Homoeopathy a System of Holistic Healing as an Alternative Treatment for PCOS – a Review

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Abstract

Background: Polycystic ovarian syndrome (PCOS) is a complex hormonal and metabolic disorder characterized by oligomenorrhea or amenorrhea, hyperandrogenism and infertility. Global prevalence of PCOS is estimated to be between 06% and 26%. Homoeopathy, being a system of holistic healing can be accepted as one of the alternative treatments for PCOS. Aim & Objective: The aim of the study is to review clinical data, where the intervention was aimed to treat PCOS through Homoeopathy. The objective of the study is to identify the therapeutic approach, assessment criteria, treatment outcomes through an alternative therapy i.e., Homoeopathy in cases of PCOS. Methods: A systematic literature search was conducted in the month of June 2021 following International/National search databases for all clinical studies published in the period from 2000 to 2021. This search was aimed to target the entire literature of randomized trials or controlled trials, observational studies case studies/reports on PCOS in homoeopathy. Result: 28 articles related to Homoeopathy on PCOS were identified. Out of these 28 studies, 22 studies (01 RCT, 02 NRCT, 06 observational studies, 04 case series and 09 case reports) were included in this review. All studies were published in peer reviewed journals. Conclusions: To establish the evidence-based efficacy of the homoeopathic treatment in cases of RCT more pragmatic studies need to be planned in the future based on proper diagnostic criteria.

Keywords: PCOS, Review, Homoeopathy, Holistic healing, Rotterdam Criteria, Individualization

Introduction

Polycystic ovary syndrome (PCOS) is a common endocrinopathy in the reproductive age group of females [1]. PCOS is a complex hormonal and metabolic disorder characterized by oligomenorrhea or amenorrhea, hyperandrogenism, and infertility. Hormonal imbalance relates to emotional disturbances; also, infertility is a common disorder that deeply affects the personal and social health and quality of life of individuals [2]. It has been shown that excess body weight and obesity are increasingly associated with PCOS and which may, in turn, worsen the hormonal and metabolic features of PCOS and may, possibly, reduce the responsiveness to the most common therapeutic strategies extensively used worldwide [3]. Three groups have offered the diagnostic criteria for PCOS: the National Institutes of Health/ National Institute of Child Health and Human Disease (NIH/NICHD), the European Society for Human
Reproduction and Embryology/American Society for Reproductive Medicine (ESHRE/ASRM), or the 'Rotterdam Criteria'; and the Androgen Excess and PCOS Society [4,5]. The current consensus is that the use of the Rotterdam criteria is appropriate for adult women. According to the Rotterdam criteria, a clinical diagnosis of PCOS requires that a patient present with two of the following symptoms [5]:

- Oligo-ovulation or anovulation;
- Hyperandrogenism, clinical (including signs such as hirsutism) or biological (including a raised free androgen index or free testosterone);
- Polycystic ovaries are visible on ultrasound.

The global prevalence of PCOS is estimated to be between 6% and 26% [6]. In India prevalence of PCOS ranges from 3.7 to 22.5 percent depending on the population studied and the criteria used for diagnosis [7]. Community-based studies using Rotterdam criteria among reproductive age group women have demonstrated varied prevalence figures in a few Asian countries ranging from 2% to 7.5% in China to 6.3% in Sri Lanka and India prevalence of PCOS as 9.13% to 36% [8]. A high percentage of individuals estimated to be as high as 75% remain undiagnosed even after visiting multiple health care providers [9].

The timely diagnosis of PCOS makes the patient aware of possible fertility concerns, dysfunctional bleeding, endometrial cancer, obesity, diabetes, dyslipidemia, hypertension, and theoretical increased risk of cardiovascular disease. Therefore, the need of the hour is to understand the factors responsible for PCOS and explore the available treatment through a holistic approach. Conventional Interventions include metformin, combined oral contraceptive pills (COCPs), spironolactone, clomiphene, citrate, antiandrogens, tamoxifen, aromatase inhibitors, glucocorticoids, gonadotropins, and local treatments for hirsutism and acne [10]. Surgical intervention is required in cases of failure of conventional medical treatment and for infertility related to PCOS [11].

In the present scenario, the holistic approach for healing is the need for time. The holistic health model concerns the harmony among mental, physical, social, spiritual, emotional domains [12]. Homoeopathy, being a holistic healing system, can be chosen as one of the alternative treatments for PCOS. According to the recent WHO report, around 100 countries acknowledge Homoeopathic therapy [13].

