

#### Clinical Researches

# Clinical efficacy of *Ayurveda* treatment regimen on Subfertility with Poly Cystic Ovarian Syndrome (PCOS)

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#### **Abstract**

Poly Cystic Ovarian Syndrome (PCOS) is the most common endocrinopathy in women of reproductive age, resulting from insulin resistance and the compensatory hyperinsulinemia. This results in adverse effect on multiple organ systems and may result in alteration in serum lipids, anovulation, abnormal uterine bleeding and infertility. According to Ayurvedic view PCOS can be correlated with Aarthava Kshaya. It was revealed that most of subfertility patients who were presented Osuki Ayurveda Centre suffered from the PCOS. Therefore the present study was carried out for the clinical evaluation of the efficacy of Ayurveda treatment regimen on subfertility with PCOS. Total 40 patients were selected by using purposive sampling method. According to the Ayurveda theories of Shodhana, Shamana and Tarpana, the treatment was conducted in 3 stages for the duration of 6 months. The response to the treatment was recorded and therapeutic effects were evaluated by symptomatic relief and through Trans Vaginal Scan and LH, FSH hormone levels. The results revealed that, subfertility due to PCOS can be cured successfully by using this Ayurveda treatment regimen.

Key words: Aarthava Kshaya, Subfertility, Poly Cystic Ovarian Syndrome.

#### Introduction

Poly Cystic Ovarian Syndrome is a relatively common endocrine disorder in women of reproductive age group. It is found in around 70% of women who have ovulation difficulties leading to subfertility.

Poly Cystic Ovarian Syndrome is a condition that has cysts on the ovaries that prevent the ovaries from performing normally. Symptoms of Poly Cystic Ovarian Syndrome include Amenorrhea or infrequent menstruation, irregular bleeding, infrequent or no ovulation, multiple immature follicles, increased levels of male hormones, male pattern baldness or thinning hair, excess facial and body hair growth, acne, oily skin or dandruff, dark coloured patches of skin specially on neck, groin, underarms, chronic pelvic pain, increased weight or obesity, diabetes, lipid abnormalities and high blood pressure<sup>1</sup>.

Fertility problems experienced by women with Poly Cystic Ovarian Syndrome may be related to the elevated hormone,

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insulin or glucose levels, all of which can interfere with implantation as well as development of the embryol. Increased Leutenizing hormone reduces the chance of conception and increase miscarriage. Additionally abnormal insulin levels may also contribute to poor egg quality, making conception more difficult<sup>1</sup>.

It is estimated the 50 - 60% of women who presented to the Osuki Ayurveda Centre for subfertility treatment were with Poly Cystic Ovarian Syndrome for the last 2 years. There is a special Ayurveda treatment regimen used in Osuki Ayurveda centre to cure Poly Cystic Ovarian Syndrome. Observing for nearly a period of two years of this treatment regimen, it is understood that this treatment regimen has a powerful effect for the management of Subfertility with Poly Cystic Ovarian Syndrome. But so far no scientific studies was carried out; hence the present study was carried out to scientifically evaluate the efficacy of this Ayurveda treatment regimen in subfertility with Poly Cystic Ovarian Syndrome.

#### **Material and Methods**

Preparation of drugs: All medicines were prepared by "Beem" chemicals under supervision of the principal author.

Clinical study: In the present study, 40 patients of subfertility with Poly Cystic Ovarian Syndrome were selected from Osuki Ayurveda Centre, Rajagiriya, Sri Lanka.

 These patients were subjected to detailed clinical examination and investigations specially FSH, LH level and its ratio, Testosterone, FBS, Lipid profile, Liver function test and USG.

#### Criteria for diagnosis:

The presence of at least 3 of the following criteria:

- Polycystic Ovaries on USG
- Oligomenorrhea or anovulation
- Clinical or bio-chemical evidence of Hyperandrogenism
- Elevated LH
- LH: FSH ratio > 3 and

25 - 40 years age grouped subfertility patients were selected to the present study. The patients suffering from diabetes mellitus, hypertension, thyroid disorders, hyper prolactinemia, congenital adrenal hyperplasia, other gynaecological disorders, heart diseases and renal failure were excluded from the research. The male partners of selected couples had neither any abnormalities in Seminal Fluid Analysis nor any condition which leads subfertility.

