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## Clinical Efficacy Of Kalyanaka Kshara In The Management Of PCOS Infertility W.S.R Anovulation

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### ABSTRACT

#### Background :

Ovulatory dysfunction is the primary cause of infertility, which affects 12-24% of couples. Serial ultrasonography can be used to evaluate follicular development, and to diagnose the ovulation.

#### Methodology:

The present study is a three-year prospective study conducted at NRS Govt ayurvedic college attached teaching hospital, AL Govt, Ayurvedic Hospital Vijayawada,AP, 100 patients with either primary or secondary infertility with PCOS were recruited in the study, as per inclusion criteria and no pelvic pathology were involved in the study. They are divided into 2 groups. Group I included anovulatory women whose infertility was caused by PCOS, and administered Kalyanaka Kshara and Group II comprised anovulatory women, infertility caused by PCOS, and administered Rajapravarthin Vati and Varunadhi Kashaya. Follicular study was performed using Transvaginal Ultra Sonography to assess the ovulation, in this study ovulation rate and conception rate were studied.

**Results :** 56% of the patients had primary infertility and most appeared after 3-6 years of infertility. 98% of the patients were between the ages of 21 and 35 years. All the cases had ovulatory dysfunction, and polycystic ovarian disease (PCOD) was the most frequent cause of anovulation. The leading follicular diameter was substantially bigger (22-24 mm) in the K.K Kshara administered cycle compared to the Rajapravarthinivati cycle (16-21 mm). In both the group cycles, the endometrial thickness displayed a linear development pattern during the pre-ovulatory phase and plateaued during the luteal phase. With Kalyanaka Kshara group there was a 26(52%) ovulation rate, 24(48%) in Rajapravarthin Vati Group a 32%, 23% conception rate was noted in both groups.

**Conclusion :** Kalyanaka Kshara increases the rate of ovulation and pregnancy in females having anovulatory cycles in PCOS infertility.

**Keywords:** Anovulation, kalyanaka kshara, Rajapravarthinivati, transvaginal ultrasound, PCOS infertility, oligo-ovulation.

#### INTRODUCTION:

Infertility is defined as inability to conceive with minimum one year of regular unprotected coitus. In Ayurveda, Vandhyatwa is a condition where a female fails to conceive and unable to continue pregnancy, there are many reasons for this Infertility, Anovulatory factor is one the cause of Infertility.

PCOS is a multifactorial and polygenic condition. Diagnosis criteria is any two of this three

1. Oligo-ovulation or anovulation manifested as oligomenorrhea or amenorrhea
2. Hyperandrogenism (clinical evidence of androgen excess) or hyperandrogenemia (biochemical evidence of androgen excess).
3. Polycystic ovaries (as defined on ultrasonography)<sup>[1]</sup>

In PCOS hormonal imbalance affects follicular growth during the ovarian cycle causing the affected follicles to remain in the ovary. The retained follicle forms into a cyst, with each ovarian cycle a new cyst is formed leading to multiple ovarian cysts, ultrasonic morphologic evidence of  $\geq 12$  follicles measuring 2.9mm diameter in single plane during quiescent phase of ovary i.e. 27 days of cycle associated with obesity, oligomenorrhea, anovulation, hyperandrogenism, hyperinsulinemia- increased level of insulin in the blood is due to sensitivity of cells to insulin, androgen secretion by the ovarian stroma, and reduces serum sex hormone binding globin (SHBG) causing increased levels of free testosterone. Due to the presence of increased androgen in the ovary, the follicle undergoing maturation in the ovarian cycle is affected causing anovulation of particular follicle.

According to recent population-based research, infertility affects between 12% and 24% of couples<sup>[2]</sup>. Infertility affects 10-15% of the population, with female factors accounting for 40-45%, male factors accounting for 25-40%, both male and female factors accounting for 10%, and the remaining 10% having no known cause<sup>[3]</sup>. Between 30% and 40% of female infertility is caused by ovulatory dysfunction, polycystic ovary syndrome (PCOD) being the most common<sup>[4]</sup>.

Ovulation is under control of Vata in current study, an effort has been made to study the effect of Kalyanaka Kshara and Rajapravarthini Vati on Anovulation, which is caused by PCOS. Patients of female infertility having anovulatory factor being diagnosed by Trans vaginal scan for two consecutive cycles.

Garbhsambhava Samagri such as Ritu, Kshetra, Ambu, Beeja.<sup>[5]</sup> Beeja, most essential part among the four has been considered as Antahpushpa<sup>[6]</sup> i.e., ovum. As there are many causes of anovulation due to Aartava Nasha or Nastartva. Other causes of anovulation are PCOS. Due to H.P.O axis is disturbed and menstrual cycle becomes anovulatory. Anovulation can be included under Beeja Dushti. Ovarian factor contributes 15-25%<sup>[7]</sup> and is the second common cause of infertility. Tridosha plays a major role in all the process involved in ovulation. Vata stands for proliferation and division of cells, rupture of follicle. Pitta helps in maturation of graffian follicle by its function of Paka Karma. Kapha gives nutrition for growth of cells. Ovulatory process manifest due to aggravation of all three Doshas but mainly Vata Dosha.

