OPEN LABEL, SINGLE CENTRE, PROSPECTIVESTUDY TO ASSESS THE EFFICACY OF *RAJAHPRAVARTINI VATI* IN THE TREATMENT OF PCOS

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ABSTRACT

Initially PCOS was related to infertility only but now it starts with puberty & ends with menopause. The most debilitating underlying disorder which causes Menstrual irregularities, acne, obesity is PCOS, which is not only a reproductive endocrinopathy, but also a metabolic syndrome. As per Ayurveda it is a disease caused by *artavavahastrotas dushti* may be correlated with *udara*, *vidradhi* etc. There are number of formulation which can be used in the symptoms of PCOS. Modern prescriptions for Delayed Menstruation are temporary in effect. Thus there is a need for an effective long lasting medicine. *"Rajahpravartini* is the prescribed *vati"* formulation for Menstrual Disorders. Thus, the present study is planned for 30 patients to study action of *"Rajahpravartinivati* on treatment of PCOS with special reference to Ovulation study. Observation of study shows total three month treatment gives satisfactory result.

Keywords: *Rajahpravartini,* PCOS

INTRODUCTION

Diseases pertaining to the reproductive system of the women are becoming increasingly common because of modern ways of lifestyle. Modern women are forced to face higher level of stress as they are not only home makers, but are also working women. First and foremost to show systemic abnormal functioning under increased stress is Endocrine system, which in turn effects the menstrual cycle. Thus menstrual abnormalities are becoming increasingly common among working women.

Polycystic ovarian syndrome[1] (PCOS) is a heterogeneous disorder characterized by menstrual irregularities, clinical and / or biochemical hyperandrogenism and hyperinsulinemia

secondary to reduced insulin sensitivity[8] and is the most common endocrinopathy in women, affecting 5–10%

PCOS can be study as **anukta vyadhi**.
PCOS has been defined by number of groups. The first was by the National Institute of Health (NIH) ON APRIL 1990 ,Which laid down three criteria i) hyper androgenesism, or hyper androgenemia ii) oligo ovulation & iii)exclusion of other known disorder.
According to Ayurveda *AcharyaSushruta*[2] has described *vandhya* (suut 38/10) a type of *yonivyapada* whose symptom is amenorrhea or oligomenorrhea. Similaraly, *Acharya Charaka*[3] has mentioned *Arajask ayonivyapada* indicating amenorrhea. As per Ayurveda *artavakshaya* involves *vata pitta kapha dushti*, *rasaraktamedashukra dhatu dushti* & *artavvahsrotasa*.
Kapha predominance manifests as increased weight, sub-fertility, hirsutism, diabetic tendencies. *Pitta* predominance manifest as hair loss, acne, painful menses. *Vata* predominance causes dysmenorrheal, scanty menses, irregular menses.

Etiopathogenesis - according to ayurveda *Kashyapa* mentioned *pushpaghni* & *revati* having some resemblance with symptoms of PCOS in *revati kalpa adhaya*[3]. The term *jatiharini* is responsible for female infertility; this concept of *jatiharini* is explained in kalpa sthan of *kashyap samhita*.
In *Charak Chikitsa* 30/7/8 due to improper diet &life style disturb the ovulatary function.

AIM:
1. To assess the effect of *Rajahpravartini Vati* in the treatment of patients having PCOS.

2. To determine the effect of *Rajahpravartini Vati* on Ovulation process in patients having PCOS with the help of USG for Follicular study.

OBJECTIVE:
1. To assess the effect of *RajahpravartiniVati* in minimizing the symptoms in patients of PCOS.

