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Effect of Amree Plus and Amycordial on Clinical and Biochemical Parameters in Polycystic Ovarian Syndrome (PCOS)

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Objectives : To assess the effect of three months of Amree Plus and Amycordial therapy, non-hormonal anti-diabetic and menstrual regulator respectively, in patients of PCOS by various clinical parameters. Along with efficacy, the safety of the formulation was also assessed.

Introduction

Polycystic Ovarian Syndrome (PCOS) is a common disorder affecting 6-10% of women in reproductive age group. It is poorly understood and managed problem. The understanding of the pathophysiology of this syndrome has undergone dramatic changes ever since it was first described by Stein and Leventhal in 1935.

Currently, a great emphasis is being laid on insulin resistance in patients of PCOD (Atleast 30% of patients with PCOS are insulin resistant). Insulin resistance causes hyperinsulinaemia, which further results in a chronic hyperandrogenic state particularly testosterone and androstenedione and by decreasing the sex hormone globulin concentration. The high level of androgenic hormones interfere with the pituitary ovarian axis leading to increased LH levels, anovulation, amenorrhoea, menstrual irregularities and infertility. This signifies clinical implications like hirsutism, sub-optimal obstetrical outcome and long term complications like impaired glucose tolerance, gestational diabetes, diabetes mellitus Type II, dyslipidaemia, coronary artery disease and endometrial hyperplasia. It is the most common cause of endocrinopathy in women and is the most common cause of androgen excess.

The condition appears to have a genetic component. Those affected often have both male and female relative with adult-onset diabetes. Obesity, elevated blood triglycerides, high blood pressure and female relatives with infertility, hirsutism and menstrual problems.

PCOS ovaries contain 2-3 times the number of 2 mm or greater follicles than do normal ovaries. Polycystic ovaries as defined by ultrasound is the presence of 10 or more 2-8 mm follicles and an increased echodense stromal area, this occurs in 70-80% of women who meet the standard diagnosis of anovulation and hyperandrogenism. Hyper-

Table 1 : Amree Plus Granules

Composition : (in percentage w/w)

Karela Ghanasatv (Momordica charantia) 40% Gudmar Gudmar ghansatv (Gymnema sylvestre), vijaysaar Ghansatv (Perocarpus marsupium), Bilv Patr Ghansatv (Aegle marmelos), Kutaki Ghansatv (Picrorrhiza Kurroa) Tejpar Ghansatv (cinnamonum tamala) 50% each, Jamunpatr Ghansatv (syzigium jambos), Methi Seeds Ghansatv (Trigonella foenum graecum), Kalmegh Ghansatv (andrographis paniculata), Chandra Prabha Vati (RTS-1) (Ayur. Comp. Form.) 3% each Sadabahar Ghansatv (catharanthus roseus) Neem Patr Ghansatv (Azadirachtra. indica), Giloe Ghansatv (Tinospora cordifolia), Sudh Shilajeet (RTS-1) (Purified Asphaltum), Swaran Makshik Bhasm (AFI) (Ayur. Comp. Form), Gularpatr Ghansatv (ficus racemosa), Bhringraj Ghansatv (Eclipta alba), Punernava Ghansatv (Boerhavia diffusa), Amla Ghansatv (Emblica officinalis), Kanwar Patha (Aloe Conc.) 2% each, Bimbi Ghanstv, (Tecomeila undulata), Yashad Bhasma (AFI) Calcinated Zinc) 0.5 each, Excipients Q.S.

Processed in the decoction of Triphala, Gudmar, Giloe, Jamun Giri, Karela, Vijaysaar and Dashmul.

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Table 2 : Amycordial Capsules

Composition Capsules : Each Capsule Contains		
Ashok Chaal Ghan	(Ext. of Saraca indica)	50 mg
Lodhra Chaal Ghan	(Ext. of Symplocos racemosa)	50 mg
Vanshlochan	(Bambusa arundinacea)	30 mg
Sudh Laksha	(Exudate Lacifera lacca)	30 mg
Rasaunt	(Berberis extractum)	20 mg
Praval Pishti (AFI)	(micronized Corralium rubrum)	20 mg
Mukta Shukti Bhasma (AFI)	(calcinated oyster)	20 mg
Mandoor Bhasma (AFI)	(Ferrusoferric Oxide)	20 mg
Phitkari Sudh	(Purified Potash Alum)	10 mg
Bansa Patr Ghan and dried extracts from :	(Ext. Adhatoda vasica)	10 mg
Chikni Supari	(Areca catechu)	50 mg
Shatavar	(Asparagus racemosa)	50 mg
Ashwagandha	(Withania somnifera)	45 mg
Manjisth	(Rubia cordifolia)	30 mg
Jeevanti	(Leptadenia reticulata)	30 mg
Nagkesar	(Mesua ferra)	30 mg
Draksh Kali	(Vitis Vinifera)	30 mg
Rakt Chandan	(Pterocarpus santalinus)	20 mg
Kutaj Chaal	(Holarrhea antidysenterica)	20 mg
Mochras	(Salmalia malabarica)	20 mg
Chaulai Mool	(Amaranthus paniculatus)	20 mg
Gainda patr	(Tagates erecta)	20 mg
Amla	(Emblica officinalis)	20 mg
Sunthi	(Zingiber officinale)	15 mg
Phool Priyangu	(Callicarpa marcrophylla)	10 mg
Excipients		Q.S.

androgenism is the sine qua non of PCOS.

