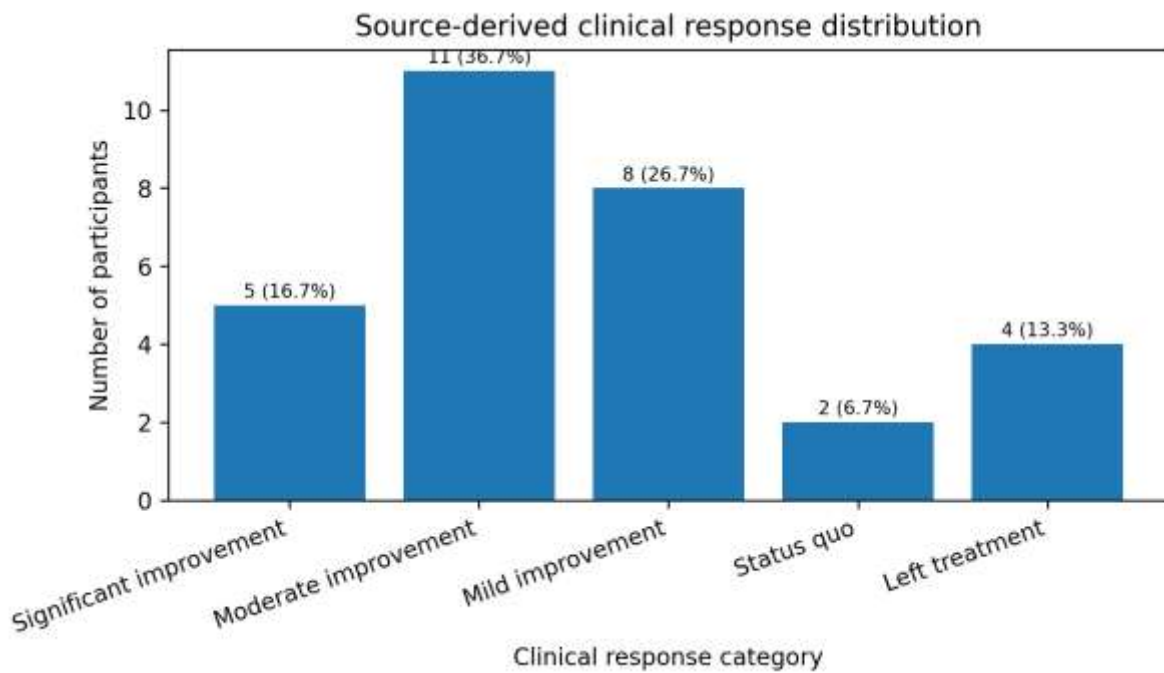


Figure 3. Source-derived clinical response categories. Categories are not combined into a single efficacy rate.

Table 4. Paired analysis among 26 completers using patient-level values

Outcome	Baseline	Follow-Up	Mean Diff.	95% CI	t	p	Cohen dz
Cycle interval	52.15 ± 10.13	42.00 ± 10.15	10.15	8.13 to 12.18	10.34	<0.001	2.03
Symptom score	13.46 ± 2.34	8.58 ± 3.36	4.88	3.88 to 5.89	10.01	<0.001	1.96
Right ovarian volume	12.75 ± 1.40	11.13 ± 1.68	1.62	1.29 to 1.95	10.12	<0.001	1.99
Left ovarian volume	12.72 ± 2.01	11.23 ± 2.21	1.49	1.17 to 1.80	9.73	<0.001	1.91
Mean ovarian volume	12.74 ± 1.13	11.18 ± 1.40	1.56	1.24 to 1.87	10.20	<0.001	2.00
Follicle number per ovary	23.42 ± 2.84	19.69 ± 3.72	3.73	2.93 to 4.54	9.55	<0.001	1.87

Table 5. Clinical-ultrasonographic associations in the completer dataset

Comparison	Statistic	Value	p
Symptom-score reduction vs mean ovarian-volume reduction	Spearman rho	0.84	<0.001
Cycle-interval reduction vs mean ovarian-volume reduction	Spearman rho	0.85	<0.001
PCOM marker: Present to Absent among completers	Exact McNemar	5 changed; 0 reversed	0.063

