Original Article

Evaluation of homoeopathic treatment in polycystic ovary syndrome: A single-blind, randomised, placebo-controlled pilot study

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Abstract

Background and Objectives: This study was conducted with the primary objective of evaluating efficacy of Homoeopathy in establishing the menstrual regularity with improvement in either ultrasonological findings or hirsutism/acne. The quality of life was also assessed using polycystic ovary syndrome questionnaire (PCOSQ). **Materials and Methods:** A single-blind, randomised, placebo-controlled pilot study was conducted from February 2014 to May 2015 at two research centres. The cases fulfilling the eligibility criteria were enrolled ($n = 60$) and randomised to either the homoeopathic intervention (HI) ($n = 30$) or identical placebo (P) ($n = 30$) with uniform lifestyle modification (LSM) for 6 months. **Results:** The menstrual regularity with improvement in other signs/symptoms was 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). In PCOSQ, also, 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* was the most frequently indicated medicine ($n = 12$, 40%). **Conclusion:** HI along with LSM has shown promising outcome; further comparative study with standard conventional treatment on adequate sample size is desirable.

Keywords: Homoeopathy, Hyperandrogenism, Lifestyle modification, Menstrual regularity, Polycystic ovary syndrome, Polycystic Ovary Syndrome Questionnaire

Introduction

Polycystic ovary syndrome (PCOS) is a complex metabolic, endocrine and reproductive disorder.[1] Overall, the disorder appears to be an ancient complex genetic trait, perhaps dating at least 50,000 years ago.[2] Various guidelines[3-6] have been issued regarding diagnosis of PCOS. While there are certain consistencies between the criteria offered by the different groups, important differences exist. Each issuing group considers PCOS a diagnosis of exclusion. Because 20%–30% of otherwise normal women have evidence of multiple cysts on their ovaries, the presence of polycystic ovaries (PCOs) alone was not considered sufficient by any group. The prevalence estimates also vary according to the criteria from 4%–8% as per the NIH/NICHD criteria to as high as 15%–20% when the ESHRE/ASRM criteria are used.[7] A cross-sectional study among adolescent and young girls in Mumbai, India, indicated the prevalence of 22.5% by Rotterdam and 10.7% by Androgen Excess Society criteria.[8] Its clinical characteristics include hyperandrogenism, chronic anovulation, insulin resistance and infertility. Whilst reproductive features are prominent, it has potential for major metabolic consequences including obesity, type 2 diabetes mellitus (DM2) and cardiovascular disease.[9] It remains a syndrome, and as such, no single diagnostic criterion (such as hyperandrogenism or PCO) is sufficient for diagnosis. Known disorders such as late-onset

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congenital adrenal hyperplasia that mimic the PCOS phenotype should be excluded.[10] A meta-analysis suggested that PCOS is significantly associated with increased coronary heart disease risk.[11] Endometrial cancer also seems to be more frequent in women with PCOS. Therefore, PCOS has numerous long-term health risks.[12]

In conventional medical system, metformin, oral contraceptives, antiandrogens, clomiphene citrate and thiazolidinediones are used for symptomatic management. Metformin is commonly used either alone or in combination with other medicines.[13] It reportedly reduced hyperinsulinaemia and hyperandrogenaemia, independently of changes in body weight. In a large number of cases, these changes were associated with striking, sustained improvements in menstrual abnormalities and resumption of ovulation,[14] but it causes gastrointestinal intolerance in 30% (nausea, abdominal pain and/or diarrhoea) of patients. It is contraindicated in liver disease and certain other clinical conditions. Other medicines recommended too have side effects for long use; hence, there is a need to explore the possibility of its management with Homoeopathy.[15] Sanchez-Resendiz and Guzman-Gomez[16] and Gupta[15] have evaluated homoeopathic intervention (HI) in PCOS and have shown positive outcomes, but were lacking in choosing appropriate diagnostic criteria. Therefore, this study was conducted with the primary objective to evaluate the efficacy of HI in establishing the menstrual regularity with either ultrasonological improvement or improvement in hirsutism/acne.

Lifestyle modification (LSM) is also essential, and it is reported that even 5%–10% weight loss has led to significant clinical benefits improving psychological outcomes, reproductive and metabolic features.[17]

Studies suggest that women suffering from PCOS are most exposed to several psychological problems. It exerts a negative impact on female identity and contributes to the deterioration of quality of life. The mental consequences can be depression and mood disorder.[18,19] The depression and anxiety are more common as compared with healthy women. Depression is often associated with obesity and metabolic abnormalities.[20,21] The depression and anxiety did not show a significant change after treatment with oral contraceptive pills (OCPs).[22] Biological, social and psychological consequences of PCOS among women of reproductive age are opening a new perspective on management of women's health in these patients. Therefore, as secondary objective, PCOS questionnaire (PCOSQ), which evaluates emotional aspects along with body hair, weight, infertility and menstrual problems, was used for the assessment of quality of life.[23]

Materials and Methods

Study design

A randomised, placebo-controlled study with 6-month intervention and follow-up was conducted at two centres.

