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EFFECT OF TRYUSHANAADYALOHAANDKANASHATAHWADIKASHAYA IN POLYCYSTIC OVARIAN SYNDROME

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Abstract

Poly Cystic ovarian syndrome is a heterogenous, multisystem endocrinopathy in women of reproductive age with the ovarian expression of various metabolic disturbances and a wide spectrum of clinical features such as obesity, menstrual abnormalities and hyperandrogenism. Changing lifestyle of modern society-sedentary lifestyle, high calorie diet, and intolerable stress has led to increase in the prevalence of PCOS up to 20-30%.It affects the richness of feminity as infertility stands out as one of its major complication. The most appropriate correlation of PCOS is Pushpagnijaataharini mentioned in Kasyapasamhita. Here the effect of Ayurvedic yoga TryushanaadyalohaandKanashathahwadikashayam is evaluated in PCOS, as a treatment which is safe, non hormonal and effective against the associated symptoms still remains a challenge. The study drug Tryushanaadyaloha is mentioned under medorogachikitsa in Yogaratnakara and Kanashathahwadikashayam is mentioned under gulmaprakarana of Sahasra Yoga. The study design is interventional study-pre and post test with a sample size of 30. Females in the age group 20-35 yrs with PCOS attending the OPD and IPD of Govt Ayurveda College hospital for women and children Poojappura Thiruvananthapuram was selected for study as per Rotterdam Criteria. Their symptoms were assessed before starting treatment using a case proforma, USG and necessary lab investigations. Administration of drug starts on the 1st day of visit and continued till the onset of next menstrual cycle excluding the days of menstruation for three consecutive cycles. Kanashatahwadikashaya was given in the dose of 48ml bid along with a pinch (250mg) of hingu, 30 minutes before food. Tryushanaadyaloha was given in the dose of750mg after triturating with madhu and ghritha in unequal quantities, 10 minutes before food. Follow up without medicine was done for next 3 consecutive cycles. Data obtained was analysed statistically .The study drug was found to be effective in normalizing menstrual interval, reducing the volume of ovaries and reducing the BMI though it was not effective in reducing the number of follicular cyst and in induction of ovulation.

Key Words: Polycystic Ovarian Syndrome; Pushpagnijaataharini; Tryushanaadyaloha; Kanashatahwadikashaya.

Introduction

Polycystic ovarian syndrome is a common endocrinopathy typified by oligoovulation or anovulation, signs of androgen excess and multiple small ovarian cysts. These signs and symptoms may vary widely between women as well as individuals over time. Motherhood which is a great dream and most beautiful event of a women's life is seriously affected as infertility stands out as one of its major complication. The diagnosis of PCOS is as per Rotterdam criteria. The basic underlying pathology appears to be hyperinsulinaemia. Genetic factors, lifestyle changes and environmental factors also augment the incidence of PCOS in the present scenario.

In Ayurveda there is no direct reference of PCOS but the symptoms can almost be correlated to a disease called *PushpaghniJataharini* described by *AcharyaKasyapa* in *RevathiKalpaAdhyaya*. In this condition it is described that the patient will be having regular but futile cycles and corpulent cheeks with excessive hair. *Nashtarthava* described by *AcharyaSusrutha* mentions that due to *Vatha-Kaphaavarana, arthavanasha*occurs in females which can be correlated with amenorrhoea associated with PCOS. In *vandhya yoni vyapt, artava*is destroyed. This can be considered as secondary amenorrhoea or anovulation which ultimately causes inability to conceive a child.

Materials and Methods

The Present Study "Effect of *TryushanaadyaLoha*and*Kanashatahwadikashaya* in Polycystic Ovarian Syndrome" is aimed to bring out the influence of Ayurveda in treating PCOS as it is a silent destroyer of feminity.

Objective of the Study: To evaluate the effect of *Tryushsanadyaloha* and *Kanashatahwadikashayam* in Poly Cystic Ovarian Syndrome.

Study Design: Single group interventional study (Pre and Post),The patient's status after treatment is compared with the status before treatment.

Study Setting: Cases registered as PCOS at the OPD and IPD of Govt. Ayurveda College Hospital for Women and Children Poojappura , Thiruvananthapuram.

