ORIGINAL RESEARCH PAPER

Ayurveda

EFFECT OF CHITRAKAGRANDHYADI KASHAYAM WITH NAVAKA GUGGULU IN POLYCYSTIC OVARIAN SYNDROME

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ABSTRACT

Introduction: Polycystic ovarian syndrome is one of the most common metabolic and reproductive disorders among women of reproductive age. PCOS is *kaphavata* predominant disease manifested due to *agnimandya*, *ama* and *srotovaigunya*. The treatment should be *kapha vatahara*, *deepanapachana*, *srotosodhana* and *pitta vardhaka* along with *nidana parivarjana*. By considering the above facts *Chitrakagrandhyadi Kashayam* which is *kaphavatahara, lekhana* and *deepana*, and *Navaka guggulu* which is *kaphavatahara* and *medohara* were selected for the study.

Objectives of the study: To assess the effect of *Chitrakagrandhyadi kashayam* with *Navaka guggulu* in Polycystic ovarian syndrome.

Materials and Methods: Pre and post interventional study. Females of the age limit 18-34 years, who are diagnosed with Polycystic Ovarian Syndrome as per Rotterdam Criteria were selected. The study drug was given continuously for a period of 3 months excluding the first three days of each menstrual cycle. Following this, next 3 months were considered as follow up period and the clinical changes in the patient were assessed carefully.

Results and interpretation: The combination of above drugs was effective in normalizing menstrual interval, reducing the volume of ovaries and reducing the BMI.

INTRODUCTION

Polycystic Ovarian Syndrome (PCOS), an ill-defined heterogenous condition with a complex pathophysiology, is one of the commonest endocrine metabolic disorders affecting 6-10 % of women in their reproductive age[1]. PCOS is quite commonly encountered in clinical practice but its prevalence varies considerably due to heterogeneity in its presentation. Features of PCOS may manifest at any age ranging from child hood (premature puberty), teenage years (hirsutism, menstrual abnormalities), early adult hood and middle life (infertility, glucose intolerance) to later life (diabetes mellitus and cardiovascular disease).[2]

Being a metabolic disorder, it is difficult to find an exact correlation of PCOS. *Pushpagni jathaharini[3] in Kasyapa samhita* shows some resemblance in presentation. 'Vridha pushpam' may be correlated to anovulatory cycle and *lomasa ganda* to hirsutism. Menstrual irregularities in PCOS ranges from amenorrhoea to menorrhagia. These symptoms can be correlated to various references in classics like *Arthava nasa* (amenorrhoea) due to obstruction of *srotas* by *vata* and *kapha* in *Nashtarthava[4]*, 'Yadhochitakaala adarsana' (delayed cycles) and *alpata* (decreased quantity) in *Arthavakshya[5]* and *Arthava vriddhi* (increased bleeding) in *Asrigdhara[6]*. Anovulation resulting in amenorrhoea or irregular cycles is described under the disease *Vandhya yonivyapad[7]*.

This study was a modest attempt to give a hope to the agonizing sufferers of PCOS through Ayurveda, which is safe, non-hormonal and without side effects. The conventional methods only provide symptomatic relief, which includes hormonal therapy and invasive techniques.

Chitrakagrandhyadi kashaya[8] is a *kashaya yoga* in *gulma prakarana* of *Ashtanga Hridaya Chikitsa sthana* and *Navaka guggulu[9]* is a *guggulu* preparation mentioned in *Vataroga prakarana* in *Ashtanga Hridaya Chikitsa sthana* are selected for oral administration in the clinical study.

MATERIALS AND METHODS

Study design: Pre and post interventional study.

The patient's status after treatment is compared with the status before treatment.

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

Study population:
30 patients diagnosed with PCOS, fulfilling the inclusion criteria in the age group 18-34, attending the OPD and IPD of Govt. Ayurveda College Hospital for Women and Children, Poojappura, Thiruvananthapuram.

Inclusion criteria:
Females of the age limit 18-34 years, who are diagnosed with Polycystic Ovarian Syndrome as per Rotterdam Criteria is included. Diagnosis is based upon the presence of any two of the following three criteria.[10]

- Oligo ovulation /anovulation
- Hyperandrogenism (clinical/biochemical)
- Polycystic ovaries (12 or more follicles in at least one ovary measuring 2- 9mm in diameter or a total ovarian volume greater than $10cm^3$)

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 various systemic illness
- Androgen producing adrenal tumour and other neoplastic growth
- Patients diagnosed as DUB

Sampling technique:
Consecutive cases with their consent and who satisfy the inclusion criteria and till attaining sample size.

Study tools
Assessment was done using case proforma, Ultrasonography (abdomen and pelvis), Lab investigations – Blood and Urine routine, FBS, PPBS, S. Insulin, S. Testosterone, FSH, LH.

Duration of study
Duration of the study was 18 months.

Study procedure

30 patients were selected from study setting as per inclusion and exclusion criteria. Study was conducted in a single group and clinical symptoms of patients were assessed before starting the treatment. Ingredients of medicines were purchased, powdered and made into *kashaya choorna* packets and tablets. Mode of preparation and administration were also explained to the patients along with written advice in their own local language. *Pathya aahara* and *vihaara* were also recommended. The patients were asked to report on the first day of next menstrual cycle. During that visit amount of bleeding, duration, menstrual interval etc of the previous cycle were recorded. During each visit *kashaya choorna* which was required to prepare *kashaya* and prepared *Navaka guggulu* tablets were given. The study drug was given for a period of 3 months continuously excluding the first three days of each menstrual cycle. Following this, next 3 months were considered as follow up period and the clinical changes in the patient were assessed carefully.