Participants

The inclusion criteria were as follows: (1) females aged between 18 and 36 years; (2) participants with oligomenorrhoea (intermenstrual period of more than 35 days for 3 consecutive cycles)/amenorrhoea for more than 3 months (2 years after menarche); (3) participants with ultrasound findings of PCOs (the PCO had at least one of the following: either 12 or more follicles measuring 2 ± 9 mm in diameter or increased ovarian volume [>10 cm^3]. If there was evidence of a dominant follicle [>10 mm] or a corpus luteum, the scan was repeated during the next cycle. Only one ovary fitting this definition or a single occurrence of one of the above criteria is sufficient to define the PCO[24]); (4) participants with clinical evidence of hirsutism (Ferriman score 8 and above)[25] and/or acne (acne global severity scale score 1 and above);[26] (5) participants with body mass index (BMI) of 23 and above; (6) participants willing to adopt healthy diet and to regular exercise (at least 30 min of exercise at least 5 days a week) regimen and (7) participants willing to provide written informed consent.

The exclusion criteria were as follows: (1) cases with a history of DM, Cushing's disease and hyperprolactinaemia; (2) untreated hypo- or hyperthyroidism; (3) history of adrenal hyperplasia and adrenal tumour; (4) ovarian tumour; (5) hyperthecosis; (6) significant renal impairment; (7) history of intake of drugs aldactone/metformin or history of OCP use or intake of drugs known to interfere with carbohydrate metabolism prior 4 weeks before enrolment; (8) pregnancy and breast feeding and (9) any other systemic diseases.

The study was conducted at Dr. D. P. Rastogi Central Research Institute (H), Noida, and Extension Clinical Research Unit of Drug Standardization Unit at Princess Durru Shehvar Children's and General Hospital, Hyderabad. Two trained homoeopaths, 1 at each centre with experience of more than 5 years, were the investigators. They were given training before initiation of the study to minimise the bias. The patients were screened for eligibility and underwent pelvic ultrasound, complete blood count with erythrocyte sedimentation rate, fasting glucose, thyroid function test, serum prolactin, basal morning 17α-hydroxyprogesterone, complete urine examination and urine pregnancy test in case of married women with amenorrhoea before enrolment.

Patients fulfilling the eligibility criteria were enrolled and randomised as per computer-generated randomisation chart[27] to receive either the HI or the identical placebo (P) as illustrated in Figure 1. Medicines were given in Q, 6c, 30c, 200c or 1M potency as per the prescribing totality. Mother tinctures were only prescribed in persistent amenorrhoea. The medicines were repeated as per need in accordance with the principles of Homoeopathy.[28] All the study participants were asked to follow healthy diet and to take up regular exercise (at least 30 min of exercise at least 5 days a week).

Criteria for baseline assessment and follow-up

All the enrolled participants underwent complete case taking along with clinical examination, baseline

