



“A comparative study of *Vamana- Virechana Karma* and *Kanchnar Guggulu* in management of Polycystic Ovarian Syndrome”

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Abstract

Background: Polycystic ovarian syndrome (PCOS) is an endocrinological disease of women in reproductive age. It's seen in women seeking medical help for irregular menstrual cycles in addition to infertility. It affects women of all age group from early adolescence, reproductive aged women and also perimenopausal and post-menopausal women. In Ayurvedic literature Acharya Charaka described under the *Vinshati yoni vyapad*, Acharya Sushruta as *nashtartava*, Acharya Kashyapa as *Pushpaghni jataharini* having symptoms like PCOS.

Aim and Objectives: To study the comparative effect of *Vamana-Virechana Karma* and *Kanchnar Guggulu* in the management of Polycystic Ovarian Syndrome.

Methodology: We will plan that 60 patients will be divided randomly into two groups (30 in each). Group A- *Vamana-Virechana karma* will be done for 33days and Group B- *Kanchnar Guggulu* 2gm in divided dose will be administered orally for 33 days after food.

Results: Changes will be observed in subjective and objective parameters.

Conclusion: *Vamana-Virechana karma* and *Kanchnar guggulu* will reduce the symptoms of PCOS, the follicle no. per ovary, weight, BMI and it regularize menstrual cycle and LH:FSH (1:2)ratio.

Keywords: *Vamana-Virechana karma*, *Kanchnar Guggulu*, PCOS, *Bauhinia variegata*.

Introduction:

Polycystic ovarian syndrome is a most common endocrinopathy. Polycystic ovarian syndrome (PCOS) was first identified in 1935 by Stein and Leventhal as a disease characterized by amenorrhea, hirsutism and obesity associated with enlarged polycystic ovaries [1]. Because of sedentary lifestyles, excessive consumption of junk food and pollution, the incidence of this disease is continue raising. It is most common among women seeking medical help for infertility or irregular menstrual bleeding, majority of these cases can be managed with

hormones, medications or surgery. The focus of this research will emphasize on careful management of polycystic ovarian syndrome. Polycystic ovarian syndrome is a hormonal imbalance that inhibits follicular growth during the ovarian cycle causing the affected follicles to remain in the ovary.

With each ovarian cycle, the retained follicle transforms into a cyst. During a quiescent phase of ovary, a new cyst forms, resulting in multiple ovarian cyst ultrasonic morphologic evidence of >12 follicles measuring 2.9mm diameter in single plane, which is related with obesity, anovulation, oligomenorrhoea, hyperandrogenism & hyperinsulinemia (increased level of insulin in the blood is due to sensitivity of cells to insulin). A substance in the blood promotes androgen secretion by the ovarian stroma, the connective tissue of ovary, and lower serum sex hormone binding globin (SHBG) resulting in rise in free testosterone level. The follicle undergo maturation in the ovarian cycle is altered due to high androgen in the ovary, resulting in anovulation of particular follicle. The ovarian cycle is controlled by a hormonal feedback loop that is managed by the brain. To correctly regulate the release of follicle stimulating hormone (FSH), luteinizing hormone (LH) from the anterior pituitary gland, it requires regular hormonal feedback. The hypothalamus is receiving hormonal feedback as a result of excessive levels of oestrogen produced from free androgens in the peripheral tissue. [2]

Polycystic ovarian syndrome (PCOS) is an endocrinological disease of women in reproductive age. Its prevalence is around 2.2-26 % worldwide. In India, prevalence of PCOS range from 9.13 % to 36 % in women of reproductive age. It affects women of all age group from early adolescence (Acne, hirsutism, menstrual irregularities and secondary amenorrhea), reproductive aged women (anovulatory infertility, recurrent pregnancy loss, glucose intolerance and menstrual irregularities) and also perimenopausal and post-menopausal women (cardio-vascular risk, diabetes mellitus, endometrial carcinoma, metabolic syndrome) .[3] WHO estimated that there are one out of forty newly reported cases of PCOS worldwide. Incidence of clinical features: oligomenorrhea (87%), hirsutism (80%), amenorrhea (26%), infertility (20%), obesity (50%), acne (30%), acanthosis-nigricans (5%).