Study Population: Females in the age group 20-35 yrs with Poly Cystic Ovarian Syndrome attending the OPD and IPD of Govt. Ayurveda College Hospital for Women and Children Poojappura , Thiruvananthapuram.

Inclusion Criteria: Females of the age limit 20-35 yrs who are diagnosed as Poly Cystic Ovarian Syndrome as per Rotterdam Criteria. Any of the two features in following three are required for PCOS to be diagnosed

a. Oligoovulation/anovulation
b. Hyperandrogenism (clinical/biochemical)
c. Poly cystic ovaries (12 or more follicles in atleast one ovary measuring 2- 9mm in diameter or a total ovarian volume greater than $10cm^3$).

Exclusion Criteria

- Acromegaly
- Cushing's syndrome
- Primary and secondary amenorrhoea
- Concurrent or previous use of Oral contraceptive pills within last 3 months
- Patients under prolonged medications for various systemic illness
- Androgen producing adrenal tumour and other neoplastic growth
- Patients diagnosed as DUB

Sample Size:-Sample size will be 30.

Sampling Technique: Consecutive cases with their consent and who satisfy the inclusion criteria and till attaining sample size.

Data Collection: The qualitative data related to clinical condition was collected as per the case proforma. The information included in the case proforma were the data related to the patient such as name, age, domicile etc followed by presenting complaints with duration, history of presenting complaints to reveal the gravity of the problem, associated symptoms to know about the metabolic and other abnormalities, past history to know the previous episodes of various illness, personal history to find out the diet, appetite, bladder and bowel habits, allergies and addictions if any, family history to know the genetic patternie occurrence of the same complaints in mother or siblings, and treatment history to know the previous treatments done and its response. General, local and systemic examinations were done to know the intensity of the disease or any other associated diseases.

For clinical evaluation, data required for scoring the signs and symptoms and all the possible information which will reveal the clinical profile of the patient were collected. Investigations included blood and urine routine examination, FBS, PPBS, serum cholesterol and serum testosterone. Weight and height was also measured. USG of abdomen and pelvis was also done to confirm the diagnosis.

Study Tools: Assessment was done using case proforma, Ultrasonography (abdomen and pelvis) and necessary lab investigations.

Duration of Study-Duration of the study was 18 months.

Intervention: 30 patients were selected from study setting as per inclusion and exclusion criteria. Their primary data was collected using a case proforma and necessary lab investigations .USG (abdomen & pelvis) was performed to confirm the diagnosis .Study was conducted in a single group and clinical symptoms of patients were assessed before starting the treatment. *Kanashatahwadikashaya* was given in the dose of48ml bid along with a pinch (approximately equal to 250mg) of *hingukalka*, 30 minutes before food. *Tryushanaadyaloha* was given in the dose of750mg each which was triturated with *madhu* and *ghritha* in unequal quantities and administered 10 minutes before food. *Pathyaaahara* and *vihaara* were also recommended. The patients were asked to report on the first day of next menstrual cycle. During that visit amount of bleeding, duration, menstrual interval etc of the previous cycle were recorded. The study drug was given for a period of 3

months continuously excluding the first three days of each menstrual cycle. Following this, next 3 months were considered as follow up period and the clinical changes in the patient were assessed carefully.

Observation, Analysis and Interpretation

The observations of the subjective and objective parameters are analysed, tabulated and interpreted to prove the efficacy of the study drug.

- Section A: Data related to Clinical Picture.
- Section B: Data related to Effectiveness of treatment.

Table 1

Presenting Complaints		Frequency	Percentage
Menstrual interval(in days)	<35	0	0
	35-60	15	50
	61-90	6	20
	91-120	6	20
	>120	3	10
Menstrual duration(in days)	<3	12	40
	3-5	13	43.33
	6-7	4	13.33
	>7	1	3.33
Amount of bleeding	Spotting	4	13.33
	Scanty	8	26.67
	Moderate	15	50
	Mild excess	2	6.67
	Excessive	1	3.33
Acanthosisnigricans	Present	17	56.67
	Absent	13	43.33
Hirsutism	Present	9	30
	Absent	21	70

1. Menstrual Interval

Menstrual interval was calculated in days. Normal menstrual interval was taken as 21-35 days. For the purpose of categorisation grading was done as follows:

- Grade 0 – less than 35 days
- Grade 1- 35 to 60 days
- Grade 2 – 61 to 90 days.
- Grade 3 - 91-120 days
- Grade 4 - more than 120 days.