Around 100 million people depend solely on homeopathy for their medical care in India [14]. Despite gaining worldwide popularity, there is a lack of data on evidence-based research for many disorders. This lack of data makes it challenging to reflect the effectiveness and efficacy of homoeopathy in specific disease conditions using an accurate study design. In the present paper, authors have reviewed studies where the intervention was aimed to treat PCOS through Homoeopathy.

Materials and methods

The following criteria were adopted for undertaking this review:

Eligibility criteria

This review included studies where the intervention was aimed to treat PCOS through Homoeopathy. All types of Randomized Controlled Trials (RCTs) and observational studies undertaken in any settings using homeopathic medicines in any form – individualized, clinical, complex, were included in the review. Evidence-based, well-documented, and peer-reviewed case reports were also included. Studies related to exclusively allopathic and complementary modes of therapeutics (Ayurveda, Unani, Siddha, Yoga, and Naturopathy), expert/opinion articles along with Postgraduate and Ph.D. dissertations on PCOS and review articles were excluded from this review.
Search methods for identification of studies

A systematic literature search was conducted in June 2021 following International/National search databases (PubMed, Medscape, Science Direct, CORE-Hom, Chiro ACCESS, LILACS, AYUSH portal, DOAJ) for all clinical studies published in the period from 2000 to 2021. This search aimed to target the entire literature of randomized or controlled trials, observational studies case studies/reports on PCOS in homoeopathy. It was limited to only the English language of publication. The keywords used to search articles for this review are PCOS, PCOD, homoeopathy, homeopathy, ovarian disease, infertility.

All references were screened for eligibility based on their abstract or full text and extracted data. After data extraction, a total of twenty-two (n = 22) studies were found to be eligible as per the criteria for study eligibility.

Data analysis

The data were assessed by two authors (DD, PN), and details of the study of the identified fields were added manually. The details of included studies were re-examined and re-assessed by the other two authors (RS, SS). The details of included studies as tabulated are given in Table-1. The therapeutic approach was classified according to the levels of evidence grade. Data extracted is represented in the tabular form regarding study design, a sample size of the study, intervention used, type of study, treatment approach, assessment/outcome parameters, a summary of results, levels of evidence, and type of publication.

Results

Number of articles

In this literary review, 29 articles related to Homoeopathy on PCOS were identified in which one (01) randomized controlled trial [15], two (02) non-randomized controlled trial [16,17], eight (08) observational studies [18-25], four (04) case series [26-29], nine (09) case reports [30-38], and five (05) reviews [39-43]. 28 full papers and 01 abstract were found in the search database.

Out of these 29 studies, 22 studies (01 RCT, 02 NRCT, 06 observational studies [18-23], 04 case series, and 09 case reports) were included in this review. Academic review articles and two observational studies [24,25] were excluded.

Number of Participants

In a randomized placebo-controlled trial [15], the sample size was sixty; in two NRCT [16,17] and four observational studies [19, 21,22,23], the number of participants was less than 50. In contrast, one study had more than 50 [20], and one had 50 participants [18]. Nine case reports only contained single patient data [30-38]. In addition, 07 cases were studied in one case series [28], and 03 case series included 02 cases each [26,27,29]. The range of age groups included in all studies is 12-45 years.

Diagnostic Criteria

In these reviewed studies, diagnostic criteria are based upon USG findings, hormonal assay, and symptomatic presentation of PCOS like irregular menses, acne, hirsutism, weight gain, dysmenorrhoea, acanthosis nigricans, and increased BMI.
Figure: 1 Flow Diagram
**Homoeopathic Treatment Approach**

An individualized treatment approach has been followed in RCT [15]. In two NRCT, *Calcarea carbonica* and *Lycopodium clavatus* were the experimental drugs [16,17]. In all observational studies, case reports and case series individualized prescription approaches have been followed [18-23, 26 - 38]. All these data have been tabulated in table 1.

