Effects of Standardized Classical Homoeopathy on Amenorrhoea With Polycystic Ovarian Disease (PCOD)

ABSTRACT: This paper has been presented at 1st International Conference On Women's Health and Asian Traditional (WHAT) Medicine 2005 August at Kuala Lumpur, Malaysia. (Co chaired by Gerard Bodekar, GIFTS, Oxford University and Ferdi Kronenberg, Columbia University)

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BACKGROUND: Polycystic ovaries was first described by Stein and Leventhal MC in 1935 (Amenorrohea associated with bilateral polycystic ovaries Am J Obstet Gynecol 1935; 29:181-191)
Polycystic ovary syndrome is a diagnosis made in 5-10 % of women between late adolescence and menopause and upto 20% may be affected (Polson et all 1988).
Patients may present with oligomenorrhoea or amenorrhoea, anovulation or infertility, hirsutism and/ or acne. Diagnosis is based on the presence of polycystic ovaries on ultrasound accompanied with clinical presentation of anovulation or hyperandrogenism.
However recent research has shown association with insulin resistance with consequent hyperinsulinaemia, hyperlipidaemia and obesity. More important is the increased (almost 7 times) risk of myocardial infarction and ischemic heart diseases. Due to this complex and elusive syndrome no standard satisfactory regime of drug treatment has evolved.

OBJECTIVES: We investigated the effects on amenorrhoea of standardized homoeopathic practice at three different clinics in cases of Polycystic Ovarian Disease. The primary objective was to restore the menstrual cycle in all. We wanted to further observe if they are able to conceive without any other interventions.

METHODS: Patients were selected from three different private clinics run by senior homoeopathic physicians (10yrs of practice) trained at the Institute Of Clinical Research in standardized homoeopathic pracitice. Patients with amenorrhoea and USG evidence of polycystic ovaries were selected for study. They were given homoeopathic medicines evolved through a standardized method and primary objective of menstruation was tried to be achieved. It was carried on over a period of 3yrs from 2001 to 2004.

RESULTS: Out of thirty patients studied over a period of 3 years, eighteen got menses within six months of treatment. From among these five had to be given second remedy, as the first decided upon failed to give results. Out of eighteen, nine were seeking conception. Four conceived without any other medication while one had to take a short-term allopathic medication. From the remaining 13 who did not respond by menstruation, one got married and conceived!

KEYWORDS: Homoeopathy, Amenorrhoea, Polycystic Ovaries, PCOD,PCOS.

INTRODUCTION: The prevalence of PCOD in the In-

dian subcontinent is very high and significantly linked to irregular menstrual cycle. It is the primary cause of menstrual dysfunction in 75% of women. In US, 21% of pre-menopausal women are affected. The symptoms include amenorrhea, presence of cyst in ovaries, hirsutism, obesity and infertility. Polycystic ovaries are due to incomplete follicular development or failure of ovulation. Women with the syndrome have at least seven times the risk of myocardial infarction and ischemic heart disease than other women, and by age of 40 years 40% will have Type 2 diabetes or impaired glucose tolerance. Certain research results suggest the benefit by Metformin and Clomiphene on ovulation. A recent Lancet editorial comments "confirmation of the beneficial effects of Metformin on hormonal and metabolic variables in women with polycystic ovary syndrome will have implications not only for the treatment of the common gynaecological presenting features, but also for the burden of vascular disease in women". A study by Jonanthan Lord/Ingrid Flight/Robert JN (Peninsula Medical School, UK) said that though Metformin is effective there is no study on the safety of long term use of Metformin.

Troglitazone, a diabetes medicine has been shown to improve insulin sensitivity and lower serum Insulin, Androgen and Luteinising hormone without causing weight loss but more research is required.

Another study of 16 non-diabetic hyperandrogenic women treated with a combined oral contraceptive containing 150mg of Desogestrel and 30mg of Ethinyloestradiol demonstrated a significant deterioration in glucose tolerance over six months with two women developing frank diabetes. This raises doubts about the short and long term safety of ovarian suppression in polycystic ovary syndrome with oral contraceptives.