Before treatment ,out of the 30 patients, 15(50 %) had menstrual interval between 35-60, 61-90 days menstrual interval for 6 (20 %) patients,91-120 days menstrual interval for 6 (20%) patients and more than 120 days menstrual interval for 3 (10%) patients. The minimum interval noticed was 37 days and maximum interval was 150 days.

2. Menstrual Duration

Menstrual duration or the number of days of bleeding was also calculated in days. An average of 3-5 days bleeding was considered as normal (grade 0). Grading was done as follows:

- Grade 0 – 3 to 5 days
- Grade 1 – less than 3 days
- Grade 2—6 to 7 days
- Grade 3 –more than 7 days.

Before treatment, out of the 30 patients twelve had menstrual interval less than 3 days and thirteen patients had normal menstrual duration. Four patients had menstrual duration of 6-7 days and only one had excessive bleeding i.e. more than 7 days.

3. Amount of Menstrual Bleeding

The number of pads used was counted to assess the amount of bleeding.

Table 2

Amount	Number of Pads Used	Grading
Spotting	No need of pad	0
scanty	One pad per day with minimum soaking	1
Moderate	1-3 pads per day with complete soaking	2
Mild	3-5 pads per day with complete soaking	3
Excessive	More than 5 pads per day with complete soaking	4

- Out of the 30 patients, 4 had only spotting, 8 had scanty menstruation and 15 had normal amount of bleeding. 2 patients had mild excess bleeding and only one of them had excessive bleeding.

4. Acanthosisnigricans

Acanthosisnigricans, a sign of insulin resistance, is mainly due to the hyperplasia of the basal layers of the epidermis due to the presence of extremely elevated insulin level in the body.

- Out of the 30 patients 17 (56.67%) had acanthosisnigricans before treatment.

5. Hirsutism

The presence and activity of 5- alpha reductase in the skin largely determines the presence or absence of hirsutism.

- Out of the 30 patients 9 (30%) had hirsutism before treatment.