**Table 1: Studies included in the review**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Author's Name</th>
<th>Study Design</th>
<th>No. of Participants</th>
<th>Intervention Type of homoeopathy</th>
<th>Assessment/outcome parameters</th>
<th>Summary of results</th>
<th>Medicine used and potency</th>
<th>Grade Evidence</th>
</tr>
</thead>
</table>
| 1.    | Lamba et al   | Single-blind, randomised, placebo-controlled pilot study in 02 centres | 60 | Homoeopathic medicines Constitutional prescription | **Primary outcome:** menstrual regularity as at least 5 menstrual cycles within 6 months along with either ultrasonomological improvement of PCO (normal scan or reduction in ovarian follicles/volume at 6 months) or improvement in hirsutism/acne(reduction of Ferriman acne score at 6 months).  
**Secondary outcome:** changes in domains of PCOSQ. | Menstrual regularity with improvement in other signs/symptoms observed in 60% of the cases (n = 18) in HI + LSM group and none (n = 0) in control group (P = 0.001).  
Statistically significant difference (P = 0.016) was observed in reduction of intermenstrual duration (from 76.1 ± 37.7 to 46.6 ± 38.7 days) in HI + LSM in comparison to placebo + LSM group (from 93.0 ± 65.2 to 93.9 ± 96.2 days).  
PCOSQ significant improvement was observed in HI group in domains of weight, fertility, emotions and menstrual problems (P < 0.05) with no difference in body hair (P = 0.708).  
No change was observed in respect of improvement in the ultrasound findings | *Pulsatilla pratensis,* *Natrum muriaticum,* *Calcarea carbonica,* *Belladonna,* *Sepia officinalis,* *Lycopodium clavatum,* *Phosphorous,* *China,* *Nux vomica,* *Hamamelis virginica,* *Millefolium,* *Sulphur* Q, 6c, 30c, 200c or 1M potency | B |
| 2.    | Das et.al., Non-Randomized Placebo controlled trial | 40 out of this 05 are in controlled group | 40 | Homoeopathic medicine Experimental drug: *Calcarea carbonicum& Lycopodium* | Regularity/irregularity of menstrual cycle, presence/absence of acne, hirsutism, male type alopecia, acanthosis nigricans, body/mass index (BMI)and waist hip ratio. | 40 patients showed significant modulations in traits for both the drug treatment, most of them showing the difference as statistically significant.  
Lycopodium showed better efficacy in regard to amelioration of menstrual Irregularity, hirsutism .Calc showed better action in removing acne, both had considerable effects against hairfall. In acanthosis nigricans Calc showed significant amelioration (3 out of 3) while lyco showed its efficacy in 1out of 2 patients. | *Calcarea carbonicum*  
*Lycopodium clavatum* 30, 200 | B |
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<tr>
<th>S.No.</th>
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<th>Medicine used and potency</th>
<th>Evidence Grade</th>
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<tr>
<td>3.</td>
<td>Das et al.</td>
<td>Non-Randomized Placebo controlled trial</td>
<td>40 out of this 05 are in control led group</td>
<td>Homoeopathic medicine</td>
<td>Experimental drugs: Calcarea carbonicum &amp; Lycopodium clavatus</td>
<td>Removal of cysts, along with amelioration of certain other hormones and hormone-related parameters of PCOS, such as follicle stimulating hormone, luteinizing hormone, Testosterone (Free/Total), Dehydroyepiandosterone, Progesterone, Hydroxyprogesterone, TSH including T3, T4, and Insulin</td>
<td>Both showed apparently little influence in modulating waist: hip ratio, or body: mass index (BMI). Out of 20 patients of Lyco 10 and 11 out of 20 Calc administered patients showed complete disappearance of the cysts in single or both ovaries. The differences in results between pre and post treatments in respect of menstrual history, hirsutism and poly cysts in one ovary/bboth ovaries were found to be statistically significant at p0.05 level.</td>
<td>Calcarea carbonicum 30, 200</td>
<td>B</td>
</tr>
<tr>
<td>4.</td>
<td>Gupta</td>
<td>Observational study including one case report</td>
<td>50</td>
<td>Homoeopathic medicines</td>
<td>Constitutional</td>
<td>USG</td>
<td>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.</td>
<td>Lycopodium clavatum 71.43% followed by Pulsatilla pratensis (60.00%), Natrum muriaticum (50.00%) and Calcarea carbonicum(37.50%)</td>
<td>B</td>
</tr>
<tr>
<td>5.</td>
<td>Ashok et al. 2020</td>
<td>Observational study Single arm clinical Study</td>
<td>30</td>
<td>Homoeopathic medicines</td>
<td>Constitutional</td>
<td>Irregularity of menses, weight gain hirsutism acne scanty menstrual flow, profuse flow of menses</td>
<td>Out of 30 cases, 14 cases (46.66%) showed good improvement in cases of irregular menses, 21 cases (63.3 3%) showed good improvement in acne and 25 cases (83.33%) showed good improvement in cases of health related quality of life related to PCOS.</td>
<td>Natrum muriaticum 05 (16.66%), Pulsatilla pratensis 06 (20%), Lycopodium clavatum and calcarea carbonicum was prescribed 04 each (13.33%), Phosphorus and</td>
<td>B</td>
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Homoeopathic constitutional medicine approach showed the improvement in the symptoms related to PCOS.

