COMBINED EFFECT OF SNEHANA WITH PIPPALYADIANUVASANA THAILA AND VIRECHANA WITH HINGUTHRIGUNA THAILA IN POLYCYSTIC OVARIAN SYNDROME

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ABSTRACT

The polycystic ovarian syndrome is the leading cause of female infertility in the present scenario. It is one of the top reproductive endocrine disorders in the world. In the conventional method, no definite treatment is proven for this ailment and it mainly depends upon hormonal preparations and invasive techniques. These modalities are costlier and have many side effects. In Polycystic ovarian syndrome, there is Nashtarthava which means the loss of ovulation as well as menstruation. Kapha Vatha Avarana causing Artavanasha which is explained as Nashtarthava by Susrutha can also be considered in this particular disease. Vatha is the cardinal Dosha vitiated in all these conditions. So the treatment modalities which correct Vathavaigunya can be adopted here. By considering the above facts Snehana with Pippalyadi anuvasana thaila and Virechana with Hinguthriguna thaila were selected. These treatment modalities help in correcting Mootavatha and thereby removing Arthavavaha srothorodha. The study design was a pre and post interventional study with a sample size of 30. Females in the age group 18-38 years with Polycystic Ovarian syndrome attending the outpatient and inpatient department of Govt Ayurveda College hospital for women and children Poojappura, was selected for study as per Rotterdam Criteria. The symptoms were assessed before starting treatment using a case proforma, ultra-sonogram, and necessary lab investigations. The assessment was done each month during the study period and the follow-up period. Data obtained was analyzed statistically. The treatment was found to be effective in normalizing menstrual intervals, reducing the volume of ovaries, and reducing the body mass index. It was not effective in reducing the number of follicular cysts and in the induction of ovulation within the study period.

KEYWORDS: Pippalyadi Anuvasana thaila, Hinguthriguna thaila, Polycystic Ovarian Syndrome, Snehana, Virechana.

INTRODUCTION

Polycystic Ovarian Syndrome is one of the most common gynecological and endocrine problems reported in OPDs. The prevalence of the polycystic ovarian syndrome is mainly thought to be between 3% and 10%. Due to the high degree of variability and disparity between the various diagnostic criteria, there’s a singular challenge that exists when determining the prevalence of this syndrome[1]. The disorder is associated with a wide spectrum of presenting features including ovulation, infertility, obesity, hirsutism, insulin resistance, etc. A fairly frequent finding on ultrasonography is an enlargement of ovaries, with more than ten sonolucent cystic structures, 2-8 mm in diameter scattered around a hyper echogenic thickened central stroma. The pathophysiological mechanisms indicate that etiology is multifactorial. As it is mainly a metabolic syndrome, the direct correlation of the disease according to Ayurveda is not possible. We can consider some disease entities like Prameha, Sthoulya, Gulma, and Pushpaghnijathaharini with different pathological conditions associated with PCOS.

The Medical intervention of Polycystic ovarian syndrome mainly includes hormonal therapies that have long-term health consequences. Though conventional medicines are found to be effective to induce and regularize menstruation to a certain extent, untoward effects of artificial drugs mainly in the form of hormones cannot be ignored. Ayurveda has to evolve as a mainstream of medicine in combating such emerging health problems like
PCOS without any adverse effects by competing with the allied branches of evidence-based medicine. To enhance the scope of Ayurvedic medicines further by means of materials and methods, the present clinical study has been undertaken.

Objective
To evaluate the combined effect of Snehana with Pippalyadi Anuvasana Thaila and Virechana with Hinguthriguna Thaila in Polycystic Ovarian Syndrome.

Methodology
Single group, Pre and post interventional study with sample size 30 was OPD and IPD of Govt. Ayurveda College Hospital for Women and Children Poojappura, Thiruvananthapuram.

1. Study design
   - Single group
   - Pre and post interventional study
   - The patient’s status after treatment is compared with the status before treatment.

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

3. Study population
   Females in the age group of 18-38 with Polycystic Ovarian Syndrome attending the OPD and IPD of Govt. Ayurveda College Hospital for Women and Children Poojappura, Thiruvananthapuram.