The treatment was conducted in 3 stages for duration of 6 months.

In stage 1 (Day 1 to day 14) patients were treated with 30ml of *Triphala Kwatha*, 2 pills of *Chandraprabha* and 5g of powder of *Manibhadra* twice a day in the morning and evening at 6 PM. These drugs were administrated to do the basic body purification of the patients and also all these drugs are favourable to the function of the female genital organs<sup>2</sup>.

In stage 2 (Day 15 to 4<sup>th</sup> month) patients were treated with 5g of each powder of *Shatavari* (*Asparagus racemosus*), *Shatapushpa* (*Peucedanum graveloens*) and *Guduchi* (*Tinospora cordifolia*) twice a day in the morning and evening. Further they were treated with 20ml of *Krishna Jeeraka*, twice a day in the morning and evening. *Shatavari* is used to correct the hormonal influence and enhance the follicular maturity. *Guduchi* is used to increase the immunity ("Ojas") of the patients. *Shatapushpa* act as a follicular maturity substance and as a pain relief agent. It also acts against menstrual irregularity<sup>3 4</sup>.

In stage 3 (4th to 6th month) patients were treated with 5g of each powder of Atibala (Abutilon indicum) and Shatapushpa and 4 pills (each 125mg) of Rasayana Kalpa (A. racemosus, Terminalia chebula, T.belarica, Embelica officinalae, T. cordifolia, Naredostachys jatamansi, Herpestis monnieria) twice a day in the morning and evening at 6 PM<sup>4</sup>. Further they were treated with 20ml of oil of Sahachara twice a day in the morning and evening at 8 PM. These patients were locally treated with Uttara Vasti with 5ml of oil of Shatapushpa two consecutive days per month from the day which is completely cessation of the menstrual flow in between 4th to 10th day of the cycle. Atibala is used to correct the hormonal disturbances and facilitates to avoid miscarriages. Sahachara is used to remove unwanted follicles.

The responses to the treatment were recorded and therapeutic effects were evaluated by symptomatic relief and through Ultrasonography and LH/ FSH hormones. Ultrasonography views the changes of the ovaries and the changes of the follicles regarding to the treatment. FSH/LH ratio is showing the reappearance of the hormonal levels to normal range. Pregnancy confirmed by using urine hCG test.

#### **Observation and Results**

These patients differ from each other in many ways such as physique, temperament and habits. In the present study all the patients were housewives and all they have no considerable stressful life style. They all suffered from primary subfertility and 90% of them have 4 to 6 years of marriage life.

The 80% of patients were not using any contraceptive method while 10% used oral contraceptive pills and 5% used condom and natural methods, for the treatment of 6 months or less. All patients have not taken any kind of medicine within one year for PCOS and subfertility.

They complained mostly irregular, few or absent menstruation, scanty or less menstrual blood, pain in menstruation, duration of menstruation below 3 days, excessive and increased body hair in face and chest, skin discolouration and obesity.

Assessment criteria were based on the improvement in the score of cardinal symptoms which are irregular menstruation, duration of bleeding, dysmenorrhea, quantity of menstrual blood, excessive body hair, obesity, and skin discolouration before and after the treatment. The improvement in the cardinal symptoms were compared and analyzed statistically between the end of the treatment and baseline by using student's paired 't' test.

USG reports revealed, that reduce of polycystic appearance of ovaries and improvement of follicular maturity. LH/FSH hormone reports revealed that the ratio came to the normal level.

#### Assessment of amount of bleeding

All the pads were collected and subjected to assessment of menstrual blood loss before during and after treatment. The method used by Vaishali Shinde (2004) in India was used for this study to measure the weight of pads. No. of pads were counted by using a pictorial chart, as used in previous studies by Higham in 1990 and Herve Ferdinandez in 2003.