7. Singh Observational Study 30 Homoeopathic medicines Constitutional Recovered: feeling of mental and physical well-being and no other similar complaints observed for a period of 6 months.
Improved: Feeling of mental and physical well-being along with reduction in frequency of complaints.
Not improved: No response. No reduction of complaints even after defined period of treatment.

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<th>Summary of results</th>
<th>Medicine used and potency</th>
<th>Evidence Grade</th>
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</thead>
</table>
| 8.    | Gupta et al   | prospective, observational study | 34 Homoeopathic medicines | Constitutional | **Primary outcome:** to determine the overall quality of life (QOL) using PCOS Questionnaire.  
**Secondary outcome:** to assess the changes in hormonal profiles and USG findings  
PCOSQ of the patients (mean increase ± standard error: 2.3 ± 0.5; 95% confidence interval CI:-3.2 to -1.3; P = 0.001).  
Mean reduction of cysts in the right ovary was 1.8 ± 0.5; 95%CI: 0.8 to 2.8; P = 0.001, and in the left ovary was 1.9 ± 0.5; 95%CI: 0.9 to 2.8; P = 0.001.  
Improvement in USG findings was observed in 16 patients, no improvement in 18 patients, repeat testosterone values at 01 month showed normal (n = 8), decreased (n = 4), status quo (n = 1) and worsened (n = 5). | | Calcarea carbonicum (n = 13), Lycopodium clavatum (n = 9), Natrum muriaticum (n = 5), Pulsatilla pratensis (n = 4), Nux vomica (n = 1), Sepia (n = 1), Staphysagria (n = 1) 30CH, 200CH, 1M,10M | B |
25 cases have shown favourable result, 03 were partially and 02 patients no improved after the treatment. Hence the success rate was 85%*  
<p>| | | | | | | Lycopodium clavatum, Natrum muriaticum, Sepia officinalis, Calcarea carbonica, Lachesis mutus, Arsenicum album, Staphysagria | B |</p>
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<th>Medicine used and potency</th>
<th>Summary of results</th>
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<tbody>
<tr>
<td>10</td>
<td>Thomas</td>
<td>Cases series</td>
<td>02</td>
<td>Homoeopathic medicines</td>
<td>Apismellifica 30, Nitricum acidum, Phosphorus, Platinum metallicum, Belladonna, Belladonna/Calcarea carbonicum, Carcinoce, Graphites, Kalium bromatum, Ignatia amara &amp; Naja tripudians</td>
<td>Both cases have shown improvement symptomatically as well as shown disappearance of the ovarian pathology in cases of PCOS after homeopathic treatment.</td>
</tr>
<tr>
<td>11</td>
<td>Dabhi et.al</td>
<td>Case series</td>
<td>02</td>
<td>Homoeopathic</td>
<td>Apismellifica 200, 1M and Natrum muriaticum-1M</td>
<td>Normal USG findings regular menses and symptomatic improvement.</td>
</tr>
<tr>
<td>12</td>
<td>Parveen</td>
<td>Case series</td>
<td>07</td>
<td>Homoeopathic Medicines</td>
<td>Silicea terra (200Ch, 1 and 10M), Pulsatilla nigricans(200Ch, 1M and 10M), Tuberculinum avis (200Ch, 1M and 10M), Carbunculus (200Ch, 1M and 10M), Lycodidum clavatum (200Ch and 1M), Thuja occidentalis (200Ch, 1M and 10M), Natrum muriaticum (200Ch, 1M, 10M and 50M)</td>
<td>Marked improvement in all 7 cases of PCOS. Irregular menstrual cycles and other associated symptoms became normal, along with resolution of cysts in ovaries as evidenced by USG.</td>
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<tr>
<td>S.no.</td>
<td>Author’s Name</td>
<td>Study Design</td>
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<td>Intervention Type of homoeopathy</td>
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<tr>
<td>13</td>
<td>Cardigno</td>
<td>Case series</td>
<td>06</td>
<td>Homoeopathic Medicines</td>
<td>Constitutional Clinical symptoms</td>
<td>All cases showed improvement clinically.</td>
</tr>
<tr>
<td>14</td>
<td>Rath</td>
<td>Case report</td>
<td>01</td>
<td>Homoeopathic medicine</td>
<td>Constitutional USG changes, regularity of menstrual cycle and also normal ultrasonography (USG) reports</td>
<td>Improvement in regularity of menstrual cycle and also normal ultrasonography (USG) reports</td>
</tr>
<tr>
<td>15</td>
<td>Sharma</td>
<td>Case report</td>
<td>01</td>
<td>Homoeopathic medicine</td>
<td>Constitutional Regularity of menstrual cycle, from USG reports and with increased score of PCOS questionnaire</td>
<td>Improvement is evident from regularity of menstrual cycle, from USG reports and with increased score of PCOS questionnaire.</td>
</tr>
<tr>
<td>16</td>
<td>Gupta Y</td>
<td>Case report</td>
<td>01</td>
<td>Homoeopathic medicine</td>
<td>Constitutional Irregular menses USG changes</td>
<td>Regularization of menses, normal USG findings</td>
</tr>
<tr>
<td>17</td>
<td>Pal et.al</td>
<td>Case report</td>
<td>01</td>
<td>Homoeopathic medicine</td>
<td>Constitutional USG report &amp; Infertility</td>
<td>After 11 months patient conceived and final ultrasonography also emphasized on the ovaries which were devoid of any abnormality.</td>
</tr>
<tr>
<td>18</td>
<td>Helmond</td>
<td>Case report</td>
<td>01</td>
<td>Homoeopathic medicine</td>
<td>Constitutional Regularity of menses and conception</td>
<td>Menses improved and pregnancy appeared</td>
</tr>
</tbody>
</table>

