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Research Article

Study the Efficacy of Morinda Citrifolia in Polycystic Ovarian Syndrome (PCOS)

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ABSTRACT

INTRODUCTION- Polycystic ovary syndrome (PCOS) is a common female condition typified by reproductive, hyperandrogenic, and metabolic features. Polycystic ovary syndrome is a genetic condition, exacerbated by obesity. There is a close link between obesity and PCOS based on epidemiological data, and more recently corroborated through genetic studies. There are many mechanisms mediating the effects of weight-gain and obesity on the development of PCOS. The metabolic effects of insulin resistance and steroidogenic and reproductive effects of hyperinsulinemia are important mechanisms.

OBJECTIVE-The objective of the study is to study of BMI in Polycystic Ovarian syndrome.

MATERIALS AND METHODS-Total 117 patients were enrolled. Out of them 80 patients successfully completed the course of treatment. There were two arms of this study.one was trial arm and another was control arm. For statistical analysis, Wilcoxon Signed Rank test, Friedman test and Paired t test, Me Nemar's test was done for different subjective and objective parameters.

RESULTS There was statistically significant improvement observed in the Signs and Symptoms of, Polycystic ovarian syndrome, androgen levels, LH: FSH Ratio, Volume of the ovary and regulation of menses ($p<0.05$)

CONCLUSION- The significantly effective in improving the signs and symptoms of Polycystic Ovary Syndrome (PCOS) in BMI. This treatment also showed positive effects on objective parameters such as the BMI.

Keywords: Ayurveda, Polycystic Ovary Syndrome, Morinda Citrifolia, Caesalpinia Bonducella.

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INTRODUCTION

In this Acharya Kashyap mentioned there are some conditions like, Pushpaghni Jataharini which bears some resemblance with the symptoms of Polycystic Ovarian Disease¹. In this condition, it is described that the women have regular but, ineffective cycles and plump cheeks with excessive hairs.^{2,3} Tridosha balance is essential for the menstrual cycle and ovarian cycle.^{4,5} But in Polycystic Ovarian syndrome vata is covered by kapha, which results in anovulation. Vata kapha avaran i.e., covering of vata kapha on ovaries leads to obstruction in follicle rupture hence the follicles remain in the ovaries leading to amenorrhea or artavanasha.^{6,7,8} Thus, Artavanasha can be correlated with amenorrhea associated with polycystic ovarian syndrome.⁹ Even in vandhya yonivyapata, artava is destroyed Click or tap here to enter text., i.e., Anovulation or artvanasha is seen which, causes the inability of a female to conceive.^{10,11}

In women who are genetically predisposed to development of PCOS, weight-gain and obesity often result in its clinical and biochemical manifestation.^{12,13} Accordingly, there are close links between obesity and PCOS.¹⁴ The majority of women with PCOS (38%-88%) are either overweight or obese.¹⁵ Data from the Northern Finland Birth Cohort (NFBC) 1966 show a significant association between body mass index (BMI) and features of PCOS at all ages.^{16,17} Furthermore, modest weight-loss (around 5%) often results in clinically meaningful improvements in the reproductive, hyperandrogenic, and metabolic features of PCOS.^{18,19} Outlined below are factors that mediate the effects of weight-gain and obesity on the pathogenesis of PCOS.^{20,21}

Ayurveda views PCOS as a disorder of the Kapha dosha, one of the three doshas (energies) that govern the human body.²² According to Ayurveda, Kapha dosha is responsible for providing structure and lubrication to the body.²³ When Kapha dosha becomes imbalanced, it can lead to the formation of cysts in the ovaries, resulting in PCOS.²⁴ Ayurveda identifies several factors that can contribute to Kapha dosha imbalance and the development of PCOS.²⁵

It is also known by the name Stein Leventhal syndrome.²⁶ polycystic ovarian syndrome is a generic description for a broad spectrum of clinical and morphological findings in women with endocrine dysfunction, especially abnormal androgen production and metabolism.²⁷ The causes of polycystic ovarian syndrome (PCOS) are currently unknown. In this study causes i.e., aetiology, pathogenesis, and research outcome of polycystic ovarian syndrome were studied.²⁸

AIM AND OBJECTIVES

AIM:

Study the efficacy of *Morinda Citrifolia* in polycystic ovarian syndrome

OBJECTIVES:

OBJECTIVES:

- 1) To establish concept of anovulation on the basis of ayurvedic basic principles.
- 2) To compile a literature of polycystic ovarian syndrome and *Morinda Citrifolia* and *Caesalpinia Bonducella* according to Ayurved and modern science.
- 3) To study the etiopathogenesis of polycystic ovarian syndrome in modern and Ayurvedic Literature.
- 4) To Study the effect of drug on hormones.
- 5) To compare difference between trial and control drug group.
- 6) To summarize promising area of investigation and to stimulate further research in this area.

