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Original Research Paper

Ayurveda

RANDOMIZED CONTROLLED STUDY ON KUMARYASAVA AND TANKANA BHASMA IN ANARTAVA IN POLYCYSTIC OVARY DISEASE

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ABSTRACT Polycystic ovary disease (PCOD) cannot be correlated to a single condition explained in Ayurveda. Based on menstrual abnormalities and anovulation, PCOD can be correlated to anartava. Anartava is a condition in which prakupita kapha does the avarana of apana vata there by leading to anartava and obstructing the artava pravrutti. Hence, pacifying prakrupita kapha and clearing the avarana is beneficial in the management of anaratava (PCOD). Chikitsasutra in anartava can aim at vata, kapha shamana and kapha medovilayana, garbhashaya lekhana, yakrututtejaka property and which also increases the agneyaguna of pitta may be useful for artavajanana and hence the kumaryasava and tankana bhasma were taken for the study. **AIM AND OBJECTIVE:** Trial aimed to evaluate the effect of kumaryasava alone or along with tankana bhasma in anartava. **CONCLUSION:** Kumaryasava with tankana bhasma showed statistically significant result in subjective parameter. Thus, objective of the study was fulfilled and the research hypothesis that kumaryasava with tankana bhasma is effective in the management of anartava lakshana of PCOD was accepted.

KEYWORDS : Ayurveda, Anartava, Kumaryasava, Tankanabhasma, Polycystic ovary disease

INTRODUCTION:

Amenorrhea is one of the most common gynecological conditions seen in clinical practice. The incidence of amenorrhea due to Polycystic ovary disease (PCOD) is increasing in the modern era due to changes in life style including dietary and behavioral habits, increased stress, strain and restlessness. It has also become a commonest problem amongst adolescents, developing soon after puberty. Amongst infertility in women about 20% is attributed to anovulation caused by Polycystic ovary disease[1]. Among the reproductive age group women prevalence ranges from 2.2% to 26%. Most reports have studied adult women with age ranged from 18 to 45 years.

The clinical features of the PCOD can be observed in yonivyapad and artava dushti. Arajaska yonivyapad mentioned amenorrhea as a symptom [2]. Menstrual dysfunction typically occurs in PCOD, ranging from oligomenorrhoea to amenorrhea. They manifest at the time of menarche in women with PCOD as delayed menarche, as menstrual irregularities, but women with Polycystic ovary disease may have intermittently regular and fertile cycles in spite of elevated androgen levels.

Amenorrhea may occur in up to 10% of the patients presenting with primary amenorrhea and 75% of those with secondary amenorrhea fulfill the criteria of PCOD.

Secondary amenorrhea is described as destruction of Artava (Nashtarava) as well as one of the symptoms of Artavavaha Srotasviddhalakshana[3], non-appearance of Artava (Anartava)[4]; as absence of 'Raja'[5]; as 'Rajonasha'[6].The path of Artavavaha Srotas got obstructed by vitiated Vata and Kapha, produces Anartava. It is also included as Rajonasha among eighty specific disorders of Vata.

When a woman indulges in Aharaja, Viharaja, Manasika,Vegdharna Nidanas it leads to Tridosha Prakopa causing Jatharagni Mandhyatwa. This hampered Agni produces improper Ahara Rasa resulting in improper Utpatti of Rasa Raktadi Dhatu. Artava being the Updhatu of Rasa is affected by improper Sarakitta Vibhaga of Rasa and also by Srotovarodha of Aratavavaha Srotas in Garbhashaya; producing Anartava.

The main clinical feature of Granthi is swelling or protuberance [7]. Granthi denotes its specific character i.e., glandular or nodular swelling [8]. On this basis, Granthi may be recapitulated with PCOD. Based on its location-Dhathu involvement and shape, Shotha is described with different names, thus Granthi is considered to be a type of Shotha[9]. Thus, the treatment of Granthi can be considered to as per Shotha Chikitsa.

The deranged Vata, Pitta and Kapha vitiate the Mamsa, Shonita & Meda mixed up with Kapha, they produce circular, raised & knotted inflammatory swelling called 'Granthi'[10] .This type of glandular swelling has been compared with the 'cyst'.

AIM AND OBJECTIVE:

Study aimed at evaluation of efficacy of Kumaryasava and Kumaryasava with Tankana Bhasma in Anartava(PCOD) and to compare their efficacies.