Figures of Clinical Picture

Figure 1: Percentage Distribution According to Menstural Interval

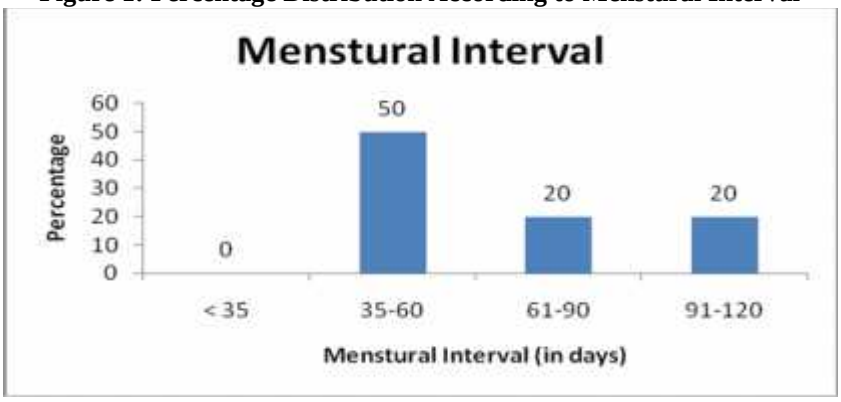


Figure 2: Percentage Distribution According to Menstural Duration

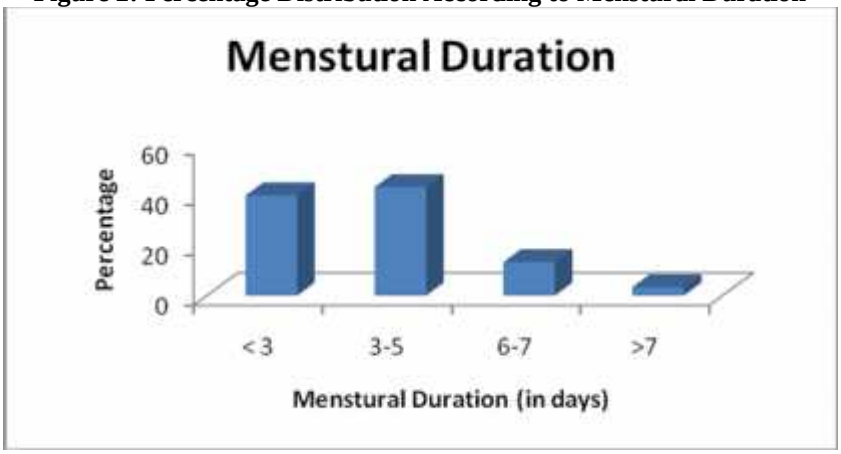


Figure 3: Percentage Distribution According to Amount of Bleeding

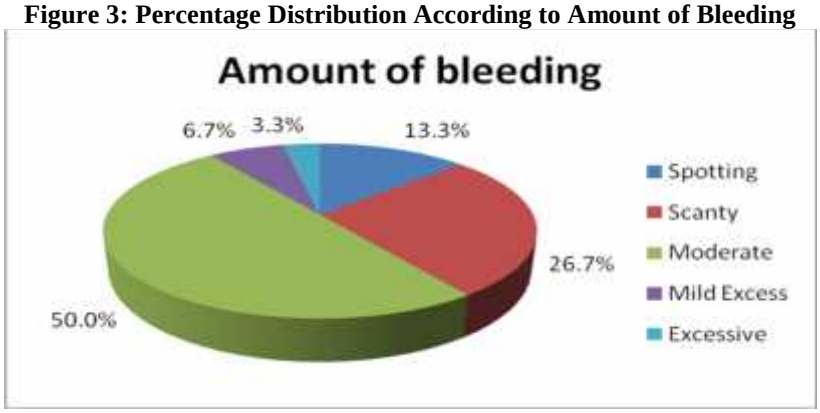


Figure 4: Percentage Distribution According to Acanthosisnigricans

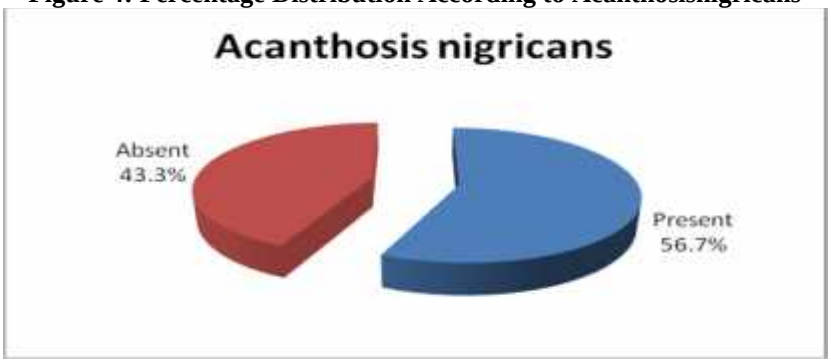
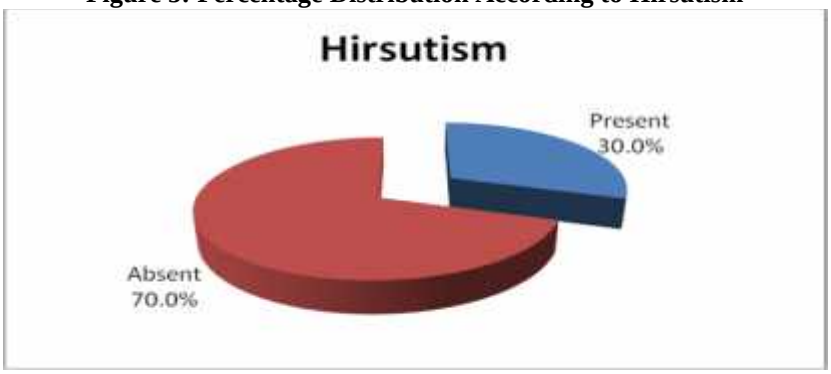


Figure 5: Percentage Distribution According to Hirsutism



Section B: Data Related to Effectiveness of Treatment

Menstrual interval was considered as the most important parameter for assessing the efficacy of the study drug along with the decrease in the severity of the associated complaints. For the purpose of comparison of the efficacy of the study drug before and after treatment, the complaints were converted into scores.

