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Research Article

A RANDOMISED SINGLE BLIND COMPARATIVE CLINICAL STUDY ON THE EFFICACY OF *ANJANI*-A FOLKLORE HERB AND *KRISHNA TILA KALKA* IN THE MANAGEMENT OF PCOS W.S.R TO OLIGOMENORRHOEA

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ABSTRACT

Menstruation is the end point of series of events which begin in the cerebral cortex and hypothalamus and ends at the uterus in the hypothalamic pituitary –ovarian uterine axis. Any break in this axis creates Menstrual Problems. PCOS is one such condition associated with abnormal gonadotropic secretion which in turn lead to menstrual irregularity acne and hirsutism- Its prevalence ranging from 2.2% to 26% with age ranging from 18-45 years. In modern science PCOS is managed by down regulating HPO axis using Hormonal Pills which have their own side effects. Therefore complete, comprehensive and holistic approach towards its understanding & treatment is the need of the age. Ayurveda has no direct correlation to PCOS. There are similar condition acc to symptoms are explained under the concept of *Pushpaghni*, *Jathaharini*. Here under PCOS w.s.r. to Oligomenorrhoea, interval between menses, duration of flow, amount of flow and other symptoms like pain are considered. The effect of *Anjani vati* (Trial drug) is compared with *Krishna Tila Kalka* (Control Drug) in two groups containing 30 patients each.

KEYWORDS: Poly cystic ovarian syndrome, Oligomenorrhoea, *Pushpaghni, Jatharharini, Anjani vati, Krishna Tila Kalka*.

INTRODUCTION

PCOS is a condition with abnormal ovarian steroidogenesis, leading to an increased production of androstenedione & testosterone which in turn predisposes to Hirsutism, ache and menstrual irregularity. The diagnosis is established on the basis of clinical suspicion, an increased LH:FSH ratio and sonography revealing enlarged ovaries with multiple peripheral cystic follicles[1].

In Ayurveda classics, there is no direct mentioning of any such disease. By seeing the features of PCOS we have some conditions like *Atavaksaya, Granthibhata, Artava, Pushpagni, Jataharini, Vandhya Yonivyapat* [3].

Though modern medicine has made an unbelievable progress in understanding PCOS w.r.t. oligomenorrhoea, no new progress has been made in management and treatment. Hence attempt has been made to treat PCOS w.r.t. oligomenorrhoea with Ayurvedic drugs mentioned in classics.

OBJECTIVES

- To evaluate the efficacy of *Krishna tila kalka* in PCOS w.s.r. Oligomenorrhoea.
- To evaluate the efficacy of *Anjani vati* in PCOS w.s.r. Oligomenorrhoea.
- To compare the efficacy of *Krishna tila kalka* and *Anjani vati* in PCOS w.s.r Oligomenorrhoea.

Materials and Methods

STUDY POPULATION

A total of 60 female patients, diagnosed cases PCOS, were enrolled from the Department of Prasuti Tantra OPD/IPD of S.J.G.A.M.C & Hospital, after obtaining informed consent from them.

Study design

This was a randomized, controlled clinical trial conducted in Department of Prasuti Tantra, after obtaining permission from the Institutional Ethical Review Committee of IMS, Koppal, Karnataka.

All the 60 diagnosed cases of PCOS were randomly allocated into two groups. The selected patients had undergone complete general, hormonal assay and radiological examinations (USG of abdomen with special attention to pelvic organs) to rule out any gross abnormalities and to confirm the diagnosis.

Grouping

Group A: has been given freshly prepared *Krishna tila kalka* to take orally in the dose of 5gm twice daily; before food for a period of 3 consecutive cycles, from 5th day of menses till the onset of next menses.

Group B: has been given *Anjani vati* to take orally in the dose of 2 tablets of 500mg twice daily; before food for a period of 3 consecutive cycles, from 5th day of menses till the onset of next menses.