Materials and methods:
Source of Data:
a) Source of drug - Genuine raw materials will be collected from authentic sources.
b) Place of work
❖ Preparation of the test drug done in Department of *Bhaishjya Kalpana*, Shree Saptashrungi Ayurved Mahavidyalaya and Hospital, Kamal Nagar, Hirawadi, Nashik
❖ Experimental study conducted in Shree Saptashrungi Ayurved Mahavidyalaya and Hospital, Kamal Nagar, Hirawadi, Nashik

INCLUSION CRITERIA:
❖ Patient willing to give voluntarily free written informed consent.
❖ Female patient having age group between 18 yrs to 35 yrs.
❖ Patient diagnosed with known case of PCOS.
❖ Patient having anovulatory cycle diagnosed by USG
❖ Patient having Dysmenorrhoea.

EXCLUSION CRITERIA:

❖ Hypersensitivity or idiosyncratic reaction to any drugs or herbal products.
❖ Congenital deformities of reproductive system
❖ History of allergic conditions
❖ History of autoimmune disorders e.g. systemic lupus erythematosus, Haemolytic anemia, RA
❖ History of psychiatric disorders.
❖ Intake of any medication within 14 days before start of the study
❖ Subjects who are scheduled to undergo hospitalization for surgery during the study period.
❖ Presence of clinically significant abnormal laboratory results during screening.

❖ Pregnancy or breastfeeding
❖ Females of childbearing age potential not using medically accepted contraceptive measures, as judged by the investigator.
❖ Use of any recreational drugs or a history of drug addiction.
❖ Participation in a clinical study of any investigational product 1 month prior to visit 1 or during the study.

Material & Methods
Material –

Tankanamhingumkasisamkanyasaramsamansaam| Kumariswarasenevchanakpramitavati||
Rajorodhamkashtarajavedanashatadudbhava
|Rajapravartinivatitrunamvinshyet ||
Bhai. Rat.57/58[4]

Table No. 1-[5& 6]

Contain	Latin name	*rasa*	*Vipak*	*Virya*	Action
Tankan	Borax	-	-	-	*Lekhan, chedanStrotoshodhankaphaghan*
Hingu	Ferula narthex	*Katu*	*Katu*	*Ushana*	*Vedanasthapak, anulaman Vatakaphashamak*
Kasis	Ferrous sulphate	*Amlatiktakashaya*	-	*Ushana*	*Raktavardhak, raja pravartak*
Kanyasara	Aloe veratourex	*Katu,tikta*	*Katu*	*Shita*	*Garbhashayashodhak Artavjanan*

Preparation of *"Rajahpravartinivati"*.
ShuddhaHingu, ShuddhaKaseesa, Shuddha-Tankana and Kanyasara is to be taken in equal quantity. All the ingredients are processed in *Kumariswarasa* (*Aloe vera* Linn) for 3 days and 3 *ratti* (375mg) weighing *vati* will be prepared.

STUDY DURATION:

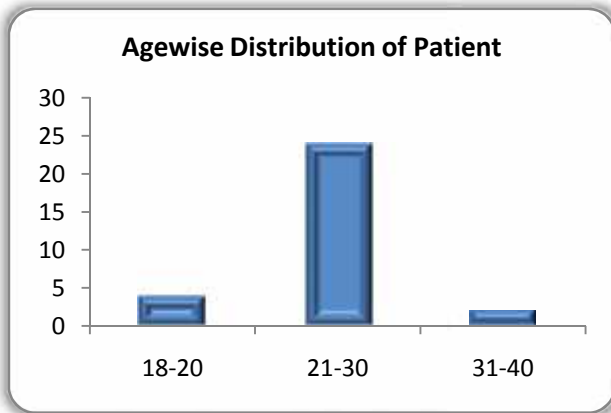This is 18 months study, in which patients will be studied for 15 months & 3 months for data analysis.

First 15 months –SSAM, Nasik for clinical assessment & follow-up will be taken of each patient. Data Analysis –In next 3 months data collection & analysis will be done.

