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Efficacy Of Kumari Asav On Anovulatory Cycle In Subjects Of Polcystic Ovarian Disease

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Abstract:

Background: Anovultionand menstrual abnormality is the most common sign in Polycystic ovarian disease affecting most of the women of fertile age and the leading cause of infertility in modern age due to changing life style. In Ayurveda it is interpreted as nashtarthava. Poly cystic ovarian disease is a condition where avarana is observed i.e. avarana of kaphadosha on vatadosha. Similar samprapti of avarana is observed in Udararoga. So, this formulation is selected for study. It is diagnosed by presence of more than 12 follicles by USG, increase in ovarian volume, irregular menses, hyperandroidism, hyperinsulinemia etc. The treatment given for Polycystic ovarian disease is symptomatic and there are chances of reoccurrence of it, if the treatment is discontinued. In modern science, the treatment includes oral contraceptives, hypoglycemic agents and surgical drilling of ovarian cyst. As, polycystic ovarian disease has the same disease process i.e. samprapti as of in Udarroga, Kumariasav which is effective in udarroga is used in polycystic ovarian disease to reduce the kaphaavarana by studying the pathophysiology and doshadhatu mala siddhanta. Poly cystic ovarian disease leads to many life threatening complications if not diagnosed and treated early.

Methodology: This study is a open clinical labelled study. It includes thirty subjects from OPD of BharatiAyurved Hospital Pune.

Duration: Subjects were given 30 ml Kumariasav twice a day with equal quantity of warm water for three months. Follow up taken after every 15 days for 3 months.

Results: The results were compared before treatment and after treatment and conclusions were drawn from the collected data from the statistical analysis.

Conclusion: 1. Decrease in follicular size and ovarian volume were seen. As per assessment parameter 't' value showed significant result on signs and symptoms of PCOD and decrease in follicle size and ovarian volume. So treatment showed better result on signs and symptoms of PCOD and decrease follicle size and decrease in ovarian volume.

2. No adverse effects or hypersensitivity was clinically noticed during the study.

Keywords: Ayurvedic medicine, polycystic ovarian disease.

I. INTRODUCTION

Ayurveda has given great importance to *'Stree'* and is said to be the root cause of progeny.[1]According to *Ayurveda*, essential four factors, are the prime requisite for *Garbhadharana* (conception) viz. *Ritu*(menstrual cycle), *Kshetra*(Uterus), *Ambu*(Hormonal status) and *Beeja*(Ovum) and is called as *GarbhaSambhava Samagri*. *Beeja*i.e. Ovum is the most essential part among the four prime requisite.*Beeja* is produced every month for fertilization and if fertilization doesn't occurs, it gets excreted along with *raja*i.e. menstrual flow.

Rutukaala, is the period where reproductive system is prepared for conception. It is the most fertile period of the cycle. Ovulation, the important event of conception occurs in *rutukaala*, along with increase in the thickness of

endometrium as a preparation for embedding the fertilized embryo. It is explained that,in this period the *puran raja* i.e. endometrium is shadedand there is growth of new *raja*up to mark, *yoni* becomes *shudha* and the *beeja*or *arthava* is in its *prakrutavastha*, all these are the factors favourable for conception.

There are many conditions which affects women's capacity of child bearing and conception leading to infertility. Poly cystic ovarian disease is one of the conditions which affect her fertility and Anovulation being one of its major symptom. Ovulation is the rupture of the mature follicle during the proliferative phase of the menstrual cycle. Anovulation, is when the follicle doesn't get matured and remains in ovaries. Anovulation, is the result of defect observed in ovaries and the hormonal balance. There are many causes of anovulation. Poly cystic ovarian disease is one of those conditions where anovulation is present and its prevalence is observed widely around the world.

Polycystic ovarian disease is a most complex reproductive and endocrine disorder typified by Anovulation, oligomenorrohea, signs of hyperandrogenism, hyperinsulinemia, metabolic, psychological disorder etc., leading to many health issues like cardio-vasculardisease, diabetes, infertility etc. The incidence of this is increasing day by day, due to sedentary lifestyle, pollution, excessive intake of junk foods, busy and stressful life at work places and home etc. which contribute to a derangement in the biological activities of the women.