4. Sample size:
The sample size was 30.

Inclusion criteria
Females of the age limit 18-38yrs, who are diagnosed with Polycystic Ovarian Syndrome as per Rotterdam Criteria.

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 a various systemic illness, Androgen producing adrenal tumor and other neoplastic growth and patients diagnosed as DUB.

Outcome variable
1. Mean changes in the interval of menstrual cycle assessed by case proforma during follow up period.
2. Mean changes in ovulation assessed by follicular study.
3. Mean change in BMI assessed by the formula – Wt in kg / Ht in M²
4. Mean changes in no. of the follicular cyst and volume of ovary identified as per USG

The statistical techniques:
Wilcoxon’s Signed Rank Test was used

Table 1: Description of the Study protocol

| Day        | Procedure                  | Medicine                                                                 |
|------------|----------------------------|--------------------------------------------------------------------------|
| Day 1 to Day 3 | Deepana and Pachana       | Hinguvachadi choorna 10 gm BD orally.                                   |
| Day 4 to Day 10 | Snehapana                 | Pippalyadi Anuvasana thaila (Progressively increasing the dose 25ml to 175ml) |
| Day11 to Day 13 | Abhyanga (oleation) and hot water bath | Bala thaila                                                                  |
| Day15      | Rest                       |                                                                          |
| Day16 to Day 22 | Mathravasthi              | Pippalyadi Anuvasana thaila (Dose-60ml, administered at 2 pm on full stomach) |
| Day 23 to Day 83 | Oral administration of medicine | Pippalyadi Anuvasana thaila. (10ml) was given twice daily morning and evening ½ hr before food for the 60 days after IP management |

The Sodhana therapy was suspended during the bleeding phase

OBSERVATION AND RESULT
The Analysis showed among the study population 66.7% having sedentary habits and only 20% were hard working. Most of the patients (66.7%) were practicing a mixed diet and increased intake of chicken, egg, meat, etc. Regarding Psychological status 46.7% of the patients were either stressed or anxious and were depressed. Most of the patients had Vatha Kapha Prakruthi. Among the subjects in the study, 63.3% had relevant family history of PCOS.

Data Related to the Effectiveness of the Treatment
A. Distribution of different grades of menstrual interval N= 30
   The Menstrual interval was considered as the most important parameter for assessing the efficacy of the treatment modalities along with the decrease in the severity of the associated complaints. For the purpose of comparison of the efficacy of the treatment modalities before and after treatments, complaints were converted into scores.
After three months of treatment, a considerable reduction in the menstrual interval was noticed. Before treatment, out of the 30 patients, 24 (80 %) had the menstrual interval between 35-60 days, 61-90 days of menstrual interval for 2 (6.7 %) patients. There was no patient with the menstrual interval between 91-120 days and 4 (13.3%) patients had more than 120 days of menstrual interval. After 3 months of treatment 4 (13.3%) had menstrual interval less than 35 and 24 (80%) had menstrual interval of 35-60 days and 1 (3.3%) had menstrual interval more than 120 days. 1 patient among the 30 did not have menstruation even after the treatment modalities. After the follow-up period for 3 months, 16 (53.3 %) patients had menstrual interval less than 35 days. 12 (40%) had menstrual interval between 35-60 days and 1 (3.3%) had menstrual interval 61-90 days. There was no patient with menstrual interval between 90-120 days. Out of 30 patients 1 (3.33%) had no menstruation even after follow up of 3 months.

### Table 2: Distribution of different grades of menstrual interval N= 30

| BT (Before treatment) | AT (After treatment) | FU (After follow up) |
|-----------------------|----------------------|----------------------|
| less than 35 days     | N=0, 0.0             | N=4, 13.3            |
|                       | 35- 60 days          | N=24, 80.0           |
|                       |                      | 35- 60 days          |
|                       | 61 - 90 days         | N=2, 6.7             |
|                       | 61 - 90 days         | 61 - 90 days         |
|                       | 91 - 120 days        | N=0, 0.0             |
|                       | 91 - 120 days        | 91 - 120 days        |
|                       | More than 120 days   | N=4, 13.3            |
|                       | Total                | N=30, 100            |