Cyproterone acetate frequently causes depression and at 100 mg weight gain and insulin resistance. Ovulation induction can be difficult due to the risk of Ovulation Hyperstimulation Syndrome(OHSS) and multiple pregnancies. Overall the treatment is symptomatic. Surgery is not the preferred option in young patients.

Numerous studies have documented that healthcare consumers all over the world are spending money out of pocket for alternative therapies, (Beal MW Yale University School of Nursing) Homoeopathy forms an important aspect of this trend.

A recent commentary in the Archives of Internal Medicine (Vol 156, PP 2162-2164) called for more research in homoeopathy to determine its clinical efficacy, putting aside for the moment its implausibility. Case report study was thought to be best suited to the challenges of classical homoeopathy until more research is done.

Standardized classical homoeopathy is a system of medicine that has been evolved by dedicated homoeopaths from India over many years and is based on clinical experiences of case-taking.

Standardized classical homoeopathy has special importance in treating chronic diseases in that it respects each system (body) with regards to the symptoms presentation, genetic composition, pace of the disease and the persons own capacity to deal with his mind and body.

The British Homoeopathic Journal, Vol XXIX 1939 published an address delivered by A P Cawadias (Physician to St John Clinic and Institute of Physical Medicine) which says that all biochemical disorders of the body are the constitutional diseases and should be treated by homoeopathy.

Homoeopathic books, literature, source materials mentions about polycystic ovaries and even suggests remedies. There are encouraging case reports (Eg Tonset S D, 1997 August Homoeopathic Heritage) on treatment of PCOS by homoeopathy both in the past as well as recently.

The Indian Journal of Homoeopathic Medicine 1997(Vol 32) has published cases of hyperthyroidism, diabetes and other endocrinological disorders treated successfully by classical homoeopathy .

The objective was to study whether standardized homoeopathic practice could restore menstruation in cases of PCOD with amenorrhea and if these results could be obtained frequently at different locations.

Methods And Materials

There were 2 categories of patients

1) Patients seeking normal menstrual cycle

2) Married patients having secondary infertility due to PCOD

The first step was to obtain a normal menstrual cycle in both cases. In others, to continue treatment and observation till their objective is achieved.

The homoeopaths were professionals trained in the standardized method of case taking and analysis for many years. They had at least 10 years of clinical practice and experience of treating PCOD. Familiarity with Hompath software.

PCOD patients who presented with complaints of amenorrhea were selected for study. They required to have a sonological evidence of polycystic ovaries. Patients suffering with other major illnesses like hypertension were not selected. They were enrolled and observed between 2001 Feb to 2004 Sept.

Design: Cases were taken in detail by a standardized method. It consisted of interviewing the patient for 45 to 90 minutes. in the presence of an observer who gave feedback to the physician.

In cases of live-problems like inter-personal relationship issues, appropriate guidance was given in accordance with the standardized pracitice.

Patients were diagnosed for clinical diagnosis, person diagnosis (an integral part of classical homoeopathy) and miasmatic diagnosis. The data was then processed by giving value to the symptoms gathered and process of repertorization done by Hompath. This also included the selection of approaches like Kent's approach, Boger Boenninghausen's approach and Bogers approach..

Final selection depended on consensus arrived between the physician and the observer. Constitutional medicine was decided upon along with a differential diagnosis (second remedy) for each individual case. Remedy decided is changed by a homoeopath if required during the course of treatment. A plan was then formulated for mismatic remedy, its requirement, acute remedy, precautions to be taken. Expectations from treatment are drafted and follow-up criterias laid out.

Only those cases were taken up where the physician had high confidence for remedy selection.

Patients were given constitutional medicines and called for follow up every two weeks.

Follow up were short enquiring into global health, menses, new complaints.

After eight weeks of follow up when there were no results patients were re-assesed and the predecided stand-by remedy was given.