MATERIALS AND METHODS:

Subjects were recruited from outpatient department of Prasuti Tantra Evam Striroga, Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

Method of collection of data:

30 patients were screened and selected based on the screening form prepared. Data was collected using specially prepared case report form.

DIAGNOSTIC CRITERIA

Signs and symptoms of Artavadushti like

1. Anartava (complete absence of menstruation)
2. Nastartava (Secondary amenorrhoea) and
3. Rajonasha (Anovulation)

Signs and symptoms of PCOD as per Rotterdam Criteria:

To include two out of three of the following:

1. Menstrual irregularity (Oligomenorrhoea/Amenorrhea)
2. Hyperandrogenism (a) Clinical- Hirsutism, acne, acanthosisnigricans

i.(b) Biochemical- high serum androgen concentration.

ii.(c) Polycystic ovaries – Unilateral / Bilateral/ Single /Multiple cysts.

3. Ultrasonography– Pelvis (PCO)

INCLUSION CRITERIA:

Patients aged between 18-40 years, either married or unmarried,

Patients of anartava (Secondary amenorrhea) more than 45 days to 6 months.

EXCLUSION CRITERIA:

Women with clinical features of PCOD with other systemic diseases like malnutrition, perimenopausal syndrome, premature ovarian failure, cervical tumor, polyp, cervical cancer, uterine fibroid, congenital anomalies in female genital tract, tubercular endometritis, congenital adrenal hyperplasia, HIV/VDRL/HbsAg positive, systemic endocrinal disorders like diabetes mellitus, thyroid dysfunction and subjects with impaired cardiac/ hepatic/ renal function, tuberculosis and severe psychiatric ailments were excluded from the study.

LABORATORY INVESTIGATION:

Urine pregnancy test (if necessary), CBC, Blood group, HIV/ VDRL/ HbsAg, serum insulin level, serum testosterone (if necessary), Random blood glucose level, Hemoglobin percentage and Ultrasonography: Transvaginal scan/Transabdominal scan were carried out according to the clinical presentations.

Study Design:

The study was an open label double arm clinical study with convenient sampling, pre and post-tested sign with sample size of Anartava (PCOD) among 30 subjects.

INTERVENTION AND TREATMENT PLAN:

STUDY GROUP K- (15 patients): Kumaryasava 15 ml anupana with equal amount of water after food in morning and evening [17].

STUDY GROUP KT- (15 patients): Kumaryasava 15 ml mixed tankanabhasma 1Ratti (125mg) with equal amount of water after food morning and evening.

FOLLOW-UP: First follow up- on 15th day, subsequent follow up once in every 15 days and total study duration: 2 months.

ASSESSMENT CRITERIA:

SUBJECTIVE PARAMETER: Onset of menstruation, interval of menstruation between two cycles, duration of menstrual flow and pain associated with menstruation.

OBJECTIVE PARAMETERS: Ultra-sonography (Pelvis) –For confirmation of PCOD appearance, follicle size and anovulation.

OBSERVATION:

Table-01: Showing the Distribution of subjects based on duration of chief complaints

Parameter	Frequency	%
1 to 6months	4	15.4
6 to 12 months	5	19.2
1 to 2 years	7	26.9
2 to 3 years	4	15.4
3 to 4 years	2	7.7
4 to 5 years	4	15.4
Total	26	100

Table-02: Showing the Distribution of subjects based on Anartava

Parameter	Frequency	%
2months	14	53.8
3months	7	26.9
4months	4	15.4
6months	1	3.8
Total	26	100

Table-03: Showing the Distribution of subjects based on BMI of Pt

RESULTS

Results obtained from 24 patients were interpreted as follows

SUBJECTIVE PARAMETER

Table.04. Effect on Interval between two cycles (Friedman's Test)

Interval between two menstrual cycles Gp K	N	Mean rank	X2	P	Remarks
BT	12	2.58	3.000	.392	NS
Dt1		2.58			
DT2		2.42			
AT		2.42			
Interval between two menstrual cycles Gp KT	N	Mean Rank	X2	P	Remarks
BT	12	3.25	19.729	.000	S
DT1		3.04			
DT2		2.21			
AT		1.50			

Table.05. Wilcoxon signed rank test for Interval between two Menstrual cycles with Bonferroni correction P =.000