➢ **Scoring Pattern of Follicles :-**[6]
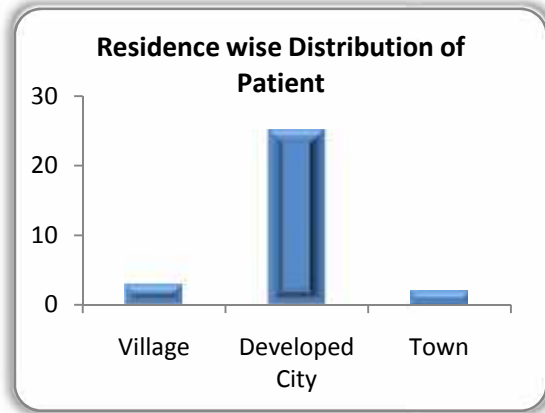
0 - < 12 mm
1 - 12 – 20 mm
2 - > 20mm
3 - Ovulated.

Observations

Table No: 2

Agewise Distribution of Patient

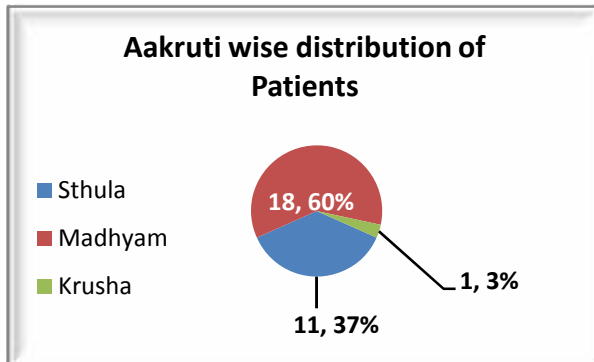**Table No: 3:**

Residence wise Distribution of Patient

Age wise distribution of 30 pt. shows maximum prevalence of PCOS in **Age group:** 21-30 As PCOS is having predominance in adolescence & pubertal age.
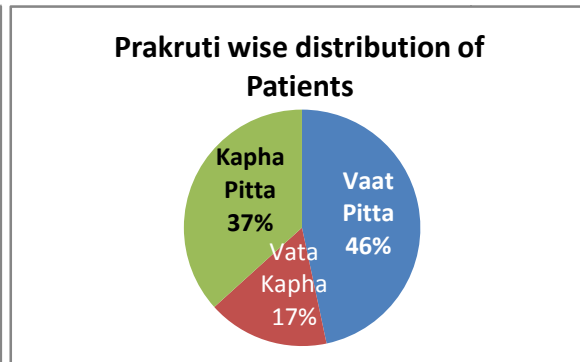
Residence wise distribution shows PCOS is common in city, as PCOS has relation to lifestyle changes.
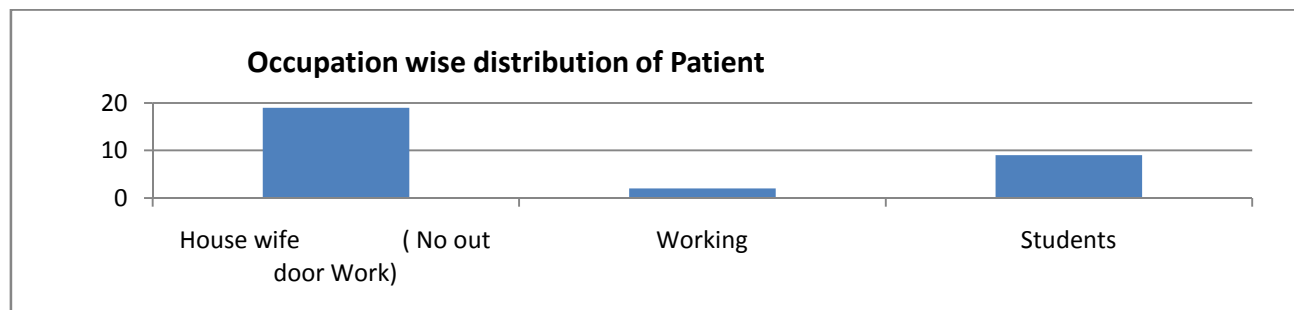
Table No: 4

