# "Role of Homoeopathic Medicines in Cases of Polycystic Ovarian Disease Assessed by Modern Diagnostic Parameters"

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### **Abstract**

50 well-diagnosed cases of PCOD have been short listed for this study from OPD record of Gaurang Clinic and Centre for Homoeopathic Research. In all cases, pre and post treatment pelvic ultrasound was done apart from detailed hormone analysis i.e. LH, FSH, Oestrogen, Progesterone, Prolactin, and Testosterone in a few cases. It was repeated in cases in which any one of them was found to be abnormal.

Out of 50 patients treated with homoeopathic medicines, complete resolution of PCOD was achieved in 22 (44.00%), significant improvement in 6 (12.00%), 18 (36.00%) maintained status quo while 4 (8.00%) did not improve. *Calcarea carbonica* was the medicine of choice in maximum number of patients (24) but maximum response was obtained with *Lycopodium*. The statistical analysis of the data showed reduction in size of ovary, number and size of cysts.

### **Background:**

The incidence of Polycystic Ovary Syndrome (PCOS) is increasing day by day around the world due to modern life style. It has encouraged several workers to conduct clinical studies to observe the role of various therapeutic interventions in PCOS patients. There are number of claims of homoeopathic practitioners having successfully treated such patients. However, very few studies had been done methodically and published in journals. A few such published studies are being quoted

here to substantiate the claims of role of individualized homoeopathic treatment in confirmed cases of PCOS.

In 1997, SanchezRJ and GuzmanGF conducted a trial on 36 women suffering from PCOS with oligomenorrhoea or amenorrhoea and fitting the mental picture of *Pulsatilla nigricans*. In this trial *Pulsatilla* 6C. At the end of the trial, 30 out of 36 women had complete resolution of cysts.<sup>(1)</sup>

In the clinical study by Sharma D from 2011 to March 2014 on 132 patients with age group from 14 to 35 years, 91 (68.9%) patients were successfully treated, 23 (17.4%) improved, 14 (10.6%) were dropped out and 4 (3.1%) were referred to higher centers due to congenital abnormality. Homoeopathic medicines used in 30C to 1000C were *Apis mellifica*, *Aurum muriaticum natronatum*, *Bryonia alba*, *Calcarea carbonica*, *Lac caninum*, *Lachesis*, *Natrum muriaticum*, *Oophorinum*, *Sepia* and *Sulphur*.<sup>(2,3)</sup>

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Gupta G conducted a clinical study on PCOD and published the results in 2009<sup>(4)</sup> followed by another systematic study by Gupta G.et. al. in 2015. In this study pelvic ultrasonography/transvaginal sonography was the main parameter for diagnosis and assessment to therapeutic intervention. Hormone profile was carried out at the beginning of the treatment and those found altered were repeated during the course of treatment in a few cases. All cases were repertorised using Hompath Classic Software (Ver.8). The result of this work came out to be overwhelming with improvement in 68% cases with normalization of altered hormone level in a few cases. (5)

In 2014, The Central Council for Research in Homoeopathy (CCRH) designed a protocol based multi-centric, randomized, placebo controlled pilot study with a 6-month intervention and follow up period entitled "Homoeopathy in polycystic ovarian syndrome: A randomized placebo-controlled pilot study" to evaluate the efficacy of homoeopathic intervention using established diagnostic criteria. (6)

In 2016, Rath P published two clinical cases of PCOS in "Treatment of infertility with PCOS by Homoeopathic medicine". These married females of 24 and 31 year age, having PCOS with primary and secondary infertility diagnosed 2 years back, were treated by *Pulsatilla* and *Sepia* respectively on the basis of individualization and followed up over a period of 1½ year with marked improvement, followed by conception and delivery. (7)

### Introduction

Polycystic ovarian disease (PCOD) is one of the most common, complex and heterogeneous female endocrine disorder of unknown etiology producing symptoms in approximately 5% to 10% of women of reproductive age (12-45 years old) and is thought to be one of the leading causes of female subfertility. (8-14)

The exact pathophysiology of PCOD is unknown but stress is known to increase the incidence. PCOS can affect a woman's menstrual cycle, fertility, hormones, insulin production, heart, blood vessels and appearance. Its prevalence ranges from 2.2% to 2.6% in the age group between 18 to 45 years in various countries. (15)

The sign and symptoms are infrequent or no menses, infertility, early breast development, male-pattern baldness, hirsutism, acne, obesity, male fat storage pattern, sleep apnea and acanthosis nigricans. (16,17)

### Aim

To ascertain the usefulness of Homoeopathic medicines in the treatment of patients suffering from PCOD.