PCOS can lead to infertility, gestational diabetes or pregnancy-induced high blood pressure, miscarriage or premature birth, nonalcoholic steatohepatitis—a severe liver inflammation caused by fat accumulation in the liver—and metabolic syndrome—a group of conditions characterized by high blood pressure, high blood sugar, and abnormal cholesterol or triglyceride levels that significantly increase the risk of heart disease and stroke, diabetes type 2 or prediabetes, sleep apnea, depression, anxiety, and eating disorders, abnormal uterine haemorrhagia, uterine lining cancer (endometrial cancer).

There is no definite test to diagnose PCOS. Your doctor will most likely begin by going over your medical history, including your menstrual periods and weight fluctuations. A physical examination will entail screening for sign of increased hair growth, insulin resistance and acne. Your doctor can then propose; Pelvic examination -Doctor visually and manually inspect reproductive organ for lumps, growths or other abnormalities. Blood test: Hormone levels can be measured by analysing blood. Additional blood tests may be performed to assess your glucose tolerance as well as your fasting cholesterol and triglyceride levels. Ultrasound: A transducer is implanted in the vaginal canal to assess the appearance of the ovaries and the thickness of the uterine lining (transvaginal ultrasound). Sound waves are emitted by the transducer, which are translated into visuals on a

computer screen. Additional tests to rule out issues include depression and anxiety screenings, as well as screening for obstructive sleep apnea.

Though another *Dosha* may be present, Ayurveda believes that this is a Vata type ailment (*Apan Vayu*), in part because the gynaecological condition is mostly due to vitiation of *Vata*, *Pitta*, *Kapha*, *Medas*, *Ambhuvahasrotas*, and *Artava Dhatu* are all involved in PCOS. According to Ayurveda, the causes of PCOS are excessive sweet and *kaphagenic* foods, mandagni, which causes *kapha* to become aggravated in PCOS, resulting in *kapha* disease, as well as *vata* and *pitta dosha* imbalances. Because all three *doshas* play a significant and different part in the formation, development, maturation, and release of the ovum, the ovarian cycle and menstrual cycle are under their control. The experimental medication was chosen based on the *dosha dushya dushti* and the hypothesized *samprapti*. In Ayurvedic classics there is no any definite cause, etiology, symptomatology and line of treatment mentioned for PCOS. However under the *Vinshati yoni vyapad* (Ch. Chi 30/45), some gynaecological disorders are mentioned which explain about infertility. [4] On review of Ayurvedic literature, the following conditions were found which point toward the symptomatology and complication of PCOS. ***Pushpaghni jataharini*** (*Ka. Rewati kalpa* 33 pages, 192)- having clinical features of futile ovulation (*vrutha pushpa*) and corpulent hairy cheek (*sthula lomasha ganda*).[5] ***Nashtartava*** (*Su Sha.* 2/23)- caused due to vitiation of *vata* and *kapha dosha* as they do *margavarodha to artava vaha srotas* leading to absence of flow of *artava*.[6] It can be understood as the *sannipataja dosha* manifestation with *samprapti* of *rasa dusti*, *medadusti*, *aavarna* of *vata* and *aartava dusti* with *beejopaghata* as factor.

Aim and objective:

Aim:To Compare the effect of Vamana-Virechana karma and Kanchnar guggulu in PCOS.

Objective-

- 1.) To compare the therapeutic effect of Vamana-Virechana karma (Shodhana chikitsa) and Kanchnar Guggulu (Shamana chikitsa) in PCOS.
- 2.) Changes in PCOS features (i.e. acne, hirsutism) and investigative procedure.

Case Definition

A diagnosed case of PCOS with clinical symptoms of menstrual irregularities, weight gain, acne, hirsutism, increase in follicle no. per ovary in USG.

Diagnostic Criteria of PCOS:

ASRM / ESHRM (Rotterdam) criteria [7]-

Two out of three requirements must be followed by the affected patient

- Polycystic ovaries (confirmed or USG)
- Hyperandrogenism (clinical / biochemical)
- Oligo and/or anovulation

Research Questions:

Whether the *Vamana-Virechana karma* is as effective as *Kanchnar guggulu* to reduce the symptoms of PCOS?