REVIEW OF LITERATURE

Ayurveda is a branch of science that provides solutions for most lifestyle disorders. Rather than just finding a cure for a disease, Ayurveda delves deep into understanding the cause, symptoms and manifestation of the disease. This holistic approach makes Ayurveda a complete science in itself. Although PCOS (Polycystic Ovary Syndrome) is not explicitly mentioned in any Ayurvedic texts, there are scattered references to the topic.²⁹

Ayurveda doesn't focus on naming a disease, but on understanding the vitiated doshas and dushyas responsible for it, as the same vitiated tridosha can cause different diseases in different parts of the body. Therefore, the disease must be understood in accordance with its samuthana vishesha and sthanantargata manifestations, to adopt an appropriate treatment.³⁰

In the case of PCOS, the disease is primarily caused by the vitiated kapha dosha, which deranges the function of the vata dosha as well. The initial manifestations of the disease appear in the garbhashaya, with symptoms of rasa and medovaha srotho dushti lakshanas. This work will provide a chronological order of the nidana, to facilitate a better understanding of PCOS.³¹

MATERIALS AND METHODOLOGY

Ethical clearance:

Ethical clearance was obtained from the institutional ethics committee (IEC) of BVDU College of Ayurved, Pune, Maharashtra. (EEC No. SDMCAH/IEC/156/13-14 dated 05-04-2014 SDMCAH/IEC)

Plan of Study: -

Place of Research –

The research was carried out at the Bharati Vidyapeeth Deemed to be University College of Ayurved and Hospital Department of Streeroga and Prasutitantra, Dhankawadi, Pune-43.

Type of study:

Open randomized control comparative clinical trial

Sample size: 40 patients in each group according to prevalence.

Place: Bharati Ayurved Hospital; OPD and IPD.

Case record format: Case Record format prepared according to department of Streeroga and Prasutitantra

Consent: obtained from each patient.

Complete systemic examination of patient done.

- Patients with irregular menses / scanty menses.
- Polycystic ovaries diagnosed by Ultrasonography.

Exclusion criteria –

Congenital anomalies in female genital tract

Ovarian growth

❖ Uterine Fibroid

❖ Patient with Thyroid Dysfunction

❖ Known Diabetes Mellitus

❖ Any malignancy related to genital tract

❖ Tubercular endometriosis

Discontinuation criteria: -

- If patient has developed untowards side effect then treatment has to be discontinued.
- Non-Compliance of the patient.
- Voluntary withdrawal by the patients.
- If patients are not regular for follow up then she will be removed from the study.

Assessment Criteria:

Subjective:

General Examination: - BP, Pulse, RS/ CVS, P/A, PV (Selected Cases)

Hirsutism

Blackening of skin

Agni examination

Prakruti examination

Udarshool

Objective:

Duration of bleeding (no. of days)

Menstrual interval (duration between two menstrual cycle)

Amount of bleeding pads per day

USG - before and after treatment

Weight,

Serum levels of FSH, LH, Sr. Testosterone, TFT, Sr.

Prolactin, AMH, HBA1C

METHODOLOGY

Selection criteria

- ❖ Patients presenting with complaints of menstrual abnormalities, hirsutism, and infertility etc. features of PCOS were taken for the study.
- ❖ Detailed histories of all the cases including age, occupation, socio-economic status, parity, menstrual and obstetric history etc. were recorded in a specially prepared proforma.
- ❖ A thorough physical examination of all the cases were carried out including general body built, weight, height etc. was carried out. Laboratory investigations necessary were carried out.

Diagnostic criteria: -

Rotterdam's criteria are fulfilled, they are as, out of three if two are present

- 1) Anovulation.
- 2) Hyperandrogenism.
- 3) Polycystic ovary in Ultrasound.

Inclusion criteria –

- Patients of age group 18 to 45 yrs.

OBSERVATIONS, STATISTICAL ANALYSIS AND RESULT

TABLE 1 - INCIDENCE OF AGE WISE DISTRIBUTION

AGE	Group A	Group B	Total
<20 years	0	4	4
20-30	31	29	60
>30 years	9	7	16
Total	40	40	80

OBSERVATION- more patients observed at 20-30 years of age in both group.

TABLE 2 - INCIDENCE OF HORMONAL PILL USERS

Hormonal pill users	Gr.A	Gr.B	Total	%
Used	28	23	51	63.75
Not used	12	17	29	36.25

OBSERVATION- more patients observed as hormonal pill users in both group.