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<th>Evidence Grade</th>
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</thead>
<tbody>
<tr>
<td>19</td>
<td>Sabharwal</td>
<td>Case report</td>
<td>01</td>
<td>Homoeopathic medicine</td>
<td>Constitutional Regularity of menses, primary infertility</td>
<td>Natural menses appeared, 6 months of treatment and regular cycles, the follicular study was repeated which showed a dominant follicle of good growth. Unfortunately, patient was unable to complete the study to confirm ovulation but she conceived in the same cycle.</td>
<td>Carcinosin 1M three doses monthly (pre-menstrual) and Folliculinum 30 bd from day 4 for 15 days.</td>
<td>C</td>
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<tr>
<td>20</td>
<td>Rath</td>
<td>Case report</td>
<td>01</td>
<td>Homoeopathic medicine</td>
<td>Constitutional USG &amp;positive result for conception</td>
<td>Regularization of menstrual cycle, reduction in serum testosterone level, significant improvement in insulin sensitivity,</td>
<td>Sepia officinalis 30,200,1M, 10M</td>
<td>C</td>
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https://doi.org/10.51910/ijhdr.V2014.1126
normalization of ultrasound pattern of ovaries followed with conception and normal delivery with homoeopathic medicine were observed.

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<tbody>
<tr>
<td>21.</td>
<td>Chakravarty</td>
<td>Case report 01</td>
<td>Regularity of menses &amp; changes in USG</td>
<td>PCOS was disappeared and menses was regular and Gall bladder calculi size also reduced.</td>
</tr>
<tr>
<td></td>
<td>Homoeopathic</td>
<td>Constitutional</td>
<td>Chionanthus virginica 30, Lycopodium clavatum 200</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Homoeopathic</td>
<td>Constitutional</td>
<td>Pulsatilla nigricans 30, 200 Nux vomica 30</td>
<td></td>
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</table>

### Duration of Treatment

Duration of treatment ranged from 3 months to 3 years. In RCT duration of treatment is 06 months in both groups [15]. 18 months treatment duration with follow-up in both NRCT studies [16,17]. All 06 Observational studies treatment duration ranged from 06 months [19] to 02 years [18] including 01 year duration in 02 studies [20,22], in other 02 studies duration of treatment were not mentioned [21,23]. In a case report and a case series duration of treatment 01 month to almost 02 years, less than 24 months in 04 case series [26-29] and in 01 case reports it’s 30 days [32], 02 case reports less than 06 months [34,38]. In 02 case reports [35,37] duration of treatment is 06 months, further in 04 case reports its more than 06 months [30,31,33,36].