### Table 3: Data and Test of significance relating to the effectiveness of the treatment in reducing the menstrual interval

| Test | Menstrual interval | Loss Percentage | P value |
|------|-------------------|-----------------|---------|
| BT   | 60.00 (SD 41.111) | BT-AT 36.6      | .000**  |
| AT   | 38 (SD 27.36)     | AT-FU 13.5      | .000**  |
| FU   | 33 (SD 27.91)     | BT-FU 45        | .000**  |

*Significant at 5% level (P<0.05), **Significant at 1% level (P<0.01), NS: Not significant (P>0.05)

**BT – Before treatment, AT- After treatment, FU-After follow up, SD- Standard deviation**

As per Wilcoxon’s Rank Test, there exists statistically significant change in menstrual interval during BT-AT (P<.01), AT-FU (<.01) and BT-FU (<.01). Before treatment median of interval of menstrual cycle was 60 with SD of 41.11 and range 36 - 180. But after treatment the median of interval of menstrual cycle reduced to 38 with SD 27.36 and Range 30-180 indicating a loss of 36.6%. After follow up median of interval of menstrual cycle was 33 with SD 27.91 and range 30-180. This reveals that the treatment is effective in reducing the menstrual cycle.

### Table 4: Effect of Treatment Reducing the Number of Follicular Cysts

| Number of follicular cyst | BT | AT | FU |
|--------------------------|----|----|----|
| Numerous                 |    |    |    |

As per Wilcoxon’s Rank Test, there exists statistically significant change in menstrual interval during BT-AT (P<.01), AT-FU (<.01) and BT-FU (<.01). Before treatment median of interval of menstrual cycle was 60 with SD of 41.11 and range 36 - 180. But after treatment the median of interval of menstrual cycle reduced to 38 with SD 27.36 and Range 30-180 indicating a loss of 36.6%. After follow up median of interval of menstrual cycle was 33 with SD 27.91 and range 30-180. This reveals that the treatment is effective in reducing the menstrual cycle.

### Table 5: Distribution of BMI* before treatment, after treatment and after follow up

| BMI Kg/m2 | BT | AT | AF |
|-----------|----|----|----|
| Under weight(<18) | N | % | N | % | N | % |
| Normal weight(18-24.9) | 14 | 47 | 14 | 47 | 14 | 47 |
| Over weight(25-29.9) | 10 | 33 | 10 | 33 | 10 | 33 |
| Obese (30-35) | 5 | 17 | 5 | 17 | 5 | 17 |
| Severely obese(>35) | 1 | 3 | 1 | 3 | 1 | 3 |
| Total | 30 | 100 | 30 | 100 | 30 | 100 |

*Based on Obesity Foundation of India BMI categories
Before treatment 17% patients were obese. 47% patients each were in the category of normal weight and overweight. 3% patients were severely obese. After the treatment period and follow up the percentage remains the same.

### Table 6: Data and Test of significance relating to effectiveness of treatment in reducing BMI

| Test  | BMI (kg/m²) | Loss Percentage | P-value |
|-------|-------------|-----------------|---------|
| Mean  | Median      | SD              | Range   | BT-AT | 3.20 | .001** |
| BT    | 26.179      | 25.85           | 4.789   | 18-36 |     |       |
| AT    | 25.836      | 25              | 4.326   | 19-35 | AT-FU | 0    | .120   |
| FU    | 25.793      | 25              | 4.925   | 13-35.43 | BT-FU | 3.2  | .000** |

*Significant at 5% level (P<0.05), **Significant at 1% level (P<0.01), NS: Not significant (P>0.05)

As per Wilcoxon Signed Rank Test, there exist statistically significant changes in BMI during BT-AT (P<.01) and BT-FU (P<.01). Before the treatment the median of BMI was 25.85 with SD of 4.789 and range 18-36. After treatment mean BMI reduced to 25 with SD 4.326 and Range 19-35 indicating a loss of 3.2. After follow up BMI not changed. This reveals the efficacy of the treatment in reducing BMI after treatment. The treatment effect is sustained after the follow up period also.