Table 3: Effectiveness of the Treatment in Reducing Menstrual Interval

Interval of Menstural Cycles	BT		AT		AF	
	N	%	N	%	N	%
Less than 35 days	0	0.0	17	60.7	27	96.4
35- 60 days	14	50.0	10	35.7	0	0.0
61 - 90 days	6	21.4	0	0.0	0	0.0
91 - 120 days	6	21.4	1	3.6	1	3.6
More than 120 days	2	7.1	0	0.0	0	0.0
Total	28	100.0	28	100.0	28	100.0

Wilcoxon Signed Rank Test	BT - AT	AT- AF	BT-AF
Z	4.696	3.162	4.627
P	<0.001	<0.001	<0.001

After three months of treatment, considerable reduction in the menstrual interval was noticed. Before treatment , out of the 30 patients , 15(50 %) had menstrual interval between 35-60 days, 61-90 days menstrual interval for 6(20 %) patients,91-120 days menstrual interval for 6(20%) patients and more than 120 days menstrual interval for 3 (10 %)patients. After 3 months of treatment 17(60.7%) had menstrual interval less than 35 and 10 (35.7%) had a menstrual interval of 35-60 days. There were no patients who had a menstrual interval of 61-90 days and only 1 had a menstrual interval of 91-120 days .Two patients among the 30 did not have menstruation even after the administration of the study drug for the period of three months. After the follow up period for 3 months 27 (96.4 %) patients had menstrual interval between 35-60 days and only one (3.6 %) had menstrual interval between 91-120 days.

As per Wilcoxan signed rank test we have statistically highly significant p value less than 0.001 after treatment and after follow up period. This reveals the efficacy of the treatment in reducing menstrual interval after treatment and after follow up period.

Table 4: Effectiveness of the Treatment in Reducing the Number of Follicular Cysts

	BT	AT	AF
Number of Follicular cysts	Numerous	Numerous	Numerous

After three months of treatment and follow up there was no reduction in the number of follicular cysts in any of the 30 patients. This reveals that the treatment was not effective in reducing the number of follicular cysts.

Table 5: Effectiveness of the Treatment in Reducing the Volume of Right Ovary

	N	Volume of Right Ovary (cm^3)		Paired Comparison	Paired Differences		Paired Sample t Test	
		Mean	Sd		Mean	Sd	T	P
BT	28	12.18	2.05					
AT	28	11.60	1.98	BT - AT	.59	.58	5.44	.001
AF	28	11.59	1.98	BT - AF	.59	.58	5.44	<0.001

After three months of treatmentwe can find considerable reduction in the volume of right ovary. Before treatment, the mean volume of right ovary was 12.18 cm^3. It was reduced to 11.60 cm^3 after the treatment period of three months which again reduced to 11.59 cm^3 after the follow up period. Two patients among the 30 had no change in the volume of right ovary even after the administration of the study drug for the period of three months.

As per Paired sample t testwe have statistically highly significant p value less than 0.001 after treatment and after follow up period. This reveals the efficacy of the treatment in reducing the volume of right ovary after treatment and after follow up period.

Table 6: Effectiveness of the Treatment in Reducing the Volume of Left Ovary

	N	Volume of Left Ovary (cm^3)		Paired Comparison	Paired Differences		Paired Sample t Test	
		Mean	Sd		Mean	Sd	T	P
BT	28	12.18	2.05					
AT	28	11.60	1.98	BT - AT	.40	.44	4.93	.001
AF	28	11.59	1.98	BT - AF	.40	.44	4.93	<0.001

After three months of treatmentwe can find considerable reduction in the volume of left ovary. Before treatment, the mean volume of left ovary was 12.18cm^3.It was reduced to 11.60 cm^3 after the treatment period of three months which again reduced to 11.59 cm^3 after the follow up period. Two patients among the 30 had no change in the volume of right ovary even after the administration of the study drug for the period of three months.

As per Paired sample t testwe have statistically highly significant p value less than 0.001 after treatment and after follow up period. This reveals the efficacy of the treatment in reducing the volume of left ovary after treatment and after follow up period.

Table 7: Effectiveness of the Treatment in Induction of Ovulation

Ovulation	BT		AT		AF	
	N	%	N	%	N	%
Yes	0	0.0	2	6.9	0	0
No	30	100.0	27	93.1	29	100.0
Total	30	100.0	30	100.0	30	100.0

Wilcoxon Signed Rank Test	BT - AT	AT- AF	BT-AF
z	1.414	1.414	0.000
p	0.157	0.157	1.000

Ovulation was absent in all the 30 patients before treatment. After three months of treatment one had ovulation and one patient conceived. But after the follow up period, none of them had ovulation.