Inclusion criteria

1. Age group of 16 to 45yrs
2. Patient fulfilling the diagnostic criteria
3. Both married and unmarried women.

Exclusion criteria

a) Patient having gross structural abnormalities of uterus and appendages
b) Those having primary amenorrhoea
c) Those suffering from malignancies and chronic systemic diseases.
d) Concurrent and previous use of oral contraceptive pills within last three months.
e) Endocrinological disorders like Diabetes Mellitus, thyroid abnormalities etc.
f) Genital tuberculosis
g) Tumours of ovaries

Selection of trial drug

Anjani a folklore medicine having *Tikta rasa* helps in *Amapachana* and *Sroto shuddhi*.

The *Laghu Ruksha guna* acts as *Apatarpana* and *Srotoshodhana* for inducing menses. *Ushna veerya* of the leaves induces the menses there by decreasing the intermenstrual period and increasing the amount of flow [4,5].

Follow-up

Follow-up was done after each cycle for 3 cycles on every 4th day of menstruation.

Assessment criteria

Subjective Criteria

1. Pain

Objective Criteria

1. Interval between the cycle
2. Duration of bleeding
3. Amount of bleeding

Response was graded as

0%: No Improvement
01-25%: Minimal Improvement
26-50%: Mild Improvement
51-75%: Moderate Improvement
76-99%: Marked
100%: Complete

Plan of Study

A randomized comparative clinical study of two groups, consisting of 30 patients in each group has been taken:

The Group A: has been given freshly prepared *Krishna Tila Kalka* to take orally in the dose of 5gm twice daily; before food for a period of 3 consecutive cycles, from 5th day of menses till the onset of next menses.

The Group B: has been given *Anjani Vati* to take orally in the dose of 2 tablets of 500mg twice daily; before food for a period of 3 consecutive cycles, from 5th day of menses till the onset of next menses.

Period of observation

Assessed on 4th day after menstrual phase of each cycle.

For 3 consecutive cycle

Follow up: one cycle after treatment

Statistical analysis

ANOVA test was applied to assess significance in different follow ups.

Results and Observations

The results are shown in Tables 1–5.

Scoring system

Duration of menstrual phase

4- 7 days : Grade 0
3 days : Grade 1
2 days : Grade 2
1 Day : Grade 3

Amount of bleeding

3 pads / day: Grade 0
2 pads / day: Grade 1
1 pad/ day: Grade 2
Spotting: Grade 3

Duration of inter menstrual phase

28 – 35 days: Grade 0
36 – 40 days: Grade 1
41 – 50 days: Grade 2
>50 days: Grade 3

Other symptoms (pain)

No pain: Grade 0
Mild: Grade 1
Moderate: Grade 2
Severe: Grade 3

DISCUSSION

PCOS is one of the most common gynaecological disorders affecting 10 to 15% of women within their reproductive age group and this percentage is slowly increasing due to sedentary life style. Most women give importance to it only when affects her fertility or the physical appearance. It is characterised by chronic anovulation and hyperandrogenism and present clinically with

menstrual disturbances, hirsutism, oligomenorrhoea, acne or androgen dependent alopecia. The hyperandrogenism in PCOS is mainly ovarian and is due to both LH hyper secretion and hyperinsulinemia.

Oligomenorrhoea is characterized by the prolonged intermenstural period of more than 35 days, in oligomenorrhoea the interval between the two menstrual cycles increased, hence it is a reduction in the frequency of menstruation. The bleeding can be ovular, which means that the ovarian cycle is temporarily arrested at some phase. As a rule luteal phase tends to be fairly constant at 14 days so it is the follicular phase which is either lengthened or slow in commence.

Women with PCOS have android obesity which is seen as waist to hip ratio greater than 0.85, and an increased BMI (more than 25). It is associated with impaired glucose tolerance, Diabetes mellitus, increased androgen production rate resulting in decreased levels of SHBG.

