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Effectiveness of *Shuddhabala Taila Matra Vasti* on Polycystic ovary syndrome

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Abstract

Polycystic ovary syndrome (PCOS) is a common hormonal abnormality found in women worldwide. Rotterdam criteria is used to diagnose the PCOS. Polycystic Ovarian Syndrome is characterized by excessive production of androgen, and it interfere with ripening of ovarian follicles and aetiology is not known. A Clinical Study was carried out to find out the effectiveness of *Shuddhabala Taila Matra Vasti* in case of polycystic ovary syndrome, at special subfertility clinic, Gampaha Wickramarachchi Ayurveda teaching hospital. Sixty PCOS patients were randomly selected according to inclusion, exclusion and diagnostic criteria and randomly divided in to two groups as group A and B. Group A were treated with oral drugs and Group B treated with oral drugs and Matra Vasti for one month, after taking the written consent. Kanchanara guggulu and Punarnawashtaka Panta were used as oral drugs and Shudhabala Taila was used for Matra Vasti. Data was collected through an interview-based questionnaire and findings of day 12 Trans-Vaginal Scan Reports. Data was analysed by using Wilcoxon sign rank test and Mann-Whitney U tests. According to the data, Acne identified as the most common symptom (65%) and hirsutism and boldness were identified as the least common symptoms (51.66%) related to this study. When comparing the treatment efficacy between group A (only oral drug treatment) and group B (oral drugs with Vasti treatment), it shows that the treatment of group B was significantly effective for Polycystic Ovarian Syndrome with respect to Oligomenorrhea and Dysmenorrhea, while it (treatment of group B) has not shown a significant efficacy over the group A (oral drug treatment) with respect to improvement of endometrial thickness and Follicular maturity, in Polycystic Ovarian Syndrome at 5 percent level of significance.

Keywords: Polycystic ovarian syndrome; Oligo menorrhea; Ayurveda; Subfertility

1. Introduction

Stein and Leventhal identified seven women suffering from amenorrhea, hirsutism, and enlarged ovaries with numerous cysts in 1935, and it was the first reported Polycystic ovary syndrome in the modern medical literature [1]. Polycystic Ovarian Syndrome (PCOS) is the most common hormonal abnormality found in present. Between 1 in 10 women of childbearing age has PCOS. As many as 5 million women in the United States may be affected. It can occur in girls as young as 11 years old [2]. The major endocrine disruption of this disorder is excessive androgen secretion or activity, and a large proportion of women also have abnormal insulin activity. The cause of polycystic ovary syndrome is unknown, but studies suggest a strong genetic component that is affected by gestational environment, lifestyle factors, or both [3].

Polycystic ovary syndrome is characterized by multiple small cysts on the ovaries, menstrual irregularities, and features of excess androgen production such as hirsutism (excess facial or body hair), male or female pattern balding (hair loss), acanthosis nigricans (skin discolorations) and acne. In terms of menstrual irregularity, menses may be irregular; there may be oligomenorrhoea (reduced frequency of menstruation) or amenorrhoea (periods of six months or more without menstruation). PCOS is associated with obesity as well particularly central obesity, insulin resistance, hypertension,

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raised blood lipids and metabolic syndrome. Also, a woman with PCOS may enter her elder years with an increased risk of type II diabetes and heart disease [4].

According to Ayurveda, PCOS is a disorder involving *Vata, Pitta, Kapha, Medas, Ambhuvaha Srotas*, and *Shukra/ Arthava Dhatu* and its cysts are like *Kaphaja Granthi*. According to Ahstangahridaya and Susruta Samhitha, it refers to nodular or glandular swelling with hard, knotty, and rough appearance [5, 6, 7].