Hypothesis:**Null Hypothesis [H₀] -**

There is no difference in efficacy of *Vamana-Virechana Karma (Shodhana chikitsa)* and *Kanchnar Guggulu (Shamana chikitsa)* yoga in treating PCOS.

Alternate Hypothesis

[H₁] - *Vamana- Virechana (Shodhana chikitsa)* is more efficient than *Kanchnar Guggulu (Shamana chikitsa)* in treating PCOS.

[H₂] – *Kanchnar Guggulu (Shamana chikitsa)* is more effective than *Vamana-Virechana (Shodhana chikitsa)*.

Study Type

Interventional

Trial Design

Randomized Open Interventional Comparative Clinical Trial.

Sample Selection Technique

Simple Randomization by lottery method.

Methodology**Study Setting**

The study will be conducted in SKGAC & H, Kurukshetra.

GROUP-1 Vamana:

Name	Botanical Name	Part Used
<i>Madanphala</i> ^[8]	<i>Randia dumetorum</i>	Fruit seed powder

Virechana:

Name	Botanical Name	Part Used
<i>Trivrit</i> ^[9]	<i>Operculina turpethum</i>	Root

GROUP-2

Kanchnar Guggulu 2gm in divided dose with luke-warm water ½ hour after meal.

Inclusion criteria-

- Patient willing to give voluntary informed consent.
- Female patient of age group between 18-40 years (both married and unmarried).

ASRM / ESHRM (Rotterdam) criteria-

Two out of three criteria must be followed by affected patient

- Polycystic ovaries (confirmed or USG)
- Hyperandrogenism (clinical / biochemical)
- Oligo and/or anovulation

Exclusion Criteria-

- Patient who is not willing to give voluntary informed consent.
- Women of age < 18 years and > 40 years.

- Patient with chronic systemic illness (cardiac failure, cirrhosis of liver, hypertension, diabetes mellitus, tuberculosis, chronic renal disease).
- Patient with reproductive system abnormalities (excluded clinically and radiologically, hydrosalpinx, endometriosis, adenomyosis, carcinoma of reproductive organ)
- Long term medication.
- Any type of malignancy.
- Patient with positive STDs, HIV, Hepatitis B antigen (HBsAg).
- Patient suffering from adrenal hyperplasia, severe insulin resistant androgen secreting neoplasm, thyroid abnormalities, cushing syndrome.

Interventions of the groups:

Grouping	Group A	Group B
Sample size	30	30
Intervention	Vamana-virechana	Kanchnar guggulu
Duration	33 days	33 days
Follow up	3 months	3 months

Criteria for Discontinuing or Modifying

Allocated Intervention

Patient will withdrawal from the study if there will be any adverse effect was occurs and then he or she will be treated from the same in free of cost till becomes alright. **Follow up:** 3 months **Primary Outcome:**

We will see the effect of *Vamana-Virechana Karma* and *Kanchnar Guggulu* in treating menstrual irregularities.

Secondary Outcome:

We will see the effect of *Vamana-Virechana Karma* and *Kanchnar Guggulu* to reduce the symptoms of PCOS, the follicle no. per ovary, weight, BMI and to regularize menstrual cycle and LH: FSH (1:2) ratio.

Discussion

PCOS occurs due to the vitiation of *vata* and *kapha* dosha as they do *margavarodha* to *artava vaha srotas* leading to absence of flow of artava. It can be understood as the *sannipataja dosha* manifestation with *samprapti* of *rasa dusti*, *medodusti*, *aavarna* of *vata* and *aartava dusti* with *beejopaghata* as factor. After *shamana chikitsa* *dosha* may be aggravate again but in *shodhana chikitsa* all *dosha* are eliminated by root so they can never be reoccurred [10]. *Shodhana* eliminates body toxins and normalize the endocrine function by its purifying action (bio-cleansing property).