As per Wilcoxan signed rank test we have p value greater than 0.001 after treatments and after follow up period. This reveals that the treatment was not effective in inducing ovulation.

Table 8: Effectiveness of the Treatment in Reducing BMI

	N	BMI		Paired Comparison	Paired Differences		Paired Sample t Test	
		Mean	Sd		Mean	sd	T	P
BT	28	23.86	4.11	BT - AT	.56	.40	7.439	<0.001
AT	28	23.30	3.96	AT - AF	.19	.27	3.720	.001
AF	28	23.11	3.83	BT - AF	.75	.47	8.382	<0.001

After three months of treatmentwe can find considerable reduction in BMI. Before treatment, the mean BMI was 23.86. It was reduced to 23.30 after the treatment period of three months which again reduced to 23.11 after the follow up period. Two patients among the 30 had no change in BMI even after the administration of the drug for the period of three months. As per Paired sample t testwe have statistically highly significant p value less than 0.001 after treatment and after follow up period. This reveals the efficacy of the treatment in reducing BMI after treatment and after follow up period.

Figure 6: Effectiveness of the Treatment in Reducing Menstrual Interval

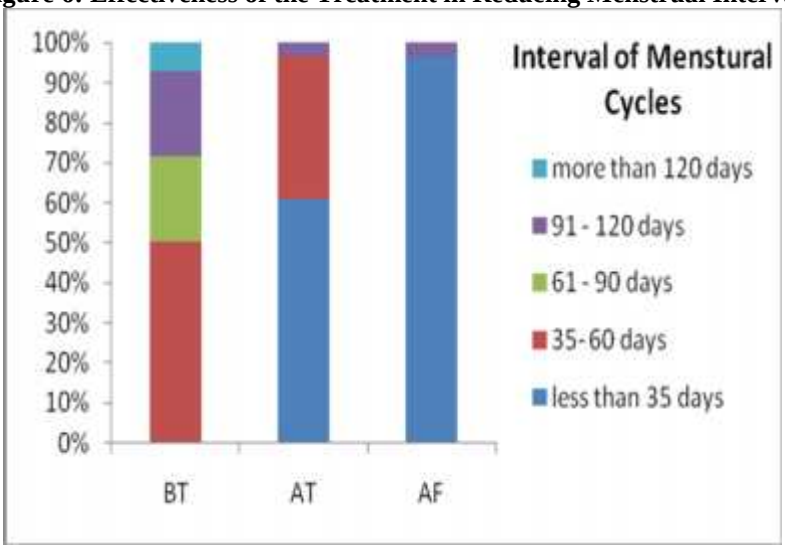


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Figure 7: Effectiveness of the Treatment in Reducing the Number of Follicular Cysts