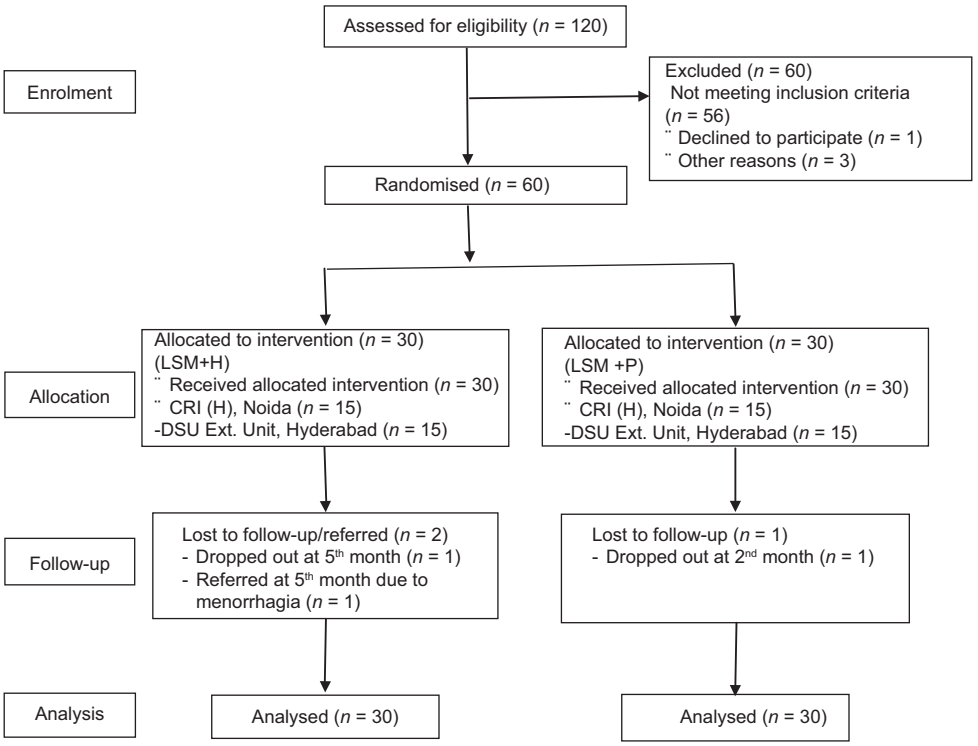

Figure 1: Study flowchart

investigations for sex hormone-binding globin, luteinising hormone/follicle-stimulating hormone (LH/FSH) ratio, total testosterone, dehydroepiandrosterone sulphate, fasting serum insulin, glucose insulin ratio, tryglycerides and high-density lipoprotein-cholesterol at baseline and filled PCOSQ.

Patients were assessed at monthly interval (or earlier as per the need) for 6 months. Symptomatic assessment, clinical examination and PCOSQ evaluation were done at every month. Patients reported the menstrual cycle data (duration of bleeding, length of cycle, i.e. number of days from beginning of menstrual period to the beginning of next one, characteristic of discharge, etc.) and filled up PCOSQ. The presence of male-pattern terminal hair growth on the face or body, indicating androgen excess, was assessed with the modified Ferriman–Gallwey visual scoring method. The nine body areas were rated from 0 (absence of terminal hairs) to 4 (extensive terminal hair growth), and the numbers in each area were added to obtain the total score. A score ≥8 was taken to define hirsutism and maximum possible score was 36.[29] Acne was evaluated by investigator as per acne global severity scale score from 0 to 1 wherein 0 represented normal skin and 5 reflected most inflammatory acne. Any intercurrent complaint was managed as per the presenting signs and symptoms in both the groups. During follow-up, assessment was made in both the groups equally by the investigators; however, in the placebo group, different nomenclature was used for prescribing placebo. At completion of the study, in addition to these assessments, pelvic ultrasound was done to evaluate any change in PCO. The investigations which were out of range at baseline were repeated at end of the treatment.

Outcomes

Primary outcome was the establishment of menstrual regularity which was defined as having at least 5 menstrual cycles within 6 months along with either ultrasonological 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 outcomes were to compare the changes in domains of PCOSQ. Five domains consisting of emotions, body hair, weight, infertility and menstrual problems were quantified, so that the patient's subjective feelings could be compared initially and at the end of the study. Each domain has a range of questions wherein each question is associated with a 7-point scale in which 7 represents optimal function and 1 represents the poorest function.

Sample size

Being a pilot study, 60 cases of PCOS were enrolled, 30 in verum and 30 in placebo group.

Randomisation

Separate sets of random numbers were generated for the two study sites using stratified (centre as the strata) randomisation method.

Allocation

The patients fulfilling the eligibility criteria were enrolled and randomised as per computer-generated randomisation chart and received either the HI or the identical placebo. Allocation concealment was not done.

Only the patients were blinded to the identity of the treatment group. Homoeopathic and placebo medicines were identical.

The taste of the medicines was kept identical so as to blind the patients' gustatory sense.

Study duration

The study was conducted from February 2014 to May 2015.

Data collection

Each case in both the groups was followed up for 6 months to assess the outcome results of the treatment. The study data were collected at baseline, every follow-up (monthly or early if required) and at final/termination visit. The patients were evaluated for symptomatic, clinical assessment, laboratory parameters and adverse events, if any.

Statistical methods

Data obtained during the study were verified and analysed using Statistical Package for the Social Sciences version 20. Data were managed in a pre-designed pro forma and managed in an excel sheet. Before statistical analysis, normality assessment was done using Kolmogorov–Smirnov test. Accordingly, the demographic details and baseline characteristics of both the groups were compared using Chi-square test. BMI, waist–hip ratio, Ferriman scale, laboratory investigations, etc., were compared using Independent Student's *t*-test.

In lost to follow-up cases, the changes in menstrual cycle were considered as per the last LMP reported; however, the last observation carry forward method was applied for the assessment of Ferriman and acne score. Data are expressed in *n* (%), mean ± standard deviation. Statistical significance was considered at $P < 0.05$.

Regulatory and ethical approval

The study protocol was in accordance with the latest revision of the Declaration of Helsinki[30] on human experimentation and the good clinical practices, India.[31] Necessary clearance of the institutional ethics committee was obtained. All the patients were enrolled in the study after getting their consent. The trial is registered with Clinical trial registration India (CTRI).

Results

Of 120 cases of PCOS screened from the outpatient department of both the study sites, 60 were enrolled according to the inclusion criteria. Flow diagram of the progress through the phases of a parallel randomised trial of Homoeopathy + LSM and placebo + LSM (i.e. enrolment, intervention allocation, follow-up and data analysis) is depicted in Figure 1. Baseline characteristics were comparable in both the groups and were not statistically significant in spite of some variation. History of abortion was in four cases in Homoeopathy and five cases in placebo arm. All the laboratory investigations were within normal range except LH/FSH ratio which was above 2 in both the groups [Table 1].

