TO EVALUATE THE EFFICACY OF SINGLE DRUG THERAPY OVER POLYCYSTIC OVARIAN SYNDROME.

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ABSTRACT
Polycystic ovary syndrome (PCOS) affects 20-25% of women of reproductive age and up to 30% in some high-risk groups. PCOS leads to irregularity in the menstrual cycle and the appearance of superfluous male hormones (androgens/testosterones). Menstrual cycles might be regular prior but subsequently turn out irregular, or the incipience of menses may be delayed. Women may experience infertility by meagerness of ovulation in the menstruation cycle resulting out for difficulty in conceiving. Ayurvedic single drug therapy has been emerging in addition to established medical and surgical medication for PCOS. PCOS is a disorder involving Pitta, Kapha, Medas, Ambhuvahasrotas & Artava Dhatu. The causes of PCOS as per Ayurveda can be taken as eating excessive sweet and kaphagenic foods, mandagni because of this is kapha getting aggravated in PCOS, we find kapha disorder. In present case study, we have studied safety and effectiveness of exclusive single drug therapy with use of reserve wellness wrapping technique in PCOS patients. Study eventuate reveal that majority of hormonal level significantly changed post-medication compared to pre-medication. Study results shown that there was statistically significant improvement in Luteinizing Hormone (LH), Prolactin, AMH, Fasting Insulin, SGPT, post medication from the preoperative values (P<0.05). LH/FSH Ratio at pre-medication was 2.82:1, which was reduced to 1.01:1 at post medication (p<0.001). No adverse event was reported during conduct of present study.

KEYWORDS: Polycystic ovary syndrome, Ayurveda, Artava Dhatu, hormones.

INTRODUCTION
PCOS (Polycystic ovary syndrome) is coined since detection of enlarged ovaries carrying multiple small cysts. PCOS has also been referred to as Stein-Leventhal syndrome and polycystic ovarian disease (PCOD). Polycystic ovary syndrome (PCOS) affects 20-25% of women of reproductive age and up to 30% in some high-risk groups. PCOS leads to irregularity in the menstrual cycle and the appearance of superfluous male hormones (androgens/testosterones). Menstrual cycles might be regular prior but subsequently turn out irregular, or the onset of menses may be delayed. Women may experience infertility by meagerness of ovulation in the menstruation cycle resulting out for difficulty in conceiving. Hirsutism; excessive, abundant, pigmented hair growth occurs on the upper lip, chin, around the nipples, and on the lower abdomen, acne and baldness due to an increase in the production of androgens (male hormones) by the ovaries in PCOS. Women with PCOS have truncate levels of the hormone progesterone resulting in growth stimulation of the endometrium, leading to dysfunctional uterine bleeding and breakthrough bleeding and consequently develop endometrial hyperplasia and uterine cancer. Insulin resistance, weight gain, and obesity are also common in PCOS. Observers have suggested that about one-half of women with PCOS are obese. Insulin resistance, accompanied by elevated blood levels of insulin, occurs in most women with PCOS, independent of the presence of obesity. Women with PCOS have also been reported to have an increased risk of developing type 2 diabetes, and many studies have shown abnormal blood lipid levels and elevated levels of C-reactive protein (CRP), a predictor of coronary artery disease. The combination of type 2 diabetes, elevated cholesterol and LDL levels, and elevated CRP levels suggest an increased risk of coronary heart disease on women with PCOS, although this risk has not yet been scientifically established[1]. In Ayurveda majority of gynaecological disorders have been described under the heading of Yonivyapada, though some of the menstrual abnormalities like Asrigdara. For complete knowledge of menstrual disorders, the knowledge of Yonivyapada & Aartvadushti is essential. Acharya Sushruta described...
Bandhya Yonivyapada whose main feature is Nashtartava.[2] Ayurveda suggests that this is vata type disorder (Apan vayu) though the involvement of other dosha can be there but in some measure because the gynaecological disorder are mainly supposed to be due to vitiation of vata. PCOS is a disorder involving Pitta, Kapha, Medas, Ambhuvasaras & Artava Dhatu. The causes of PCOS as per Ayurveda can be taken as eating excessive sweet and kaphagentic foods, mandagni because of this is kapha getting aggravated in PCOS, we find kapha disorder. As well as pitta and vata dosha disorder. Because of all three doshas play important & distinctive role in the production, development, maturation & release of ovum & therefore the ovarian cycle & menstrual cycle is under control of three doshas.In Ayurveda, Several drugs and formulae are available in Ayurveda classics for the remedy of PCOS/PCOD, among them Shatapushpa (Anethum sowa Kurz.) Churna (powder) mentioned by Kashyapa Samhita is selected for clinical study.[3]

MATERIALS AND METHODS

Null Hypothesis -H0= Shatapusha churna orally oral has no effect over the PCOS.
Research Hypothesis -HR= Shatapusha churnaorally has effect over the PCOS.
Research Question: Whether Shatapusha churna orally has role of over the PCOS.

Source and method of collection of the data

Data of 10 PCOS diagnosed patients were taken for the study, from the OPD & IPD of All India Institute of Ayurveda, Sarita Vihar, and New Delhi. A special proforma including consent form was made incorporating all points of history taking, physical signs and symptoms of PCOS and lab investigations. Accordingly, the patients were selected and were subjected to a detailed clinical history and complete examination.