TABLE 3 - EFFECT OF GROUP A ON BMI IN POLYCYSTIC OVARIAN SYNDROME: -

parameter	Mean		X	% of improvement	T	P VALUE
	BT	AT				
BMI	27.09	26.82	0.27	0.99%	-1.846	0.072

the mean of BMI BT was 27.09 which was decreased to 26.82 after treatment. X value is 0.27. The mean increment in score was 1% which is not significant as observed by “paired t test” (as p value>0.05) and t value

is -1.846. Thus it can be said that there is no significant increment BMI in polycystic ovarian syndrome. I.e. Group A was minimum effective BMI in polycystic ovarian syndrome.

TABLE 4 - EFFECT OF GROUP B ON BMI IN POLYCYSTIC OVARIAN SYNDROME.

Parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
BMI	26.25	25.85	0.40	1.53%	3.428	0.001

The mean of BMI BT was 26.25 which was decreased to 25.85 after treatment. The mean increment in score was 1.53% which is significant as observed by “paired t test” (as p value<0.05) thus it can be said that there is

significant increment BMI in polycystic ovarian syndrome i.e. Group B was effective on BMI in polycystic ovarian syndrome.

TABLE 5 - COMPARISON OF GROUP A AND GROUP B ON BMI IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
BMI	Group A	1.00%	-0.907	0.367
	Group B	1.53%		

On analyzing the effect of treatment 1% improvement seen in Gr.A and 1.53 % improvement seen in Gr.B.t value is -0.907 As p value>0.05 we found that there was no statistical significant difference between Group A and Group B on BMI in polycystic ovarian syndrome. Here Group B was effective on BMI in Polycystic Ovarian Syndrome

RESULT-

The study aimed to evaluate the effectiveness of different interventions on Body Mass Index (BMI) improvement in women diagnosed with polycystic ovarian syndrome (PCOS). The data presented reveals a comparison between two groups, Group A and Group B, with respective BMI improvements of 1.00% and 1.53%. The statistical analysis was performed using a t-test, with Group A showing a t-value of -0.907 and a p-value of 0.367, indicating a lack of statistical significance.

TABLE 6 - EFFECT OF GROUP A ON DURATION OF BLEEDING IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Duration of Bleeding	3.98	4.05	0.07	1.24%	1	0.323

The mean of Duration of Bleeding BT was 3.98 which was increased to 4.05 after treatment. The mean increment in score was 1.24% which is not significant as observed by “paired t test” (as p value>0.05) thus it can be said that there is no significant increment Duration of

Bleeding in polycystic ovarian syndrome. but as we observed clinically duration of bleeding improved.. I.e. Group A was effective Duration of Bleeding in polycystic ovarian syndrome.

TABLE 7 - EFFECT OF GROUP B ON DURATION OF BLEEDING IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Duration of Bleeding	3.60	3.65	0.05	1.39%	-0.404	0.688

The mean of Duration of Bleeding BT was 3.60 which was increased to 3.65 after treatment. The mean increment in score was 1.39% which is not significant as observed by “paired t test” (as p value>0.05) thus it

can be said that there is no significant increment Duration of Bleeding in polycystic ovarian syndrome. I.e. Group B was minimum effective Duration of Bleeding in polycystic ovarian syndrome.

TABLE 8 - COMPARISON OF GROUP A AND GROUP B ON DURATION OF BLEEDING IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
Duration of Bleeding	Group A	1.24%	-1.246	0.216
	Group B	1.39%		

On analyzing the effect of treatment 1.24 % improvement seen in Gr.A and 1.39 % improvement seen in Gr.B.As p value>0.05 we found that there was no statistical significant difference between Group A

and Group on Duration of Bleeding in polycystic ovarian syndrome.Here both Group A and Group B was effective on Duration of Bleeding in polycystic ovarian syndrome.

TABLE 9 - EFFECT OF GROUP A ON MENSTRUAL INTERVAL IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Menstrual Interval	62.50	55.88	6.63	10.60%	4.723	0

The mean of Menstrual Interval BT was 62.50 which was decreased to 55.88after treatment. The mean increment in score was 10.60% which is significant as observed by “paired t test” (as p value<0.05) thus it can

be said that there is significant increment Menstrual Interval in polycystic ovarian syndrome.I.e. Group A was effective on Menstrual Interval in polycystic ovarian syndrome

TABLE 10 - EFFECT OF GROUP B ON MENSTRUAL INTERVAL IN POLYCYSTIC OVARIAN SYNDROME

Parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Menstrual Interval	53.88	44.88	9.00	16.71%	7.026	0

The mean of Menstrual Interval BT was 53.88 which was decreased to 44.88 after treatment. The mean increment in score was 16.71% which is significant as observed by “paired t test” (as p value<0.05) thus it can

be said that there is significant increment Menstrual Interval in polycystic ovarian syndrome.I.e. Group B was effective on Menstrual Interval in polycystic ovarian syndrome.