### Table 7: Data and Test of significance relating to effectiveness of the treatment in reducing the Volume of the Right Ovary

| Test  | Volume of the right ovary in cm³ | Loss Percentage | P-value |
|-------|----------------------------------|-----------------|---------|
| Mean  | Median                          | SD              | Range   | BT-AT | 8.3  | .000** |
| BT    | 13.047                          | 12              | 2.8742  | 9-24  |     |       |
| AT    | 11.583                          | 11              | 1.880   | 9-16  | AT-FU | 4.54 | .024** |
| FU    | 11.433                          | 10.50           | 1.99    | 9-16  | BT-FU | 12.5 | .000** |

*Significant at 5% level (P<0.05), **Significant at 1% level (P<0.01), NS: Not significant (P>0.05)

As per the Wilcoxon Signed Rank Test, there exists statistically significant changes in volume of the right ovary during BT-AT (P<.01), AT-FU (P<.01), and BT-FU (P<.01). Before the treatment the median of the volume of right ovary was 12 with SD of 2.874 and range 9-24. But after treatment median of ovarian volume significantly reduced to 11 with SD 1.880 and Range of 9-16 indicating a loss of 22.20%. After follow-up ovarian volume again reduced to 10.50 with SD 1.99. This reveals that the treatment is effective in reducing ovarian volume.

### Table 8: Data and Test of significance relating to effectiveness of the treatment in reducing the Volume of Left Ovary

| Test  | Volume of left ovary in cm³ | Loss Percentage | P-value |
|-------|-----------------------------|-----------------|---------|
| Mean  | Median                      | SD              | Range   |
| BT    | 12.847                      | 12              | 2.357   | 9-20  | BT-AT | 8.3  | .000** |
| AT    | 11.6                        | 11              | 2.2833  | 2.28-8 | AT-FU | 4.54 | .219 |
| FU    | 11.53                       | 10.50           | 2.2550  | 9-80  | BT-FU | 12.5 | .000** |

*Significant at 5% level (P<0.05), **Significant at 1% level (P<0.01), NS: Not significant (P>0.05)

As per Wilcoxon Signed Rank Test, there exists statistically significant changes in volume of left ovary during BT-AT (P<.01), and BT-FU (P<.01). There is no significant change during AT-FU (P>0.05). Before the treatment the median of the volume of left ovary was 12 with SD of 2.35 and range 9-20. Median of ovarian volume significantly reduced to mean of 11 with SD 2.28 and Range 2.28-8 indicating a loss of 8.3% after treatment. After follow up the median of the ovarian volume shows no significant reduction. This reveals the treatment is effective in reducing the volume of ovary only during the study period.
Table 9: Effectiveness of the treatment in induction of Ovulation

| Ovulation | BT  | AT  | FU  |
|-----------|-----|-----|-----|
|           | N   | %   | N   | %   | N   | %   |
| YES       | 0   | 0.0 | 1   | 3.33| 1   | 3.33|
| NO        | 30  | 100.0| 29  | 96.67| 29  | 96.67|
| Total     | 30  | 100.0| 30  | 100.0| 30  | 100.0|

Wilcoxon signed rank test

|          | BT - AT | AT - FU | BT - FU |
|----------|---------|---------|---------|
| P        | .317    | 1.000   | 1.000   |

BT – Before treatment, AT- After treatment, FU-After follow up, SD- Standard deviation

Ovulation was absent in all the 30 patients before treatment. After three months of treatment one patient conceived and this is the confirmatory sign of ovulation. After follow up of 3 months the status remains same. As per Wilcoxon signed rank test we have p value greater than 0.001 after treatment and follow up period. This reveals that the treatment was not effective in inducing ovulation.

FIGURES

**Fig -1** Effectiveness in treatment for reducing the menstrual interval

**Fig -2** Effectiveness in treatment for reducing BMI

**Fig -3**: Effectiveness of treatment in reducing Volume of Right Ovary
DISCUSSION

Polycystic Ovarian Syndrome (PCOS) is a heterogeneous disorder characterised by excessive androgen production by the ovaries mainly, which interferes with the reproductive, endocrine and metabolic function [2]. Change in life style, diet and stress of modern society has led to increase in the incidence of PCOS.