### **Objectives**

- 1. To prescribe homoeopathic medicines selected on holistic basis after repertorisation.
- 2. To scientifically validate the role of homoeopathic medicines in the treatment of PCOD by assessment through ultrasonography (USG).

### **Materials and Methods**

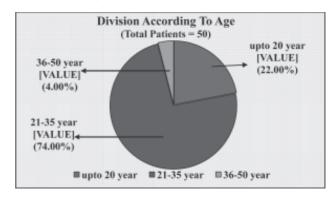
- 1. Patients: A total of 50 cases were included in the study. The cases were selected on the basis of predefined inclusion and exclusion criteria between the age group of 15 to 45 years. The duration of study was 2 years and was conducted at Gaurang Clinic and Centre for Homoeopathic Research, B-1/41, Sector A, Kapoorthala, Aliganj, Lucknow.
- 2. Inclusion criteria: Ultrasonographically proved cases (either per-abdominal or trans-vaginal) uncomplicated and benign cases of PCOD with oligomenorrhoea (<8 spontaneous menses per year) between 15-45 year of age were included irrespective of their caste, religion, socioeconomic status, marital status, parity and duration of illness.
- 3. Exclusion criteria: Pregnant ladies, those who took oral contraceptives, steroid hormones 3 months prior to study, taking hormone replacement therapy, medications like cyclosporine, fibrates, niacin, antifungal agents, macrolide, antibiotics etc., complicated with androgen producing malignancy, Cushing's syndrome or acromegaly, thyroid dysfunction, diabetes and those who did not continue the treatment for minimum 3 months were excluded from the study.

- 4. Diagnostic criteria:Clinical criteria was the patients suffering from recurrent amenorrhoea/ oligomenorrhoea. The main parameter for diagnosis and assessment of response to treatment in follow-up was per-abdominal or trans-vaginal ultrasonography.
- 5. Brief study procedure: Case taking was done considering the totality of symptoms, constitution, family history, past history and physical examination of the patient. Analysis and evaluation of the symptoms was done according to the case followed by repertorisation by Hompath Classic Software (Version 8.1) using Complete, Kent and Phatak's repertory.
- 6. Selection of medicine: Selection of medicine was done on holistic basis i.e. causation, mental general, physical general and menstrual symptoms on the basis of the repertorial analysis and constitution of the patient.
- 7. Auxiliary measures: Supportive diet counselling, yoga and exercises were advised to patients.
- **8. Follow-up:** The patient was followed-up at an interval of 15-30 days.
- 9. Statistical techniques and Data analysis: Data were summarized as mean ± SD. Groups were compared by paired t test. A two-tailed p<0.05 was considered statistically significant. Data analyses were performed on SPSS software (Windows version 17.0).
- **10. Outcome assessment criteria:**Following parameters were fixed according to the type of response obtained aftertreatment:
- Resolved: Feeling of mental and physical wellbeing with complete relief in all signs and symptoms for which the patient originally approached, with no evidence of PCOD on ultrasonography.
- Improved: Feeling of mental and physical wellbeing with reduction in all signs and symptoms for which the patient originally approached, with significant reduction in ovarian bulk, number and size of cysts on ultrasonography.
- Status Quo: No change in mental and physical

- state, signs and symptoms as well as ovarian bulk, number and size of cysts on ultrasonography.
- Not Improved: Worsening of mental and physical state, signs and symptoms as well as increase in ovarian bulk, number and size of cysts on ultrasonography.
- 11. Procuring of medicines: Medicines were procured from ShardaBoiron Limited-GMP certified company) and dispensed at Gaurang Clinic and Centre for Homoeopathic Research, Lucknow.