As mentioned previously polycystic ovary syndrome (PCOS) is recognized as the most common endocrine/metabolic disorders of women. Its prevalence depends in part upon the diagnostic criteria used to define the disorder [8,9]. As an example, in a report of 827 women with World Health Organization class II Olig ovulation (eu-estrogenicnormogonadotropic ovulatory dysfunction), 456 (55 percent) were classified as having PCOS by the NIH 1990 criteria (irregular menses, biochemical and/or clinical hyperandrogenism, and other causes of hyperandrogenism excluded). In contrast, 754 (91 percent) women were considered to have PCOS using the Rotterdam 2003 criteria (which requires two out of three of the following: oligo- and/or anovulation, clinical and/or biochemical signs of hyperandrogenism, and polycystic ovaries [by ultrasound] [9,10]. Other causes of hyperandrogenism must also be excluded for the Rotterdam criteria.

PCOS is related to ovarian dysfunction and *Tridoshas* have an impact over all the process involved in ovulation. *Vata* stands for proliferation, division of cells (granulosa and theca cells) and rupture of the follicle etc. [11]. Pitta is associated with its conversion power, like, conversion of androgens to estrogen in Graafian follicle and maturity of follicle by its function of *Paka Karma* [11,12,13].

Kapha stands as a building and nutritive factor [5]. It binds all the cells together and gives nutrition for growth and development of the cells. Among the three Doshas, *Vata* plays a major role in physiology and pathology of reproductive tract and *Vasti* is the best treatment for *Vataja* disorders [5]. Thus, *Vasti Karma* is a specific therapeutic procedure, in which medicines are administered into body through *Gudamarga* (per rectum) [14]. *Matra Vasti* is a simplest type of *Vasti* [5]. *Matra Vasti* is the effective and major treatment modality and is said to be *Vrimhana* and *Vata Rogahara* which can be adopted without any restrictions at O.P.D. level without any complications.

The drug selected in the present study is *Shuddhabala Taila*, advocated in *Vataja* disorders including *Nashta Rajas* [15].

Considering these facts, it is evaluated the significant impact of *Shuddhabala Taila Matra Vasti* in case of polycystic ovarian syndrome.

2. Material and methods

2.1. Study Design – Single blind comparative clinical trial

2.1.1. Clinical Trial

Clinical trial carried out for 6 months of period (February 2015 to August 2015).

2.1.2. Population of the Study

Total patients- 60

2.1.3. Selection of Patients

Patients were selected from Special sub-fertile clinic of Gampaha Wickramarachchi Ayurveda teaching hospital, Yakkala, Sri Lanka and patients will be randomly divided in to 2 groups (Group A and Group B).

2.2. Inclusion criteria

- Primary and secondary sub-fertile women
- Age group 25-40 years.

2.3. Exclusion criteria

- Patients having any other conditions for causing oligomenorrhea and anovulation except PCOS.
- Patients suffering from the other chronic illness, cardiac diseases, and thyroid disorders, Hypertension, severe insulin resistance, androgen secreting neoplasm, etc.

- Infertility associated with other factors like tubal blockage, uterine factors, etc.

2.4. Diagnostic criteria

Rotterdam (2003) Diagnostic criteria for PCOS - two out of three of: [16]

- Clinical Hyperandrogenism or Biochemical Hyperandrogenism
- Oligomenorrhea or Oligo-Ovulation
- Polycystic Ovaries on Ultrasound

2.5. Drugs (selected regime)

Shuddhabala Taila, which is the main drug of this research prepared under the advice of research supervisor and other drugs, (*Kanchanara guggulu, Punarnawaashtaka panta*) were obtained from the Wickramarachchi Ayurveda pharmacy of Yakkala, Sri Lanka. All drugs were identified in the *Dravya Guna* department of Gampaha Wickramarachchi Ayurveda Institute, University of Kelaniya, Sri Lanka.

2.6. Preparation of the *Suddhabala Taila*

Prepared the oil according to *Taila Paribhasha* as mentioned in Sharangadhara Samhitha [17] and Sneha Shatakaya [18] which mentioned ingredients and amount, same as in Ayurveda Pharmacopeia [15].

Used ingredients With Amount

- Root of *Sida cordifolia* – 12kg
- Water – 122.88L
- Cow's milk – 122.88L
- Prepared sesame oil – 15.36L
- Root paste of *Sida cordifolia* (For Kalka) – 1200g

2.7. Method of Drug Preparation

Root of *Sida cordifolia* Boiled with the water, until it becomes 30.72L (4 →1). Add milk, prepared sesame oil and the root paste of *Sida cordifolia* to decoction of *Sida Cordifolia* and prepared the oil.