### Medicines used frequently

Medicines that are frequently prescribed in the cases of PCOS were identified in review as *Arsenicum album, Apis mellifica, Aurum muraticum natronatum, Belladonna, Borax veneta, Bryonia alba, Calcarca carbonica, Carcinosin, China, Chionanthus virginica, Folliculinum, Graphites, Ignatia amara, Kalium bromatum, Kalium phosphoricum, Lac caninum, Lachesis mutus, Lycopodium clavatum, Naja tripudians, Natrum muriaticum, Natrum phosphoricum, Nitric acid, Nux vomica, Oophorinum, Palladium metallicum, Phosphorus, Platinum metallicum, Pulsatilla pratensis, Sepia officinalis, Staphysagria, Sulphur, Sycamore seed, Thuja occidentalis*. Frequently used potencies are 30, 200,1M potencies. In a few cases, 12, 10M, 50C were prescribed. No information about the potency is provided in one case series.

### Assessment / Outcome Parameters

In a randomized controlled trial, the primary outcome was the establishment of menstrual regularity, which was defined as having at least 5 menstrual cycles within 6 months along with either ultrasound improvement of PCOS (normal scan or reduction in ovarian follicles/volume at 6 months) or improvement in hirsutism/acne (reduction of Ferriman acne score at 6 months). Secondary outcomes were to compare the changes in domains of PCOSQ.
In addition, five domains consisting of emotions, body hair, weight, infertility, and menstrual problems were quantified to compare the patient’s subjective feelings at the beginning and at the end of the study.

In both non-randomized controlled trials, two experimental drugs, *Calcarea carbonica*, and *Lycopodium clavatum* selected based on their traditional use for the removal of ovarian cysts. In one study, the assessment parameters were based on regularity/irregularity of menstrual cycle, presence/absence of acne, hirsutism, male-type alopecia, acanthosis nigricans, body/mass index (BMI), and waist-hip ratio. In another NRCT (07 days medicine then withdraw for 07 days again repeat until the desired amelioration was observed), conducted by the same investigators the assessment was done by removal of cysts, and hormone-related parameters of PCOS, such as follicle-stimulating hormone, luteinizing hormone, Estradiol, Testosterone (Free/Total), Dehydroepiandrosterone, Prolactin, Progesterone (17-Hydroxyprogesterone), TSH including T3, T4, and Insulin were studied.

In observational studies, the diagnosis and assessment were conducted based on per-abdominal or transvaginal ultrasonography [18] reduction in the interval of menses [19], clinical presentation (regularity of menses [23], general well-being, acne, secondary hirsutism, lethargy, reduction in obesity, infertility) [20], overall quality of life (QoL) using PCOS Questionnaire, changes in hormonal profiles (progesterone, estradiol, insulin, thyroid-stimulating hormone (TSH), testosterone, follicle-stimulating hormone (FSH), luteinising hormone (LH), LH/FSH and prolactin) [22]. In one study, no information has been provided regarding the assessment criteria [21].

In 09 case reports, the assessment was made based on ultrasonographic (USG) changes. Further, symptomatic assessment, hormonal review, follicular study, conception status was done to assess the efficacy of the homoeopathic intervention. In 04 case series, USG and hormonal assay were the parameters for assessment.

**Treatment outcomes**

All the studies reported positive outcomes in symptomatic improvement like irregular menses, hormonal assay, infertility, acne, and hirsutism, reflecting the effectiveness of homoeopathic intervention in treating PCOS.

01 RCT [15] showed the statistically significant difference (P = 0.016) in reduction of intermenstrual duration (from 76.1 ± 37.7 to 46.6 ± 38.7 days) in HI (Homoeopathic intervention) + LSM (Lifestyle modification) in comparison to placebo + LSM group (from 93.0 ± 65.2 to 93.9 ± 96.2 days). In PCOSQ, also, significant improvement was observed in the HI group in domains of weight, fertility, emotions, and menstrual problems (P < 0.05) with no difference in body hair (P = 0.708). No change was observed in respect of improvement in the ultrasound findings.