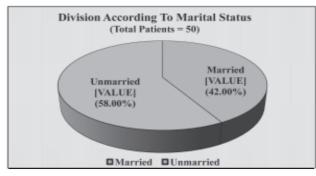
### **Observations and Results**

• As shown in the graph1, maximum incidence was observed in the age group between 21-35 years (74.00%), whereas minimum incidence was seen in age group between 36-50 years (4.00%).



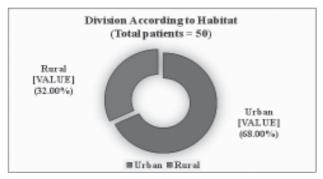
Graph 1: Graphical Representation of Cases According to Age

As shown in the graph 2, out of 50 patients, 29 (58.00%) were unmarried whereas 21 (42.00%) were married.



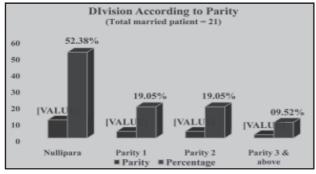
Graph 2:Graphical Representation of Cases According to Marital Status

• As shown in the graph 3, out of 50 patients, 34 (68.00%) patients were urban while 16 (32.00%) were from rural background.



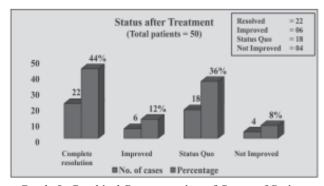
Graph 3: Graphical Representation of Cases According to Habitat

• As shown in the graph 4, out of 21 married patients, 11 (52.38%) patients were nulliparous, 4 (19.05%) were primiparous, 4 (19.05%) were biparous while 2 (09.52%) were multiparous.



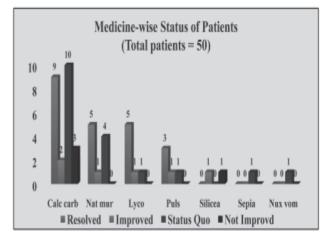
Graph 4: Graphical Representation of Cases According to Parity

• As shown in the graph 5, out of 50 patients treated with homoeopathic medicines, complete resolution of PCOD was achieved in 22 (44.00%), significant improvement in 6 (12.00%), 18 (36.00%) maintained status quo while 4 (8.00%) did not improve.



Graph 5: Graphical Representation of Status of Patients after Treatment

• As evident from graph 6, though *Calcarea carbonica* was indicated in maximum number of patients (24) followed by *Natrum muriaticum* (10), *Lycopodium* (7) and *Pulsatilla* (5) but maximum response was obtained with *Lycopodium* i.e. 71.43% followed by *Pulsatilla* (60.00%), *Natrum muriaticum* (50.00%) and *Calcarea carbonica* (37.50%).



Graph 6: Graphical Representation of Medicine-wise Status of patients

## Statistical analysis

Data were summarized as mean  $\pm$  SD. Groups were compared bypaired-ttest. A two-tailed p<0.05 was considered statistically significant. Analyses were performed on SPSS software (Windows version 17.0).

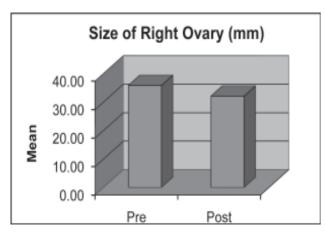
The present study evaluates the effect of different medicines on PCOD. Total 50 patients aged between 15-45 years were recruited and evaluated. The primary outcome measures of study were size of ovary, number of cysts and size of cysts on both sides.

In pre and post-treatment ultrasonography report of 50 patients, size of ovary was available in 44 patients on both sides, number of cysts were available in 18 on right and 19 on left and size of cysts was available in 39 on right and 40 on left side for statistical analysis.