TABLE 11 - COMPARISON OF GROUP A AND GROUP B ON MENSTRUAL INTERVAL IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
Menstrual Interval	Group A	10.60%	-2.417	0.018
	Group B	16.71%		

As p value<0.05 we found that there was statistical significant difference between Group A and Group on Menstrual Interval in polycystic ovarian Also as percentage of improvement seen from above table we

get percentage of improvement in Group B was more than Group A hence we can say that Group B is more effective as compared to Group A on Menstrual Interval in polycystic ovarian

TABLE 12 - EFFECT OF GROUP A ON AMOUNT OF BLEEDING (PADS/DAY) IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		X	% of improvement	T	P VALUE
	BT	AT				
Amount Of Bleeding (pads/day)	1.68	1.75	0.08	4.48%	-1.778	0.083

The mean of Amount of Bleeding (pads/day) BT was 1.68 which was increased to 1.75after treatment. The mean increment in score was 4.48% which is not significant as observed by “paired t test” (as p

value>0.05) thus it can be said that there is no significant increment Amount of Bleeding (pads/day) in polycystic ovarian syndrome. I.e. Group A was effective Amount of Bleeding (pads/day) in polycystic ovarian syndrome.

TABLE 13 - EFFECT OF GROUP B ON AMOUNT OF BLEEDING (PADS/DAY) IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		X	% of improvement	t	P VALUE
	BT	AT				
Amount Of Bleeding (pads/day)	1.60	1.73	0.13	7.81%	-2.36	0.023

The mean of Amount of Bleeding (pads/day) BT was 1.60 which was increased to 1.73 after treatment. The mean increment in score was 7.81% which is significant as observed by “paired t test” (as p value<0.05) thus it

can be said that there is significant increment Amount of Bleeding (pads/day) in polycystic ovarian syndrome. I.e. Group B was effective on Amount of Bleeding (pads/day) in polycystic ovarian syndrome.

TABLE 14 - COMPARISON OF GROUP A AND GROUP B ON BLEEDING (PADS/DAY) IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
Amount Of Bleeding (pads/day)	Group A	4.48%	-0.236	0.814
	Group B	7.81%		

As p value > 0.05 we found that there was statistical significant difference between Group A and Group B on Amount of Bleeding (pads/day) in polycystic ovarian syndrome.

Here both Group A & B was effective Amount of Bleeding (pads/day) in polycystic ovarian syndrome.

TABLE 15 - EFFECT OF GROUP A ON HIRSUTISM IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Hirsutism	1.05	1.05	0.00	0.00%	-	

On analyzing the effect of treatment on Hirsutism by applying the Friedman's test statistically, it was noted that mean value before and after treatment was same in

group A. I.e. Group A was not effective Hirsutism in polycystic ovarian syndrome.

TABLE 16 - EFFECT OF GROUP B ON HIRSUTISM IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	T	P VALUE
	BT	AT				
Hirsutism	1.45	1.43	0.02	1.72%	1	0.323

The mean of Hirsutism BT was 1.45 which was decreased to 1.43 after treatment. The mean increment in score was 1.72% which is not significant as observed by "paired t test" (as p value > 0.05) thus it can be said

that there is no significant increment Hirsutism in polycystic ovarian syndrome. I.e. Group B was not effective Hirsutism in polycystic ovarian syndrome

TABLE 17 - COMPARISON OF GROUP A AND GROUP B ON HIRSUTISM IN POLYCYSTIC OVARIAN SYNDROME

Parameter	Group	% of improvement	T	P VALUE
Hirsutism	Group A	0.00%	0.965	0.338
	Group B	1.72%		

On analyzing the effect of treatment on Hirsutism by applying the Friedman's test statistically, it is noted that mean value after treatment not improved in Gr.A and 1.72 % in Gr.B. As p value > 0.05 we found that there was

no statistical significant difference between Group A and Group on Hirsutism in polycystic ovarian syndrome. Here both Group A and Group B was not effective on Hirsutism in polycystic ovarian syndrome.

TABLE 18 - EFFECT OF GROUP A ON BLACKENING OF SKIN IN POLYCYSTIC OVARIAN SYNDROME

Parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Blackening of Skin	0.20	0.23	-0.03	-12.50%	-1	0.323

On analyzing the effect of treatment on Blackening of Skin by applying the Friedman's test statistically, it was noted that mean value before and after treatment was almost same in group A. The mean of Blackening of Skin BT was 0.20 which was increased to 0.23 after treatment. The mean increment in score was -12.50 %

which is not significant as observed by "paired t test" (as p value > 0.05) thus it can be said that there is no significant increment Blackening of Skin in polycystic ovarian syndrome. I.e. Group A was not effective Blackening of Skin in polycystic ovarian syndrome.