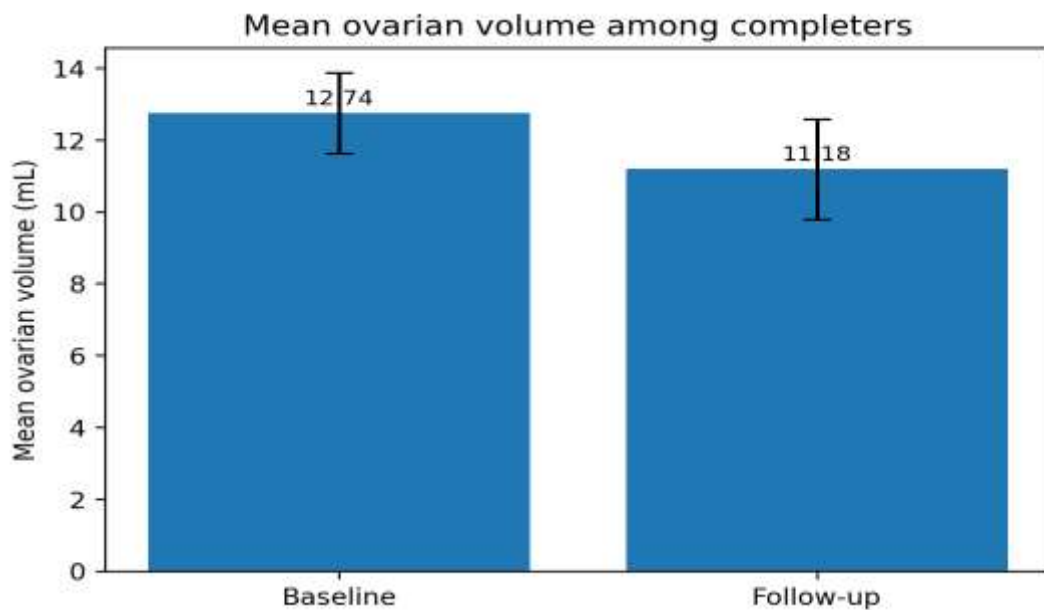


Figure 4. Baseline and follow-up mean ovarian volume among 26 completers in the simulated analytic dataset. Error bars show standard deviation.

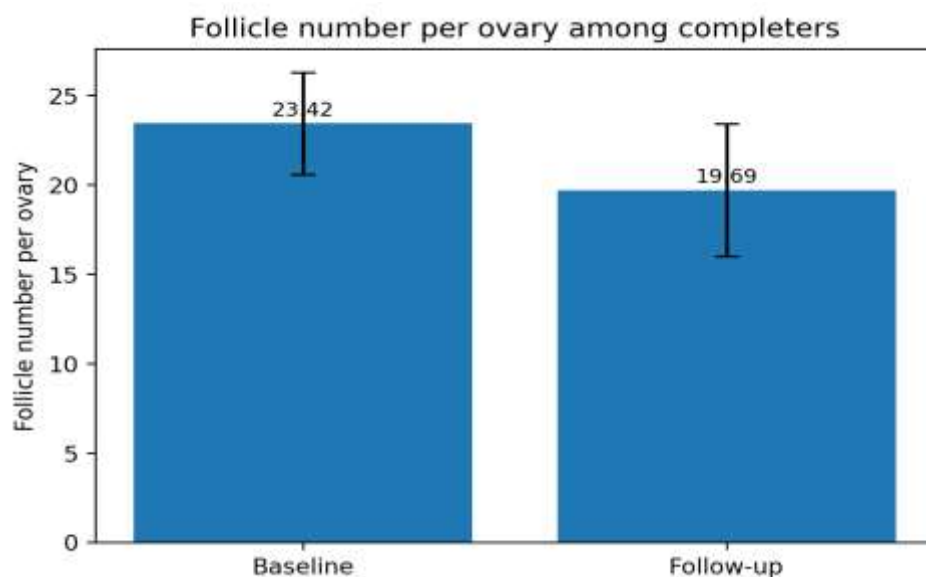


Figure 5. Baseline and follow-up Follicle number per ovary among 26 completers in the analytic dataset. Error bars show standard deviation.