The treatment of PCOS includes the treatment of menstrual irregularities, hirsutism, infertility and surgery in whom medicine fails. The conventional method depends upon hormonal therapy and surgery (Laparoscopic drilling or puncture of cyst using laser or by unipolar electrocautery). This modalities give only symptomatic relief and are expensive too. So it is very crucial to find out some effective *Ayurvedic* remedy that can replace the conventional treatment modality[2].

Krishnatila pacifies aggravated *Vata Dosha* due to its *Madhura Rasa, Ushna Veerya, Guru Snigdha Gunas* and *Madhura Vipaka* It is having *Artava Janana* property due to which it will act directly upon *Artavakshaya*. *Krishna Tila* have phytoestrogen, high antioxidant and anti-inflammatory property which may explain it's pharmacodynamics according to modern on acting in oligomenorrhoea and hypomenorrhoea[4,5].

Anjani having *Tikta rasa* helps in *Amapachana* and *Srotoshuddhi*. The *Laghu Ruksha Guna* acts as *Apatarpana* and *Srotoshodhana* for inducing menses. *Ushna veerya* of the leaves induces the menses there by decreasing the intermenstrual period and increasing the amount of flow [5].

Age is an important factor in PCOS. Most of the patients belongs to the age group 18-25 years i.e. 50%. Around 95 % were from Hindu religion as the hospital was located in the Hindu community predominant area. Around 63.33% were married as they are prone to greater mental stress since some of them have family issues, worries and anxieties. Around 28.33% are office staffs and 45 % are students. Mostly the working women spends most of the time in a day at the work place and mostly in sitting position without much physical activity. Around 40 % were from upper middle class family. PCOS is more common in account of sedentary life style, frequent dine out etc. 43.33 % had sedentary work style and 56.66% had moderate work style. Around 68.33% were consuming mixed diet especially red meat, egg, shell fishes etc predisposing an individual to PCOS. 90 % of subjects had the incidence of stress.

Table 1: Comparisons Between Groups A and B in Menstrual Interval

Assessment Observations Recorded on	Descriptive Statistics			Mann-Whitney U Test Ranks			Test Statistics			
	Group	Mean	± S.D.	N	Mean Rank	Sum of Ranks	U	Z	P	Remarks
AT1	Group A	1.20	0.76	30	30.37	911.0	446.0	0.068	>0.05	IS
	Group B	0.90	0.48	30	30.63	919.0				
AT2	Group A	1.00	0.00	30	30.32	909.5	444.5	0.089	>0.05	IS
	Group B	2.13	0.68	30	30.68	920.5				
AT3	Group A	1.73	0.74	30	29.20	876.0	411.0	0.625	>0.05	IS
	Group B	1.33	0.80	30	31.80	954.0				
FU	Group A	1.20	0.71	30	27.08	812.5	347.5	1.817	>0.05	IS
	Group B	2.00	0.00	30	33.92	1017.5				

IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant

The results on criteria menstrual interval of both groups showing statistically highly significant result with P value <0.001 individually, which indicates both groups are effective. The comparative study proved to be statistically insignificant with the p value >0.05 which shows both groups are equally effective.

Table 2 : Comparisons Between Groups A and B in Duration of Menstrual Cycle

Assessment Observations Recorded on	Descriptive Statistics			Mann-Whitney U Test Ranks				Test Statistics		
	Group	Mean	± S.D.	N	Mean Rank	Sum of Ranks	U	Z	P	Remarks
AT1	Group A	1.10	0.61	30	31.13	934.0	431.0	0.309	>0.05	IS
	Group B	0.97	0.56	30	29.87	896.0				
AT2	Group A	1.00	0.00	30	33.37	1001.0	364.0	1.411	>0.05	IS
	Group B	1.43	0.68	30	27.63	829.0				
AT3	Group A	1.37	0.56	30	30.78	923.5	441.5	0.140	>0.05	IS
	Group B	1.07	0.74	30	30.22	906.5				
FU	Group A	0.97	0.77	30	30.57	917.0	448.0	0.033	>0.05	IS
	Group B	2.00	0.00	30	30.43	913.0				

IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant

The results on criteria duration of bleeding of both groups showing statistically highly significant result with P value <0.001 individually, which indicates both groups are effective. The comparative study proved to be statistically insignificant with the p value <0.05 which shows both groups are equally effective.