Aakruti wise distribution of Patients

- Sthula
- Madhyam
- Krusha

18, 60%
1, 3%
11, 37%

Table No: 5

Prakruti wise distribution of Patients

Kapha Pitta 37%
Vaat Pitta 46%
Vata Kapha 17%

Akruti wise distribution shows that out of 30 pt. 17 pt. *madhyamakriti* & 12 pt. are of *sthula*. *dehaprakruti* wise distribution shows dominance of PCOS in *vatapittaprakruti* followed by *pitta kaph prakruti*.

Table No: 6

Occupation wise distribution of Patient

Occupation &working history os 30 pt. shows sedentary lifestyle is having symptoms of PCOS.

Results of Difference between LMP:

Table No: 7

	Difference between LMP 1 & 2	Difference between LMP 2 & 3 treatment
Mean	43.66	47.166
Standard Deviation	16.416	30.131
Standard Error	2.997	5.501
P value	>0.1	>0.1

The two tailed P value is 0.5785 i.e. Not significant t = with 58 degree of freedom
Insignificant result of difference between LMP shows regular ovulation, which manifest significant result in amenorrhea which is cardinal symptom of PCOS.

Ovulation Results:
Trans-abdominal ultra sound is completely reliable in assessing the size and number of follicles for the prediction of pre ovulatory events however, trans-vaginal scanning with its superior evaluation is useful, so it is done for the evaluation of Ovary. For ovulation USG follicle study was done for 3 months of each patients and ovulation is observed.

Table No: 8

	Once Ovulation	Twice Ovulation	Thrice Ovulation	Other result- Hemorrhagic cyst	Un-ovulation
Number of patients	5	9	5	1	9
Out of	90	90	90	90	90
%	5.555555556	10	5.555555556	1.111111	10

Table No: 9

	First time Ovulation	Second timeOvulation	Third time Ovulation	Other result- Hemorrhagic cyst	Un-ovulation
No of pt.	10	12	18	1	9
Out of	30	30	30	30	30
%	33.333333	40	60	3.333333	30

It Suggest that Patient need to continue treatment for at least three months for regular ovulations.

Repeated Measures Analysis of Variance

The P value is 0.0116, considered significant. Variation among column means is significantly greater than expected by chance.

ANNOVA Comparisons Test for Follicle Size every month total duration three month

If the value of q is greater than 3.408 then the P value is less than 0.05.

Mean

Comparison Difference P value

Column A vs Column B-0.37932.199nsP>0.05

Column A vs Column C-0.75864.398**P<0.01

Column B vs Column C-0.37932.199nsP>0.05

Mean95% Confidence Interval

Difference From To

Column A - Column B-0.3793 -0.96710.2085

Column A - Column C-0.7586-1.346 -0.1708

Column B - Column C-0.3793 -0.96710.2085

Intermediate calculations. ANOVA Table:

Source of Degrees of Sum of Mean

Variation freedom squares square

Treatment (between columns) 28.3454.172

Individual (between rows) 2887.2643.117

Random (residual) 5648.3220.8629

Total 86143.93

F = 4.835=Menstrual Treatment

Assumption test: Was the matching effective?

This test uses a second value of F and a different P value.

F = 3.612= (Menstrual Treatment)

The P value is < 0.0001, considered extremely significant. Effective matching (or blocking) results in significant variation among means. With these data, the matching appears to be effective.

DISCUSSION

1. The function of Reproduction is the noblest and should be the most reverent of all human power. God has given his Magnanimous gift only to the woman therefore he made Mother. Woman is considered as one of the greatest human race.

Women health care is not at all a new concept in the field of Ayurveda.