Inclusion criteria
Female aged 15-35yrs.
Diagnosed Cases of PCOS

Exclusion criteria
Oligomenorrhea
An ovulation
Amenorrhoea,
Dysmenorrhoea,
Metrorrhagia
Metrorrhagia
Uterine fibroids
Hirsutism
Obesity not due to PCOS.
Pregnant females
Systemic illness.

Assessment Criteria[4]

Subjective criteria
Menstrual cycle Interval between two cycles
Duration of bleeding
Quantity of bleeding
Acne
Hirsutism
BMI

Objective Criteria
Ovulation

Intervention

A total of 10 females who fulfilled predefined inclusion/exclusion criteria were enrolled in present study. Baseline demography of Patient age, height and weight was recorded for individual patients. Individual patient was given prescheduled appointment and asked to visit clinic for study procedure which was done for approximately 1 hour and repeated every 4th day for 1 complete menstrual cycle. Medication was recommended to be taken after meal.5 ml blood was collected on 3rd day of menstrual cycle to investigate hormonal level in individual patient at baseline before medication and post medication (3rd day of next menstrual cycle). Laboratory investigation for hormones AMH, FSH, Prolactin, LH, TSH, Insulin resistance was performed for efficacy evaluation. Efficacy was evaluated by Improvement in hormone balance (AMH, LH, FSH, LH/FSH ratio, Prolactin, TSH and Insulin resistance). Safety was evaluated throughout study procedure as well as at end of study. Safety was evaluated by analyzing number of adverse events and patients with adverse events

RESULTS

All enrolled (10) patients had completed the study and were included for safety and efficacy analysis. Mean age of patients enrolled in present study was 25.65 ± 4.52 years.

Minimum–maximum of age (in years), height (in cm), weight (in kg) and BMI at baseline is presented in Table Below:-

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Age (In Years)</th>
<th>Height (In cm)</th>
<th>Weight (In Kg)</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>25.65</td>
<td>152</td>
<td>65.44</td>
<td>28.3</td>
</tr>
<tr>
<td>SD</td>
<td>4.75</td>
<td>3.55</td>
<td>4.19</td>
<td>-</td>
</tr>
<tr>
<td>Min</td>
<td>19</td>
<td>150</td>
<td>64.5</td>
<td>-</td>
</tr>
<tr>
<td>Max</td>
<td>35</td>
<td>163</td>
<td>79.2</td>
<td>-</td>
</tr>
</tbody>
</table>

Study results revealed that majority of hormonal level significantly changed post medication compared to pre-
SGPT and LH/FSH ratio there was statistically significant improvement, post-medication from the preoperative values (P<0.05).

Study results had shown that there is significant difference between pre and post medication at all hormonal levels given in the table below:

<table>
<thead>
<tr>
<th>S. NO.</th>
<th>HARMONES</th>
<th>Pre Treatment</th>
<th>Post Treatment</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>FSH</td>
<td>10.84</td>
<td>6.79</td>
<td>0.18</td>
</tr>
<tr>
<td>2</td>
<td>LH</td>
<td>11.52</td>
<td>5.2</td>
<td>0.94</td>
</tr>
<tr>
<td>3</td>
<td>Prolactin</td>
<td>36.36</td>
<td>29.35</td>
<td>1.32</td>
</tr>
<tr>
<td>4</td>
<td>TSH</td>
<td>3.63</td>
<td>3.62</td>
<td>0.64</td>
</tr>
<tr>
<td>5</td>
<td>AMH</td>
<td>10.84</td>
<td>6.79</td>
<td>0.18</td>
</tr>
<tr>
<td>6</td>
<td>Fasting Insulin</td>
<td>15.77</td>
<td>15.32</td>
<td>1.53</td>
</tr>
<tr>
<td>7</td>
<td>SGPT</td>
<td>35.83</td>
<td>29.4</td>
<td>1.68</td>
</tr>
<tr>
<td>8</td>
<td>LH/FSH Ratio</td>
<td>2.76</td>
<td>1.21</td>
<td>0.09</td>
</tr>
</tbody>
</table>

The present study was performed to evaluate safety and efficacy of Shatapushpa Churna in patients of PCOS. Hormones play vital role in female reproduction system. Improvement in hormonal balance may be beneficial in many gynaecological diseases including polycystic ovary syndrome (PCOS). There was statistically significant improvement in follicular stimulating hormone (FSH), luteinizing hormone (LH), Prolactin, AMH, fasting insulin, SGPT and LH/FSH ratio, post-medication from the preoperative values (p<0.05).

DISCUSSION AND CONCLUSION

In Ayurveda majority of gynaecological disorders have been described under the heading of Yonivyapada, though some of the menstrual abnormalities like Asrigdara. For complete knowledge of menstrual disorders, the knowledge of Yonivyapada & Aartvadushti is essential. Acharya Sushruta described Bandhya Yonivyapada whose main feature is Nashtartava. Detailed analysis of PCOS showed dominance of kapha and Vata. Through understanding the lakshanas, doshic involvement and samprapti, an effective treatment can be planned which helps in pacification of dosha, and samprapti vighatana, which in turn controls the disease effectively. Shatapushpa possess madhura, kasaya, snigdha, rashya and bruhmana property resulting in yoni shodhana, pathya, artava janaka, and increases bala of the patient. Shatapushpa is a phytoestrogen; it exerts both estrogenic and anti-estrogenic activity depending on condition. It acts in both high oestrogenic and low oestrogenic condition. Shatapushpa Churna helps in regulate & normalises the menstrual cycle, regulates ovulation, and helps in weight loss. A longer observation period may be taken as there will be scope to analyse the effect comprehensively.

REFERENCES