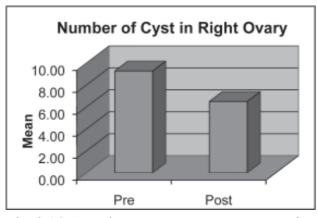
The pre and post treatment outcome measures in case of right ovary are summarized in Table-1 and Graphs no. 1.1, 1.2 and 1.3 which showed that the mean outcome measures on right side has decreased after the treatment. Comparing the pre and post mean outcome measures, paired t test showed significant decrease in size of ovary.

Table-1: Pre and post treatment outcome measures (Mean ± SD) in case of Right Ovary
(Total patients: 50)

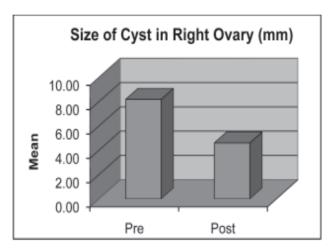
Outcome measures	No of patients	Pre	Post	Change (Post-Pre)	t value	pvalue
Size of ovary (mm)	44	$35.80 \pm 5.91$	$32.05 \pm 7.07$	$-3.75 \pm 7.31$	3.40	0.001
No of cysts	18	$9.28 \pm 1.45$	$6.50 \pm 4.34$	$-2.78 \pm 3.90$	3.02	0.008
Size of cysts (mm)	39	$8.18 \pm 2.59$	$4.59 \pm 4.31$	$-3.59 \pm 4.16$	5.39	< 0.001



Graph 1.1: Pre and post treatment outcome measures in case of Size of Right Ovary



Graph 1.2: Pre and post treatment outcome measures for No. of Cyst in Right Ovary

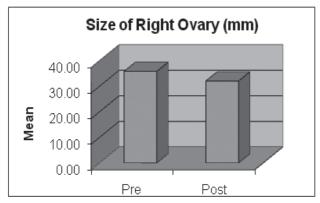


Graph 1.3: Pre and post treatment outcome measures for Size of Cyst in Right Ovary

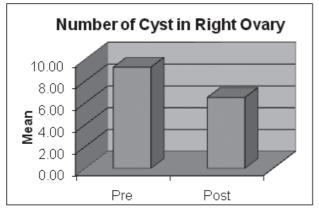
The pre and post treatment outcome measures in case of left ovary are summarized in Table-2 and Graphs no. 2.1, 2.2 and 2.3 which showed that the mean outcome measures on left side has also decreased after the treatment.

Table-2 : Pre and post treatment outcome measures (Mean ± SD) in case of Left Ovary (Total patients: 50)

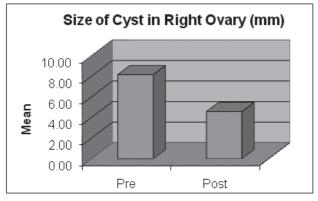
Outcome measures	No of patients	Pre	Post	Change (Post-Pre)	t value	pvalue
Size of ovary (mm)	44	$37.00 \pm 6.29$	$32.59 \pm 7.01$	$-4.41 \pm 6.91$	4.23	< 0.001
No of cysts	19	$9.05 \pm 1.72$	$6.21 \pm 4.47$	$-2.84 \pm 3.80$	3.26	0.004
Size of cysts (mm)	40	$8.03 \pm 2.50$	$5.50 \pm 4.93$	$-2.53 \pm 4.55$	3.51	0.001



Graph 2.1: Pre and post treatment outcome measures in case of Size of Left Ovary



Graph 2.2: Pre and post treatment outcome measures for No. of Cyst in Left Ovary



Graph 2.3: Pre and post treatment outcome measures for Size of Cyst in Left Ovary

#### A Model Case

### **Presenting Complaints**

A 22-year-old unmarried female patient was having delayed menses (by 15 to 20 days) since menarche at the age of 13 years. (LMP-3/9/14). P/V brownish discharge < before menses. She was also complaining

of Right hemicrania < mental tension, being stressed, noise, pressure since 2 years; falling of hair with mild dandruff on scalp since 1 year; tiny warty growth on face, axilla and chest since 4 years.