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P Value	Remarks
	N	MR	SR	N	MR	SR					
BT-T1	3	2.67	8.00	1	2.00	2.00	8	12	-1.134	.257	NS
DT1-DT2	7	4.00	28.00	0	.00	.00	5	12	-2.428	.015	S
DT2-AT	8	4.50	36.00	0	.00	.00	4	12	-2.585	.010	S
BT-AT	9	6.00	54.00	1	1.00	1.00	2	12	-2.862	.004	S

Table.06. Mann-Whitney U Test for Interval between two menstrual cycles between the groups

Parameter	Group-K			Group-KT			Mann Whitney	Wilcoxon	Z value	P Value	Remark
	N	MR	SR	N	MR	SR					
BT	12	12.00	120.00	12	11.08	133.00	55.000	133.000	-.913	.361	NS
DT1	12	13.00	130.00	12	10.25	123.00	45.000	123.00	-1.658	.097	NS
DT2	12	15.65	156.50	12	8.04	96.50	18.500	96.500	-3.029	.002	S
AT	12	15.85	158.50	12	7.88	94.50	16.500	94.500	-3.225	.001	S

Table.07. Effect on duration of Menstrual flow (Friedman's Test

Duration of menstrual flow Gp K	N	Mean Rank	X2	P	Remarks
BT	12	2.40	3.000	.392	NS
DT1		2.40			
DT2		2.60			
AT		2.60			
Duration of menstrual flow Gp KT	N	Mean Rank	X2	P	Remarks
BT	12	2.38	9.000	.029	S
DT1		2.38			
DT2		2.38			
AT		2.88			

Table.08. Effect on Pain during Menstrual cycle (Friedman's Test)

Pain during menstrual cycle Gp K	N	Mean Rank	X2	P	Remarks

BT	12	2.65	1.000	.801	NS
DT1		2.45			
DT2		2.45			
AT		2.45			
Pain during menstrual cycle Gp KT	N	Mean Rank	X2	P	Remarks
BT	12	2.58	3.000	.392	NS
Dt1		2.58			
DT2		2.42			
AT		2.42			

Table.09. Mann-Whitney U Test for Pain during Menstrual cycle (between the groups)

Pain during menstrual cycle	Group-K			Group-KT			Mann - Whitney	Wilcoxon	Z Value	P Value	Remark
	N	MR	SR	N	MR	SR					
BT	12	11.00	110.00	12	11.92	143.00	55.000	110.00	-.378	.706	NS
DT1	12	10.50	105.00	12	12.33	148.00	50.000	105.00	-.776	.438	NS
DT2	12	11.00	110.00	12	11.92	143.00	55.000	110.00	-.402	.688	NS
AT	12	11.00	110.00	12	11.92	143.00	55.000	110.00	-.402	.688	NS

OBJECTIVE PARAMETER

Table.10. Independent t Test for volume of ovaries (Between the groups)

Parameter	Mean Group K	Mean Group Kt	Mean Difference	Std. Error Difference	T	P	Remarks
Volume of Rt ovary BT	5.66	6.916	-1.256	1.116	-1.125	.274	NS
Volume of Rt ovary AT	6.17	6.000	.17000	1.0377	.164	.872	NS
Volume of Lt ovary BT	6.050	6.867	-.8167	1.1795	-.692	.497	NS
Volume of Lt ovary AT	6.370	6.150	.2200	1.1361	.895	.848	NS

Table.11. Independent t Test for Endometrial thickness (Between the groups)

Parameter	Mean Group K	Mean Group Kt	Mean Difference	Std. Error Difference	t	P	Remarks
Endometrial Thickness BT	10.560	8.208	2.351	1.051	2.237	.037	NS
Endometrial Thickness AT	10.120	8.166	1.953	1.023	1.909	.071	NS

DISCUSSION

Subjective parameter

Effect on Interval between Two Cycles

The severity of symptom **Interval between two cycles** was decreased after administration of drugs in the groups and the results were statistically significant in group KT. The difference score in symptom Interval between two cycles was P value .

392 in group K and P value .000 in group KT. All these means were statistically highly significant by **Friedman's Test.**

When comparison between two groups was done, group K was found no improved as compare to group KT.