Kalyanaka kshara<sup>[8]</sup> mentioned in AsthangaHridaya Chikitsa Sthana - Arshochikitsa is a PaneeyaKshara which can be applied in the Doshik status of PCOS. Ingredients include Trikatu, Triphala, Danthi Bhalathaka, Chitraka, Eranda Taila and Gomutra and should be prepared under proper purificatory as per classical reference. Kalyanaka Kshara is effective in normalizing Vata. The drugs of Kalyanaka kshara has Kapha Vata Shamana property, Vata Anulomana and as it is Kshara preparation it should be Chedana, Bhedana and Lekhana property. Chedana, Bhedana and Lekhana properties of the drugs helps in reducing the cyst size, ovarian volume, normalize ovulation. Kapha Vata Shamana and Vata Anulomana.

**Raj Pravartini Vati** - It is helpful in the treatment of amenorrhoea. Its main effect on uterus and ovaries. It helps in stimulation of ovulation and corrects the ovarian function

**Mode of Action of Kshara in PCOS:**

Kalyanaka Ksharahaving Ushna, Teekshna, Deepana, Pachana, Darana Chedya, Bhedya, Kshapana, Ksharana and Kshanana property of Kshara executes Kapha Medohartwa and increases the Agneya property of Pitta acts mainly on the Doshik status of PCOS

**MATERIAL AND METHODS:**

**Aim:** 1. to study the efficacy of Kalyanakshara and Rajapravathini Vati in PCOS Infertility, with special reference to anovulation.

**STUDY DESIGN:**

The present study is a three-year prospective study conducted at NRS Govt ayurvedic college attached teaching hospital, AL Govt, Ayurvedic Hospital Vijayawada, AP, the selection of patients from the OPD of Prasuthi Streeroga department, 100 patients with either primary or secondary infertility with PCOS were recruited in the study, as per inclusion criteria and no pelvic pathology were involved in the study. and the patients were divided into two groups: Group I included anovulatory women whose infertility was caused by PCOS, and administered Kalyanaka Kshara and Group II comprised anovulatory women, infertility caused by pcos, and administered Rajapravarthin Vati and Varunadhi Kashaya. Follicular study was performed using Transvaginal Ultra Sonography to asses the ovulation. in this study ovulation rate and conception rate were studied

The selection of patients for the study was done from patients attending the Prasuthi Streeroga Department for Infertility, either primary or secondary. All females between the ages of 21 and 40 years who had been unable to conceive for more than a year while having unprotected intercourse and were willing to participate in the trial were screened for various causes of infertility. The patients were examined clinically and relevant histories were recorded. Everyone willing to take part was enrolled, and those who were not ready or had any pelvic pathology were excluded from the study.

**INFERTILITY ETIOLOGICAL FACTORS:** the etiological factors are ovulatory factors, Tubal factors, uterine factors, cervical factor, male factor, unexplained. Ovulatory dysfunction, which accounted for 50% of cases, was the most common cause of infertility, The most common cause of anovulation was PCOD, premature ovarian failure, hyperthyroidism, prolactemia, lutenising factor, idiopathic cause

Following the screening, 100 well established Pcos Infertile patients were chosen for the study and divided into two groups: Group I consisted of 50 PCOS Infertile women with anovulatory cycles. Given Kalyana Kshara. 250mg with honey, trail group, Group II consisted of 50 infertile women with anovulatory cycles. given Rajapravrthinivati 250mg with, Varunadhi Kashayam, Detailed studies of follicular study was conducted in both groups.

Normal follicular development and size throughout the menstrual cycle:

- Small antral follicles (Days 1-5): 2-5 mm
- Growing follicles (Days 6-10): 5-12 mm
- Dominant follicle (Days 11-14): 14-18 mm
- Pre-ovulatory follicle (Day 14): 18-24 mm
- Ovulation: Follicle ruptures and releases an egg

The normal endometrial thickness throughout the menstrual cycle:

- Early proliferative phase (Days 1-5): 4-6 mm
- Late proliferative phase (Days 6-14): 6-10 mm
- Ovulation (Day 14): 8-12 mm

- Early secretory phase (Days 15-18): 10-14 mm
- Late secretory phase (Days 19-28): 12-16 mm

Endometrial texture: Homogeneous, hyperechogenic (during proliferative phase) or heterogeneous, hypoechogenic (during secretory phase)

