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An experimental study to ascertain the effectiveness of *Pulsatilla Nigricans* in cases of polycystic ovary syndrome (PCOS)

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Abstract
Background: The precise definition of PCOS remains unclear because of the heterogeneity of this abnormality. Polycystic Ovarian Syndrome (PCOS) is a chronic heterogeneous endocrinopathy characterized by oligo-anovulation, hyperandrogenism and polycystic ovaries. It is associated with metabolic syndrome.
Materials and Methods: Demographic details and clinical data were collected with all signs and symptoms from 30 patients registered for the study with their written concern and according to inclusion criteria from OPD at Sainath Homoeopathic Hospital, Rajkot homoeopathic Medical College (affiliated to Parul University), Rajkot, Gujarat. From February 2022 to August 2022.
Results: The effectiveness of *Pulsatilla Nigricans* with the help of PCOSQ for Polycystic Ovary Syndrome was assessed and out of 30 cases 23 cases showed marked improvement (76.66%) and rest showed mild to no improvement after 6 months of individualised Homoeopathic Treatment.
Conclusion: *Pulsatilla Nigricans* was found effective in cases of PCOS and was able to improve the quality of life of the patient.

Keywords: *Pulsatilla Nigricans*, PCOS, PCOSQ, homoeopathy, patient

Introduction
Polycystic Ovarian Syndrome (PCOS), it is hormonal disorder causing enlargement of ovaries with fluid filled small cavities making outer edges hard. It is caused due to increase in androgens in female body which don't allow ovulation and multiple ovules at various stage of its maturation remains intact causing cysts Symptoms like hyperandrogenaemia, hyperinsulinemia, hyperprolactinemia, insulin resistance, low FSH, low serum SHBG etc. is observed. This disease is mainly observed at the reproductive age of a female from 12-45 years of age. Yet the exact cause of this disease is not known but according to some observations it is genetic or it is due to unhealthy lifestyle. According to the various surveys approximately 6% - 26% cases globally, according to WHO 116 million women in world, 3.7%-22.5% in India, i.e., 1 in 5 women suffering from PCOS. Considering it as a serious problem in women's health, precautionary and curative steps should be taken.

Objectives of study
1. To ascertain the effectiveness of *Pulsatilla Nigricans* in cases of PCOS diagnosed by specific diagnostic test (USG).
2. To assess the quality of life in the cases of PCOS, with the help of PCOSQ.

Review of literature
The precise definition of PCOS remains unclear because of the heterogeneity of this abnormality. Polycystic Ovarian Syndrome (PCOS) is a chronic heterogeneous endocrinopathy characterized by oligo-anovulation, hyperandrogenism and polycystic ovaries. It is associated with metabolic syndrome. A hormonal disorder causing enlarged ovaries with small cysts on the outer edges. The cause of polycystic ovary syndrome isn't well understood, but may involve a combination of genetic and environmental factors. Symptoms include menstrual irregularity, excess hair growth, acne and obesity. Treatments include birth control pills to regularize periods, medication called metformin to prevent diabetes, statins to control high cholesterol, hormones to increase fertility and procedures to remove excess hair.

Aetiology

PCOS can be described as an oligogenic disorder in which the interaction of a number of genetic and environmental factors determine the heterogeneous, clinical, and biochemical phenotype. Although the genetic etiology of PCOS remains unknown, a family history of PCOS is relatively common; however, familial links to PCOS are unclear. A lack of phenotypic information prevents a formal segregation analysis. Nonetheless, the current literature suggests that the clustering of PCOS in families resembles an autosomal dominant pattern.

Environmental factors implicated in PCOS (e.g., obesity) can be exacerbated by poor dietary choices and physical inactivity; infectious agents and toxins may also play a role. The reproductive and metabolic features of PCOS are sometimes reversible with lifestyle modifications such as weight loss and exercise [9].

Pathophysiology

The pathophysiology of PCOS involves primary defects in the hypothalamic-pituitary axis, insulin secretion and action, and ovarian function. Although the cause of PCOS is unknown, PCOS has been linked to insulin resistance and obesity. The association with insulin function is expected; insulin helps to regulate ovarian function, and the ovaries respond to excess insulin by producing androgens, which can lead to anovulation. Follicular maturation arrest is a hallmark sign that an ovarian abnormality exists.