The primary objective was achieved in 60% of cases in Homoeopathy + LSM and none in the placebo + LSM groups which was statistically significant ($P = 0.001$). In secondary outcomes also, statistically significant difference was observed in PCOSQ scores in the domains of weight, fertility, emotions and menstrual problems. Significant changes were not observed in ultrasonography (USG) findings [Table 2].

Mean reduction of intermenstrual duration (from first menstrual period after enrolment and from baseline) was significant in Homoeopathy group. The BMI and acne showed significant reduction from baseline to end of the study. Hirsutism did not show any change in both the groups as per Ferriman scale and PCOSQ. Three pregnancies were reported in the Homoeopathy and two in placebo group during the study period [Table 2]. However, five more pregnancies were reported within 2 months after the study period in the Homoeopathy group without any additional treatment. At baseline, LH/FSH was out of range in 15 patients (3.4 ± 1.7) in Homoeopathy and in 18 patients in placebo group (2.6 ± 0.5). After 6 months of treatment, it reduced in 9 cases in both the groups (1.5 ± 1.0), which was not statistically significant.

Dietary advice was followed by all the patients in both the groups. Exercise schedule was followed by 26 and 27 patients in Homoeopathy and placebo groups, respectively.

Acute illnesses (diarrhoea, vomiting and upper respiratory infections) were reported in four cases (two in Homoeopathy and two in placebo group). These cases were given homoeopathic medicines in frequent doses and resolved without any other treatments.

The commonly indicated medicines were *Pulsatilla* (*n* = 12), *Natrum muriaticum* (*n* = 4), *Sepia* (*n* = 3), *Calcarea carbonica* (*n* = 3), *Lycopodium* (*n* = 3), *Phosphorus* (*n* = 2), *China* (*n* = 1), *Nux vomica* (*n* = 1) and *Sulphur* (*n* = 1). The single medicine was given to 23 cases and 7 cases required the change of medicine [Table 3].

Discussion

The study was undertaken keeping in view the growing incidence of PCOS causing reproductive, endocrine and metabolic dysfunction. Primary objective, i.e. the establishment of regular menstrual cycle along with improvement in either ultrasonology or hirsutism/acne, was achieved in 60% of cases in Homoeopathy + LSM and in none in the placebo + LSM groups. The same trend was seen in PCOSQ showing statistically significant difference in the domains of weight, fertility, emotions and menstrual problems, except hirsutism. Significant changes were not observed in USG findings of PCO. Although USG indicated that five cases were worse (increase in ovarian volume and/or number of follicles) but only two reported increase in intermenstrual duration as compared to baseline in Homoeopathy group, whereas in placebo group, USG of 12 cases was worse but 19 reported increase in intermenstrual cycle. Therefore, composite factor assessment is essential rather than one factor assessment.[3] *Pulsatilla* was the most frequently indicated medicine (*n* = 10, 33.3%) in this study population.[18,19] Single medicine was indicated in 23 cases which did not require subsequent change in prescription.

Table 1: Baseline characteristics

Parameter	LSM + Homeopathy (*n*=30)	LSM + Placebo (*n*=30)	*P*
Age (years)#	24.6±5.6	24.4±4.6	0.90
Menarche Age (years)#	12.6±1.3	13.4±1.7	0.06
Duration of Problem (Years)#	4.2±3.1	5.8±4.9	0.13
Marital status*			
Single	17 (56.7)	12 (40.0)	0.302
Married	13 (43.3)	17 (56.7)	
Divorce	0 (0)	1 (3.3)	
Educational status*			
Intermediate	6 (20.0)	7 (23.3)	0.12
High school	2 (6.7)	6 (20.0)	
Graduation	11 (36.7)	14 (46.7)	
Post Graduate	10 (33.3)	3 (10.0)	
Able to read and write without formal qualification	1 (3.3)	0	
Occupation*			
House wife	4 (13.3)	10 (33.3)	0.11
Private job	3 (10.0)	5 (16.7)	
Professional	10 (33.3)	6 (20.0)	
Student	9 (30.0)	2 (3.3)	
Labourer	0 (0)	1 (3.3)	
Not specified	4 (13.3)	6 (20.0)	
Family Income*			
High income	11 (36.7)	8 (26.7)	0.70
Middle income	13 (43.3)	15 (50.0)	
Low income	6 (20.0)	7 (23.3)	
BMI#			
[(Height in metres/(Weight in Kg)/M^2]	28.5±5.3	28.8±4.5	0.80
Waist Hip Ratio#	0.86±0.06	0.86±0.04	0.68
Family History of PCOS*			0.64
Yes	4 (13.3)	4 (13.3)	
No	26 (86.7)	26 (86.7)	
Inter menstrual duration at Baseline (days)#	76.1±37.7	93.0±65.2	0.22
History of Duration of flow (days)#	5.1±3.3	5.1±3.6	0.94
Character of flow*			
Spotting	5 (16.7)	8 (26.7)	0.419
Scanty	10 (33.3)	6 (20.0)	
Normal	15 (50.0)	16 (53.3)	
Gravida*			0.64
Nullipara	6 (20.0)	8 (26.7)	
Primipara	2 (6.7)	2 (6.7)	
Multipara	5 (16.7)	8 (26.7)	
Ferriman score#	10.2±6.9	9.3±5.9	0.56
Acne global severity score#	1.5±1.1	2.1±1.3	0.12
Acanthosis*			
Yes	12 (40.0)	11 (36.7)	0.791
No	18 (60.0)	19 (63.3)	
PCOSQ#			
Weight	3.9±1.9	3.2±1.8	0.13
Fertility	4.8±1.5	4.0±1.8	0.07
Body hair	4.3±2.0	4.0±1.8	0.50
Emotions	4.4±1.2	3.5±1.3	0.01
Menstrual Problems	4.0±1.6	3.0±1.3	0.01
Investigations#			
Right Ovarian volume (cc)	15.2±6.0	12.3±4.7	0.05
Left Ovarian volume (cm^3)	14.1±4.3	15.3±8.3	0.49