2.8. Special precautions

- Maintained the intensity of fire throughout the preparation.
- The mixture was stirred continuously.
- Cow's milk added little by little, to avoid overflow.
- Keep an intension to determine the *Madhya Pāka.*

2.9. Identification of *Madhya Pāka*

According to Sharangadhara Samhitha, *Kalka* is not sticky and can be made in to *Varti* between the fingers, due to free from water [19].

2.10. Investigations

Assessment of day 12 Trans-Vaginal Sonography (TVS) carried out before starting the treatment, at the end of the treatment and at follow-up period.

2.11. Consent

Written consent was taken from each patient, prior to the initiation of the study.

2.12. Method of Drug administration

2.12.1. Grouping

Selected patients were randomly divided into two groups. One group consist of 30 patients.

Group B

Patients were given *Punarnawaashtaka Panta* (They were advised to make decoction from it) and 02 pills of *Kanchanara guggulu* with water, 2 times per day. Along with these oral drugs, *Shuddhabala Taila Matra Vasti* was given in the dose of 60 ml for 7 days after cessation of menses.

Group A

Patient of this group were treated with only oral drugs in the same dosage and the same duration of group B.

2.12.2. Duration

- Clinical trial - 6 months
- Time allocated for a single patient – 3

2.12.3. Preparation method of Panta

Add 15 g of row powder in to 120 ml of hot water and stirred well and then filter after fifteen minutes.

Method of Administration of *Matra Vasti*

The procedure of administration of *Vasti* in general can be divided into three stages, as follows:

- *Purva Karma*

The patients were instructed to come after a light diet (neither too *Snigdha* nor too *Ruksha,* and not more than three-fourth of their usual diet). They were also advised to come after elimination of stools and urine. The patients were mainly subjected to local Abhyanga and *Mridu Swedana* prior to the administration of *Matra Vasti*.

- *Pradhana Karma*

After *Purva Karma*, the patient was advised to lie down in the left lateral position on the *Vasti* (enema) table with the left lower extremity kept straight and the right lower extremity flexed at the knee and hip joints. The patient was asked to keep her left hand below the head. *Shuddhabala Taila* was applied to the anus in a small amount. Ninety milliliters of lukewarm *Shuddhabala Taila* were taken in an enema syringe and a rubber catheter lubricated with *Shuddhabala Taila* was attached to the enema syringe. After expelling the air from the enema syringe, the rubber catheter was passed through the anus of the patients up to the length of 4 inches. The patients were asked to take deep breaths and to lie still while the catheter, and the drug, was introduced. The total amount of *Taila* was not administered to avoid the entrance of *Vayu* into the *Pakwashaya*.

- *Pashchat Karma*

After the administration of *Vasti,* the patient was advised to lie in supine position with the arms and legs spread out freely over the table. Both legs were raised for few minutes to raise the waist and gently tapped over the hips. Simultaneously, gentle taps were also given on her soles and over the elbow and palms so that the *Matra Vasti* would spread throughout the body and be retained for the required period. After some time, the patient was advised to get up from the table and rest in her bed but to avoid sleeping during the day. *Vasti Pratyagamana Kala* was noted in each case [20].

- *Pathyapathya*

Patients were advised to take less amount of diet and correct their dietary habits. Especially they were advised not to take chicken and artificial foods/drinks. Mild to moderate exercise as per their capacity is suggested.

They were also advised for intercourse during *Rutukala* (from 10th to 20th day of menses) and not to take much of stress.

2.13. Follow-up study

Follow-up study was conducted for 1 cycle after completion of the treatment.

2.14. Statistical Analysis

Wilcoxon sign rank test and Mann-Whitney U test were used to arrive the results.