### **Past History**

Bone tuberculosis 9 years back (took ATT for 1 year) Acne on face 4 months back (applied some ointments)

### **Family History**

Father-Diabetes: Mother-Asthma

### Life space

She was of reserved nature and highly confused. She broods on the matters which hurts. She had poor concentration in studies, difficulty in calculations and in taking decisions. On deep enquiry, she disclosed that she had a delusion of someone behind. She also had repeated dreams of missing examinations. Her attitude towards life was negative. She was chilly and had tendency to catch cold easily. She had perspiration in palms and soles.

### **Treatment History**

Homoeopathic treatment elsewhere.

Pain killers for migraine.

### **Physical and Mental Generals**

a.	Appetite:	Normal
<b>b.</b>	Thirst:	Normal

c. Desire/Cravings: Sweet and salt both

d. Aversion/Repugnance: Nonee. Stool: Normalf. Urine: Normal

g. Perspiration: Palms and soles

h. Sleep: Normal

i. Dreams: Unsuccessful efforts

(missing exams)

Frightful

j. Thermal reaction: Chilly patient

*k. Behaviour:* Short tempered, obstinate, reserved, confused and dull.

### **Initial Investigations**

Ultrasonography of Pelvis (20/10/14):Both ovaries are mildly enlarged in size measuring 33x19x31 mm (vol.-10.7 ml) on right and 34x18x20 mm (vol.-6.7 ml) on left with small cystic areas (Polycystic Ovarian Disease).

# Initial ultrasonography film and report (Before treatment)







### **Hormone Profile (11/11/2014)**

LH-9.03, FSH-8.54, PRL-46.62 '!, Progesterone-1.11, Oestrogen-32.25 (Follicular phase)

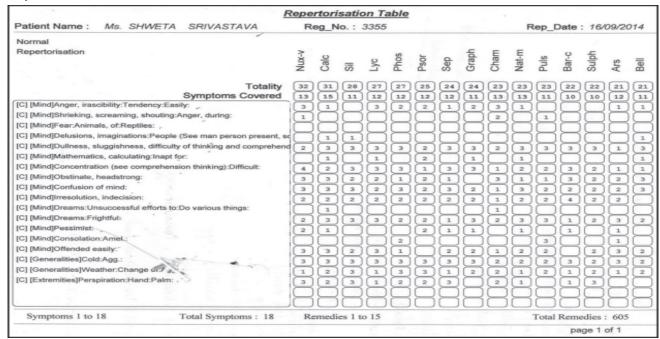


### **Rubrics for Repertorisation**

Anger easily	Irresolution
Shouting anger during	Dreams: Unsuccessful efforts
Fear: Reptiles	Dreams: Frightful
Delusion: Someone behind him	Pessimist
Dullness	Consolation: Amel.
Mathematics: In apt for	Offended easily
Concentration: Difficult	Cold: Agg
Obstinate	Change of weather: Agg
Confusion of mind	Perspiration: Palm

### Thermal: Chilly patient

### **Repertorisation Chart**



### **Result of Repertorisation**

Remedies	Nuxvom	Calcareacarb	Silicea	Lycopodium
Total score	otal score 32 31		28	27
Rubrics covered	13/18	15/18	11/18	12/18

Medicine Selected: Calcarea carbonica

**Justification of Prescription:** The rubrics-dreams frightful, of unsuccessful efforts, delusion of someone behind, difficult concentration, obstinate behavior, offended easily, pessimism and chilly constitution favoured the selection of Calcarea carbonica.

### Date-wise follow-up

**September 16, 2014:** *Calcarea carbonica* **30** once a week followed by placebo for 4 weeks.

October 21, 2014: Menses appeared on 11.10.14. P/V discharge before menses lasted for 3 days. Right hemicrania off and on. *Calcarea carbonica* 30 was repeated once a week followed by *Sanguinaria* 30 twice a day for 4 weeks.

**November 25, 2014:**Menses appeared on time i.e. 10.11.14. P/V discharge reduced. Right hemicrania off and on. *Calcarea carbonica* 30 was repeated once a week followed by *Sanguinaria* 30BD for 4

weeks.Patient was advised to get ultrasonography repeated.