Effect on duration of Menstrual Flow

The main score of sensitivity to **Duration of Menstrual flow** in group K showed P value.392 and group KT showed P value.029. Group K was statistically not significant. And group KT was statistically highly significant by **Friedman's Test**.

Effect on Quantity of Menstrual Blood

The reduction in the severity of **Quantity of Menstrual blood** was statistically no significant (p=.494) in group K and statistically highly significant (p=.029) in group KT. Further the comparison to two groups denotes that group KT is superior than group K. So here also it is clear that combined effect of Kumaryasava with Tankana bhasma is superior to Kumaryasava.

Effect on Pain during Menstrual Cycle

A difference in mean of 1.000 was noticed in group K which is statistically insignificant (P=.801) on statistical analysis. In same way, a difference in mean of 3.000 was observed in group KT which is statistically insignificant (p=.392). Both groups were statistically not significant in pain during menstrual cycle.

When comparison between two groups was done, both Groups were found insignificant. This confirms that both the treatment is not much effective to correct them pain during menstrual cycle.

Effect of treatment on objective parameter

Effect on Volume of Ovaries

The mean volume of Rt Ovary value in group K was 5.6600 before and 6.1700 after the treatment. The mean volume of Lt Ovary value in group K was 6.0500 before and 6.3700 after the treatment. In group KT. it was 6.9167 before and 6.1700 after treatment. The mean volume of Lt Ovary value in Group KT was 6.8667 before and 6.1500 after the treatment. The improvement of volume of both ovaries in the both groups in statistically not significant.

When comparison between two groups was done, both groups were found insignificant. This confirms that both the treatment is not much effective to correct to reduction of volume of ovaries.

These results suggest that both Kumaryasava and Kumaryasava with Tankana bhasma are not much helpful in improving volume of ovaries in subjects.

Effect on Endometrial Thickness

The mean endometrial thickness value in Group K was 10.5600 before and 10.1200after the treatment. And in group KT it was 8.2083 before and 8.1667 after the treatment. Both groups were statistically not significant on improving ET on comparing also.

Probable Mode of action of Kumaryasava

Drugs: Kumaryasava

contains Kumari Swarasa, Guda, Haritaki, Jala, Madhu, Dhataki, Jatiphala, Lavanga, Kankola, Jantamansi, Kababaka, Cavya, Chitra, Jatipatri, Karkatashrngi, Bibhitaki, Puskarmoola, Tamrabhasma and Lauhabhasma. Most of the ingredients are having Kapha,Vatahara and Medohara property, beneficial in abnormalities of Artava and Nastapuspa[12].

Kumaryasava by its Ushna virya, Katu, Tikta rasa, Katu vipaka, Ushna, Ruksha and Tikshna guna, there by stimultes Agni there by clearing the Ama caused by Kapha. So it initiates the proper function of Ahara rasa and updhatu Artava. This action also clears the Apanavata avarana caused due to Prakupita Kapha in the Artava srotas. The

Chalagati of the Apanavata will be triggered helps to initiation of Artava. This action is evident in these cases by regularizing of menstruation. Ushna virya of the drug favors the Vata shamana and Sroto shodhana and there by relieving the Avarana, which leads to normal functions of Vata and menstruation, occurs.

Tankanabhasma–

It is Katu rasa, Rukshna-Teekshna guna, Ushna veerya, Katu vipaka and KaphaVata shamaka, Kshareeya in nature (alkaline) possesses qualities like Lekhana, Rechana, Pitta-Karaka, Artava-Janaka. In Anartava condition it mainly induces contraction in uterus to maintain menstruation flow[13] Yonivishodhana- which can be understands as shedding the hyperplasic endometrium. Due to Anulomana, facilitates the function of Apana Vayu that in turn will help in its proper functioning.

CONCLUSION

Anartava (PCOD) was more commonly observed among the age group of 18 to 25 years, especially in students and the girls who were intaking more junk food. Kumaryasava alone was less effective than Kumaryasava with Tankana Bhasma in reducing interval between two cycles, enhancing the quantity of menstruation, duration of blood flow, and mild effective in improving dysmenorrhea. A slight reduction in volume of ovaries and enhancement in endometrial thickness was also observed. Early medication and following dietetic regimen have a key role to overcome symptoms of PCOD. Kumaryasava with Tankanabhasma showed significant result in both subjective and objective parameters and effective in the management of Anartava (PCOD).

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