3. Results

For age wise distribution of patients with PCOS, 10 (33.3%) in group A and 11 (36.6%) in group B were between 25-30 years, 10 (33.3%) in group A and 13 (43.3%) in group B were between 31-35 years, 10 (33.3%) vs 6 (20%) patients were between 36-40 years in group A and B respectively, More number of patients were in the 31-35 age category, compared to other two age categories. Most of the patients were housewives in Group A and B. Group A patients were complained Hirsutism than group B. In the present study, there were more than 50% (51.66%) patients who have hirsutism. Out of 60 patients 65% of patients observed acne and 18 (%) vs. 21 (%) in group A and B respectively. When considering Obesity most overweight patients were recorded in group B and there were 53.33% obese patients in Study. There is not much deference in group A and group B patients who recorded acanthosis nigricans. 18 patients were in group A and 16 patients in group B recorded as they have acanthosis nigricans. Total number of patients who observed acanthosis nigricans were 56.66%. Boldness was observed in 16 (53.4%) vs. 15 (50%) in group A and group B respectively. Total number of patients in study who have boldness were 31 (51.66%). In the present study 55% patients were observed skin tags, 17 (56.7%) vs. 16 (53.4%) in group A and group B.

None of a patient was having very severe pain in abdomen in both study groups. Out of 28 patients, 9 of them were with severe pain before the treatment stage could be identified and that amount was down to one patient after giving the treatment in only oral drugs group (Group A). Considering the group B (Oral drugs with *Vasti* Treatment), none of patients initially come with "No Pain" category. But after giving *Vasti* treatment with oral drugs, 11 patients out of 25 (44 %) have come to that category. None of a patient was with one day of menstrual flow in group A. Comparing percentages of patients with respect to duration of flow, more than 30 percent of patient indicated five days or more after giving *Vasti* treatment with oral drugs (Group B). But in Group A, that amount of improvement cannot be seen after the treatment. However, in that group 25 percent of patients has come to the "Five days or more" category in follow up stage. When considering amount of menstrual bleeding, it can be seen a rapid improvement in group B over the group A in normal amount of bleeding category after giving the treatment. When considering endometrial thickness, it can be seen enhancements of endometrial thickness after giving the treatments in both groups.

It can be seen improvements of largest follicle size of the patients after giving the treatments in both groups.

3.1. Hypothesis Testing

3.1.1. Hypothesis – 1

- H0: Treatment given to each group was not efficient in cases of polycystic ovarian syndrome.
- H1: Treatment given to each group was efficient in cases of polycystic ovarian syndrome.

Table 1 Testing# the efficacy of drugs given for each group

Comparison		**Group A** (Only Oral Drugs)		**Group B** (Oral drugs with Vasti Treatment)	
		Z-Statistic	**p-value**	**Z-Statistic**	**p-value**
Pain in abdomen	Before & After Treatment	3.166	0.001*	4.491	0.000*
	After Treatment & Follow Up	-2.121	0.983	-3.300	0.999
Duration of flow	Before & After Treatment	2.449	0.014*	4.001	0.000*
	After Treatment & Follow Up	0.302	0.382	-2.309	0.990
Amount of bleeding	Before & After Treatment	2.646	0.004*	-4.583	0.000*
	After Treatment & Follow Up	-1.732	0.959	-3.000	0.999

Wilcoxon sign rank test for related samples; * Significant at 5% level

Since all the p-values were less than 0.05 for each symptom, significant treatment efficacies can be seen for considered symptoms after giving the treatment stage than before giving the treatment for both study groups.

But there were not significant statistical differences between treatment efficacies for pain in abdomen, duration of flow and amount of bleeding after and follow up treatment stages.

Table 2 Testing# the efficacy of the drugs given for each group based on scan reports

Comparison		Group A (Only Oral Drugs)		Group B (Oral drugs with Vasti Treatment)	
		Z-Statistic	p-value	Z-Statistic	p-value
Endometrial Thickness	Before & After Treatment	2.530	0.006*	2.496	0.007
	After Treatment & Follow Up	0.632	0.264	-1.090	0.862
Largest follicle Size	Before & After Treatment	2.486	0.007*	2.887	0.002*
	After Treatment & Follow Up	-0.258	0.602	-0.847	0.802

Wilcoxon sign rank test for related samples; * Significant at 5% level

Since two p-values were less than 0.05 for endometrial thickness and largest follicle size, significant treatment efficacies can be seen after giving the treatment stage than before giving the treatment for both study groups.