Clinical signs of PCOS include elevated luteinizing hormone (LH) and gonadotropin-releasing hormone (GnRH) levels, whereas follicular-stimulating hormone (FSH) levels are muted or unchanged. As a result of the increase in GnRH, stimulation of the ovarian thecal cells, in turn, produces more androgens. Follicular arrest can be corrected by elevating endogenous FSH levels or by providing exogenous FSH. Some studies suggest that PCOS is a primary defect in young girls who are entering puberty and who have a family history of the disorder. Approximately 25% of patients with PCOS have elevated prolactin levels. Therapeutic interventions are designed to reduce insulin levels and ovarian androgen production, ultimately correcting sex hormone-binding globulin (SHBG) levels. This increase in SHBG levels can be used to effectively manage the symptoms of PCOS. Studies have reported that thecal cells in patients with PCOS produce higher amounts of testosterone, progesterone, and 17-hydroprogesterone than in normal patients. These cells have been altered in PCOS patients whose cytochrome P450 (CYP) *11A*, *3-HSD2*, and *CYP17* genes exhibit elevated levels. Obesity is a common comorbidity of PCOS but is not required for diagnosis.

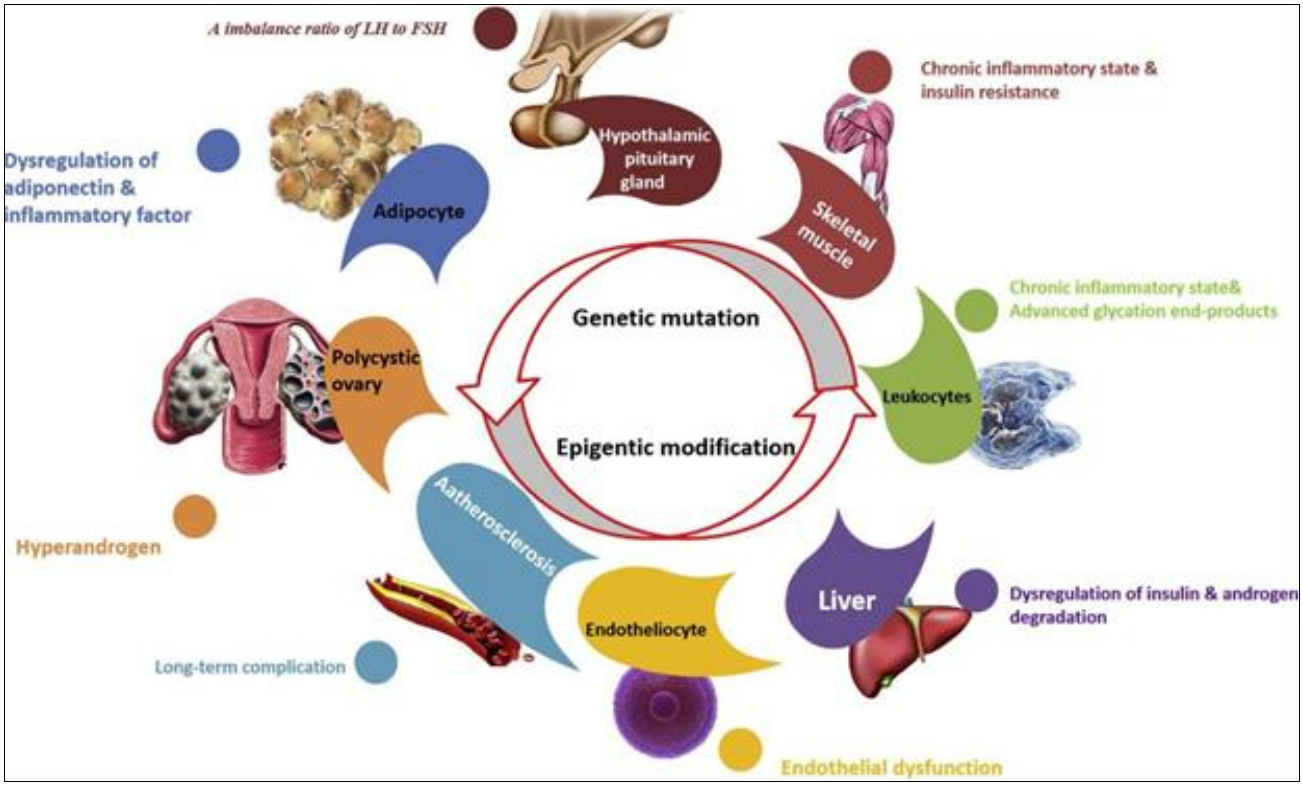

Fig 1: Show Genetic mutation and Epigentic modification

Clinical Features

1. **Menstrual Irregularities:** There may be amenorrhea of irregular menstrual cycle. Menses come late always.
2. **Infertility:** Patient may suffer from infertility, if the ovarian cyst associated with anovulation.
3. **Pain:** The patient may have complained of dull lower an abdominal pain or sever pain.
4. **Haemorrhage:** Massive intra-peritoneal Haemorrhage may take place due to rupture of the cyst.
5. **Acne:** Inflammatory lesion on face, neck, chest, upper back is mark.
6. **Hirsutism:** Excessive body hair in upper lip, chest, body, lower abdomen, and areola are common site. Male pattern hair style is mark.
7. **Obesity:** In some cases, there is marked increased weight.
8. **Acanthosis Nigricans:** Neck back area is darker than other part of body.

9. Other symptoms are:

a. As the tumour is increases in size distinct pressure symptom appear, due to pressure on near organs.
b. There is enlargement of abdomen, swelling of feet from pressure on vein, pain from pressure on nerves and dyspnea from pressure on the diaphragm.
c. Ovarian cyst grows slowly, usually, taking several years to reach a large size.
d. Pattern Alopecia

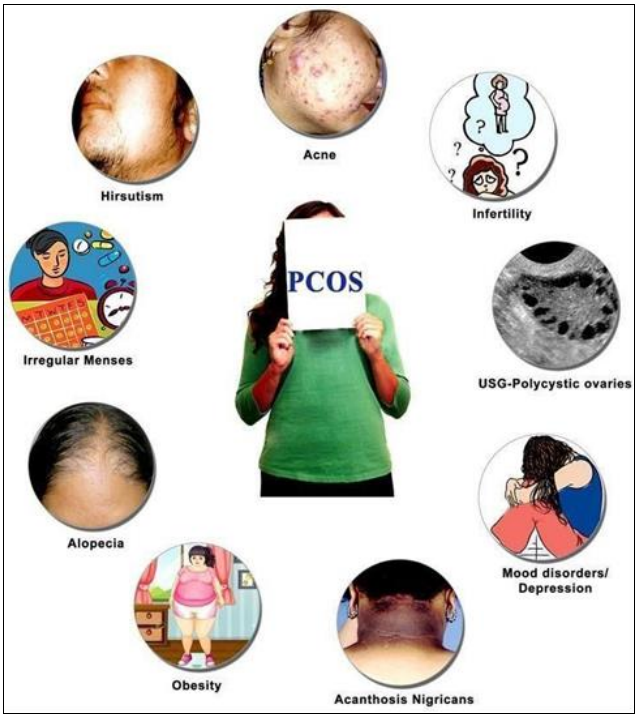

Fig 2: Show Polycystic Ovarian Syndrome (PCOS)

Fig 3: Show Acne presentation

Material and Methodology

A. Source of collection of data

The patients for the study were selected from the below mentioned center of Rajkot Homoeopathic Medical College (affiliated to Parul University), Rajkot, Gujarat.

- Sainath Homoeopathic hospital, OPD, Rajkot.
- Peripheral Regular Camps carried out by Sainath Homoeopathic Hospital, Rajkot.

B. Duration of Study: 6 Months Enrolment

- Time: 3 months
- Minimum Visits: 6 (or for period of 3 months)
- Follow Ups: every 15 days

C. Selection of Sample

- Sample Size: 30 cases
- Selection of Cases: The cases were selected randomly

a) Inclusion Criteria

- Only females are included
- Female from 20-35 years of age.
- Female having menstrual irregularities (Oligo menorrhea).
- Had clinical and laboratory evidence of hormone imbalance and PCOS diagnosed by ultrasound.
- Patients of all the socio-economic status, irrespective of caste and religion.
- Already taken other treatment but not cured or having relapses again.
- Patients who will give consent to participate in research.
- New cases both which are pre diagnosed and which had to be diagnosed for PCOS were included.

b) Exclusion Criteria

- Females of age >35yrs and <12yrs.
- Patients who are diagnosed with systemic disease or end stage disease, like Immune compromised
- patients, HIV, and chronic malignant disorders like conformed cases of cancer.
- In cases of lactating and pregnant women.
- Patients with other kind of cysts, like chocolate cyst, corpus luteum cyst, Fibroids, etc.
- Patients who had denied to give consent to participate in research.

D. Diagnostic Criteria: Diagnosis was done on the basis of specific diagnostic test and from the clinical symptoms of PCOS presented by the patient.

