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PROSPECTIVE RANDOMIZED CONTROL CLINICAL STUDY OF *KANCHANARA GUGGULA* IN POLYCYSTIC OVARIAN SYNDROME IN UNMARRIED WOMEN

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ABSTRACT
The individual human being has its origin in *"Garbhashaya"* where *Shukra* and *Shonita Sanyoga* take place. Thus the role of women is very important in reproduction. The health of nation mainly depends on the health of the women because the healthy & happy women lay the first step of a prosperous nation. Any defect in physical or psychological factor directly affects her attitude and efficiency which adversely affects the family. Hence forth disease which causes physical or psychological concern to a woman should be immediately taken care of & so equally weighed in medical science. The clinical study has been done on 60 patients, selected randomly and divided in two groups. Group A i.e. trial group patients were treated with oral dose of *Kanchanara Guggula*. The Group B patients i.e. control group, were treated with Metformin. The clinical assessment was done on the basis of clinical presentation of PCOD, before and after the treatment. The findings of the study have been statistically analyzed with the help of *t-test* and the result of the study found significant.

KEYWORDS: *Ayurveda, Suprajanan, Kanchanar Guggula,* PCOD, *Antastravi Granthi.*

INTRODUCTION
Hormonal imbalance is a common problem now a day. Gradual changes in life style, poor diet, western habits and declining rate of physical exercise plays very vital role in many aspects of women's health. Mostly younger population is prone to disorder related to hormonal dysfunction. Hormones are very important for the metabolism of minerals, fluid regulation, sexual function and response to stress. Polycystic ovarian syndrome (PCOS) is mostly caused by hormonal imbalance and it is the major cause of infertility.[1]

PCOS is a disorder related to endocrine system of women from the reproductive age group and is characterized by the formation of single or multiple cysts in ovaries which in turn causes irregular menstrual cycle. Hormonal imbalance and genetics play important role in this disorder while excessive consumption of contraceptive pills also contributes to this disease.Generally androgen is a male hormone which is also found in female body in a very small quantity.[2]
Diagnosis of PCOS is by physical examination, past history, symptoms, menstrual history, blood examination, thyroid profile and confirmation is made by ultrasonography. The modern treatment approach involves use of hormonal therapy and surgical intervention. If it is detected in early stages then proper treatment reduces the risk of infertility, obesity, diabetes and heart attacks.[3]

In Ayurvedic point of view PCOS is mainly a disorder associated with *Kapha Dosha*. All three *Doshas* play a vital role in the production of menses in females. Main function of *Vata* is movement of follicle. Action of hormone is mainly due to *Pitta* and cool quality of *Kapha Dosha* is responsible for the proper nutrition of the follicle. In *Samhita* literature PCOS have a close resemblance with the sign and symptomology of the disease *Granthi*. *Vata* is vitiated due to specific *Nidana Sevena* gets aggravated and enters into *Garbharshaya* which ultimately leads to obstruction in the *Aartava Vaha Strotas.*[4, 5]

The treatment of PCOS in *Ayurveda* involves using a combination of powerful herbs that strengthen the reproductive system. *Kanchanar Guggula* is one of these

Ayurvedic formulations which may give good resultsin the conditions of cyst and fibroids. It also treats inflammation and hormonal imbalance that is the root cause of PCOS. It also offers beneficial effect in menstrual system and helps to balance aggravated *Dosha* and regulate *Aartava Dhatu*. Certain herbs also work against other complications of PCOS such as digestive disorders, weight gain, insulin sensitivity and improving mood. The immune boosting effect of *Kanchanar Guggula* offer *Prajasthapana*, *Garbhashyyadaurbalyahara* and *Ojovardhahana* effects. *Kanchanar Gugguala* possesses *Tikta*, *Kashaya* and *Katu Rasa*, *Katu Vipaka* and *Ushnaveerya* thus offer *Kaphahara*, *Lekhana*, *Chedana* and *Granthihara* properties which helps to reduce *Granthi.*[6, 7]

Keeping all these facts in mind, a clinical study was designed on the basis of *Sampraptivighatana Chikitsa* for polycystic syndrome - *Granthi*. *Kanchanar Guggula* having disease modifying potential and good safety profile thus evaluated for therapeutic benefits in such type of disease conditions.