TABLE 19 - EFFECT OF GROUP B ON BLACKENING OF SKIN IN POLYCYSTIC OVARIAN SYNDROME

Parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Blackening of Skin	0.28	0.28	NO change	0.00%	-	

The mean of Blackening of Skin BT was 0.28 before and after treatment which was remain same after treatment. The mean increment in score was 0.00% which is not

significant as observed. Thus it can be said that there is no significant increment blackening of Skin in polycystic ovarian syndrome. I.e. Group B was not

effective Blackening of Skin in polycystic ovarian syndrome

TABLE 20 - COMPARISON OF GROUP A AND GROUP B ON BLACKENING OF SKIN IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	T	P VALUE
Blackening of Skin	Group A	0.00%	0.325	0.746
	Group B	12.50%		

As p value>0.05 we found that there was no statistical significant difference between Group A and Group on Blackening of Skin in polycystic ovarian syndrome Here

both Group A and Group B was not effective on Blackening of Skin in polycystic ovarian syndrome.

EFFECT OF GROUP A ON OVARIAN VOLUME IN POLYCYSTIC OVARIAN SYNDROME

Parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Ovarian Volume	9.38	8.97	0.41	4.37%	2.93	0.006

The mean of Ovarian Volume BT was 9.38 which was decreased to 8.97 after treatment. The mean increment in score was 4.37% which is significant as observed by “paired t test” (as p value<0.05) thus it can be said that

there was significant increment Ovarian Volume in polycystic ovarian syndrome. I.e. Group A was effective on Ovarian Volume in polycystic ovarian syndrome.

TABLE 21 - EFFECT OF GROUP B ON OVARIAN VOLUME IN POLYCYSTIC OVARIAN SYNDROME

Parameter	Mean		x	% of improvement	T	P VALUE
	BT	AT				
Ovarian Volume	8.91	8.33	0.58	6.51%	3.912	0

The mean of Ovarian Volume BT was 8.91 which was decreased to 8.33 after treatment. The mean increment in score was 6.51% which is significant as observed by “paired t test” (as p value<0.05) thus it can be said that

there is significant increment Ovarian Volume in polycystic ovarian syndrome. I.e. Group B was effective on Ovarian Volume in polycystic ovarian syndrome

TABLE 22 - COMPARISON OF GROUP A AND GROUP B ON OVARIAN VOLUME IN POLYCYSTIC OVARIAN SYNDROME

Parameter	Group	% of improvement	T	P VALUE
Ovarian Volume	Group A	4.37%	-0.959	0.341
	Group B	6.51%		

As p value>0.05 we found that there was no statistical significant difference between Group A and Group on Ovarian Volume in polycystic ovarian syndrome. But as percentage of improvement seen from above table we get percentage of improvement in Group B was

more than Group A hence we can say that Group B is more effective as compared to Group A on Ovarian Volume in polycystic ovarian.

TABLE 23 - EFFECT OF GROUP A ON FSH IN POLYCYSTIC OVARIAN SYNDROME

Parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
FSH	8.07	9.01	0.95	11.73%	-4.722	0

The mean of FSH BT was 8.07 which was increased to 9.01 after treatment. The mean increment in score was 11.73% which is significant as observed by “paired t test” (as p value<0.05) thus it can be said that there is

significant increment FSH in polycystic ovarian syndrome. I.e. Group A was effective on FSH in polycystic ovarian syndrome.

TABLE 24 - EFFECT OF GROUP B ON FSH IN POLYCYSTIC OVARIAN SYNDROME

Parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
FSH	8.51	9.88	1.37	16.12%	-5.59	0

Mean of FSH BT was 8.51 which was increased to 9.88 after treatment. The mean increment in score was 16.12% which is significant as observed by “paired t test” (as p value<0.05) thus it can be said that there is

significant increment FSH in polycystic ovarian syndrome. I.e. Group B was effective on FSH in polycystic ovarian syndrome

TABLE 25 - COMPARISON OF GROUP A AND GROUP B ON FSH IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
FSH	Group A	11.73%	-1.104	0.273
	Group B	16.12%		

As p value>0.05 we found that there was no statistical significant difference between Group A and Group on FSH in polycystic ovarian But as percentage of improvement seen from above table we get percentage

of improvement in Group B was more than Group A hence we can say that Group B is more effective as compared to Group A on FSH in polycystic ovarian syndrome.

TABLE 26 - EFFECT OF GROUP A ON LH IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	T	P VALUE
	BT	AT				
LH	9.26	9.18	0.08	0.87%	-0.308	0.76

The mean of LH BT was 9.26 which was decreased to 9.18 after treatment. The mean increment in score was 0.87% which is not significant as observed by “paired t test” (as p value>0.05) thus it can be said that there is no

significant increment LH in polycystic ovarian syndrome. I.e. Group A was not effective LH in polycystic ovarian syndrome

TABLE 27 - EFFECT OF GROUP B ON LH IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
LH	9.95	9.76	0.18	1.85%	0.806	0.425

The mean of LH BT was 9.95 which was decreased to 9.76 after treatment. The mean increment in score was 1.85% which is not significant as observed by “paired t test” (as p value>0.05) thus it can be said that there is no

significant increment LH in polycystic ovarian syndrome. I.e. Group B was not effective on LH in polycystic ovarian syndrome.