Material and Methods

A randomized trial of Amree Plus (Table 1) + Amycordial (Table 2) and Placebo was undertaken in 24 women with symptoms of PCOS for a period of 3 months. Patients were selected from private gynaecological OPD in an urban setup. All the patients were literate and provided written informed consent before enrolment. Patients were selected on the basis of inclusion and exclusion criteria.

Inclusion criteria

- Eight or fewer menstrual periods in a year
- Hirsutism, acne obesity
- Desire to conceive
- Good general health
- Age group of 18-39 years
- Must not have taken oral contraceptive pills or hormonal therapy for 3 months prior to enrolment.

Exclusion criteria

- Patients with history of diabetes
- History of kidney, liver heart or thyroid disease.

Study Methodolgy

Patients in the reproductive age group who complained of menstrual irregularities, inability to

conceive, growth of facial hair, acne and weight gain for a period of more than a year were selected for the trial. Baseline characteristics (menstrua! history, hirsutism scoring, acne grading/a body weight were assessed initially at first visit (0 day), and the end of third month after beginning the therapy. This was followed by general, systemic and pelvic examination Patients were advised lifestyle modifications like low calorie diet, exercise and stress reduction). Recruited patients were enrolled into the trial after diagnosing PCOS with ultrasound techniques and hormonal assays. Patients were called for follow-up at 30 days, 60 days and 90 days for general consultation and to know if experienced any adverse effect with the medicines 10 patients were simultaneously administered Metformin due to severe insulin resistance. Three group were thus formed in this clinical trial:

Group I : 10 patients who received Amree Plus Amycordial

Group II : 10 patients who received Metformin along with Amree Plus and Amycordial.

Group III : 4 patients who received placebo only.

Mode of Administration

Group I and II patients were advised to take 1 tsp of Amree Plus granules 1/2 hr before meals and 2 Amycordial Capsules or 2 tsp thrice a day for period of 3 months. Group II patients were to simultaneously take metformin in the recommended doses. Group III patients were to be take continuously irrespective of the menstruation.

Advice and Follow-up

The patients during their monthly follow up visits the evaluation of efficacy on the basis of menstruation were also advised to notify occurrence of any adverse event. The patients were asked to report earlier if they experienced disturbing side effects while taking the drug at any point of time during the study period.

Results

All the patients who were enrolled in the trial, completed it. The Table presents the initial symptoms of the patients and the no of patients in each group.

Symptom	Group I	Group II	Group III
Irregular menstruation	05	02	03
Anovulation	08	05	02
Infertility	09	10	02
Obesity	04	04	02
Hirsutism	04	01	02
Acne	02	02	02

The mean age of the patients enrolled was 26.5 years. The mean duration of the aforesaid symptoms was 3 years. Some of the patients had 2 symptoms while many had multiple gynaecological disorders.

10 women of Group I showed improvement in menstrual cycle, ovulation pattern and 3 of them conceived. Their acne improved and there was a decrease in BMI fasting insulin/glucose index.

Out of 10 patients of Group II, 4 patients conceived by the end of the trial duration. Others reported decrease in body weight, reduction in acne and improvement in their menstrual cycles. These patients had significant decrease in BMI.

Group III patients who were on placebo did not show positive results rather their symptoms deteriorated one patient reported in her menstrual rhythm.

Conclusion

The relation of PCOS with hyperinsulinaemia has revolutionzed the treatment modalities and the success rates have been higher with the use of Insulin Sensitisers. They also prove to be cheaper methods of treatment moreover this is not associated with the adverse effects.

Patients who followed the drug, dietary, and life-style modifications revealed more improvement as compared to those who did not, thus substantiating that weight reduction plays a significant role in restoration of ovulation in obese women with PCOS.

The present clinical trial has clearly established the role of Amree Plus and Amycordial in PCOS.

(The herbal preparations have proved effective in reducing the symptoms like irregular menstruation obesity, hirsutism and acne). The therapy improved the fertility rate, which is the major challenge with gyaecologists treating PCOS patients. Patients on placebo did not show any results, rather their symptoms worsened and immediately after treatment, they were advised to continue with Amree Plus, Amycordial and metformin.

None of the patients reported any adverse effect during the duration of the trial.

Hence it is concluded from this study that combined therapy of Amree Plus and Amycordial can be tried to be effective therapy in prompt restoration of ovarian functions and good alternative therapy in treating PCOS and in fertility related problems.

Let her enjoy *the feel of motherhood !*

by overcoming

PCOS

(Polycystic Ovarian Syndrome)

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CORDIAL FOR ENDOGENOUS & ENDOMETRIAL FUNCTIONS

2 capsules thrice a day for 10-16 weeks

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=

Multicentric clinical studies establishes

Improves fertility rate : 60% of the patients conceived with the therapy*

- Restores ovarian functions & hormonal level
- Increases the level of SHBG
- Significantly lowers insulin resistance

*STUDIES CONDUCTED AT MUMBAI BY :-
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Dr. Mrs. Sarita V. Pandya (M.F.A.M.)
Dr. Madhu Aggarwal (M.S.)

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