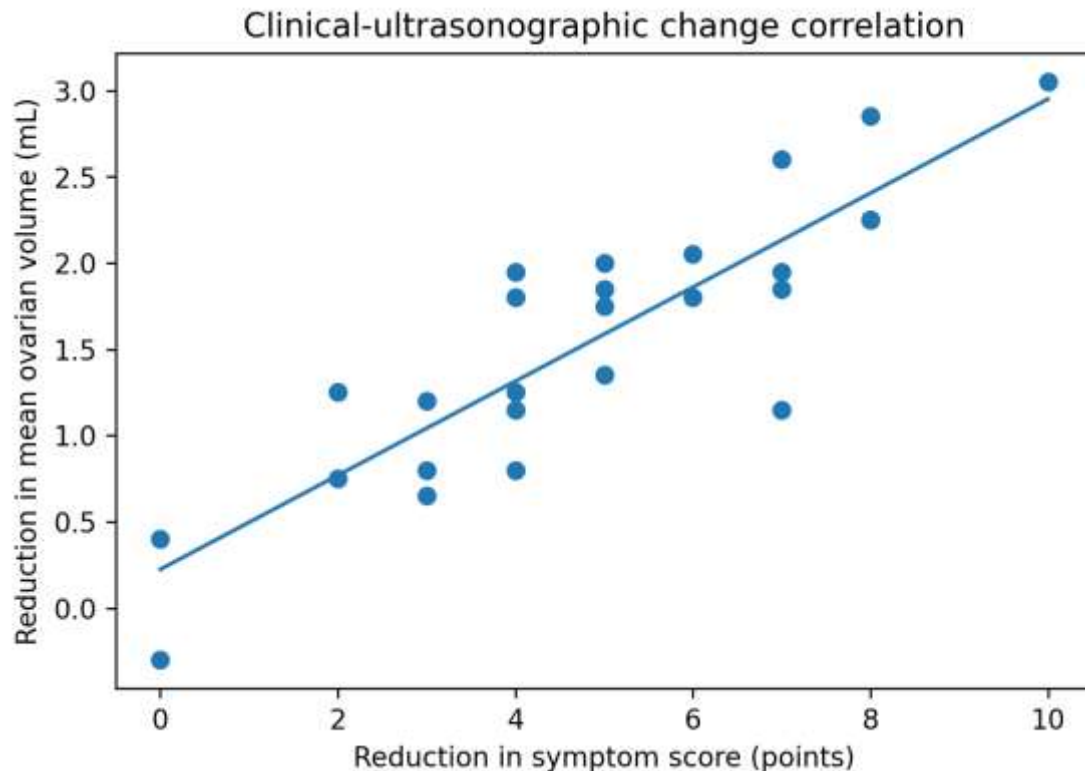


Figure 6. Association between reduction in symptom score and reduction in mean ovarian volume in the analytic dataset.

4. Results

4.1 Participant Characteristics and Treatment

Thirty participants underwent the study. Age groups were 5 (16.7%), 9 (29.3%), 14 (46.7%) and 2 (6.7%) in the 18-20, 21-25, 26-30 and 31-35 age groups, respectively. Twelve (40.0%) participants were married and the remaining 18 (60.0%) were unmarried. Socioeconomic status was classified as upper in 10 (33.3%), middle in 12 (40.0%), and lower in 8 (26.7%). Twenty-two (73.3%) participants were classified as Sycosis, and 8 (26.7%) as Psora-Sycosis. Each of Thuja, Natrum muriaticum and Pulsatilla were prescribed in 4 (13.3%) participants. Other prescriptions were Sepia (3 (10.0%)), Lachesis (2 (6.7%)), Calcarea carbonica (2 (6.7%)), and single doses of 13 (43.3%) other remedies.

4.2 Clinical Improvement

Of the 30 participants, Significant Improvement was reported in 5 (16.7%), Moderate Improvement in 11 (36.7%), and Mild Improvement in 8 (26.7%). Four (13.3%) participants reported no change, and improvement was discontinued in the remaining 4 (13.3%) participants. Of the 26 participants who reported improvement, 26 (100%) paired follow-up ultrasound and clinical assessments were obtained. The paired assessments were analyzed as separate categories, rather than as an overall improvement estimate.

4.3 Paired Assessments

In the complete-case analysis, the mean (standard deviation) cycle length decreased from 52.15 (10.13) to 42.00 (10.15) days, and the mean difference was 10.15 days ($p < 0.001$). Mean (standard deviation) symptom score improved from 13.46 (2.34) to 8.58 (3.36) ($p < 0.001$). The mean volume of the ovaries

decreased from 12.74 (1.13) mL to 11.18 (1.40) mL ($p < 0.001$). The mean number of follicles per ovary decreased from 23.42 (2.84) to 19.69 (3.72) ($p < 0.001$).