There are some conditions like, *Pushpaghni Jataharaini* which bears some resemblance with the symptoms of Poly cystic Ovarian Disease. In this condition, it is described that the women have regular but, futile cycles and corpulent cheeks with excessive hair. *Tridosha* balance is essential for menstrual cycle and ovarian cycle. But, in Poly cystic ovarian disease, *vata* is covered by*kapha*, which results into block of ovarian function and leads into anovulation. *Vatakaphaavaran* i.e. covering of *vatakapha* on ovaries leads to obstruction in follicle rupture hence, the follicles remain in the ovaries leading to amenorrhoea or *arthavanasha.* Thus, *Arthavanasha* can be correlated with amenorrhoea associated with Poly cystic ovarian disease. Even in*vandhyayonivyapata, arthava* is destroyed, i.e. Anovulation or *arthvanasha*is seen which, causes inability of female to conceive a child.

Poly cystic ovarian disease if occurs at an early agecan lead to life threatening condition in late age. Oestrogen is the hormone secreted from the ovaries. Normal functioning of ovaries is responsible for normal secretion ofoestrogen in the body. Oestrogen stimulates the release of nitric oxide and decreases the risk of high blood pressure and high cholesterol levels leading to cardiac protection. In Poly cystic ovarian disease, follicular growth is affected leading the follicles to remain in ovaries. As the follicles are not ruptured the oestrogen secretion is hampered, thus leading to cardiac disease and other high risk conditions. Thus, to avoid these high risk factors it is necessary to treat Poly cystic ovarian disease.

In modern science there is no specific treatment for Poly cystic ovarian disease. The treatment given is symptomatic and duration remains for a longer period. The treatment module includes oral contraceptive, hormonal supplementation, ovulation induction drugs, antiestrogenic etc., which given for long term can produce severe ill effects on the body. Surgical drilling is one of the treatments given, but even its effect is temporary.

This study deals with ovulation in anovulatory cycles in Poly cystic ovarian disease and regularizing the menstrual cycle. *Kumariasav* is one of the *Ayurvedic* formulation used (referred in *Sharangdhar Samhita*) in *Udarroga*. *Udarroga* is the disease, caused due to *Avarodha* or *avarana* of *kaphadosha* on *vatadosha*. As, *Kumariasav* removes the *avarana* of *kaphadosha*, thus by its action it willremove the *avarana* on the ovaries and will initiates ovulation.Thus, it is used in Poly cystic ovarian disease for ovulation.

AIM

To assess the efficacy of *KumariAsav* on Anovulatory cycle in Polycystic Ovarian disease.

OBJECTIVES

- ✓ To evaluate the efficacy of *KumariAsav* in Polycystic ovarian disease.
- ✓ To observe untoward effects if any.
- ✓ Conceptualization of Anovulation on the basis of *Ayurvedic* basic Principles.

II. ETIOLOGICAL FACTORS

Ayurvedic classics explainsthe following etiological factors:

- ✓ *Mithyahara*:-It includes both *mithya- ahara* (abnormal diet) and *mithya- vihara*.
- ✓ *Pradusta – Artava*
- ✓ *Bijadosa*

*SPECIFIC HETUS OF PCODin our study are***:**

VATAPRAKOPAKHETU

Food that are *katu, tikta, kashaya rasa pradhana, ruksya*and *sheeta*. e.g. *Nachni*, peas, *usher, turi*, fermentated foods like idli, dosha, vada etc. Suppressing the natural urges like flatulence, urination, defecation or aggravating them when not necessary, not taking rest during menstrual cycles, indulging in excessive, strenous work, late sleeping and not getting early in morning, fasting, taking food at improper time. These all caused vitiation of *Vata*changing its normal *gati* and getting*vimargaman*, leading to *Vataprakopa*.

KAPHAPRAKOPAKHETU

Food that is *madhura, amla, lavana* in taste.*Snigdha, sheeta, guru* and *picchila*, like Wheat, *udit,snigdha*, fruits like grapes, guvava, banana and dates, coconut, fish dishes. Excessive intake of rice, sugarcane juice, sugar, ghee, curd, cheese, potato and fast foods like pizza, burger, fried chips.

Vihar - Excessive sleep, long working hours etc.Improper cleaning of *yoni sthana* (Improper Genital Hygiene).