TABLE 28 - COMPARISON OF GROUP A AND GROUP B ON LH IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
LH	Group A	0.87%	0.606	0.546
	Group B	1.85%		

As p value>0.05 we found that there was no statistical significant difference between Group A and Group on LH in polycystic ovarian syndrome. Here both Group A

and Group B was not effective on LH in polycystic ovarian syndrome.

TABLE 29 - EFFECT OF GROUP A ON LH FSH RATIO IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
LH FSH Ratio	1.25	1.13	0.12	9.56%	2.209	0.033

The mean of LH FSH Ratio BT was 1.25 which was increased to 1.13 after treatment. The mean increment in score was 9.56% which is significant as observed by “paired t test” (as p value<0.05) thus it can be said that

there is significant increment LH FSH Ratio in polycystic ovarian syndrome. I.e. Group A was effective on LH FSH Ratio in polycystic ovarian syndrome.

TABLE 30 - EFFECT OF GROUP B ON LH FSH RATIO IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
LH FSH Ratio	1.07	0.94	0.14	12.65%	3.916	0

The mean of LH FSH Ratio BT was 1.07 which was increased to 0.94 after treatment. The mean increment in score was 12.65% which is significant as observed by “paired t test” (as p value<0.05) thus it can be said that

there is significant increment LH FSH Ratio in polycystic ovarian syndrome. Group B was effective on LH FSH Ratio in polycystic ovarian syndrome

TABLE 31 - COMPARISON OF GROUP A AND GROUP B ON LH FSH RATIO IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
LH FSH Ratio	Group A	9.56%	2.6	0.011
	Group B	12.65%		

As p value<0.05 we found that there was statistical significant difference between Group A and Group on LH FSH Ratio in polycystic ovarian. Also as percentage of improvement seen from above table we get

percentage of improvement in Group B was more than Group A hence we can say that Group B is more effective as compared to Group A on LH FSH Ratio in polycystic ovarian.

TABLE 32 - EFFECT OF GROUP A ON SR. PROLACTIN IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Sr. Prolactin	17.60	17.25	0.35	2.00%	1.267	0.213

The mean of Sr. Prolactin Ratio BT was 17.60 which was decreased to 17.25 after treatment. The mean increment in score was 2.00% which is not significant as observed by “paired t test” (as p value>0.05) thus it

can be said that there is no significant increment Sr. Prolactin Ratio in polycystic ovarian syndrome. I.e. Group A was not effective Sr. Prolactin Ratio in polycystic ovarian syndrome

TABLE 33 - EFFECT OF GROUP B ON SR. PROLACTIN IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Sr. Prolactin	16.92	16.22	0.70	4.15%	2.244	0.031

The mean of Sr. Prolactin Ratio BT was 16.92 which was decreased to 16.22 after treatment. The mean increment in score was 4.15% which is significant as observed by “paired t test” (as p value<0.05) thus it can

be said that there is significant increment Sr. Prolactin Ratio in polycystic ovarian syndrome. I.e. Group B was effective on Sr. Prolactin Ratio in polycystic ovarian syndrome

TABLE 34 - COMPARISON OF GROUP A AND GROUP B ON SR. PROLACTIN IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
Sr. Prolactin	Group A	2.00%	-1.194	0.236
	Group B	4.15%		

As p value>0.05 we found that there was no statistical significant difference between Group A and Group on Sr. Prolactin in polycystic ovarian. Here only Group B

was effective on Sr. Prolactin in polycystic ovarian syndrome.

TABLE 35 - EFFECT OF GROUP A ON SR. TESTOSTERONE IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		X	% of improvement	t	P VALUE
	BT	AT				
Sr. Testosterone	36.60	30.01	6.59	18.00%	0.906	0.021

The mean of Sr. Testosterone BT was 36.60 which was decreased to 30.01 after treatment. The mean increment in score was 18.00% which is significant as observed by “paired t test” (as p value<0.05) thus it can be said that

there is significant increment Sr. Testosterone in polycystic ovarian syndrome. I.e. Group A was effective Sr. Testosterone in polycystic ovarian syndrome.

TABLE 36 - EFFECT OF GROUP B ON SR. TESTOSTERONE IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
Sr. Testosterone	28.94	27.92	1.02	3.52%	2.664	0.011

The mean of Sr. Testosterone BT was 28.94 which was decreased to 27.92 after treatment. The mean increment in score was 3.52% which is significant as observed by “paired t test” (as p value<0.05) thus it can be said that

there is significant increment Sr. Testosterone in polycystic ovarian syndrome. I.e. Group B was effective on Sr. Testosterone in polycystic ovarian syndrome.