Further, out of 02 studies (NRCT), one showed one-way ANOVA differences in results between pre and post-treatments in respect of menstrual history, hirsutism, and polycystic in one ovary/both ovaries were found statistically significant at p - 0.05 level [16]. In another NRCT study[17], the results showed the statistically significant difference in LH levels, FSH levels, LH: FSH ratio (>2:1), DHEAS levels, Insulin fasting (>15), Insulin PP (>75), and glucose fasting (>110) in both experimental medicinal groups, i.e., *Calcarea carbonicum*, *Lycopodium*. No statistically significant difference has been seen in serum testosterone and prolactin levels.

In 06 observational studies, statistical analysis of the data showed a reduction in the size of the ovary, number and size of cysts [18], also statistically significant differences have been observed in PCOSQ, drop in the number of cysts in both ovaries, LH & Prolactin levels [22].
In other 04 observational studies, changes in the improvement of the PCOS symptoms/signs (acne, secondary hirsutism, obesity, general well-being, infertility)[20], a statistically significant reduction in the intermenstrual interval [19] were observed. No proper outcome of the results has been documented in 01 observational study [21]. In another observational study, only improvement status has been reflected in the result section; no details regarding the domain or symptoms in which these improvement indices have been measured [23]. 13 studies (09 case reports & 04 case series), including case reports and case series, identified the changes in USG findings, showed absence or reduction of the number of cysts in ovaries, and in 02 case reports, conception has occurred [36,38]. Ultrasound reports are attached in 05 case reports/series.

**Type of Publication:** All the RCT& NRCT included in the study were published in peer-reviewed journals. All observational studies six were published in a peer-reviewed journal. Thirteen (13) case reports/series were published in peer-reviewed journals.

**Level of evidence for clinical research**

The level of evidence for clinical research in the reviewed articles is ‘B’ for nine studies which include the randomized controlled trial, non-randomized controlled trial, and uncontrolled observational studies, whereas, for thirteen studies, the level of evidence is ‘C’ including the case reports and case series.

**Discussion**

This literature review is an attempt by the authors to review the existing treatment approach for PCOS through homeopathic intervention. Homoeopathy comes under the system of complementary & alternative medicines. The terms “complementary medicine” or “alternative medicine” refer to a broad set of health care practices that are not part of that country’s tradition or conventional medicine and are not fully integrated into the dominant healthcare system. They are used interchangeably with traditional medicine in some countries [44].

PCOS reflects itself as a complex of signs & symptoms such as irregular menses, acne, hirsutism, weight gain, infertility, etc. All these complex symptoms can exhibit disturbances at a different level in the patients like acne, hirsutism, and weight gain may be the prime concern for the adolescent’s age group as these can affect their physical appearance; further, infertility may cause stress due to social stigma mainly in Indian scenario, associated depression, stress causes disturbance in the mental health of the individuals. So, as this syndrome involves disorders at different levels, this treatment should be at multifactorial domains like the HOLISTIC HEALTH MODEL approach. The holistic health model concerns the harmony among mental, physical, social, spiritual, and emotional domains.

Homoeopathy system of medicine is based on the holistic approach of the treatment. According to the principle of homoeopathy, treatment should be found on the individualization to select the correct similimum for the patient. The concern of PCOS symptoms is different in various patients, so for an individualized approach, it is important to identify the main area of problem in the patient, like how she is taking her problems? What are her primary concerns related to PCOS? How is she reacting towards society? All these form the totality of symptoms which individualize that patient from the others. So, the medicine will be different for each patient according to their constitution (mental generals, temperaments, physical general, body appearance, etc.), unlike conventional therapy, where oral contraceptives pills are the prime instrument for regularizing the menstruation cycles, normalizing the hormonal levels also expensive treatments for infertility like IUI (intrauterine insemination), IVF (in-vitro fertilization). The review studies showed the effectiveness of homoeopathic intervention in infertility cases, where patients have conceived after the...
homoeopathic treatment [35,37]. Therefore, homoeopathy is also a cost-effective treatment option for developing countries.

Although homoeopathy is widely used to treat PCOS, there are very few controlled trials done investigating its efficacy. Using a comprehensive search strategy, authors isolated only one controlled trial with interpretable results investigating homoeopathic treatments for PCOS. Performing RCT of homoeopathic treatment is toilsome because a theory of individualization, wherein remedy is tailored for each individual. But at the same time, randomized control trial is the best way of testing the efficacy of the intervention by preventing the biased through the randomization process. Therefore, the review studies in this study are mostly observational and individual case reports.