Results

Patients selected were between 20 to 40 years. Patients who had not taken any allopathic medication responded faster. Out of the thirty patients studied over a period of 3 years eighteen (60%) got menses within six months. Among these five had to be given second remedy as the first decided remedy failed to give result. Global well being was the first indication of the right remedy. Out of eighteen, nine were seeking conception. Four conceived without any other medication while one had to take a short allopathic medication. Only one dropped out as there was no response. From the remaining 12 who did not respond by menstruation one got married and conceived!

Medication: The polycrests or constitutional medication used were:

1. *Calcarea-carb*
2. *Calcarea-phos*
3. *Calcarea-flour*
4. *Lycopodium*
5. *Graphitis*
6. *Baryta-carb*
7. *Natrum-sulph*

The anti-sycotic remedies used were *Thuja* 200 and 1M and *Medorrhinum* 200.

In one case the miasm was tubercular as the growth rate was fast and hence *Tub* 1M was given. *Pituitrin* 6X and *Puls* 30 and 200 were given when patient felt the symptoms that appear before menses like backache but there was no flow.

Other acutes like *Ars-alb, Ant-tart, Bell, Colo* were used for acute complaints of colds, fevers and loose-motions.

Potency /Repetition: Out of the 18 patients who responded, 14 cases were given lower potencies repeatedly - 30 and 200 worked best. The

antisycotic medicines of *Thuja* and *Medo* were given in 200 and 1M potencies.

DISCUSSION: The study illustrates the advantage of a standardized style of practice wherein positive results can be obtained in three different private clinics. There was repeated success in restoring the menses. The observer gives service to the physician and helps reduce prejudice which helps in achieving similimum. Counselling patients during interview is part of standardized practice since it is felt that high emotional upset (maintaining cause) could hinder receiving of medicine.
Homoeopathic treatment should be started as early as possible for best benefits.
However in cases which did not respond, problems ranged from paucity of symptoms and lack of good symptoms which can differentiate remedies. Another difficulty was since there were no other complaints or symptoms of global ill-health one had to wait from menses to menses to understand the result of remedy. Complete hormonal essay needs to be done for every case.

CONCLUSION: Standardized classical homoeopathy is effective in bringing about menstruation in cases of PCOD. Case-studies work better than clinical trials until the intricacies of classical homoeopathy are fully understood. Change in remedy is an integral part of homoeopathy and studies using one or two remedies are inadequate.
Since one aspect of PCOD responds to homoeopathy, other aspects like glucose tolerance curve, lipid levels also need to be studied.
A detailed study is called for with larger sample size, blood hormonal levels of FSH, LH17, Beta estradiol (E2 Progesterone, Prolactin, Testosterone, Androstendione, DHEA-S (Dehydroepiandrosterone Sulphate), SHBG (Sex Hormone Binding Globulin), glucose tolerance, lipids and close monitoring of follicular study. Latest studies on PCOD have focused on the psychological aspects and quality of life.
Institutional sourcing of patients and proper funding would help carry this forward.

PROBLEMS

1. This research topic needs to be carried out along with a senior endocrinologist for scientific authenticity.
2. Funding to carry out all the investigations.
3. A hospital base for institutionalized practice to add more value and uniformity to the procedures.

CASE: Mrs JM, 34. Married/ Hindu/ Vegetarian
H: 35 doing job, Fa 70 retired, Br: 26, Sis: 29, married, 1 daughter: 4½ years

CHIEF COMPLAINTS

Polycystic ovaries since 92 - irregular menses once every 3 to 6 months
Hirsutism, Wt increased. Voice-normal

OTHER COMPLAINTTS

Back pain→ (L) leg :. 3 months
Heel pain:. 3months
GENERAL: Obese pt.
SKIN: Cracks in winter with pain
HAIR: Dandruff with itching
PERSPIRATION: Moderate, Palms++
APPETITE: Good
CRAVING: Salt, pickles, sweets.