At the end of the aforesaid *Ayurveda* treatment regimen 85% of the patients were successfully get cured from Poly Cystic Ovarian Syndrome, while 75% of the patients get conceived.

#### **Discussion**

Poly Cystic Ovarian Syndrome is one of the main causes of subfertility in women. It is associated with anovulation,

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Table 1: Duration of bleeding				
Duration	Grade	Score		
3-5 days	Nil	0		
1-2 / 6-7 days	Mild	1		
1 / 8-9 days	Moderate	2		

Bleeding I or above days are considered as bleeding throughout the day., Spotting is considered as bleeding just 2 or 3 drops.

Severe

Spotting / >9 days

IMP (days)	Grade	Score
28 days	Nil	0
28 - 45	Mild	1
45 - 60	Moderate	2
Above 60	Severe	3

Table 3: Amount of bleeding & quantity of Menstrual blood

No. of pads per cycle	Grade	Score
<15	Nil	0
15-19	Mild	1
20-25	Moderate	2
>25	Severe	3

Table 3 (1): Quantity of Menstrual blood					
Blood loss	Grade	Score			
80g - 100g	Nil	0			
101 - 120g	Mild	1			
101-120g	Moderate	2			
>120a	Severe	3			

Table 4: Pain during Menstrual period

Pain	Grade	Score			
No pain	Nil	0			
Menstruation is painful but daily activities are not affected, no need of analgesics	Mild	1			
Daily activities are affected, need to take analgesics	Moderate	2			
Daily activities are inhibited, pain continuous after administration of analgesics	Severe	3			

Table 5: General weakness

Weakness	Grade	Score
No weakness	Nil	0
Mild weakness	Mild	1
Weakness is severe but perform routine activities	Moderate	2

Table 6: Prognosis of the cardinal symptoms

Symptom	No. (n)	Mean	score	Mean	Relief	SD	SE	t
		B.T.	A.T.	d	%			
Irregular Menstruation	40	2.475	0.250	2.225	75	0.733	0.116	19.19
2. Duration of bleeding	40	2.350	0.425	1.925	57.5	0.5723	0.0905	21.27
3. Dysmenorrhea	40	1.000	0.050	0.950	95	0.597	0.0944	10.06
Quantity of Menstrual blood	40	1.900	0.150	1.750	70	1.104	0.174	10.03
5. Excessive body hair	40	1.950	1.875	0.075	_	0.2667	0.0422	1.78
6. Obesity	40	1.700	0.200	1.500	85	0.5991	0.0947	15.83
7. Skin discolouration	40	1.750	0.125	1.625	87.5	0.705	0.111	14.58

Table 7: Overall effect of the therapy

	Mean	Mean score		SD	SE	t
	B.T.	A.T.				
Ayurveda Treatment Regimen	1.875	0.4393	1.4357	0.9557	0.0571	25.14

androgen excess, obesity and subfertility. PCOS results in increased free testosterone, ovarian androgen secretion, free estradiol and estrone. It's favouring LH secretion and steady state follicle stimulating hormone levels which effect on follicular maturation. This hyperandrogenic, normoestrogenic environment results in an anovulatory state, no progesterone is available to disrupt the constant estrogen stimulation of the endometrium<sup>1,5</sup>.

In allopathic medicine oral contraceptives, progestins, anti androgens and ovulation induction agents remain standard therapies.

Aartava-kshaya, which can be correlated with PCOS has been described as deficiency or loss of artava, artava dose not appears in time or is delayed, is scanty and dose not last for three days. Pain in vagina also can be seen. According to Ayurveda, Aartava-kshaya is a disorder involving Pitta and Kapha doshas, Medas, Ambu/Rasa, Shukra/Artava Dhatu and Rasa, Rakta, Artava Vaha Srotas<sup>6</sup>. Therefore Poly Cystic Ovarian Syndrome can also be described with same involvement of Dosha, Dhatu and Upadhatu Kapha predominance manifests as increased weight, subfertility, hirsutium, diabetic tendencies and coldness. Pitta

predominance manifests as hair loss, acne, painful menses, clots and heart problems. *Vata* predominance manifests with painful menses, scanty or less menstrual blood and severe menstrual irregularity<sup>6,7,8</sup>.