III. SIGNS AND SYMPTOMS

According to *dosh dushti*-

- ✓ *Vatadosha*: Because of *vatadosha* vitiation *Raja kshay or vrudhi* (menorrhagia, oligomenorrhea), Irregular menses, *katishool*, *udershool*, cramps in leg, multiple follicles is seen in poly cystic ovaries.
- ✓ *Pitta dosha*: Because of *Pitta dosha* vitiation, hair loss, acne, hirsutism, burning micturation, *Krushnaartava*, clots, heart related problems (cardiac disease, heart attack) are observed.
- ✓ *Kaphadosha*: Because of *Kaphadosha* vitiation, white discharge, itching over vulval region, *MedoVruddhi* (obesity), *Alasya* (Fatigue)

According to *dhatudushti*-

Rasa dhatu: *Aruchi, Agnimandya*.

Mansa dhatu: *Gurugatrata*.

Medadhatu: *Hasta padadaha*, *Sthulata* (increase in waist to hip ratio), diabetes, coronory heart disease.

In Poly cystic ovarian disease, aetiological factors mentioned above disturb the function of *agni*at different levels leading to formation of *aama. Sama rasa* leads to *vitiation* of *Kapha* which causes increased *snigdhata*. *Aama* and *Kapha* in combination results in *srothorodha* which in turn causes vitiation of *vata*. the menstrual flow is manifested by vata in the form of *Apana*, the affection of the same may affect the menstrual cycle. *srothorodha* and resultant *vatavaigunya* when affects the *shukra* and *arthava*vaha*srotas* leads to *anovulation* and *arthavavyapads* leading to *subfertility.*

Agneya property of pitta is responsible for the maturation and functioning of *arthava*. Eventhough *pitta* seems not to be *ksheena* in quantity. the increased unctuousness alters the functioning of *pitta* by affecting the *agneya* property.

Thevitiated *kapha* then affects the *medodhatu*, because of the common *panchabhoota* constitution. *medodusti* leads to *santarpanjanya*vyadhies including *sthoulyam* and *prameham*.it will also cause impaired formation of asthi*dhatu*. *Kesha*and *loma* are *dhatumala* of *asthi*.

The next *dhatu* to be affected is *majja* resulting in increase in *shleshma* of body. *pitta* is responsible for *prabha, varnam*, and *mardavam* in our body. relative diminution in *pitta* affects *prabha* and *varnam* which causes *Karshnyam*. It also manifests due to *vatadushti*.thus*Karshnyam* or Acanthosis can be attributed to *vatavriddh*i and *pitta kshayam* which is seen in Poly cystic ovarian disease.