MATERIALS AND METHODOLOGY[8-10]

DRUG

- ***Kanchanar Guggula* (Trial)**

Preparation *(Yogratnakar Galaganda Rogadhikar)*

Preparation of *Kanchanar guggulu* was carried out at institute research study centre under department of pharmacy.

Main ingredients

1.	Kanchanartvak	Bauhinia variega	10 pal
2.	Amalki	Emblicaofficinalis	2 pal
3.	Haritaki	Terminaliachebula	2 pal
4.	Bibhitaki	TerminaliaBellerica	2 pal
5.	Sunthi	Zingiberofficinale	1 pal
6.	Maricha	Piper nigrum	1 pal
7.	Pipali	Piper longum	1 pal
8.	Varunatvak	Crataevareligiosa	1 pal
9.	Tvak	Cinnamomumzeylanicum	1 karsh
10.	Ela	Elettariacardamomum	1 karsh
11.	Patra	Cinnamonumtamala	1karsh
12.	Guggul	Commiphoramukul	(equal part of above 1 to 11 drug)

Preparation of Trial drug

1. All the above all raw drugs were purchased from the local market
2. Their proper authentication and standardization from a GMP certified pharmacy.
3. All the drugs were taken in fine powder and *Vati* (Tablet) was prepared according to *Vati Kalpana* mentioned in *Sharangadhara Samhita*.
4. Each *Vati* weighs 500 mg.

2. Metformin (Control)

Metformin was the first insulin sensitizing drug to be used in PCOS to investigate the role of insulin resistance in pathogenesis of the syndrome. Some study reported that there is a significant improvement in the menstrual regularity and reduction in circulating androgen levels as well as significant reduction in body weight .Insulin sensitizing drug works in PCOS by reducing the insulin level. It is also effective in restoring ovulation, reducing weight, reducing circulating androgen level and reducing risk of gestational diabetes. It is also observed that metformin is useful in the ovarian stimulation regime in in vitro fertilization (IVF).

- **METHODOLOGY**

1. This is a prospective randomized controlled single blind clinical trial
2. 70 cases were selected according to the inclusion criterion with prior written consent.
3. These selected cases were grouped into two groups namely Trial group and Control group comprising 35 patients each.
4. Trial group cases were given Tab. KanchanarGuggul while control group cases were given tab.metformin.
5. The study done was for 3 months with a follow up of every 7 days.
6. The changes in the signs and symptoms were recorded in a separate cases paper format.

Table No. 1: Drug Intervention.

S. No.	Particulars	Trial Group –A	Control Group - B
1.	Drug	*Kanchanar Guggul*	Metformin (Glumet)
2.	Form	*Vati*	Tablet
3.	Dose	500 mg	500 mg
4.	Route	Per oral	Per oral
5.	*Anupan*	*Jala*	*Jala*
6.	*Kaal*	BD Before meals	BD Before meals
7.	Duration	3 Months	3 Months

Follow up – Every 7th Day for 3 Months.

- **Inclusion Criteria**

1. Patients having sign & symptoms of polycystic ovarian syndrome.
2. Patient having unilateral or bilateral PCOS.
3. Unmarried women.
4. The patients of age group between 14 -25 years.

- **Exclusion Criteria**

1. Anaemic patient having Hb< 8 gm %.
2. Malnourished patient (As per age, height & weight proportion.)
3. Bleeding disorders (Increased B.T & C.T)
4. Patients suffering from systemic diseases such as HIV, Tuberculosis, Diabetes mellitus, Abdominal tumor, Hepatitis-B, Malignancy, Deep vein thrombosis, Arterial ulcer, Neurogenic ulcer, Leprosy, Pregnancy, Acute & Chronic renal failure, septicaemia, Jaundice & cirrhosis of liver.

ANALYSIS OF RESULTS OBTAINED ON EACH PARAMETER

- **Irregular Menstrual Cycle**

For Trial group the mean score before treatment (BT) was 3.4 and after treatment (AT) it was 1.8. *p*- value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction of Irregularity of MC for trial group.