Contd...

Table 1: Contd...

Parameter	LSM + Homeopathy (*n*=30)	LSM + Placebo (*n*=30)	*P*
Total no. of follicles in Right ovary	12.5±4.6	13.9±4.8	0.25
Total no. of follicles in Left ovary	12.2±4.5	14.3±4.7	0.07
SHBG (nmol/L)	32.3±13.7	29.5±11.6	0.39
LH/FSH	2.0±1.6	2.0±0.8	0.50
Total testosterone (ng/dl)	50.7±23.9	54.9±17.6	0.44
DHEAS (µg/dl)	123.7±107.5	135.3±103.7	0.67
Fasting Serum insulin (mU/L)	14.0±10.0	10.2±6.8	0.09
Fasting Glucose (mg/dl)	86.8±12.6	82.2±7.3	0.09
Glucose insulin ratio	13.0±21.7	10.8±5.6	0.05
Triglycerides (mg/dl)	134.3±57.8	119.7±57.6	0.33
HDL (mg/dl)	38.2±5.0	38.6±3.8	0.70
Hb (gm %)	12.0±1.5	11.5±1.3	0.23

Data expressed as n(%), Mean±SD#

Table 2: Outcomes

Primary outcome	LSM + Homeopathy (*N*=30)	LSM + Placebo (*N*=30)	*P*
Menstrual regularity with improvement either in USG or Acne or Hirsutism*	18 (60.0)	0 (0)	0.001**
Secondary outcome			
Ultra Sound Assessment (USA) *			
Normal	8 (26.7)	4 (13.3)	0.095
Improved	8 (26.7)	10 (33.3)	
Worse	5 (16.7)	12 (40.0)	
Not assessed	9 (30.0)	4 (13.3)	
PCOSQ#			
Weight	0.7±1.2	-0.1±0.6	0.001**
Fertility	-0.6±1.1	-1.3±1.1	0.029**
Body hair	0.1±1.2	-0.1±0.8	0.708
Emotions	1.1±1.1	-0.3±0.7	0.001**
Menstrual Problems	1.6±1.8	-0.3±0.9	0.001**
Related outcomes	**LSM + Homeopathy (*N*=30)**	**LSM + Placebo (*N*=30)**	***P***
Pregnancy with improvement either in USG or Acne or Hirsutism*	3 (10.0)	2 (6.7)	0.640
			0.01*
Reduction in inter menstrual duration (days) (although not within the normal range) with improvement either in USG or Acne or Hirsutism*	7 (23.3)	9 (30.0)	0.559
Increase in inter menstrual duration (days) *	2 (6.7)	19 (63.3)	0.001**
Mean reduction of Inter menstrual duration (days) (From first Menstrual period after enrolment) #	46.6±38.7	93.9±96.2	0.016**
Mean reduction of Inter menstrual duration (days) (From baseline)#	53.9±42.7	101.5±93.9	0.01**
Ferriman score#	0.3±5.0	-1.3±1.6	0.11
Acne global severity score#	1.3±1.1	0.0±1.0	0.001**
Reduction of BMI (From baseline)#	4.7±9.4	0.8±5.1	0.04**
Reduction of Waist Hip Ratio (From baseline)#	0.1±0.3	0.0±0.1	0.16
Dietary advice complied*			
Yes	30 (100)	30 (100)	
No	0	0	
Exercise regime followed*			
Yes	26 (86.7)	27 (90.0)	0.871
No	4 (13.3)	3 (10.0)	
Daily duration of physical activity (in minutes)#	31.3±4.5	31.1±5.1	0.860