The subject has been emphasized since the problem related to *ArtavaVikaras* is of much importance. Menstrual disorder is the common gynecological compliant. Ratio of Menstrual disorder (20-30%) is rising as a precursor of infertility. In Ayurvedic context as far as the ailment 'Alpartava' is concerned it is not coded as an individual disease. But there are many diseases, in which it is described as a symptom. Hence it should be included as *anukta vyadhi.*

2. *Rajahpravartinivati* is one of the best formulations utilized in the treatment of menstrual disorder.

Main ingredient of *rajhapravartini vati are hingu, kasis, tankan & kanyasar i.e. kumari. Hingu* act as *vatanulomak, vedanshamak* which may give relief in dysmenorea. *Kasis* is having property of *raktavardhak & atravja-*

nan. *Tankan* is of alkaline in nature which is having *lekhan*, *strotovishodhan* property, which may give result in amenorrhea, ovarian cyst & increased ovarian volume.

Aloevera (*kanyasara*) is also having stimulant activity on uterus.

3. This study point out that sedentary work, irregular diet habits, absence of exercise shows more prevalence of PCOS.

4. 21-30 Yrs. age group, patients in developed city are more prone to PCOS.

5. Statistically insignificant result of T-test in difference between LMP shows regular ovulation.

6. ANOVA comparison test for follicle size and ovulation suggest significantly greater than expected by at chance as P value is 0.0116.

Table No: 10
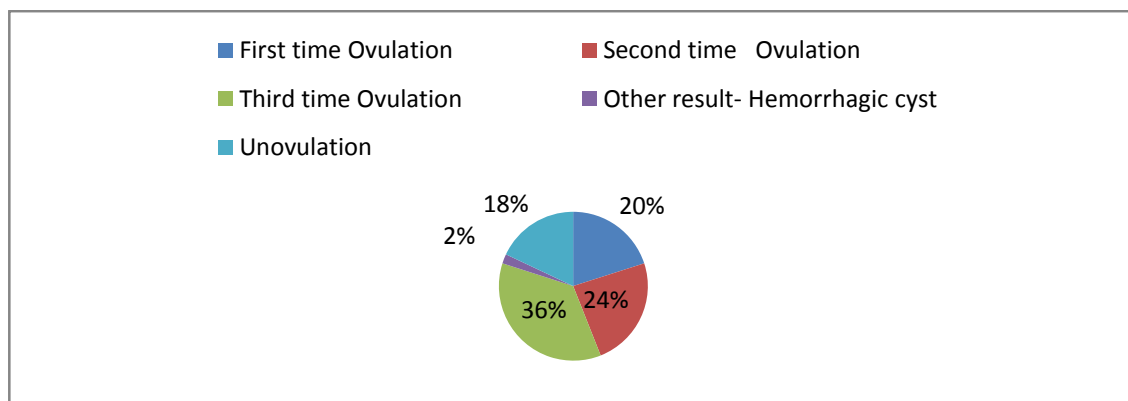
This research study obser*vatio*n shows significant result in ovulation by ultrasound study. Also decreased interval between menstrual cycles shows regularity in menstruation.

RESULT-

Open label, Single centre, Prospective study of *Rajahpravartini Vati* in the treatment of PCOS shows significant result in the ovulation by ANNOVA TEST. The statistical test suggests that overall result of treatment are satisfactory, ovulation study by USG suggest three month treatment duration is needed for regulation of menstrual cycle.

CONCLUSION

Obser*vatio*n of study shows total three month treatment gives satisfactory result.

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Details of Table:

Sr. No.	Details
1	*Rajahpravartinivati* contains & Property
2	Age wise distribution of 30 patients
3	Residence wise distribution of 30 patients
4	Akruti wise distribution of 30 patients
5	Prakruti wise distribution of 30 patients
6	Occupation wise distribution of 30 patients
7	Results of Difference between LMP
8	Ovulation Result (a)
9	Ovulation Result (b)
10	Pie Diagram of Ovulation

Source of Support: Nil
Conflict Of Interest: None Declared