IV. METHODS AND MATERIALS

MATERIALS

Name	Latin name	Rasa	Virya	Vipak	Doshaghnata
Kumari	Aloe vera	*Katu*	*Sheeta*	*Tikta*	*Kaphapitta har*
Guda	Jaggery	*Madhur*		*Madhur*	
Madhu	Iron calx.				
Shunthi	Zingiberoffic inate	*Katu*	*Ushna*	*adhur, Katu*	*Kaphavata shamak*
Marich	Piper nigram	*Katu*	*Ushna*	*Katu*	*Kaphavata shamak*
Lavang	Syzigiumaro maticum	*Katu,Tikta*	*Sheeta*	*Katu*	*kaphapittas hamak*
Twak	Cinnomumze ylanicum	*Katu,Tikta, Madhur*	*Ushna*	*Katu*	*kaphavatas hamak*
Ela	Elletariacard amomum	*Katu,madhu r*	*Sheeta*	*madhur*	*Tridoshaha r*
Nagkesh ar	Mesuaferrea	*Kashay, tikta*	*Ushna*	*Katu*	*Kaphapitta shamak*
Chitrak	Plumbagoze ylanica	*Katu*	*Ushna*	*Katu*	*Kaphavata shamak*
Haritaki	Terminaliach ebula	*Mabhur,Am la, Tikta,Kasha y, Katu*	*Ushna*	*Madhur*	*Tridoshash agna*
Bibhitak	Terminaliabe llerico	*Kashay*	*Ushna*	*Madhur*	*Tridoshagn a*
Amalaki	Emblicaoffic inalis	*Madhur,Am la, Tikta,Kasha y, Katu*	*Sheet*	*Madhur*	*Tridoshgna*
Vidang	Embeliaribes	*Katu, kashay*	*Ushna*	*Katu*	*Kaphavata shamak*
Chavya	Piper retrofractum	*Katu*	*Ushna*	*Katu*	*Kaphavata shamak*
Hapush a	Juniperusco mmunis	*Katu, tikta*	*Ushna*	*Katu*	*Kaphavata shamak*
Dhanya k	Coriandrums ativum	*Kashay ,tiktamadhu r,katu*	*Ushna*	*Madhur*	*Tridoshaha r*
Kramuk a	Betel nut	*Kashay, madhur*	*Sheeta*	*Katu*	*Kaphapitta shamak*
Katuroh oni	Picrorrhizacr uroo	*Tikta*	*Sheeta*	*Katu*	*Kaphapitta har*
Musta	Cyperusrotu ndus	*Tikta, katu,kashay*	*Sheeta*	*Katu*	*Kaphapitta shamak*
Rasna	Pluchealance olata	*Tikta*	*Ushna*	*Katu*	*Kaphavata shamak*
Devdaru	Cedrusdeoda ra	*Tikta*	*Ushna*	*Katu*	*Kaphavata shamak*
Haridra	Curuma longa	*Tikta, katu*	*Ushna*	*Katu*	*Kaphavata shamak*
Daruhar idra	Berberisarist ata	*Tikta, kashay*	*Ushna*	*Katu*	
Yashtim adhu	Glycirrhizagl abra	*Madhur*	*Sheeta*	*Madhur*	*Vatapittash amak*
Dantimo ola	Balliospermu mmontanum	*Katu*	*Ushna*	*Katu*	*Kaphapitta har*
Pushkar moola	Inularacemos a	*Tikta ,Katu*	*Ushna*	*Katu*	*Kaphavata shamak*
Bala	Sidacordifoli a	*Madhur*	*Sheeta*	*Madhur*	*Vatapittash amak*
Atibala	Abutilon indicum	*Madhur*	*Sheeta*	*Madhur*	*Vatapittash amak*
Gokshur	Tribulusterre stris	*Madhur*	*Sheeta*	*Madhur*	*Vatapittash amak*
Punarna va	Boerhaviadif fusa	*Madhur,tikt a, Kashay*	*Ushna*	*Madhur*	*Tridoshaha r*
Dhatum akshika	Makshikbhas ma				
Dhataki	Woodfordiaf ruticosa	*Kashay*	*Sheeta*	*Katu*	*Kaphapitta shamak*

Table 1: Pharmaco-Dynamics Of Kumari Asav

METHODOLOGY

Thirty subjects out of fifty, satisfying with selection criteria were selected for study and their primary data was collected by interview, observation and relevant investigation. A detail history, general examination, USG and complete Haemogram, urine routine and microscopic, Serum Oestrogen, sr. Progesterone, sr. Testosterone, sr. Prolactin, sr. Leutinizing, sr. Follicle stimulating hormone and Thyroid stimulating hormone, were done prior to the administration of medicine and then the treatment was started. The study drug KumariAsav was given to the subjects and advised to use in the dose of 20ml twice a day with equal quantity of water. Water was used as anupana. The patient were asked to report every 15 days for follow up. The study drug was given for three months of period. Following this, next three months were considered as follow up period and then changes in the sonography.

SELECTION CRITERIA

DIAGNOSTIC CRITERIA

Rotterdams three criteria are fulfilled, they are as,

- ✓ Anovulation.
- ✓ Hyperandrogenism.
- ✓ Polycystic ovary in Ultrasound.

INCLUSION CRITERIA

- ✓ Age group 20 to 35 yrs.
- ✓ Irregular menses / scanty menses.
- ✓ Polycystic ovaries diagnosed by Ultrasonography.

EXCLUSION CRITERIA

- ✓ Any malignancy related to genital tract.
- ✓ Tubercular Endometriosis.

DISCONTINUATION CRITERIA

- ✓ Developed untoward side effect.
- ✓ Non Compliance.
- ✓ Voluntary withdrawal.
- ✓ Not regular for follow up.