Data expressed as *n* (%)*, Mean±SD# , *P*<0.05 significant**

A 6-month study of metformin and pioglitazone improved menstrual cyclicity in more than 90% of cases of PCOS; the other features of PCOS, i.e., weight gain and cosmetic problems although mentioned, were not evaluated.[32] Thus,

Table 3: Medicines prescribed

Medicine prescribed at baseline	1st change of prescription	Subsequent change of prescription
Pulsatilla (*n*=12)	Nat mur (*n*=1)	Calc carb (*n*=1)
	Belladona (*n*=1)	Sepia (*n*=1)
Natrum muriaticum (*n*=4)	Lycopodium (*n*=1)	-
Calcarea carbonica (*n*=3)	-	-
Sepia (*n*=3)	-	-
Lycopodium (*n*=3)	Pulsatilla (*n*=1)	Calc carb (*n*=1)
	Sepia (*n*=1)	Lycopodium (*n*=1)
Phosphorous (*n*=2)		-
China (*n*=1)	Nat mur (*n*=1)	-
Nux vomica (*n*=1)	Hamamelis and Millefolium (*n*=1)	-
Sulphur (*n*=1)	-	-

existing treatments including the conventional, so far, have mostly been directed at the symptoms but not at the syndrome itself.[33] Therefore, Homoeopathy has an edge as it holistically treats the patient.

LSM has a positive role in the management of PCOS. The study outcome in this arm, i.e. achievement of two pregnancies, reduction in intermenstrual duration with improvement in either ultrasonology or hirsutism/acne in nine cases, USG findings suggestive of normal ovaries in 4 cases and improvement in 9 and slight reduction in BMI and FSH/LH although not significant, indicates that LSM influences the management of PCOS. However, it improves the outcome as an adjunct to the therapy. A systematic review and meta-analysis also suggested that LSM improved blood glucose or insulin levels but had no significant effect on pregnancy rate, and the effect on hirsutism was unclear.[34]

To eliminate the recall bias (a systematic error caused by differences in the accuracy of the LMP reported), intermenstrual duration was calculated from two time points. First, from the LMP reported by the patient at baseline and second, the intermenstrual duration was calculated from the menstrual period that occurred just after enrolment in the study. The overall risk of bias[35] was minimal as only one domain (allocation concealment) out of six had high risk of bias. The outcome measures were not likely to be influenced by lack of blinding as the regularisation of menstrual cycle is patient reported.

Trial limitations include the short duration of follow-up for the assessment of continuity of menstrual regularity and regarding the changes in ultrasonological appearance of PCO. Furthermore, the pregnancy was not defined as an outcome parameter considering 6-month follow-up period; however, eight pregnancies (including five pregnancies reported within 2 months after the study period in the Homoeopathy group without any additional treatment) were reported in Homoeopathy and two in placebo group. LH: FSH, fasting serum insulin, etc. were done at 6 months only for the cases in which these were out of range at baseline. Although Vitamin D deficiency can be an effective factor in the development of PCOS and Vitamin D supplementation can play a role in prevention of this condition, it was not evaluated.[36] The effect of only LSM was insignificant with respect to primary objective, although it had some influence in management of PCOS. Therefore, it is felt that it was not appropriate to have only LSM arm as this age group has major concerns for menstrual irregularity and infertility. Further, the study could not avoid the selection bias and ascertainment bias due to nonblinding and lack of allocation concealment.

Conclusion

HI along with LSM has shown promising outcome in managing PCOS and improvement in QOL; thus, HI alleviates not only the disease *per se* but also the patient as a whole. Further comparative study with standard treatment on adequate sample size is desirable.

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Conflicts of interest

None declared.

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पॉलीसिस्टिक ओवेरियन सिंड्रोम में होम्योपैथिक उपचार का मूल्यांकन– एक सिंगल ब्लाइंड प्लासिबो नियंत्रित पायलट अध्ययन

पृष्ठभूमि और उद्देश्य: इस अध्ययन का प्राथमिक उद्देश्य, मासिक धर्म की नियमितता की स्थापना के साथ साथ अल्ट्रासोनिक निष्कर्ष या अतिरोमता/मुंहासों में सुधार के साथ होम्योपैथी की प्रभावकारिता का मूल्याकंन करना था। अध्ययन में पॉलीसिस्टिक ओवेरी सिंड्रोम प्रश्नावली का उपयोग करके जीवन की गुणवत्ता का मूल्यांकन भी किया गया।

विधि/रचना: फरवरी 2014 से मई 2015 तक दो अनुसंधान केंद्रों पर एक सिंगल ब्लाइंड, यादृच्छिक, प्लासिबो नियंत्रित पायलट अध्ययन का आयोजन किया गया। पात्रता मानदंडों को पूरा करने वाले मामलों को नामांकित किया गया (एन=60) और छह महीने के लिए समरुप जीवन शैली संशोधन (एलएसएम) के साथ, होम्योपैथिक हस्तक्षेप (आईएच) (एन=30) या समान प्लासिबो (सी) (एन=30) के लिए यादृच्छिक किए गए।