E. Informed Consent

a. All the patients were informed about study.
b. All the enrolled patients gave voluntary consent to participate in the study.
c. All the participants were informed about their role in study.
d. They were informed that this study would cause any harm or side effects to them and all their details would keep confidential.

F. Withdrawal Criteria:

- Patients who are uncooperative were withdraw from the study.
- If the patient withdraws their name from research by their own.
- If the disease is becoming worse and it's not in physician's control.

G. Study Design: A Prospective Experimental study.

H. Intervention

a. **Dispensing Unit:** Sainath Homoeopathic Hospital, associated with Rajkot Homoeopathic Medical College, (affiliated with Parul University).
b. Packaging, labelling, and resupplies of medicine were done by dispensing unit of Sainath Homoeopathic Hospital.
c. **Medicine:** *Pulsatilla Nigricans*
d. **Doses:** Single dose of *Pulsatilla Nigricans* a week, and Sac Lac three times a day (TDS).
e. **Size of Doses:** In the form of globules 4-5 globules of size 40 was given.
f. **Potency:** 200 °C

I. Co-Intervention

Included Co-Intervention

- Rescue Medicines.
- In any acute disease the Homoeopathic medicines were given to patient.
- Medicines for patient having Blood Pressure, Diabetes mellitus, Thyroid were continued.
- Confounding factors like, exercise, dietary criteria, lifestyle changes, psychological counselling.

Excluded Co-Intervention

Stoppage of mainstream intervention especially standard treatments and conventional like Allopathy, Ayurvedic, other homoeopathic Medicines.

J. Selection of Tools

a. Case Taking Proforma.
b. Polycystic Ovarian Syndrome Questionnaire.

K. Data Collection

a. All the data was kept in hardcopy and softcopy.
b. Pre score and post score data was maintained.
c. **Drop-out**

- Who don't complete minimum 6 follow ups.
- In case of any emergency like accident etc. in which patient fails to come for follow-up for long time.

L. Improvement Status:

- Cured.
- Marked Improvement.
- Moderate Improvement.
- Mild Improvement.
- No Improvement.

Observations

Table 1: Age wise distribution of polycystic ovarian cases

Sr. No.	Age group	Number of patients	Percentage
1.	20-25	10	33.33
2.	25-30	13	43.33
3.	30-35	7	23.33

Table shows, Majority of the PCOS patient were from age 25-30 yrs. (13), followed by 20-25 yrs. (10), and minor were from age 30-35yrs (7)

Table 2: Distribution of PCOS cases based on occupation

Sr. No.	Occupation	Number of patients	Percentage
1.	Student	12	40
2.	Home Maker	10	33.33
3.	Health Worker	1	3.33
4.	I T Professional	3	10
5.	Textile Worker	1	3.33
6.	Lecturer	1	3.33
7.	Banking Professional	2	6.66

Table shows, distribution of patient according to their occupation in which majority is students (12), followed by home maker (10), IT Professional (3), banking professional (2), and minority being health worker, textile worker, lecturer (1 each).

Table 3: Distribution of PCOS patients based on marital status

Sr. No.	Marital status	Number of patients	Percentage
1.	Unmarried	8	26.66
2.	Married	22	73.33

Table shows, Distribution of patients according to their marital status in which majority patientsare married (22), and rest unmarried (8).

Table 4: Distribution based on side affected

Sr. No.	Side	Number of patients	Percentage
1.	Bilateral	21	70
2.	Unilateral	9	30

Table shows, Majority of the PCOS patients were bilaterally affected (21), rest being unilaterally affected (9).

Table 5: Distribution of PCOS cases based on Improvement Status

Sr. No.	Result	Number of patients	Percentage
1.	Cured	11	36.66
2.	Marked improvement	12	40
3.	Moderate improvement	4	13.33
4.	Mild improvement	1	3.33
5.	No improvement	2	6.66

Table shows, Distribution of cases based on Improvement Status from which majority of patients had marked improvement (12), followed by cured patients (11), moderate improvement (4), no improvement (2), mild improvement (1).