ASSESSMENT CRITERIA

SUBJECTIVE

- ✓ General Examination :- BP, Pulse, RS/CVS, P/A, PV (Selected Cases)
- ✓ Duration of bleeding(no. of days)
- ✓ Irregular menstruation(duration between two menses)
- ✓ Pain

OBJECTIVE

- ✓ USG - before and aftertreatment
- ✓ Before treatment Serum levels of Estrogen, LH, FSH, Sr. Testesterone, TSH, Prolactin.

V. GRADATION FOR SUBJECTIVE PARAMETER

SCORE	INTERVAL
0	21 TO 35 DAYS
1	36 TO 45 DAYS
2	61 TO 90 DAYS
3	ABOVE 90 DAYS

Table 2: Assessment of Interval between two menstrual cycles

Menstrual duration or the number of days of bleeding was calculated in days. Average 3 to 5 days bleeding was considered as normal

SCORE	DURATION
0	3 TO 5 DAYS
1	LESS THAN 3 DAYS
2	2- 6 TO 7 DAYS
3	MORE THAN 7 DAYS

Table 3: Menstrual Duration

It was not practical to measure the amount of blood loss, the number of absorbent pads used by subjects were counted to assess amount of bleeding

Amount	Number of pads used	Grading
Spotting	No need of pad	0
Scanty	One pad per day with minimum soaking	1
Moderate	1 to 3 pads per day with complete soaking	2
Mild excess	3 to 5 pads per day with complete soaking	3
Excessive	More than 4 pads per day with complete soaking	4

Table 4: Assessment of blood loss

SCORE	PAIN
0	NO PAIN
1	MILD
2	MODERATE
3	SEVERE

Table 5: Assessment of Pain Related with menstruation

A)	Dose	20 ml twice a day.
B)	Form	*Asav*
C)	Time	*Apan Kala* (Half hour before meal twice a day).
D)	*Anupan*	Equal quantity of drinking water.
E)	Follow up	After every 15 days for 3 months.
F)	Route of Administration	Orally
G)	Duration	3 month medicine. 3 month follow up.

Table 6: Treatment Details

VI. OBSERVATIONS

This study included 57% subjects from age group 20-25 years, 33%subjects from 26-30 years and 10% from 31-35 years. Considering the occupation 76.7% subjects were

housewives, 10% were working women and 13.3% were subjects. Considering the education 43.33% subjects were graduate, 40% were secondary and 16.67% were primary educated. 83% married subjects and 17% unmarried subjects. 56.7% subjects were from urban and 43.3% subjects from rural area. Interviewing the subjects it was observed that, most of them were living sedentary life style. i.e. 60% and 20% subjects were doing moderate type of work and 20 % were doing hard work. Considering diet pattern 83% were having mixed food habits i.e. vegetarian and non-vegetarian, and 17% were having only vegetarian food. 7% subjects were with *hina*, 73% with *madhyam*and 20% with *uttamagni* before treatment. After treatment 33.3% had *madhyamagni* and 67.7% had *uttamagni*. Hence, it was observed that there was improvement in *Agni*. 13.3% subjects were from 40-50 kg, 56.7% subjects were from 51-60 kg and 30% subjects were from 61-70 kg. Out of married subjects, 88% were nulliparous subjects, 12% subjects had previous pregnancies confirmed. 30% subjects were with *vata-pitta*, 10% subjects with *vata-kapha*, 10% with *kapha-pita*, 20% with *kapha-vata*, 10% with *pitta-vata* and 20% with *pitta-kaphaprakruti*. Considering the menstrual duration 73% subjects were with 4 days duration and 27% subjects with more duration i.e. 5-9 days. After 3 months of treatment considerable reduction in the menstrual interval was noted. Before treatment 86.6% subjects had irregular menses and 13.3% subjects had regular menses. During treatment 73.3% subjects had irregular and 26.6% had regular menses. After treatment 30% subjects had irregular menses and 70% subjects had regular menses. Ovulation was absent in all the subjects before treatment. After 3 months of treatment in 30% subjects there was 1 large follicle, 26.6% subjects had 2 follicles, 23.3% subjects had multiple small follicles. Before treatment all of the subjects had Unovulatory cycles. After treatment 76.6% subjects had Unovulatory cycles and 23.3% subjects had Ovulatory cycles. Since these observations were observed on binary scale before, during and after treatment, McNemar's test was used to test the significance and the P value observed was less than 0.05, hence it is concluded that, the effect observed was significant. Considering menstrual interval 13.33% subjects had 21-45 days, 33.33% subjects 36-60 days and 50% subjects have 61-90 days, only 3.33% subjects have above 90 days menstrual interval before treatment and after treatment 26.66% subjects have 21-35 days, 53.33% subjects have 36-60 days and 20% subjects have 61-90 days of menstrual cycle. After 3 months of treatment there was considerable reduction in ovarian volume of both right and left ovaries. Before treatment mean volume of right ovary was 10.2 cubic cm which reduced to 8.9 cubic cm after treatment. 13.3% subjects among them had no change in the ovarian volume. Before treatment mean volume of left ovary was 10.4 cubic cm which reduced to 8.5 cubic cm after treatment. 13.3% subjects among them had no change in the ovarian volume. Since these observation were quantitative (n=30), paired t-test was used and it was observed that P-Value was less than 0.05, hence was concluded that there was significant change observed.