परिणाम: अन्य संकेत/लक्षणों में सुधार के साथ मासिक धर्म नियमितता एलएसएम + आईएच समूह में 60 प्रतिशत मामलों (एन=18) और नियंत्रण समूह (पी=0.001) में शून्य (एन=0) देखा गया। प्लासिबों ं एलएसएम समूह (93.0 ं 65.2 से 93.9 ं 96.2 दिन) की तुलना में एलएसएम + आईएच में, मासिक धर्म अवधि (76.1 ं 37.7 से 46.6 ं 38.7 दिन) में सांख्यिकीय रुप से महत्वपूर्ण अंतर (पी=0.16) देखा गया। पीसीओएसक्यू में आईएच समूह में वजन, जननक्षमता, भावनाओं और मासिक धर्मसंबंधी समस्याओं (पी ≤ 0.05) और शरीर के बालों में बिना किसी अंतर (पी=0.708) के साथ महत्वपूर्ण सुधार देखा गया। अल्ट्रासाउंड निष्कर्षों में सुधार के संबंध में कोई परिवर्तन नहीं देखा गया। पल्साटिला सबसे अधिक संकेतित औषधि थी (एन = 10,33.3 प्रतिशत)।

निष्कर्ष: होम्योपैथिक हस्तक्षेप के साथ एलएसएम ने आशाजनक परिणाम दिखाया है, पर्याप्त नमूना आकार पर मानक उपचार के साथ आगे तुलनात्मक अध्ययन वांछनीय है।

Bewertung der homöopathischen Behandlung bei polyzystischen Ovarialsyndrom - Eine einzige blinde, randomisierte, Placebo-kontrollierte Pilotstudie

Hintergrund und Zielsetzung: Diese Studie wurde mit dem primären Ziel durchgeführt, die Wirksamkeit der Homöopathie bei der Feststellung der Regelmäßigkeit der Menstruation mit Verbesserung in entweder der Ultraschallbefunde oder Hirsutismus / Akne zu bewerten. Die Lebensqualität wurde auch mithilfe des Fragebogens für polyzystischen Eierstocksyndrom (PCOSQ) bewertet.

Methoden: Eine randomisierte, placebokontrollierte Blindstudie wurde von Februar 2014 bis Mai 2015 in zwei Forschungszentren durchgeführt. Die Fälle, die die Zulassungskriterien erfüllten, wurden eingeschlossen (n = 60) und randomisiert entweder für die homöopathische Intervention (IH) (n = 30) oder das identische Placebo (C) (n = 30) mit einheitlicher Lebensstilmodifikation (LSM) für sechs Monate.

Ergebnisse: Die Regelmäßigkeit der Menstruation mit Verbesserung anderer Symptome wurde in 60% der Fälle (n = 18) in der HI + LSM-Gruppe und in keiner (n = 0) in der Kontrollgruppe beobachtet (p = 0,001). Ein statistisch signifikanter Unterschied (p = 0,016) wurde bei der Reduktion der intermenstruellen Dauer (von 76,1 ± 37,7 auf 46,6 ± 38,7 Tage) in HI + LSM im Vergleich zu Placebo + LSM-Gruppe beobachtet (von 93,0 ± 65,2 auf 93,9 ± 96,2 Tage). In PCOSQ wurde auch eine signifikante Verbesserung in der HI-Gruppe in Bereichen von Gewicht, Fruchtbarkeit, Emotionen und Menstruationsproblemen beobachtet (p <0,05), ohne Unterschied im Körperhaar (p = 0,708). Bezüglich der Verbesserung der Ultraschallbefunde wurde keine Veränderung beobachtet. Pulsatilla war das am häufigsten angegebene Medikament (n = 10, 33,3%).

Fazit: LSM hat zusammen mit homöopathischen Interventionen ein vielversprechendes Ergebnis gezeigt, weitere vergleichende Studien mit Standardbehandlung bei adäquater Stichprobengröße sind wünschenswert.

Evaluación del tratamiento homeopático en el síndrome del ovario poliquístico – estudio piloto aleatorizado controlado a simple ciego

Fundamento y objetivos: Este estudio se realizó con el objetivo principal de evaluar la eficacia de la homeopatía en establecer la regularidad menstrual con mejoras en los hallazgos ecográficos o enel hirsutismo/acné. Asimismo, se evaluó la calidad de vida utilizando el PCOSQ (*PolycysticOvarySyndromeQuestionnaire*; Cuestionario del síndrome de ovario poliquístico).

Métodos/Diseño: Se efectuó un estudio piloto controlado con placebo, aleatorizado y a simple ciegodesde febrero de 2014 hasta mayo de 2015 en dos centros de investigación. Se incluyeron los casos que cumplían los criterios de elegibilidad (n=60) y se aleatorizaron o bien a una intervención homeopática (IH) (n=30) obien a un placebo idéntico (C) (n=30) con una modificación uniforme del estilo de vida (MEV) durante seis meses.