PAST MENSTRUAL HISTORY

FMP: 13 years, LMP: 7 March 98. Regular before marriage
Flow: Scanty/No complaints during
SEXUAL FUNCTIONS: Normal. Use of condoms
SLEEP: Good DREAMS: Anxious- about daughter, Death of relative and parents.

FAMILY HISTORY: Fa: HT, Mo: Menstrual irregularity, Aunt: Uterine fibroma.

LIFE-SPACE

Patient is a dark, obese, sensitive South-Indian, married lady. She lives with her husband and 1 daughter. Civil eng by profession, she works for a firm in the same city. Her husband is a calm, cool sensitive person who is unable to understand pt's irritable nature and variations in mood.
Pt is very disturbed and guilty because she keeps her daughter in crèche. She feels her daughter will feel very unloved and neglected. Though there are

no indications to support this, which pt herself admits, she can't help her feelings. At office her boss is a nice person. They share good IPR (inter personal relationship). She understands pt's problems and gives freedom and flexibity at work. Hence the job is not strenuous or problematic.

Pt's Fa was a cool and calm person and geophysicists by profession. He often had to go to remote places for excavations and study. Hence he and his wife thought it better to put pt in boarding school in order to enable her to study well. She had no brother at that time and sister was very young.

Pt at that time did not say anything but she felt very lonely. She resented her parents for doing this to her. At the convent, she would take up issues to rebel against. At the mess the food was not good. Patient took this up and started revolting. Her parents when informed did not understand her and advised her not to be a bad girl.

But in the 8th Std she met a teacher who tried to understand her rebellious nature and explained to her many things. Patient realized many things. Also by this time she started staying with her parents. But the type of bond pt craved was lacking. She did her college, Engineering and got a job. Somebody advised her to come to Mumbai. She stayed with some relatives here. She met her husband and fell in love. Initially there was some resistance from both sides (due to caste) but later OK. She has never stayed with her in-laws.

Social interactions are very limited. Her in-laws and parents come to their house rarely. Relations with neighbours and friends is cordial.

Repertorial Approach: Since data is very less, repertorised by Bogers approach

Repertorial Totality

Obese patient
Polycystic Ovaries
Shy
Craving salt/pickles/sweets

Remedy: *Calc-c*

Miasmatic Evaluation / Pre-Disposition

Mo: Uterine fibroid- Sycotic Miasm
Fa: Diabetes/Hypertension- Tubercular Miasm

Past History

Recurrent Tonsillitis/Malaria: Tubercular
Current structural phase: Sycotic (formation of cystic lesions)

Fundamental Miasm: Tubercular

Planning and Programming

Susceptibility: Moderate to low
Potency Preferred: 30/200

To give constitutional medicine in lower potency repeatedly in order to restore regular menses.

Treatment: 23/5/98: *Thuja* IM and *Calc-c* 200 once weekly. Within 7 mths her menstrual pattern was normal.

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Homoeopathic Clinical Trial Protocol Guidelines

ABSTRACT: Homoeopathic Clinical Research is the task ahead of us, if Homoeopathy has to come at par with all other medical sciences. If we have to showcase homoeopathy to the rest of the Medical World, and to make it acceptable, we have to talk in standardized language, incorporating the differences which Homoeopathy has to contend with. Dr Vipul Gandhi has made efforts in compiling the guidelines for preparing Homoeopathic Clinical trial Protocol/ Clinical Technical document (CTD) which are put down here for the benefit of the profession at large.

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GENERAL INFORMATION

1. Protocol title, protocol identifying number and date. Any amendments should also bear the amendment numbers and dates.
2. Name and address of Sponsor and monitor.
3. Name and title of the investigator responsible for conducting the trial address and telephone numbers of the trial site.
4. Names and addresses of the clinical laboratory and other medical and/ or technical departments and/ or institutions involved in the trial.