**January 16, 2015:**Menses appeared on 14.12.14, late by 2 days. P/Vdischarge much reduced. Right hemicrania reduced in frequency. Repeat ultrasonography of pelvis dated 3.1.15 revealed no improvement. *Calcarea carbonica* **200** was prescribed once in 15 days followed by *Sanguinaria* **30**BDfor 4 weeks.

**February 20, 2015:** Menses appeared on 20.2.15. No P/V discharge. Right hemicrania reduced. Her mental symptoms such as delusion someone behind and pessimism also reduced. *Calcarea carbonica* **200** was repeated once in 15 days followed by *Sanguinaria* **30**BDfor 4 weeks.

April 07, 2015: Menses appeared on 21.3.15. Serum prolactin which was initially raised became normal on follow-up blood examination dated 21.2.2015. *Calcarea carbonica* 200 was repeated once a week followed by *Sanguinaria* 30BDfor 4 weeks. Patient was advised to get ultrasonography repeated.

May 14, 2015: Menses appeared on 2.5.15. No hemicrania. Repeat ultrasonography of pelvis dated 11.5.15 was normal.

### **Final Investigations**

Ultrasonography of Pelvis (11/5/15):Both ovaries are normal in size measuring 32x15 mm on right and 29x18 mm left respectively.

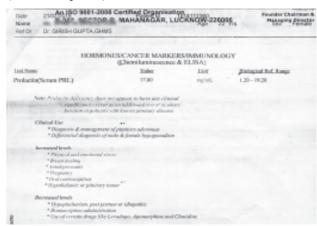
# Final ultrasonography film and report (After treatment)







# **Hormone Profile (21/02/2015):** PRL-17.80 Normal (Follicular phase)



### **Discussion**

In this study (Graph 1), it was observed that maximum 37 patients belonged to the age group between 21-35 years (74.00%) while 11 (22.00%) were less than 21 years and only 2 patients were in the age group between 36-50 years (4.00%). It is a fact that the age between 21-35 years is full of stress, tension, anxiety related to future, career, job, financial stability as well as emotional disturbances related to adjustment with peers, affair, marriage etc. These psychological factors along with mental shock, grief, mortification, vexation, suppression of emotions and anger, if present, affect the mind in one way or the other andinitiate, precipitate or aggravate the illnesses and are the root cause of most of the illnesses. Similarly, the dreams, fears and delusions also affect the mind. Suppression of emotions affect the limbic system leading to disturbance in psycho-neuro-hormonal axis and ultimately leading to imbalance in pituitary and ovarian hormones like follicle stimulating hormone (FSH) and luteinizing hormone (LH), estrogen and progesterone.

The number of females affected by PCOD belonging to urban background was 34 (68.00%) which was more than twice the number of females (Graph 3) from rural backgroundi.e. 16 (32.00%) which suggest that psychological factors like anger, grief, stress, tension, anxiety and emotional disturbances are more prevalent in urban habitat.

Though these factors equally affect both married and unmarried females but in this study (Graph 2) the preponderance was more in unmarried i.e. 29 (58.00%) patients where uncertainties related to future were more in comparison to 21 (42.00%) married ladies.

Out of 21 married patients, 11 (52.38%) patients were nulliparous, 4 (19.05%) were primiparous, 4 (19.05%) were biparous while 2 (09.52%) were multiparous (Graph 4) which gives an impression that chances of PCOS are minimized with the increasing parity. It is a matter of further enquiry that whether the same is true or those ladies who have completed their family or having at least one issue do not bother to consult for secondary infertility.

Out of 50 patients treated with individualized/indicated homoeopathic remedy, positive response has been achieved in 28 (56.00%) patients with complete resolution in 22 (44.00%) and significant improvement in 6 (12.00%) while 18 (36.00%) maintained status quo and 4 (8.00%) did not improve (Graph 5). The point to ponder over is to find out the causes of failure in about 44% cases despite well-selected remedy. It could be mainly due to the fact that most patients do not reveal the causes of emotional disturbance and other mental symptoms. The other reasons could be due to miasmatic influences on the patients. If the time would have permitted to review the non-responding cases, many new facts could have emerged enabling the physician to select other suitable remedy which could be a real similimum that could have cured the cases.