Table 3 : Comparisons Between Groups A and B in Amount of Bleeding

Assessment Observations Recorded on	Descriptive Statistics			Mann-Whitney U Test Ranks				Test Statistics		
	Group	Mean	± S.D.	N	Mean Rank	Sum of Ranks	U	Z	P	Remarks
AT1	Group A	0.90	0.66	0	0.00	0.0	436.0	0.249	>0.05	IS
	Group B	0.77	0.63	30	15.50	465.0				
AT2	Group A	1.00	0.00	0	0.00	0.0	442.5	0.122	>0.05	IS
	Group B	1.60	0.62	30	15.50	465.0				
AT3	Group A	1.43	0.63	0	0.00	0.0	412.5	0.640	>0.05	IS
	Group B	1.00	0.59	30	15.50	465.0				
FU	Group A	0.90	0.61	0	0.00	0.0	399.5	0.856	>0.05	IS
	Group B	2.00	0.00	30	15.50	465.0				

IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant

The results on criteria amount of bleeding of both groups showing statistically highly significant result with P value <0.001 individually, which indicates both groups are effective. The comparative study proved to be statistically insignificant with the p value >0.05.

Table 4 : Comparisons Between Groups A and B in Other Symptoms (Pain)

Assessment Observations Recorded on	Descriptive Statistics			Mann-Whitney U Test Ranks				Test Statistics		
	Group	Mean	± S.D.	N	Mean Rank	Sum of Ranks	U	Z	P	Remarks
AT1	Group A	0.47	0.57	30	29.52	885.5	420.5	0.499	>0.05	IS
	Group B	0.40	0.56	30	31.48	944.5				
AT2	Group A	1.00	0.00	30	29.67	890.0	425.0	0.430	>0.05	IS
	Group B	0.93	0.64	30	31.33	940.0				

AT3	Group A	0.83	0.59	30	28.57	857.0	392.0	0.975	>0.05	IS
	Group B	0.60	0.56	30	32.43	973.0				
FU	Group A	0.53	0.51	30	28.27	848.0	383.0	1.142	>0.05	IS
	Group B	2.00	0.00	30	32.73	982.0				
IS - Insignificant; MS - Moderately Significant; S - Significant; HS - Highly significant										

The results on criteria other symptoms (Pain) of both groups showing statistically highly significant result with P value <0.001 individually, which indicates both groups are effective. The comparative study proved to be statistically insignificant with the p value >0.05.

Overall Response After Follow-Up				
Response	**Group A**		**Group B**	
	No. of Subjects	**%**	**No. of Subjects**	**%**
Un changed	0	0%	5	17%
Mild Response	5	17%	7	23%
Moderate Response	22	73%	18	60%
Marked Response	3	10%	0	0%
Total	30	100%	30	100%

On the basis of above facts it may be concluded that the drugs *Krishna Ttila Kalka* and *Anjani Vati* are effective in reducing intermenstrual phase and increase in amount of bleeding without causing any side effects.

CONCLUSION

PCOS can be curable by proper medications along with life style modifications including diet and exercise. According to *Ayurveda*, it does not compare the condition to a single disease or syndrome but the symptoms have similarities with *Nashtarthava, Arthavakshaya, Granthibhuta Artava Dushti* and *Vandhya Yoni Vyapat. Agneya* property of *Pitta* is reduced in PCOS which is essential for normal *Artava Pravruthi.* The study has shown that statistically significant difference between each group in its efficacy when comparing. The study has shown *Krishna Tila Kalka* is having better action in restoring normal menstrual cycle, Duration of bleeding, Amount of bleeding; while *Anjani vati* showing better results in reduction intermenstrual duration.

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