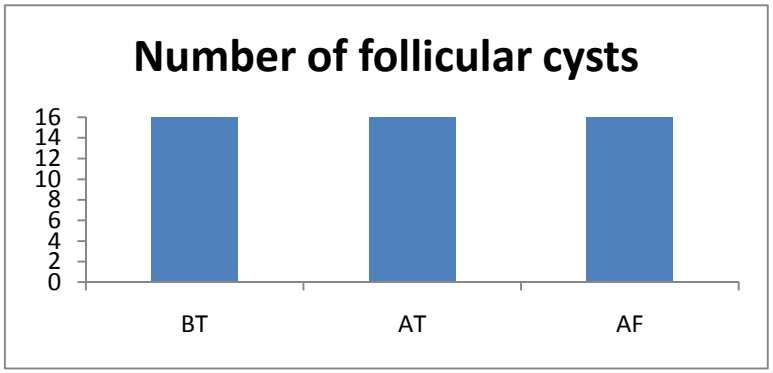

Figure 8: Effectiveness of the Treatment in Reducing the Volume of Right Ovary

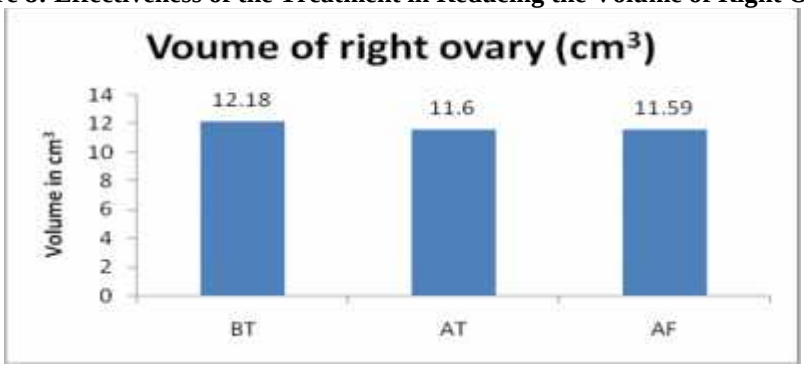

Figure 9: Effectiveness of the Treatment in Reducing the Volume of Left Ovary

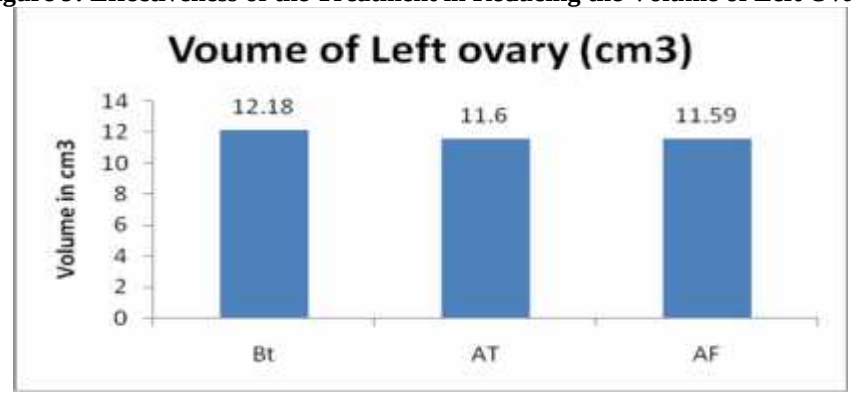

Figure 10: Effectiveness of the Treatment in Induction of Ovulation

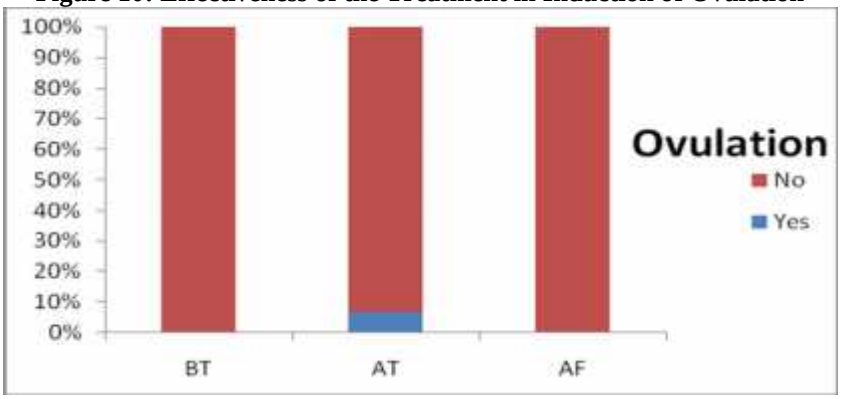

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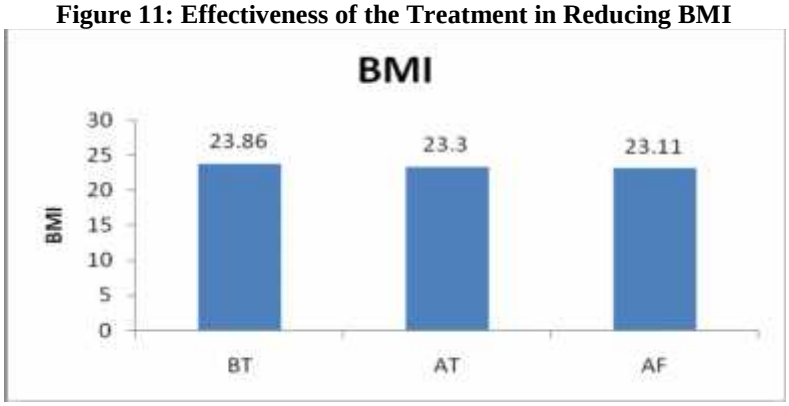
Figure 11: Effectiveness of the Treatment in Reducing BMI



Discussion

The assessment was done after treatment and after the follow up and the changes in outcome variables were analysed statistically.