Symptom	N	Mean BT AT	SD BT AT	SE BT AT	t-value	P-value
Menstrual interval	30	59.5 37.5	20.23 12.92	3.69 2.36	6.165	0.000
Ovarian volume Right	30	10.2 8.9	2.74 2.05	0.50 0.57	2.488	0.019
Ovarian volume Left	30	10.4 8.5	2.16 3.23	0.39 0.59	3.307	0.003

Table 7

BT		DURING 0-3 MONTHS		AT	
Irregular	**Regular**	**Irregular**	**Regular**	**Irregular**	**Regular**
26	4	22	8	9	21

Table 8: Menstrual irregularity

NO. OF FOLLICLES	BT		AT	
	Frequency	**Percentage**	**Frequency**	**Percentage**
MSF	30	100.0	7	23.3
1 FOLLI	0	0.0	15	50.0
2 FOLLI	0	0.0	8	26.7
TOTAL	30	100.0	30	100.0

Table 9: Effectiveness of Treatment in reducing number of Follicles

Ovulation	BT		AT	
	Frequency	**Percentage**	**Frequency**	**Percentage**
Anovulatory	30	100.0	23	76.7
Ovulatory	0	0.0	7	23.3
TOTAL	30	100.0	30	100.0

Table 10: Ovulatory/Anovulatory Cycle

VII. DISCUSSION

Maximum subjects observed were from the age group of twenty to twenty five due to change in life style i.e. sedentary life style, lack of physical activity and also those who were married, were mostly housewives who were having irregularity in their dietary and sleep pattern leading to *Kaphasanchay* which showed its higher incidence in this age group. As most of them were educated it was easy to explain the treatment and was followed sincerely. As the place of study was in urban area most of the patients were from urban area. Though, diet pattern as vegetarian and non-vegetarian was considered but their relation could not be developed. *Agni* (Digestive power) plays an important role in maintaining health according to Ayurved. Improvement in digestive power is very important in curing any disease which was observed as there was decrease in ovarian volume. As there is anovulation in PCOD, infertility was present in most of the married subjects. PCOD was observed in all types of *prakruti*. Irregular menstrual cycle is a peculiar sign of PCOD, which was corrected by this medication in maximum subjects. Oligomenorrhoea was corrected in maximum number of subjects. *Deepanpachan* followed by achieving *doshasamyaavastha* (balancing the *doshas*) lead to reduction in number of follicles. *Kaphaavaran* of *Vata* was removed by this treatment thus, ovulation was observed in maximum subjects in this study.

VIII. CONCLUSION

With the help of present study it is concluded that, though Polycystic Ovarian Disease is seen in all type of *prakruti*, but

is more prominent in *Kapha-vatapr adhanprakruti.* Irregular menstrual cycle is the unique feature of Poly Cystic Ovarian Disease, can be regularized by *Kumariasav*. Kumariasav is effective in reducing the follicular size and ovarian volume.To achieve ovulation, *Kumariasav* could be administered for more than 3 months. Mixed diet pattern to be studied in detail to establish the relation between diet pattern and Poly Cystic Ovarian Disease. No side effect of Kumariasav was observed during the study. However, large sample size is needed for detail study.

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