TABLE 37 - COMPARISON OF GROUP A AND GROUP B ON SR. TESTOSTERONE IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
Sr. Testosterone	Group A	18.00%	1.118	0.267
	Group B	3.52%		

As p value>0.05 we found that there was no statistical significant difference between Group A and Group on Sr. Testosterone in polycystic ovarian syndrome. The mean increment in score was 18.00% which is significant in Gr.A and 3.52 %in Gr.B.

I.e Gr.A was more effective on Testosterone than Gr.B. Here both Group were effective on Sr. Testosterone in polycystic ovarian syndrome.

TABLE 38- EFFECT OF GROUP A ON AMH IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
AMH	3.95	3.92	0.03	0.85%	0.253	0.803

The mean of AMH BT was 3.95 which was decreased to 3.92 after treatment. The mean increment in score was 0.85% which is not significant as observed by “paired t test” (as p value>0.05) thus it can be said that there is no

significant increment AMH in polycystic ovarian syndrome. I.e. Group A was not effective AMH in polycystic ovarian syndrome

TABLE 39 -EFFECT OF GROUP B ON AMH IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
AMH	3.96	3.83	0.13	3.10%	1.339	0.188

The mean of AMH BT was 3.96 which was decreased to 3.83 after treatment. The mean increment in score was 3.10% which is not significant as observed by “paired t test” (as p value>0.05) thus it can be said that there is no

significant increment AMH in polycystic ovarian syndrome. I.e. Group B was not effective AMH in polycystic ovarian syndrome.

TABLE 40 -COMPARISON OF GROUP A AND GROUP B ON AMH IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
AMH	Group A	0.85%	-0.505	0.615
	Group B	3.10%		

As p value>0.05 we found that there was no statistical significant difference between Group A and Group on AMH in polycystic ovarian Here both Group A and

Group B was not effective on AMH in polycystic ovarian syndrome.

TABLE 41- EFFECT OF GROUP A ON HBA1c IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
HBA1c	4.98	5.02	0.04	0.87%	-0.807	0.424

The mean of HBA1c BT was 4.98 which was increased to 5.02 after treatment. The mean increment in score was 0.87% which is not significant as observed by “paired t test” (as p value>0.05) thus it can be said that there is no

significant increment HBA1c in polycystic ovarian syndrome. I.e. Group A was not effective HBA1c in polycystic ovarian syndrome.

TABLE 42 - EFFECT OF GROUP B ON HBA1c IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
HBA1c	5.10	5.23	0.12	2.42%	-2.011	0.051

The mean of HBA1c BT was 5.10 which was increased to 5.23 after treatment. The mean increment in score was 2.42% which is not significant as observed by “paired t test” (as p value>0.05) thus it can be said that there is no

significant increment HBA1c in polycystic ovarian syndrome. I.e. Group B was not effective HBA1c in polycystic ovarian syndrome

TABLE 43 - COMPARISON OF GROUP A AND GROUP B ON HBA1C IN POLYCYSTIC OVARIAN SYNDROME

parameter	Group	% of improvement	t	P VALUE
HBA1c	Group A	0.87%	-1.01	0.316
	Group B	2.42%		

As p value>0.05 we found that there was no statistical significant difference between Group A and Group on HBA1c in polycystic ovarian syndrome. Here both

Group A and Group B was not effective on HBA1c in polycystic ovarian syndrome.

TABLE 44 - EFFECT OF GROUP A ON TSH IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
TSH	3.52	3.35	0.17	4.92%	-1.561	0.127

The mean of TSH BT was 3.52 which was decreased to 3.35 after treatment. The mean increment in score was 5.26% which is not significant as observed by “paired t test” (as p value>0.05) thus it can be said that there is no

significant increment TSH in polycystic ovarian syndrome. I.e. Group A was not effective TSH in polycystic ovarian syndrome.

TABLE 45 - EFFECT OF GROUP B ON TSH IN POLYCYSTIC OVARIAN SYNDROME

parameter	Mean		x	% of improvement	t	P VALUE
	BT	AT				
TSH	3.35	3.33	0.02	0.54%	0.108	0.916

The mean of TSH BT was 3.35 which was decreased to 3.33 after treatment. The mean increment in score was 0.54% which is not significant as observed by “paired t test” (as p value>0.05) thus it can be said that there is no

significant increment TSH in polycystic ovarian syndrome. I.e. Group B was not effective TSH in polycystic ovarian syndrome.