#### OVARIAN ASSESSMENT IN PCOS CASES:

Polycystic Ovary Syndrome (PCOS): Characteristic ultrasound features of PCOS, including multiple small cysts, peripheral distribution, and increased ovarian volume. The "string of pearls" appearance is a characteristic ultrasound feature of PCOS, where multiple small cysts are arranged peripherally around the ovary. Ovarian volume is typically increased in PCOS patients, with values >10 mL considered abnormal, (eg; Ovarian volume: Right ovary: 12.5 mL- Left ovary: 13.2 mL ) Endometrial thickness >10 mm is suggestive of endometrial hyperplasia, which is a common finding in PCOS patients

Transvaginal ultrasonography was used to assess follicles starting on D10 of the cycle and continuing on alternate days till rupture. The number of follicles, serial rise in follicle diameter, rate of growth, and thickness of the endometrium were all noted.

Ovulation is confirmed by transvaginal sonography (TVS) by the following signs:

- (1) complete disappearance of the follicles,
- (2) follicular wall irregularity,
- (3) appearance of several echoes in a previously echo-free follicle,
- (4) presence of fluid in the pouch of Douglas (POD), and
- (5) endometrium with hyperechogenic secretory tissue.

After ovulation or after rupture of the follicle, timed intercourse was advised. The patients were followed up on and asked to report if they missed their period, and pregnancy was verified using a urine pregnancy test and transvaginal sonography. The ovulation rate, pregnancy rate were analysed. Data analysis was done.

#### RESULTS:

TABLE 1. PATIENT CHARACTERISTICS:

	Kalyana Kshara. Group I		Rajapravrtthinivati , Varunadhi Kashayam Group II	
	NO OF PATIENTS (N=50)	% OF PATIENTS	NO OF PATIENTS (N=50)	% OF PATIENTS
1. TYPE OF INFERTILITY				
PRIMARY	28	56%	36	72%
SECONDARY	22	44%	14	28%
2. AGE IN YEARS				
21-25	30	60%	4	8%
26-30	10	20%	9	18%

31-35	9	18%	21	42%
36-40	1	2%	6	12%
<b>3.DURATION OF INFERTILITY IN YEARS</b>				
1-3	14	28%	10	20%
4-6	22	44%	12	24%
7-9	4	8%	18	36%
10-12	10	20%	0	0
<b>3.MENSTRUAL PATTERN</b>				
	Kalyana Kshara. Group I		Rajapravarthinivati , Varunadhi Kashayam Group II	
	BT	AT	BT	AT
AMENORROHOEA	20(40%)	2(4%)	18(36%)	10(20%)
OLIGOMENORROHEA	13(26%)	6(12%)	12(24%)	4(8%)
MENORRAHAGIA	15(30%)	4(8%)	6(12%)	5(10%)
NORMAL MENSTRUAL CYCLE	2(4%)	38(76%)	14(28%)	41(82%)

28(56%) of the patients experienced primary infertility in group 1, 36(72) % cases in group 2. 30(60%) of the patients were between the ages of 21 and 25 years in group 1, while 30(60%) were between the ages of 36 and 35 years in group 2. The greatest percentage of instances 36(72%) were documented after 1-6 year infertility in Kalyanakshara Group. 30(60%) were documented after a 4 to 9-year infertility interval in Rajapravarthini Group. 2(4%) of them had regular menstrual cycles, with amenorrhoea 20(40%), with menorrhagia 15(30%) with oligomenorrhoea 13(26%) being the most frequent menstrual irregularity in group 1, 14(28%) normal menstrual cycles, 6(12%) patients menorrhagia, 12(24%) oligomenorrhoea 18(36%) amenorrhoea patients were noted in group 2, after treatment menstrual cycle is normalised in 38(76%) patients, in group 1, 41(82%) in group-2. In both the groups like amenorrhoea and oligomenorrhoea, menorrhagia symptoms showed significant results. (Table-1)

TABLE 2 ULTRA SONOGRAPHY CHARECTERSTICS: (In Group1 And Group-2)