Resultados: En el 60% de los casos (n=18) del grupo con IH+MEV y en ningún caso (n=0) del grupo de control (p=0,001), se constató una regularidad menstrual con mejora de otros signos/síntomas. Se observó una diferencia estadísticamente significativa (p= 0,016) en la reducción de la duración intermenstrual (de 76,1±37,7 a 46,6 ± 38,7 días) en el grupo MEV+IH en comparación con el grupo MEV+placebo (de 93,0±65,2 a 93,9±96,2 días). En el PCOSQ, también se observó una mejora significativa en el grupo IH en cuanto a peso, fertilidad, emociones y problemas menstruales (p<0,05) sin diferencias en el vello corporal (p=0,708). No se constató ningún cambio en cuanto a la mejora de los hallazgos ecográficos. Pulsatillafue el medicamento más frecuentemente indicado (n=10, 33,3%).

Conclusiones: La MEV junto con la intervención homeopática han dado resultados prometedores. Se precisan más estudios comparativos con un tratamiento estándar y un tamaño de muestra adecuado.

Évaluation d'un traitement homéopathique dans le cas d'une polykystose ovarienne – Une étude pilote en simple aveugle, randomisée et contrôlée par placebo.

Contexte et objectifs: L'objectif principal de cette étude était d'évaluer l'efficacité du traitement homéopathique en vue d'établir une régularité du cycle menstruel et d'améliorer soit les résultats échographiques soit l'hirsutisme/ l'acné. La qualité de vie a également été évaluée à l'aide du Questionnaire sur le polykystose ovarienne (QPO).

Méthodes/conception: Une étude pilote en simple aveugle, randomisée et contrôlée par placebo a été menée de février 2014 à mai 2015 dans deux centres de recherche. Les sujets répondant aux critères d'admissibilité ont été inscrits (n=60) et randomisés soit pour une intervention homéopathique (IH) (n=30) soit pour un placebo identique (C) (n=30) et ils ont dû apporter les mêmes changements à leur style de vie (CSV) pendant six mois.

Résultats: Une régularité du cycle menstruel accompagnée d'une amélioration des autres signes/symptômes a été observée dans 60% des cas (n=18) au sein du groupe CVS+IH et aucun effet (n=0) n'a été constaté dans le groupe de contrôle (p=0,001). Une différence statistiquement significative (p= 0,016) a été notée quant à la réduction de la durée entre deux cycles menstruels (de 76,1±37,7 à 46,6 ± 38,7 jours) dans le cas CVS +IH par rapport au groupe CVS +placebo (de 93,0±65,2 à 93,9±96,2 jours). Dans le QPO, une amélioration importante a également été notée au sein du groupe IH en ce qui concerne le poids, la fécondité, les émotions et les troubles menstruels (p<0,05) sans aucune différence au niveau de la pilosité (p=0,708). Aucun changement n'a été constaté concernant l'amélioration dans les résultats échographiques. Le médicament le plus fréquemment recommandé est Pulsatilla (n=10, 33,3%).

Conclusion: Des CSV accompagnés d'une intervention homéopathique ont donné des résultats prometteurs, mais il est souhaitable de mener une étude comparative plus approfondie avec un traitement standard comprenant un échantillon de taille adéquate.

順勢療法治療多囊卵巢綜合症的評估：單盲隨機安慰劑對照前瞻性研究

背景和目的：進行這項研究的首要目的是評估順勢療法在重整月經規律、改善超聲波結果或多毛症/暗瘡的理想有效性。生活質素會透過多囊卵巢綜合症問卷（PCOSQ）來評估。

方法/設計：於2014年2月至2015年5月，有一項單盲、隨機、安慰劑對照前瞻性研究在兩個研究中心進行。登記符合納入標準的個案（n = 60），被隨機分配至順勢療法治療（IH）（n = 30）或一模一樣的安慰劑（C）（n = 30），並統一改變生活方式（LSM）六個月。

結果：LSM+IH組別中有60%（n=18）的個案觀察到經期規律上及其他徵象/症狀的改善，而在對照組是沒有（n=0）的（p=0.001）。LSM+IH組（從76.1±37.7至46.6±38.7日）的經期間隔時間減少比LSM+安慰劑組（從93.0±65.2至93.9±96.2日）較大，有統計學顯著性的差異（p=0.016）。在PCOSQ中，IH組在體重、生育率、情緒和月經問題上都有明顯改善（P＜0.05），體毛則無差異（p=0.708）。在超聲波檢查改善方面則沒有發現任何變化。白頭翁是最常見的處方藥物（n=10，33.3%）。

結論：LSM結合順勢療法治療有良好的療效，可更進一步進行有足夠樣本量、與標準治療比對的實驗。