In this present scenario, Polycystic Ovarian Syndrome is the leading cause of female infertility and one of the top reproductive endocrine disorders in the world. In the conventional method, no definite treatment is proven for this ailment and it mainly depends upon hormonal preparations and invasive techniques. These modalities are costly and have many side effects such as premature ovarian failure, menopausal symptoms, weight gain, mood swings, gastric problems, hyperinsulinemia, cardiac problems etc.

According to clinical symptoms most appropriate correlation of this disease as per Ayurveda is Pushapghnjathaharini of Kashyapa Samhitha [3]. The symptoms are futile menstrual cycles, fleshy & hairy cheeks which resembles the anovulation and hyperandrogenism in PCOS. Kaphavataavarana causing Arthavanasha which is explained as Nashtarthava by Susrutha Samhita[4] can also be considered in this particular disease. In PCOS there is Nashtarthava, which means the loss of both ovulation as well as menstruation. Vata is the cardinal Dosa vitiated in all these conditions. So we can adopt the treatment modalities which correct Vatavaigunya. By considering the above facts Snehapana with Pippalyadi Anuvasanathaila, Virechana with Hingutrighna thaila and Mathravasthi with Pippalyadi Anuvasana thaila are selected. These treatment modalities help in correcting Moodavatha and Arthavahasrothorodha.

An unbalanced state of Dosha can be seen in metabolic derangement, especially in PCOS. In Mithyahara Vihara along with abnormal psychological status, even the Dushithavyav explained in the Janapathodwamsaniya[5] by Charaka or the environmental factors can end up in metabolic disturbances. While describing the treatment of Janapadodwamsaniya Vyadhi Acharya mentions about Sodhana, and Rasayana therapy. Mrudu sodhana[6] is indicated in Yoniyapath chikitsa also.

The process of stimulation of Jaataragni is called Deepana. Pachana does the digestion of Ama but not increases the Agni. Both Deepana-pachana removes the Samaavastha and detaches the vitiating Doshas which are adhered to Srothases. In the present study Hinguvachadi choorna is used for Deepana Pachana. It is explained in the context of Gulmachikithsa. The Deepana and Pachana property of Hingu, Vacha, Vijaya etc, help to attain Ama Pachana and Koshtarooskshana.

Snehana (Abhyanthara and Bahya sneha) should be done after Deepana- Pachana. It gives Snigdhatha, Vishyanthatha, Mardavatha and kledatha of Sareera. Snehana is the first line of management in Vaataja Rogas. Svedana Karma does the Vilayana of Snebothklisha doshas and moves towards Koshta.
The dislodged toxins are then easily expelled out of the body by Sodhana therapy. Thailapana[7] is specially indicated in Sleshmamedomaruthajanya roga. In the present study for Snehapana Pippalyadi Anuvasana thaila (Ashtangahridryam Arshochikitsatham[8]) is selected. Pippali is considered as Pathya in Yonirogas[9]. The drugs included in the Yoga are Kapha Vatha Samana Ushnavirya, Deepana, and Vathanulomana. The drugs like Shathapushpa, Madana, Kushta etc. have Arthavajanana property[10]. The Vatha is considered as the cardinal Dosa vitiated in the Samprapti of the PCOS. The role of Vatha in the manifestation of the disease was substantiated by Prakrithi assessment i.e., Kapha Vatha Prakrithi. The Yoga is Muta Vathaanulomana i.e., it can correct the Srothorodha and thereby correct the Vatha Vaigunyatha.