		Kalyana Kshara. Group I		Rajapravrtthinivati , Varunadhi Kashayam Group II	
S.No		NO OF PATIENTS (N=50)	PERCENTAGE	NO OF PATIENTS (N=50)	PERCENTAGE
1	USG CHARECTERISTICS	USG BT ovaries	USG AT	USG BT	USG AT
	Normal study -	0	<b>26(52%)</b>	0	<b>39(78%)</b>
	Presence of multiple small cysts in one of the ovaries	10(20%)	14(28%)	16(32%)	0
	Presence of multiple small cysts in bilateral ovaries	36(72%)	0	24(48%)	1(2%)
	Presence of multiple small cysts with dominant follicles in bilateral	8(16%)	10(20%)	10(20%)	10(20%)
2	Anovulation				
	0-12-follicle size	32(64%)	10(20%)	10(20%)	-
	12-17mm	2(4%)	-	24(48%)	10(20%)
	18-23mmcystic	6(12%)	14(28%)	6(12%)	16(32%)
	ovulated	10(20%)	<b>26(52%)</b>	10(20%)	<b>24(48%)</b>
3	Endometrial Thickness				
	<7	20(40%)	12(24%)	16(32%)	8(16%)
	7-14 mm	13(26%)	2(4%)	10(20%)	13(26%)
	>14	24(48%)	36(72%)	24(48%)	29(48%)
4	FOLLICULAR STUDY .BT		FOLLICULAR STUDY .AT		
	1-12mm	10(20%)	14(24%)	9(18%)	3(6%)
	12-17mm	32(64%)	4(8%)	20(40%)	7(14%)
	18-23mm	6(12%)	6(12%)	21(42%)	11(22%)
	ovulated ,follicle ruptured	2(4%)	<b>26(52%)</b>	-	<b>24(48%)</b>

### USG: ULTRA SONOGRAPHY.

Before treatment normal study of the USG in both groups are nil. After treatment normal study of USG shown in both groups significantly increased ie 26(52%),39(78%) subsequently. before treatment Endometrial thick ness <14, also increased in both groups 36(72%),29(48%). In follicular study before treatment it was 2(4%) after treatment it increased to 26(52%) cases got ovulation in group 1, and marked increase in follicle rupture and ovulation in group 2 patients ie is 24(48%)(Table 2)

TABLE 3; Study Of Follicular Study USG in Group 1 & Group 2

USG-ultrasonography; POD- Pouch of Douglas.:

S.NO	Ultrasound Signs Of Ovulation	Number Of Patients, N=50	% of patients	Number Of Patients, N=50	% of patients
1	Appearance of multiple echos in a previously echo free follicle	14	8%	5	10%
2	Change In Shape	12	4%	2	4%
3	Disappearance Of Follicle	10	20%	13	26%
4	Appearance of free fluid in POD	14	28%	21	42%

. In 24(48%) of cases ovulation in group 1 was determined by the disappearance of the follicle and the appearance of free fluid in the POD. In contrast, group 2, ovulation was determined by the disappearance of the follicle 13(26%) and the presence of fluid in the POD 21(42%), Appearance of multiple echos in a previously echo free follicle Change In Shape are results were not significant.(Table-3)

TABLE 5, COMPARISON OF LEADING FOLLICULAR DIAMETER

Day before ovulating mean follicular diameter in mm	Group -1	Group-2
Day -1 before ovulation	22	16
Day 2 before ovulation	24	19
Day 3 before ovulation	26	21
Average number of ovulating follicles having .16mm Diameter	2.5	1

The leading mean follicular diameter was substantially larger in group 1 cycles (22-24 mm) compared to group 2 cycles (16-21 mm). Endometrial thickness increased linearly during the pre-ovulatory phase of Group 1 and Group 2 cycles before plateauing during the luteal phase. (Table-5)

#### Discussion:

In Kalyanakakshara (Group 1) cycles vs. Rajapravarthinivati (Group 2) cycles, the average rate of follicular growth was 2.1 mm/day and 1.9 mm/day, respectively. All these findings are consistent with the findings of our study where in the leading mean follicular diameter was significantly higher (22-24 mm) in Kalyanakakshara (Group-1) cycles, in contrast to Rajapravarthinivati (Group 2) cycles (16-21 mm). The average growth rate of endometrium was 0.083 cm/day in the (Group 1) cycle and 0.075 cm/day in an (Group 2) cycle,

TVS is a rapid, simple, and non-invasive way of directly observing ovarian follicle development that has no negative impact on the oocyte or reproductive system. Serial ultrasound can be used to monitor follicular growth, detect follicular maturity and to execute timed intercourse in follow-up of cases. 16 patients got conception in group Kalyanakakshara (Group 1). and 12 patients conceived in Rajapravarthini Vati (Group 2).

**CONCLUSION:** the major cause of infertility is ovulatory dysfunction and anovulation. follicular study investigation by serial ultrasonography is a safe, simple method to examine ovarian follicle development, and ovulation. ovulation is crucial time for infertility therapies, intrauterine insemination (IUI) etc. in this study Kalyanaka Kshara acts as Chedana, Bhedana and its Lekhana properties of the drugs helps in reducing the cyst size, ovarian volume, and normalize the ovulation. Kapha Vata Shamana and Vata Anulomana, helps to get fertility.

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**HUMAN ETHICS:** Consent was obtained from all the participants of the study, ethical clearance was obtained from the ethical committee of Dr. Nrs Govt Ayurvedic college Vijayawada,

**ANIMAL ETHICS:** All Authors declared no animals or tissues were used in this.

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