In all of the studies included in this review, constitutional prescriptions based on individualization to develop the patient’s picture have been used except for two studies where Calcaria carbonium and Lycopodium clavatum were selected as an experimental drug based on their traditional use for the removal of ovarian cysts. Drugs such as Calcarea carbonicum, Lycopodium clavatum, Natrum-muriaticum, Apis mellifica, Lachesis mutus, Sepia officinalis, and Sulphur are used frequently.

Diagnosis can be established by careful history, physical examination, and basic laboratory testing, with ultrasonography or other imaging, depending upon the case presentation. Hyperandrogenism can be diagnosed clinically by the presence of excessive acne, androgenic alopecia, or hirsutism. The studies reported in this review included USG, hormonal assay for investigation, and symptomatic assessment like menstrual irregularities, acne, hirsutism, obesity, which were used for the evaluation and diagnosis. The changes in the domains of the PCOS questionnaire related to the quality of life have been reported in 02 review studies.

The family history of arthritis, asthma, cancer cervix/lungs, diabetes mellitus, hypertension, hypothyroidism, irregular menses, infertility, menorrhagia ovarian cyst, polycystic ovarian disease, renal calculi has been reported in the review studies. These disorders predominately belong to the sycotic miasm, as in PCOS there is an enlargement of ovaries with small cysts on outer edges, which is also a feature of sycotic miasm. Therefore, inheritance of sycosis miasm can be a fundamental cause of PCOS; thereby, anti-sycotic medicines could be included in the treatment protocol or administered as an intercurrent remedy.

In RCT (n=1)15, it is observed that improvement in menstrual regularity and other signs/symptoms in 60% of the cases (P = 0.001); however, no significant changes had been noticed in the USG after the homoeopathic intervention, so, more pragmatic studies need to be plan and conducted to study the changes in the report in respect to the size of ovaries, number of follicular cysts. While in 01 observational study, improvement in USG findings was observed in 47% (n=16) patients. USG findings are not mentioned in other observational studies (18, 19,20,21,23) reduction in the number of follicles in the USG has been reported in 03 case series (26, 27,28) and 06 case reports (30,31,32,33,36,38).

Also, it has been seen in the reviewed studies, mainly in case reports, that they were diagnosed only based on symptomatic representation or previously done USG reports. Furthermore, the reporting was not well structured. According to today’s scenario, homoeopathy needs more evidence-based research as there is a lack of well-structured, adequately planned research studies in this therapeutic system. Practitioners should also be encouraged to form diagnoses based on authentic diagnostic criteria to overcome these issues. For PCOS, USG findings and diagnosis should be made according to Rotterdam criteria. In this way, reporting the outcomes of homoeopathic interventions will also improve. Evidence-based reporting, which is more scientific, will add to the research data in the Homoeopathic world. Also, practitioners and researchers should be encouraged to publish their
study findings in peer-reviewed journals following the appropriate guidelines like CONSORT, HOME.CARE, etc.

One future goal also includes the screening of other comorbidities. These comorbidities may include impaired glucose tolerance and type 2 diabetes, decreased quality of life, depression, anxiety, eating disorders, and altered body image. Our therapeutic approach should also include these issues.

The major limitation of this review study is that it also involves case reports/series. These all are included as the available peer-reviewed published RCT; observational studies on PCOS treated through Homoeopathic interventions are significantly less in numbers. So, to overcome this lacuna, both case reports and case series have been included to highlight the efficacy of the homoeopathic therapeutic outcomes. Another drawback is meta-analysis was not done as only one RCT is included for review.

There was supporting clinical data. However, many cases reports/ studies were small single-arm, open-label studies. Evidence for the role of homoeopathy in these is preliminary and in an emergent phase. Furthermore, Homoeopathy may present a treatment option for women with PCOS as an adjunct or alternative treatment with a high degree of acceptability by women. Still, future studies should be planned so that results are reproducible and self-explanatory.

Conclusion

The homoeopathic intervention showed a significant role in PCOS treatment in terms of USG findings and symptomatic improvement by the constitutional prescription approach. However, very a much smaller number of RCT had been conducted. So, to establish the evidence-based efficacy of the homoeopathic treatment in cases of RCT, more pragmatic studies need to be planned in the future based on proper diagnostic criteria.

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References


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