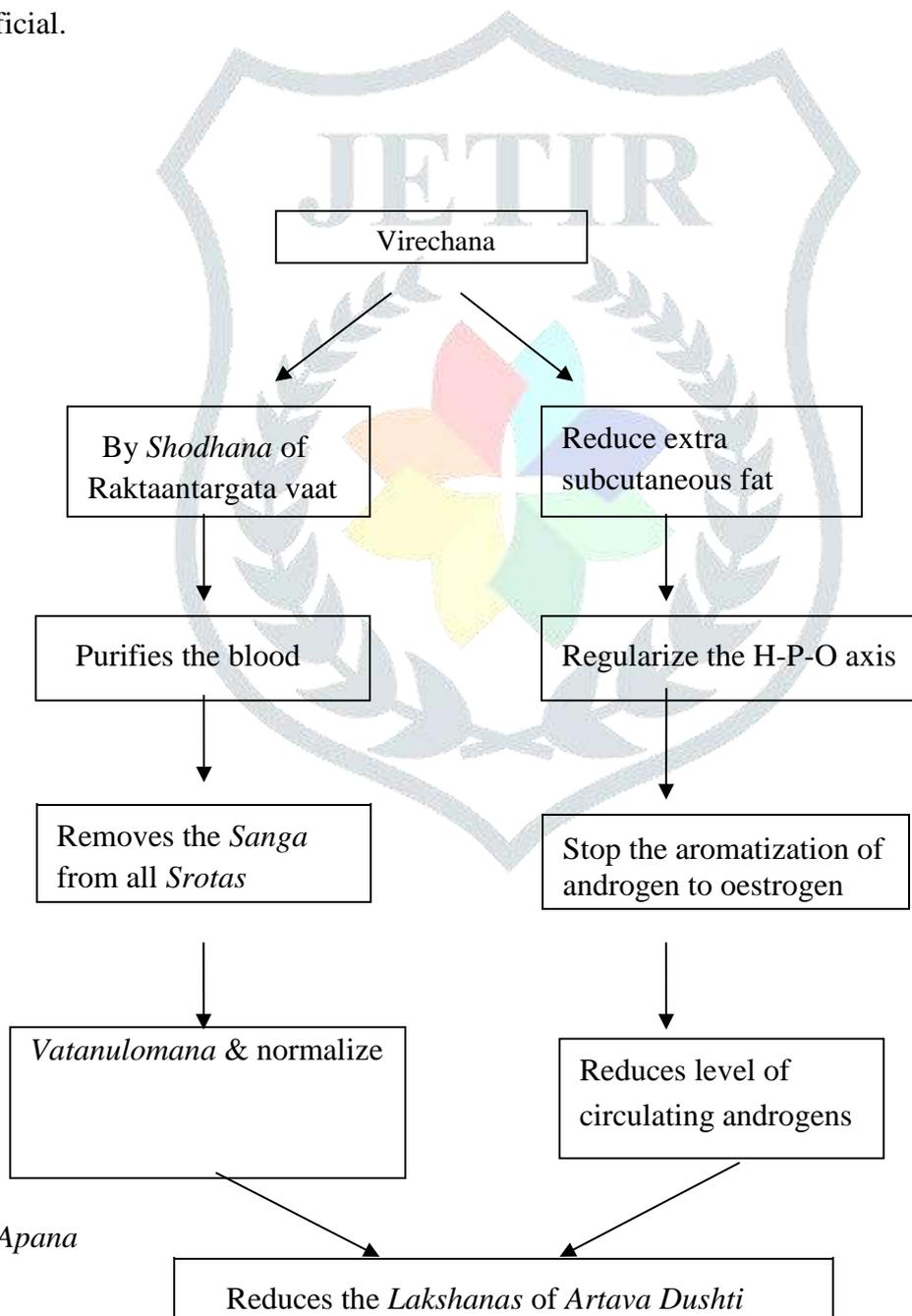
Vamana Karma

Vamana is the best therapy for the elimination of Kapha Dosha [11]. According to Ayurveda, PCOS may be considered as *Agni Vaishamyajanya Vikara* (disease caused due to vitiation of metabolism) in general and *Rasagni* (metabolism at Rasa Dhatu level) and *Medodhatvagni* (metabolism at *Meda Dhatu* level) *Mandya*, as

far as Dosha is concerned it is *Kapha-Vataja* disorder. As PCOS is metabolic disorder, Vamana helps to increase metabolism of body, thereby reducing weight and specifically act on liver metabolism which is the main site of hormone formation.