Virechana has proved efficacious in Sthoulya, Granthi, Srothorodha and Beeja Dushti[11]. In the present study Higuthriguna thaila[12] (Ashtanga Hridayayamulchakithsitham) is used as the drug of choice for Virechana. The Yoga includes Hingu, Eranda thaila and Rasona and possesses Deepana, Pachana and Adhobhagakara action. All the drugs are having Ushna Theeksnana Guna. Hingu and Rasona possess Arthavajanana property[13], Lasuna is indicated in all Avarana conditions except Pitta and Raktha[14]. According to the recent studies the ingredients of Hinguthrignathailam have immune-modulatory, antioxidant, anti-inflammatory and free radical antagonistic properties[15]. According to Acharya Kashyapa Anuvasanavasthi is the process indicated in the condition like Alpapushpa, Nashta pushpa[16] etc. In Matravasthi, less quantity of oil is used as compared to Anuvasana Vasti and it does not need to be accompanied by any strict dietary restriction or daily routine and can be administered in all seasons.

Discussion on Data Related to Response to Treatment

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

1. Menstrual interval

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

- Grade 0 - less than 35 days
- Grade 1 - 36 to 60 days
- Grade 2 - 61 to 90 days.
- Grade 3 - 91-120 days
- Grade 4 - more than 120 days.

After three months of treatment, considerable reduction in the menstrual interval was noticed. Before treatment median of interval of menstrual cycle were 60 with SD of 41.411 and range 36-180 and after treatment the median of interval of menstrual cycle reduced to 38 with SD 27.36 and Range 30-180 indicating a loss of 36.6%. After follow up the median of interval of menstrual cycle were 33 with SD 27.91 and range 30-180. This reveals that the treatment is effective in reducing the menstrual interval. Deepana, Pacana, Kapha Vatahara, Srotoshodhakara and Vathanulomana properties of the combinations and treatment modalities might have contributed in normalizing the menstrual irregularities.

Number of Follicular Cyst

After the treatment and follow up period there was no change in the number of follicular cysts. This reveals the treatment was not effective in reducing no of follicular cyst.

Volume of Ovary

Before the treatment the median of the volume of right ovary was 12 with SD of 2.874 and range 9 -24. But after treatment median of ovarian volume significantly reduced to 11 with SD 1.880 and Range 9-16 indicating a loss of 22.20%. After follow-up the ovarian volume again reduced to 10.50 with SD 1.99. This reveals that the treatment is effective in reducing the ovarian volume. Before the treatment the median of the volume of left ovary was 12 with SD of 2.35 and range 9-20. Median of ovarian volume significantly reduced to mean of 11 with SD 2.28 and Range 2.28-8 indicating a loss of 8.3% after treatment. After follow up also the median of the ovarian volume shows no significant reduction. This reveals the treatment is effective in reducing the volume of ovary during before and after treatment. Vata Kaphahara and Srothorodhahara property of the combinations might have contributed in reducing the ovarian volume.

BMI

Before the treatment the median of BMI was 25.85 with SD of 4.789 and range 18-36. After treatment mean BMI reduced to 25 with SD4.326 and Range19-35 indicating a loss of 3.2%. This reveals the effectiveness of the treatment in reducing BMI before and after the study. Snehapana, Virechana and diet restriction might have improved the body mass index.

CONCLUSION

PCOS is not a completely curable disease, but the symptoms can be alleviated by medications, lifestyle modifications and practice of adequate exercises.

The various conditions associated with PCOS shows similarities with Gulma, Prameha, Sthoulya etc. PushpagniJaataharini mentioned in Kasyapa Samhita
bears some similarity with clinical presentaions of this disease. Nashtarthava, Arthavakashaya and Vandhya yoni Vyapath mentioned in Susrutha sanshita can also be taken into account. The objective of the treatment should be correction of Srotorodha and Vatha anulomana by internal and external therapies which are Kaphavatahara, Agni deepana and Mutavathana Anulomana in nature along with the avoidance of causative factors. The treatment modalities Snehapana, Mathravasthi with Pippalyadi Anuvasana thaila and Virechana with Hinguthriguna thaila is found to effective in the management of PCOS especially in normalizing menstrual interval, reducing the volume of ovaries and reducing the BMI due to it Kaphavatahara, Srotoshodhahara and Vathanulomana properties. It is not helpful in reducing the number of follicular cyst and in inducing ovulation. Strict dietary regimen and adequate exercise played an important role in improving the clinical condition. Among 30 patients, 7 were married women, one of them had conceived after the study period.

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