For Control group the mean score before treatment (BT) was 3.367 and after treatment (AT) it was 1.767. *p*- value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction of Irregularity of MC for control group.

Thus by comparing trial and control groups the mean score before treatment and after treatment was not significantly different (*p*–value = <0.0001). Thus both trial and control group can be considered as equally effective in reducing Irregularity of MC.

- **Acne**

For Trial group the mean score before treatment (BT) was 3.4 and after treatment (AT) it was 1.367. *p*- value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction of Acne for trial group. For Control group the mean score before treatment (BT) was 3.4 and after treatment (AT) it was 1.367. p- value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction of Acne for control group. Thus by comparing trial and control groups the mean score before treatment and after treatment was not significantly different (*p*–value = <0.0001). Thus both trial and control group can be considered as equally effective in reducing Acne.

- **Obesity**

For Trial group the mean score before treatment (BT) was 2.6 and after treatment (AT) it was 1.567. *p*- value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction in Obesity for trial group. For control group the mean score before treatment (BT) was 2.6 and after treatment (AT) it was 1.567. *p*-value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction of obesity for control group. Thus by comparing trial and control groups the mean score before treatment and after treatment was not significantly different (*p*–value = <0.0001). Thus both trial and control group can be considered as equally effective in reducing Obesity.

- **Pelvic Pain**

For Trial group the mean score before treatment (BT) was 7.8 and after treatment (AT) it was 3. *p*-value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction in Pelvic pain for trial group. For Control group the mean score before treatment (BT) was 7.867 and after treatment (AT) it was 3.033. *p*- value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction in pelvic pain for control group. Thus by comparing trial and control groups the mean score before treatment and after treatment was not significantly different (*p*–value = <0.0001). Thus both trial and control group can be considered as equally effective in reducing Pelvic pain.

- **Excessive Hair Growth**

For Trial group the mean score before treatment (BT) was 2.8 and after treatment (AT) it was 2.4. *p*-value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction in excessive hair growth for trial group.

For Control group the mean score before treatment (BT) was 2.8337 and after treatment (AT) it was 2.467. *p*-value is < 0.0001 i.e. the difference between the mean score before and after treatment is significant. So, it can be said that there is significant reduction in Excessive hair growth for control group.

Thus by comparing trial and control groups the mean score before treatment and after treatment was not significantly different (p–value = <0.0001). Thus both trial and control group can be considered as equally effective in reducing excessive hair growth.

The overall analysis concludes that, all 55.6% patients from trial and 55.7 % patients from control group got improvement in their condition at final follow. Thus, overall efficacy of trial group and control group is the same.

This is not a statistically significant result, but by looking on clinical grounds we can say that there is quite good and significant improvement in cases of trial group at the said parameters like.

***Irregular Menses*:** reduced from grade 4 i.e. no menses since 9 months or more to grade 2 i.e. Menses every 3-6 months.

***Acne over face*:** improved from grade 4 i.e. cysts, abscess & wide spread scarring to grade 2 i.e. papules, come done & few pustules.

***Obesity*:** improved from grade 3 i.e. BMI of 30-32.5kg / M^2 to grade 2 i.e. BMI of 27.6 – 29.9kg / M^2.

***Pelvic Pain*:** improved from grade 8 i.e. unbearable pain to grade 4 i.e. moderate pelvic pain.

Table 2: Result of Therapy.

Parameters	Result of Therapy (Relief in %)	
	Group-A	Group-B
Irregular MC	52.94 %	52.48 %
Acne	40.2 %	40.2 %
Obesity	60.26 %	60.26 %
Pelvic Pain	38.46 %	38.46 %
Excessive Hair growth	85.71 %	87.08 %

The overall analysis concludes that, all 55.6% patients from trial and 55.7 % patients from control group got improvement in their condition at final follow. Thus, overall efficacy of trial group and control group is the same.

CONCLUSION

Kanchnar Guggula significantly reduced irregularity of menstrual cycle; pelvic pain, obesity and acne over the face. *Kanchnar Guggula* did not showed satisfactory outcome in reducing excessive facial hair growth. Further study is needed with larger sample size to establish more authenticity of efficacy of *Kanchnar Guggula* for the management of PCOS.

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