But there were not significant statistical differences between treatment efficacies for endometrial thickness and largest follicle size, after and follow up treatment stages.

3.1.2. Hypothesis – 2

- H0: *Shuddhabala Taila Matra Vasti* does not enhances the effect of oral medications in cases of polycystic ovarian syndrome.
- H1: *Shuddhabala Taila Matra Vasti* enhances the effect of oral medications in cases of polycystic ovarian syndrome.

Table 3 Comparison# between the efficacy of oral drugs with Vasti treatment and only oral drug treatment

Symptom	Z-Statistic	p-value
Pain in abdomen	2.530	0.006*
Duration of flow	2.748	0.003*
Amount of bleeding	1.941	0.026*

Mann-Whitney U test for two independent samples; * Significant at 5% level

Since all the p-values are less than 0.05, treatment effects for considered symptoms in table 8 were statistically significant at 5 percent significant level.

That means comparing the treatment efficacy between oral drugs with *Vasti* treatment and only oral drug treatment groups, it shows that the oral drugs with *Vasti* treatment group was significantly effective for polycystic ovarian syndrome with respect to pain in abdomen, duration of flow and amount of bleeding.

Table 4 Comparison# between the efficacy of oral drugs with *Vasti* treatment and only oral drug treatment based on scan reports

Symptom	Z-Statistic	p-value
Endometrial Thickness	0.939	0.174
Largest follicle Size	1.294	0.098

Mann-Whitney U test for two independent samples; * Significant at 5% level

According to the table 3.4, oral drugs with *Vasti* treatment has not shown a significant efficacy over the only drug treatment with respect to endometrial thickness and largest follicle size in polycystic ovarian syndrome at 5 percent level of significance.

4. Discussion

According to Royal College of Obstetricians and Gynaecologist, PCOS is a common disorder, often complicated by chronic anovulatory infertility and hyperandrogenism with the clinical manifestation of oligomenorrhoea, hirsutism and acne [21]. Rotterdam criteria is used to diagnose the PCOS, and aetiology is not known.

As determined by modern medicine this syndrome is treated with combined hormonal pills to legalized menses, but it further disturbs the natural hormonal pattern and worse the disease.

In Ayurveda this disease is not mentioned in authentic texts, Caraka Samhita, Susruta Samhita and Ashtangahridaya Samhita. But disease mentioned in Kashyapa Samhita Kalpasthana Revathi Kalpa, which known as *Pushpaghni revati* can be compared with polycystic ovarian syndrome.

In this study, *Kanchanara guggulu* and *Punarnavashtaka Panta* used as oral drugs. In *Kanchanara guggulu, Kanchanara* (*Bauhinia variegate*) and *Guggulu* (*Commiphra wightii*) are the main ingredients. *Punarnavashtakaya* consist with eight herbs. They are, *Punarnava* (*Boerhavia diffusa*), *Nimbha* (*Azadirachta indica*), *Patola* (*Luffa acutangula*), *Shunti* (*Zingiber Officinale*), *Tikta* (*Andrographis paniculata*), *Amurta* (*Tinospora cordifolia*), *Daru* (*Cedrus deodara*) and *Abhaya* (*Terminalia chebula*).

According to Ayurveda Polycystic Ovarian Syndrome is a disorder involving *Vata, Pitta* and *Kapha Dosha*. Therefore, in this disease, the involvement of *Dosha* is much complicated. When considering most of the signs and symptoms such as Obesity, Cysts in Ovaries etc. general treatment should focus to *Kapha Dosha*. For that purpose, *Kanchanara Guggulu* and *Punarnavashtakaya* used due to their *Kaphaghna, Shotahara* properties.