Table 6: Distribution of cases bases questionnaire scoring

Sr. No.	Score range	Pre score	Post score
1.	26-50	3	3
2.	50-100	19	5
3.	100-150	7	17
4.	150-182	1	5

Table shows, Distribution of cases bases questionnaire scoring minimum score is 26, maximum score is 182; in which 1 is the poorest function an 7 being optimal function; so out of 30 cases maximum being 19 cases ranging from score 50-100 (63.33), followed by 7 cases with 100-150), and 3 cases with 26-50 score (10), minimum being 1 cases which had 150-182 score (3.33)

Results

There were 30 cases of PCOS ultrasonographical diagnosed, 12 cases showed marked improvement, 11 were cured, there was moderate improvement seen in 4 cases, mils improvement was seen in 1 case and there was no improvement seen in 2 cases. The patients were given *Pulsatilla Nigricans* in 200 C potency. The symptoms of Oligo menorrhea was reduced and showed marked improvement in 20 cases, Dysmenorrhea was highly improved in 26 cases, acne was reduced in 22 cases, and Hirsutism was markedly improved in 19 cases, and in there was improvement seen in 18 cases for Acanthosis Nigricans. There was marked improvement seen over all in 23 cases in USG and improvement in PCOSQ. There was improvement in pre score and post score of the PCOSQ; 3 cases remained between 26-50 score, between 50-100 post score is 5 cases, from 100-150 post score is 17 cases, and from 150-182 post score case was in 5 cases.

Discussion

This prospective experimental study done at Sainath Homoeopathic Hospital, by Hetvi Gunchala, guided by Dr. Kanan Bhatt Ma'am; because of large number of cases reported of PCOS and seeing the effectiveness of Homoeopathic Medicines on PCOS cases we tried to find out the effectiveness of *Pulsatilla Nigricans* for the same.

The medicine showed very effective in cases of PCOS out of 30 cases there were very good improvements in 23 cases other being mild, moderate, and no improvement cases. The symptoms of Oligo menorrhea were reduced and showed marked improvement in 20 cases, Dysmenorrhea was highly improved in 26 cases, acne was reduced in 22 cases, and Hirsutism was markedly improved in 19 cases, and in there was improvement seen in 18 cases for Acanthosis Nigricans. There was marked improvement seen in 23 cases in USG and improvement in PCOSQ, there was improvement in pre score and *post* score of the PCOSQ; 3 cases remained between 26-50 score, between 50-100 post score is 5 cases, from 100-150 post score is 17 cases, and from 150-182 post score case was in 5 cases. This shows effectiveness of *Pulsatilla Nigricans* on PCOS cases (76.66%), which also proves homoeopathy is best effective in PCOS cases. Hence this research proved the Alternative Hypothesis being there will be improvement in the cases of PCOS after prescribing *Pulsatilla Nigricans*. This medicine is a great female remedy and now as researched for cases of PCOS it proves that *Pulsatilla Nigricans* is one of the best suited for this disease provided patients tohave improvement in their lifestyle and have marked improved results in PCOS.

Conclusion

The study indicates the possible effectiveness homoeopathic medicine *Pulsatilla Nigricans* in the treatment of PCOS. The research has helped to reduce sufferings of the PCOS patients in the society with the Homoeopathic mode of treatment. This research has added information regarding the medicine *Pulsatilla Nigricans* in our Materia Medica and as according to the result which shows great effectiveness of it in PCOS cases it will be one of the best indicated homoeopathic remedy for curing the cases of PCOS. This research also shows that homoeopathic medicines are effective for PCOS cases, as it doesn't have any side effects and easy administration with holistic approach. Also duration of the research being short enough to get better results further more research should be done to get better results and to take step forward for better future.

Summary

The aim of the research was to ascertain the effectiveness of *Pulsatilla Nigricans* in cases of Polycystic Ovarian Syndrome (PCOS) by doing prospective experimental study, with an objective to improve the life quality of PCOS patients, which was assisted by PCOS Questionnaire. It was done on sample size of 30 cases which were diagnosed with Ultrasonography or pre diagnosed cases, there complete history was taken and was administered with *Pulsatilla Nigricans* with 200C potency every 15 days. Their quality of life was assisted with the help of PCOSQ. Result showed 76.66% improvement in overall result and further it helped to improve the quality of life of PCOS patients. There were 11 cured cases, 12 cases had shown marked improvement, moderate improvement in 4 cases, there was also no improvement in 2 cases and 1 case had mild improvement out of 30 cases. Hence this research also proved Homoeopathic system one of the best suited for treating PCOS cases as it being holistic, based on nature's law of cure, and easy administration. There were limitations of this study, as its too short duration so it became difficult to get the whole proper result. Also, there were many cases needed more duration if continued they could have shown better results.

Abbreviations: Polycystic Ovary Syndrome (PCOS), Polycystic Ovary Syndrome Questionnaire (PCOSQ), Ultrasonography (USG), Out Patient Department (OPD).

Conflict of Interest: Not available

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