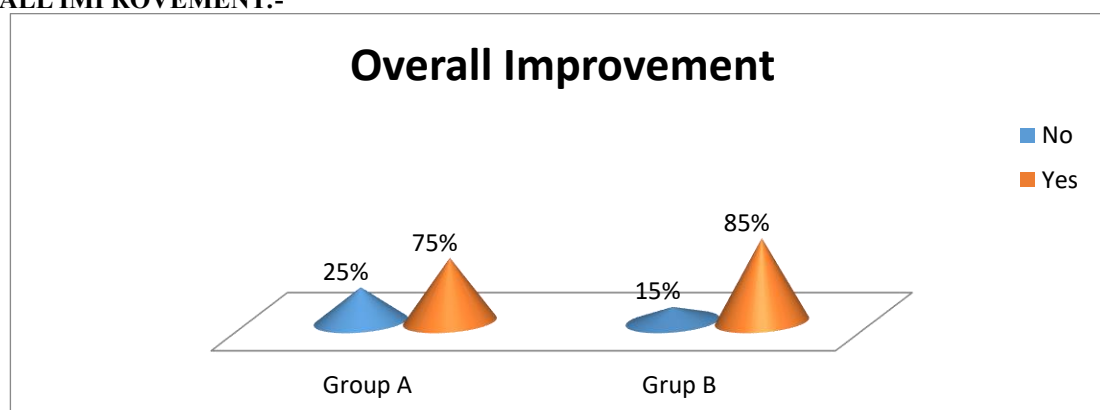
TABLE 46 - COMPARISON OF GROUP A AND GROUP B ON TSH IN POLYCYSTIC OVARIAN SYNDROME Table 121

parameter	Group	% of improvement	t	P VALUE
TSH	Group A	5.26%	0.777	0.439
	Group B	0.54%		

As p value>0.05 we found that there was no statistical significant difference between Group A and Group on TSH in polycystic ovarian syndrome.

Here both Group A and Group B was not effective on TSH in polycystic ovarian syndrome.

OVERALL IMPROVEMENT:-



Interpretation of Results

From above diagram we found that both group showed efficacy of both individual drug. Control drug showed 85% efficacy and Trial Drug showed 75% efficacy From above diagram we found that Group B is more effective as compared to Group A in polycystic ovarian Syndrome.

Clinical Implications

In clinical practice, even small reductions in BMI, Hormonal assay can contribute to improvements in metabolic health and symptomatology in PCOS patients. However, the findings from this study suggest that the intervention used in Group A may not be that much effective as the one in Group B or that the sample size might have been insufficient to detect a significant difference.

Recommendations for Future Research

To address these issues, future studies should consider the following:

1. **Increasing Sample Size:** A larger cohort may provide sufficient power to detect smaller but clinically relevant differences between groups.
2. **Longer Follow-up:** Extending the duration of the study could capture more significant changes in BMI, as weight loss and management are long-term processes.
3. **Stratified Analysis:** Conducting stratified analyses based on baseline characteristics such as BMI, age, and severity of PCOS could help identify subgroups that might benefit more from specific interventions.
4. **Multifactorial Interventions:** Considering the multifaceted nature of PCOS, combining lifestyle interventions with pharmacological treatment may yield better outcomes and should be explored in future studies.
5. **Improving Adherence:** Strategies to improve participant adherence to the intervention protocols could also be critical in realizing the potential benefits of the interventions.

Conclusion

1. This study shows PCOS is one of the major cause of infertility. This Treatment is proved to be effective in reducing the follicular size and ovarian volume.
2. In this study it was observe that even after conception in PCOS women there is risk of abortion.
3. It can be concluded that to achieve ovulation, *Morinda Citrifolia churna* and *Latakaranja Churna* capsules could be administered for more than 3 months.
4. In this study it was observe that PCOS is complex disease so it can be the combination of the 2 or more *yonivyapadas*.
5. In this study it was observe that as per the signs and symptoms PCOS were *kaphavatapradhan* disease.
6. The study demonstrated positive outcomes including acne improvement, body weight reduction, menstrual cycle regularization, bleeding normalization, significant ovarian volume decrease, FSH, Testosterone and LH: FSH ratio improvement.

7. In this study it was observe that the treatment needs some modification to near to normalize the hormonal imbalance.

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

9. It requires large sample size and long duration treatment is needed for detail study.

10. After treatment the symptoms like *katishool*, *Udarshool*, Leg Cramps acne get subside.

11. According to statistical analysis it can be conclude that treatment significant to treat symptoms of the PCOS but cannot cure the PCOS totally.

12. Irregular menstrual cycle is the unique feature of Poly Cystic Ovarian Disease and can be regularized by *Morinda Citrifolia churna* and *Latakaranja churna capsules*.

Hence, from the above study it can be conclude that one can modified the treatment and work with large sample size to get complete result in PCOS.

CONFLICT OF INTEREST -NIL

SOURCE OF SUPPORT- NONE

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