As the basis of Ayurveda, *Vata* plays a major role in all kinds of gynaecological disorders, and it governs Pitta and *Kapha* also. When considering PCOS, same theory can be applicable as Vata stands for proliferation, division of cells and rupture of the follicles. Hence *Vata Shaman Vasti* is the best treatment for Ovulation Induction of PCOS. As mentioned in Caraka Samhita *Siddhisthana, Vasti* effects are not limited only up to rectum, and it produced widespread systemic effects [22]. Therefore, in this study *Matra Vasti* which is reduced by half in quantity (day after day or at suitable periods), does not produce any complications which cannot be prevented, used as panchakarma procedure at the Ovulation Period.

Here *Shuddabala Taila* which good for *Nashta Artava* as mentioned in Ayurveda pharmacopeia, used to do Matra Vasti and main herbal ingredient of *Shuddabala Taila* was *Bala* (*Sida cordifolia*).

Sida cordifolia (linn) which belongs to Malvaceae family is a commonly used plant both in Ayurveda and Traditional medicine systems in Sri Lanka. It is also known as the "*Bala*" in Hindi and Sanskrit and "*Bavila*" in Sinhala. According to Ayurveda Pharmacological properties of Bala are *Madura* in *Rasa, Guru*, *Snigdha* and *Pichchila* in *Guna*, *Sheeta* in *Veerya* and *Madhra* in *Vipaka*. Other medicinal properties are *Vata Pitta Shamaka*, *Vedanāsthāpana, Shotha hara, Nadi Balakāraka, Snehana, Anulomana, Hridya* and *Raktapittashāmaka, Mutrala, Shukrala* and *Prajāsthāpaka*. The whole plant is used for medicinal purposes. As mentioned in Literature review, Hypoglycaemic activity, Hypertensive, analgesic activity, appetite suppressant activity, anti-inflammatory activity, Gastric anti-ulcer activity, Anti rheumatism, Apoptogenic activity, Aphrodisiac activity, Wound healing Activity, Anti-bacterial and Anti-Microbial Activity, Anti-Cancer, Hepato-protective activity, Anti-parkinsonism, CNS depressant activity, Cardio Vascular effect, Nephro-protective activity, Anti-hypercholesterolemic effect, Anti-oxidant effect and anti-Nociceptive properties of *Sida cordifolia* has been scientifically proven. *Sida cordifolia* is a *Vata Shamana* herb according to Susruta and Vagbhata Acharyas and it is a *Prajastthapaka dravya*.

Other Ingredients of *Shuddhabala Taila* were *Thila Taila* and Cow's milk. *Thila Taila* spreading throughout the body quickly (*Yogavahiguna*), entering through minute pores (*Sukshmaguna*) and decrease *Vata* and *Kapha*. Cow's milk is best to mitigate aggravation of *Vata* and *Pitta* and it is a good rejuvenator.

Therefore, all these drugs which used in this study give beneficial effects on polycystic ovarian syndrome.

5. Conclusion

In the present study, majority (38.33%) of patients belonged to age group of 31-35years, 51.66% were housewives, 65% were having Acne, 51.66% having hirsutism, 53.33% were obese, 56.66% were having acanthosis nigricans, 51.66% having boldness and 55% having Skin tags. Acne identified as most common symptom (65%) and hirsutism and boldness were identified as lest common symptoms (51.66%) related to this study. When comparing the treatment efficacy between group A (only oral drug treatment) and group B (oral drugs with *Vasti* treatment), it shows that the oral drugs with *Vasti* treatment group was significantly effective for Polycystic Ovarian Syndrome with respect to Dysmenorrhea and Oligomenorrhea, while group B (oral drugs with *Vasti* treatment) has not shown a significant efficacy over the group A (only oral drug treatment) with respect to improvement of endometrial thickness and Follicular maturity, in Polycystic Ovarian Syndrome at 5 percent level of significance. As mentioned previously Hirsutism, Acne, Baldness, Obesity, Acanthosis nigricans and skin tags identified as main symptoms of polycystic ovarian syndrome and these symptoms didn't show significant change during study period due to treatment period was limited up to three months and it was not sufficient period for change of above symptoms. However, this study provided evidence-based scientific data on the classical Ayurveda treatment.

Compliance with ethical standards

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Disclosure of conflict of interest

There were no conflicts of interest declared by the authors.

Statement of informed consent

Informed written consent was obtained from all individual participants included in the study.

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