As far as response of patients to individual medicine is concerned, *Calcarea carbonica* was indicated and prescribed in maximum number of cases (48.00%) but it could resolve PCOD in 37.5% patients. Maximum response was obtained in cases treated with *Lycopodium* i.e. 71.43% followed by *Pulsatilla* (60.00%) and *Natrum muriaticum* (50.00%) (Graph 6). While repertorising the rubrics given by patient during case history, maximum emphasis was given to causations followed by mental symptoms like dreams, delusions and fears etc. Next in order were physical generals, menstrual symptoms, constitution and thermals of the patients. Least importance was given to particular and common symptoms related to pathology of the disease.

The main parameter of the assessment was Pelvic ultrasonography in which size of ovary, number of cysts and size of cysts on both sideswere measured.

In pre and post-treatment ultrasonography report of 50 patients, size of ovary was available in 44 patients on both sides, number of cysts were available in 18 on right and 19 on left and size of cysts was available in 39 on right and 40 on left side (Table 1, 2).

After treatment comparing the pre and post mean outcome measures, paired t test showed significant decreasein size of ovary, number of cysts and size of cysts. The decrease in size of right ovary was 10.5%(Graph 1.1) and left ovary was 11.9% (Graph 2.1). Similarly, the decrease in number and size of cysts on right side was 29.9% and 43.9%(Graph 1.2, 1.3) while on left side the reduction was 31.4% and 31.5% respectively (Graph 2.2, 2.3). It was indicative of positive response of the patient to individualized treatment.

In this study, 50 well-diagnosed cases out of hundreds enrolled for treatment at Gaurang Clinic were shortlisted. In all cases, pre and post treatment pelvic ultrasound has been done apart from detailed hormone analysis i.e. LH, FSH, Oestrogen, Progesterone, Prolactin, and Testosterone in a few cases. It was repeated in cases in which any one of them was found to be abnormal.

The outcome of this study is encouragingand a ray of hope for PCOD patients who are tired of taking hormone therapy. It paves the way for detailed studies to find out the mode of action of homoeopathic medicine in cases of Polycystic Ovarian Disease.

## Limitations of the study

Every clinical study has certain limitations which affect the outcome. The present study entitled "Role of homoeopathic medicines in cases of Polycystic Ovarian Disease assessed by modern diagnostic parameters" had also some limiting factor which affected the outcome measures depending upon the non-uniformity of the available data. In this ultrasonography based clinical study, size of ovary, number of cysts and size of cysts was not mentioned in all pre and post ultrasonography reports, hence such cases were excluded from statistical analysis of the data which was summarized as mean  $\pm$  SD and the groups were compared by paired t test. A two-tailed p<0.05 was considered statistically significant. Moreover, both the ovaries were not considered as single unit but were taken as right and left ovary in the form of separate entity to facilitate the statistical

Hormone profile i.e. Oestrogen, Progesterone, Follicle Stimulating hormone, Luteinizing hormone, Prolactin and Testosterone were carried out initially in a few patients. It could not be done in all cases due to heavy cost involved. In follow up, repeat hormone profile was advised only to those patients in whom either of these were found abnormal.

Owing to the fact that this study was not sponsored by any funding agency and the cost of all the investigations had to be borne by the patients or her attendants thus it was not possible to follow a definite pre-decided protocol.

### Conclusion

The role of homoeopathic medicines in PCOD cases selected on holistic basis as per principles of Homoeopathy laid down in Organon of Medicine is positive. This study opens new vista to explore the efficacy of homoeopathic medicine in such diseases where hormone replacement therapy is the only option in modern system of medicine. More scientific studies like randomized controlled trials (RCT) on large sample size with more parameters should be done to scientifically validate the findings of previous studies.

It is, however, evident from the present study on 50 confirmed cases of PCOD that homoeopathic drugs are effective in treating cases of PCOD successfully. Moreover, these drugs are not only clinically safe but also cost effective which can save patients from long term hormone therapy.

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