Virechana Karma:

For elimination of *pitta dosha virechana* is best therapy [12]. It also has *rakta prasadhana* karma. *Shodhana* normalize *agni*, pacifies vitiated *vata kapha* dosha and clean obstruction of *srotas*. The only way is to address the problem at its root by *Srotoshodhana*, *Agnideepana* and *Vatanulomana* are the main principles to be achieved. PCOS belongs to *Santarpannottha* condition for which *Doshavsechana* is indicated. *Samshodhana* therapy is the best for the *Prakupita Dosha Nirharana* and correction of *Agni*. To remove obstruction of *Kapha* and regularize the normal function of *Vata* both *Urdhva* and *Adhobhagadosaharana* by *Vamana & Virechana* can prove beneficial.



the function of *Apana*

Vata,

Artava & Artavavaha Srotas

Kanchnar Guggulu was selected because it is prescribed in management of *gandmala, apachi, arbuda, granthi* by *Yogratnakar* [13]. *Kanchnar Guggulu* corrects the pathophysiology of PCOS with pachan, lekhana and dipana actions. *Kanchnar Guggulu* has katu - madhura rasa, usna virya and katu vipaka and help in mamsa and medo dhatu lekhana and thus helps in reducing the size and arrests further growth of multiple cysts in ovaries.

Diet and Life style

- Keep away from food items with high saturated fat content
- Drink plenty of fluids of water and avoiding sleeping after lunch or during day time
- Use of natural salt like *Saindhaiva*
- *Vyayam* – exercises the most important part of the treatment due to which medicinal treatment is much more helpful than singly done.
- *Yoga and Pranayam* – *Kapalbhati, Bhastrika, Bhramari, Anulom – vilom Simhasan, vajrasan, Shalbhasan Bhujangasan.*

Statistical Analysis-

The observations and result will be analysed and presented on the basis of respective and applicable statistical paired T-tests. **Time Duration till Follow up**

Total treatment duration will be 33 days after treatment follow up will be of 3 months. In both groups initially 33 days of treatment and follow up period after 3 months.

Follow up Period

3 months

Time Schedule of Enrolment, Interventions

Vamana-Virechana karma should be done in one group and *Kanchnar guggulu* 2gm in divided dose will be given to other group after CTRI registration. From 0 days to 33 days .

Recruitment

30(in each group, Group A and Group B) will be recruited randomizing sampling method. Total 60 Subjects (30 subjects in each group)

Group A

30 subjects will be given an established procedure of *Vamana-Virechana* karma continuous in sequence of *poorav, pardhan & paschat karma* for 33 days.[14] **Group B**

30 subjects will be given *Kanchnar Guggulu* 2gm in divided dose for 33 days.

Methods

At first we will search literature review, then frame plan of work, medicine collection, authentication of raw drugs, medicine preparation of both *Madanphala & Trivrit yog. Kanchnar Guggulu* recruitment of patients, data collection, adverse effects observe if any and analysis.

Data Collections Method

Randomized sampling

Subjective Parameters a) Acne

- b) Hirsutism
 - c) Menstrual irregularities
 - d) Anovulatory infertility
 - e) Glucose intolerance
 - f) Recurrent pregnancy loss
- Objective Parameters**

- i)USG- uterus and adnexa
- ii) Hormonal test- FSH, LH, TSH, serum prolactin

Investigations

The patients who will be fulfilled the inclusion criteria will be subjected for hematological investigations and will advise USG- uterus and adnexa and hormonal test- FSH, LH, TSH, serum prolactin before initiation of treatment an informed consent will be taken from the patient and his relatives and after that patient will be evaluated for the both subjective and objective parameters and grading will be noted according to the case Performa

Data Management

Data coding will be done by Principle investigators.

Statistical Methods

Paired t- test and unpaired for objectives parameters, non- parametric and Chi square test for subjective parameters.

Ethics and Dissemination

Research ethical approval, after critical evaluation and presentation the ethical committee has taken the research topic.

Consent or Assent

Subjects will be given detail information regarding their treatment in their own language. Then written consent will be taken from patients before starting the study.

Dissemination Policy

Will be in the form of paper publication, presentation and Monograph.

Strengths

If proposed study will result in the positive outcome then it will be established new mode of management for the PCOS. In society, we will be provided economical and effective for menstrual irregularities.

Limitations

Will be convincing the patients for *Vamana-Virechana* and for hospitalization.

Conclusion

Conclusion will be mentioned after the analyzing data.

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