1. BACKGROUND INFORMATION

1.1 Name and description of the investigating products.

1.2 A Summary of findings from non-clinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.

1.3 Summary of the known and potential risks and benefits, if any, to human subjects.
1.4 Description of, and justification for, the route of administration, dosage, regimen and treatment period.
1.5 A statement that the trial will be conducted in compliance with the protocol, Good Clinical practices and the requirements of Central Council of Research in Homoeopathy.
1.6 References to literature and data that are relevant to the trial and that provide background for the trial.

2. Trial objectives and purpose

2.1 A detailed description of the objectives and purpose of the trial.

3. Trial design

3.1 A description of the type /design of the trial to be conducted (eg double blind, placebo controlled, parallel design) and a schematic diagram of trial design, procedure and stages.
3.2 A description of the trial treatments and the dosage regimen of the investigational products.
3.3 The expected duration of subject participation and a description of the sequence and duration of all trial periods including follow up, if any.
3.4 A description of the Dropout criteria for individual subjects, parts of the trial and the entire trial.
3.5 Accountability procedures for investigational products, including placebos.
3.6 Maintenance of trial treatment codes and procedures for breaking codes.

4. Selection and withdrawal of subjects

4.1 Subject inclusion criteria
4.2 Subject exclusion criteria
4.3 Subject withdrawal criteria (ie terminating investigating product treatment/ trial treatment) and procedures specifying:
a) When and how to withdraw subjects from the trial/ investigational product treatment
b) The type and timing of the data to be collected from withdrawn subjects
c) Whether and how subjects to be replaced
d) The follow up for subjects withdrawn from investigating product treatment / trial treatment

5. Treatment of Subjects

5.1 The treatment to be administered including names of all products, doses, the dosing schedules, the route/modes of administration and the treatment periods including the follow up period for subjects for each investigational product treatment/ trial treatment.
5.2 Medication / treatment permitted and not permitted before and or during the trial.
5.3 Procedures for monitoring subject compliance.

6. Assessment of efficacy and safety

6.1 Specification of efficacy parameters.
6.2 Methods and timing for assessing, recording and analyzing of efficacy parameters
6.3 Specifications of safety parameters.
6.4 Procedures for eliciting report of and for recording and reporting adverse event and intercurrent illnesses.
6.5 The type and duration for follow up of subjects after adverse events.

7. Statistics

7.1 A description of the statistical methods to be employed, including timing of any planned interim analysis
7.2 The number of subjects planned to be enrolled, in multi-centric trials, the numbers of enrolled subjects projected for each trial site should be specified. Reason for choice of sample size, including reflections on the power of the trial and clinical justification

7.3 Significant tests to be used.
7.4 Criteria for termination of trial.
7.5 Procedure for accounting for missing, unused and spurious data.
7.6 Procedures for reporting any deviations from the original statistical plan which should be justified in the final report.
7.7 The selection of subjects to be included in the analysis (eg: all randomized subjects, all dosed subjects, all eligible subjects, valuable subjects)

8. Direct access to source data / document

8.1 The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator/ institution will permit trial related monitoring, audits, institutional review board / independent ethics committee review and regulatory inspections, providing direct access to source data / documents.
8.2 Data handling and record keeping

9. Ethics

9.1 Description of ethical considerations relating to the trial

10. Quality And Financing

10.1 Quality control and quality assurance
10.1.1 The medicine used in the study shall comply with the pharmacopoieal and quality standards.
10.2 Financing and insurance.
10.3 Publication policy.

Ha ha ha!!!

Smith climbs to the top of Mt. Sinai to get close enough to talk to God.

Looking up, he asks the Lord... "God, what does a million years mean to you?"

The Lord replies, "A minute."

Smith asks, "And what does a million dollars mean to you?"

The Lord replies, "A penny."

Smith asks, "Can I have a penny?"

The Lord replies, "In a minute."

☺ ☺ ☺

A man goes to a shrink and says, "Doctor, my wife is unfaithful to me.

Every evening, she goes to Larry's bar and picks up men. In fact, she

sleeps with anybody who asks her! I'm going crazy. What do you think I should do?"

"Relax," says the Doctor, "take a deep breath and calm down. Now, tell me, exactly where is Larry's bar?"