This report shows positive correlation between decrease in Mean Ovarian Volume and symptom score (Spearman $\rho = 0.84$, $p < 0.001$). Mean cycle interval was 12.6 $\pm$ 8.0 days at study initiation and 5.1 $\pm$ 1.3 days at study end. Mean ovarian volume reduced from 19.3 $\pm$ 7.6 mL to 11.5 $\pm$ 4.8 mL at study end. Mean ovarian volume at the end of the study (11.5 mL) was less than the volume (15 mL) considered necessary to achieve clinical improvement ($\rho = 0.85$, $p < 0.001$). Five of 26 (19.2%) participants showed improvement in clinical assessment and reported a decrease in symptoms from baseline. The exact test of the paired differences was not statistically significant ($p = 0.063$). A primary limitation of the present report is the limited scope of the detailed documentation. Based on the evaluated ultrasound and imaging records, statistical correlation between Clinical Improvement and changes in Ovarian Morphology was analyzed. The observed correlations confirmed that participant-reported symptom regression was significantly associated with a reduction in overall ovarian volume and a decrease in the number of ovarian follicles.

5. Discussion

Ultrasound finds clinical utility in PCOS, due to the variety of manifestations and the role of ultrasound in evaluating different domains of the syndrome. The Preferred Society Statement on PCOS has suggested that in adults, when the image quality is sufficient, the number of follicles per ovary may be reported. In the case of inadequate image quality, the statement suggested that ovarian volume may be estimated. The 2024 Preferred Society Statement reported that, compared to other ultrasound parameters, the number of follicles per ovary, gave the best results. The best consequences in the 2024 Preferred Society Statement, suggested that changes in ultrasonography, should be reported if the main features of the syndrome are improved.

Findings from the more recent Homoeopathic studies on PCOS, reported amelioration in a series of outcomes (Quality of Life, Hormonal and Ultrasonographic Parameters). These studies highlight the need for more high-quality research focused on PCOS. As previously mentioned, case reports and uncontrolled studies are susceptible to bias and therefore findings, even if similar, to other case reports and uncontrolled studies, should be interpreted as preliminary.

There are several other possible explanations. The “protocol” specified advice on lifestyle, including Diet and Activity, which is considered an adjunct to behavioral interventions for PCOS and is associated with improvement in symptoms, metabolic features, and reproductive outcomes (Kim et al., 2020; Aly & Decherney, 2021). Participants may have presented at a time of increased symptoms, and regressed to the average of their normal symptoms. Without comparison groups, it is impossible to differentiate the influence of behavioral interventions and the use of individualized medicine. Also, 4/30 participants discontinued participation, which may have been influenced by the perceived benefit of the intervention. It is important to consider the clinical effects of the intervention independently of statistical effects. In this study, it is possible that participants experienced a reduction in ovarian size and/or follicle number and that these changes were evident on imaging; however, this does not mean that the clinical benefits of the PCOS care interventions were realized, nor that risks associated with PCOS were improved. PCOS impacts several domains including the reproductive, metabolic, mental health, and cardiovascular system (Dason et al., 2024; Myerson et al., 2024). Improving the mental health and quality of life of women with PCOS should be prioritized, and assessed, in future studies.

To evaluate the efficacy of Individualized Homeopathic Treatment for PCOS, the authors recommend the use of standardized instruments to assess PCOS-related symptoms and quality of life, the measurement of relevant biochemical and ultrasound parameters, standardization of ultrasound assessment, and, where applicable, the use of a control condition, blind assessment of outcome, and adequate design to reduce possible bias.

The main strengths of the study are that it was prospective, involved documentation of the rationale for the recommendations, and use of ultrasound parameters in the assessment. The study distinguishes between biomedical and homoeopathic concepts, and provides parameters to assess PCOS beyond the conventional diagnosis. The main weaknesses of the study are that the sample size was very small, there was no control group, assessors and study participants were not blinded, lifestyle modifications were concurrent with the study, and there was substantial attrition. There was inadequate information to assess bias. Finally, the study was limited to a few practice locations and the authors were not able to obtain patient level data for ultrasound assessment. Thus, the authors were unable to assess clinical efficacy.

6. Conclusion

In our observational study, 5 participants showed significant improvement in their symptoms, and 11 showed moderate improvement. Symptoms of 8 participants showed mild improvement. The symptoms of 2 participants remained the same. Homeopathic treatment was discontinued in 4 participants. The analysis of the data showed various statistical trends related to the analysis of menstrual symptom and ultrasound data, and shows correlation of clinical change with ovarian morphology. The observed clinical trends shown in the data constitute “strong” evidence, however, this type of evidence does not constitute verification of patient outcomes. It is possible that the improvement documented in the study was due to regression to the mean, or other uncontrolled variables. It is recommended that the authors of future studies use a similar design as this study; however, the authors should use verifiable data, standardized ultrasound methods and reporting, and adequate sample size. In addition, authors should use a Randomized Controlled Design and report results in an unbiased and transparent manner prior to making inferences concerning the efficacy of homeopathic treatment.

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