1. Number of Follicular Cyst and Volume of Ovary

Number of follicular cyst and volume of ovary was assessed using USG. 12 or more follicles in at least one ovary measuring 2- 9mm in diameter or a total ovarian volume greater than 10cm^3 are suggestive of PCOS. After the treatment and follow up period there was no change in the number of follicular cysts. This shows that the medicine was not effective in reducing the number of follicular cysts.

After three months of treatment we can find considerable reduction in the volume of right ovary. Before treatment, the mean volume of right ovary was 12.18 cm^3. It was reduced to 11.60 cm^3 after the treatment period of three months which again reduced to 11.59 cm^3 after the follow up period. Two patients among the 30 had no change in the volume of right ovary even after the administration of the drug for the period of three months. As per Paired sample t testwe have statistically highly significant p value less than 0.001 after treatment and after follow up period. This reveals the efficacy of the treatment in reducing the volume of right ovary after treatment and after follow up period.

After three months of treatmentwe can find considerable reduction in the volume of left ovary. Before treatment, the mean volume of left ovary was 12.18cm^3.It was reduced to 11.60 cm^3 after the treatment period of three months which again reduced to 11.59 cm^3 after the follow up period. Two patients among the 30 had no change in the volume of right ovary even after the administration of the drug for the period of three months. As per Paired sample t testwe have statistically highly significant p value less than 0.001 after treatment and after follow up period. This reveals the efficacy of the treatment in reducing the volume of left ovary after treatment and after follow up period.

2. Ovulation

Ovulation was assessed using follicular study before and after treatment and after follow up. Ovulation was absent in all the 30 patients before treatment. After three months of treatment one had ovulation and one patient conceived. But after follow up none of them had ovulation. As per Wilcoxan signed rank test we have p value greater than 0.001 after treatments and after follow up period. This reveals that the treatment was not effective in inducing ovulation.

3. Menstrual Interval

After three months of treatment, we can find considerable reduction in the menstrual interval. Before treatment , out of the 30 patients , 15(50 %) had menstrual interval between 35-60 days, 61-90 days menstrual interval for 6(20 %) patients,91-120 days menstrual interval for 6(20%) patients and more than 120 days menstrual interval for 3 (10 %)patients. After 3 months of treatment 17(60.7%) had menstrual interval less than 35 and 10 (35.7%) had a menstrual interval of 35-60 days. There were no patients who had a menstrual interval of 61-90 days and only 1 had a menstrual interval of 91-120 days .Two patients among the 30 did not have menstruation even after the administration of the drug for the period of three months. After the follow up period for 3 months 27 (96.4 %) patients had menstrual interval between 35-60 days and only one (3.6 %) had menstrual interval between 91-120 days. As per Wilcoxan signed rank test we have statistically highly significant p value less than 0.001 after treatment and after follow up period. This reveals the efficacy of the treatment in reducing menstrual interval after treatment and after follow up period.

4. BMI

BMI was calculated using the formula

$$\text{BMI} = \frac{\text{Weight in Kg}}{(\text{Height in meter})^2}$$

Weight and height of the patients was measured before and after treatment and after follow up and the BMI was calculated using above formula.

After three months of treatmentwe can find considerable reduction in BMI. Before treatment, the mean BMI was 23.86.It was reduced to 23.30 after the treatment period of three months which again reduced to 23.11 after the follow up period. Two patients among the 30 had no change in BMI even after the administration of the drug for the period of three months. As per Paired sample t testwe have statistically highly significant p value less than 0.001 after treatment and after follow up period. This reveals the efficacy of the treatment in reducing BMI after treatment and after follow up period.

From the above analysis on response of the patients to the treatment, it is found that the study drug *Tryushanaadyaloha* and *Kanashatahwadikashaya* is highly effective in normalizing menstrual interval, reducing the volume of ovaries and reducing the BMI. It was not effective in reducing the number of follicular cyst and in induction of ovulation.

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