The pathology is an obstruction in the pelvic cavity (Apana Kshetra) causing disorders in the flow of Vata. This in turn leads to an accumulation of Kapha and Pitta.

The treatment principle is to clear obstruction in the pelvis, normalize metabolism and regulate the menstrual system (Aartava Dhatu). Kapha reducing, insulin enhancing and hormone rebalancing drugs help to the relieve symptoms of Poly Cystic Ovarian Syndrome.

Triphala Kwatha, Chandraprabha Vati and Manibhadra Choorna help to clear obstruction and normalize the *srotas*. Especially *Triphala* and *Guggulu* are very useful for reducing excess weight<sup>2</sup>.

Powder of A. racemosus brings balance and strength to the menstrual system and it helps to regulate Aartva Dhatu. Properties of Powder of seeds of P. graveloens, oil of Krishna Jeeraka (Nigella sativa) and oil of Sahachara (Barleria prionits) were helped to destroy cysts on ovaries and stimulate the follicular maturity. Properties of Deepana and Pachana of above drugs they elevate the Jatharagni, Dhatvagni as well as Aartavagni<sup>2</sup>. Powder of Guduchchadiya enhances the overall immunity and powder of Atibala has properties of Prajasthapana, Garbhasya DaurbalyAhara, Balya, Brunhana and Ojo Vardhana<sup>2</sup>. Therefore it helps to get conceived and avoid miscarriage<sup>3,5</sup>.

Uttara Vasti is the most effective treatment in gynaecological disorders. It helps to purification and clears the Aartava Vaha Srotas, pacifies vitiated Apana Vayu<sup>8</sup> and improve follicular maturity.

Due to Samprapti Vighatana Kriya of this Ayurveda treatment regimen the symptoms of Poly Cystic Ovarian Syndrome get reduced. The effect of therapy show highly significant result on all above symptoms of Poly Cystic Ovarian Syndrome. When considering irregular menstruation most of the patients had 2 - 4 months duration. At the end of the treatment irregularity showed

only 25% of the patients. At the end of the treatment 57.5% of patients had normal duration of menstrual bleeding, 75% of patients were relieved from Dysmenorrhea and majority of patients (70%) had average quantity of menstrual blood. When considering skin discolouration, 87.5% of patients were relieved from the symptom.

At the end of the treatment, majority of patients (85%) had normal BMI levels. But when considering the symptom of excessive and increased body hair, there was no significant relief shown.

In case of subfertility with Poly Cystic Ovarian Syndrome, 85% of patients were successfully get cured from Poly Cystic Ovarian Syndrome, while 75% of patients were conceived.

All these patients were followed for the period of one year. During that period uncured patients were treated continuously. After the four month of duration 90% were cured. The pregnant mothers were treated with Prajasthapana drugs during their ante-natal visits to the clinic. All of them delivered healthy babies. At the end of this follow up period 85% from the treated group were conceived.

#### **Conclusion**

In conclusion, subfertility due to Poly Cystic Ovarian Syndrome can be cured successfully by using aforesaid Ayurveda treatment regimen.

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### हिन्दी सारांश

## पोलिसिस्टीक ओवेरिअन सिंड्रोम संबंधित वन्ध्यत्व की चिकित्सा में आयुर्वेदीय औषधियों का अध्ययन

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पोलिसिस्टीक ओवेरिअन सिंड्रोम की आयुर्वेद में आर्तवक्षय के साथ तुलना की जा सकती है। प्रस्तुत अध्ययन में इस व्याधि से संबंधित वन्ध्यत्व की ४० रूग्णाओं का आयुर्वेदीय शोधन, शमन तथा तर्पण चिकित्सा द्वारा छ महीनों तक उपचार किया गया। परिणामों का विश्लेषण करने के बाद इस चिकित्सा से रूग्णाओं में पूर्णतः लाभ देखा गया।