STATISTICAL ANALYSIS

Descriptive statistics such as frequencies and percentage will be calculated for categorical study variables and mean ± standard deviation will be calculated for quantitative study parameters or summarizing the raw data. For finding the significant treatment effect on quantitative study variables for categorical variables Wilcoxon's Singed Rank Test was used.

ASSESSMENT
Parameters for the assessment
• Menstrual interval
• Number of follicular cysts
• Volume of ovary
• Ovulation
• BMI

RESULTS
Table 1. Effectiveness of the treatment in reducing menstrual interval

Test	Menstrual interval in no of days					
	Mean	SD	Range	Loss Percentage		P value
BT	96.16	43.66	45-80	BT-AT	69.73	<.001**
AT	29.10	11.04	0-53	AT-AF	-1.58	.015*
AF	29.56	10.23	0-60	BT-AF	69.25	<.001**

* (P<0.05) significant, **(P<0.001 highly significant), BT- Before treatment, AT- After treatment, AF- After follow up

Table 2 Effectiveness of the treatment in reducing the number of Follicular cysts

	BT	AT	AF
Number of Follicular cysts	Numerous	Numerous	Numerous

Table 3 Effectiveness of the treatment in reducing the Volume of Ovaries

Test	Volume of right ovary in cm^3					
	Mean	SD	Range	Loss Percentage		P value
BT	16.84	3.38	12-24	BT-AT	22.20	<.001*
AT	13.10	3.69	8-20	AT-AF	11.06	<.001*
AF	11.65	3.58	10-20	BT-AF	30.81	<.001*
Test	Volume of left ovary in cm^3					
	Mean	SD	Range	Loss Percentage		P value
BT	15.30	4.43	7-26	BT-AT	11.11	<.001*
AT	13.60	3.93	7-22	AT-AF	7.72	<.001*
AF	12.55	3.93	7-22	BT-AF	17.97	<.001*

* P<0.001 highly significant

Table 4 Effectiveness of the treatment in induction of Ovulation

Wilcoxon signed rank test	BT – AT	AT- AF	BT-AF
P value		.317*	1.000*	1.000*

*P> 0.05 Not significant

Table 5. Effectiveness of treatment in reducing BMI

Test	BMI (kg/m$^{2)}$				
	Mean	SD	Range	Loss Percentage	P value
BT	27.75	3.78	20.83-35.30	BT-AT	5.65	<.001*
AT	26.18	3.12	20.45-29.82	AT-AF	2.17	<.001*
AF	25.61	3.04	20.06-29.74	BT-AF	7.71	<.001*

*P<0.001 highly significant

DISCUSSION:

The etiological factors in PCOS disturbs the function of *Agni*, which leads to the formation of *asamyak pachita aahara rasa* in body and causes *sroto rodha* along with vitiated *kapha* finally leading to *vatavaigunya. Dhatwagni dushti* leads to the symptoms that manifests in the disease like *sthoulya, mughadooshika, loma vriddhi etc.* Factors like *athichinta, soka, bhaya* etc. can also cause vitiation of *vata.* Vitiated *vata* and *kapha* causes *avarana* of *arthavavaha srotas* leading to *arthavanaasa* and *vandhyatvam.* On evaluating all the signs and symptoms seen in PCOS, it can be considered as a *vata kapha* predominant condition with involvement of *rasa, rakta, mamsa, medas, asthi, majja, and sukla dhatus* and their respective *srotases*

Discussion on probable mode of action of drug
Chitrakagrandhyadi kashayam: Contents of *Chitrakagrandhyadi kashayam* are mainly *katu rasa, ushna virya, laghu, teekshna, ruksha, sookshma guna, katu vipaka* and *kaphavatahara. Katu rasa* is *sneha kleda medo soshana, deepana, pachana, srotosodhana, kaphahara. Laghu, teekshna, ruksha, sookshma gunas* are *kaphavata hara, lekhana, soshana, vivarana* respectively. *Ushna veerya* is *aasupachana, soshana* and *kaphavatahara. Katu Vipaka* is *kaphavatahara.* In short *Chitrakagrandhyadi kashayam* exerts effects like *deepana, amapachana, lekhana* and *srotosodhana* etc.

Navaka Guggulu: In *Navaka Guggulu* most of the ingredients have *katu rasa, laghu, ruksha teekshna, visada, sookshma* and *sara guna, ushna veerya, katu vipaka* and *kaphavatahara karma. Triphala, Trikatu* and *Trimada* are the groups included in *Navaka guggulu. Triphala* cures *kleda, meda, meha* and *kapha. Trikatu* is *agnimandyahara* and *sthoulya* hara. *Trimada* is *deepana, pachana* and *lekhana* and *Guggulu* is *medohara, lekhana, vrishya* and *rasayana.* In short *navaka guggulu* is *deepana, pachana, lekhana, sthoulyahara* and *rasayana.*

Discussion on effectiveness of treatment
Menstrual interval: The statistical analysis of effectiveness of treatment on criteria of menstrual interval shows P value of BT-AT = <0.001, AT-AF= <0.05, BT-AF = <0.001. This reveals that the treatment is effective in reducing the menstrual cycle. *Deepana, pachana, kaphavatahara* and *srotosodhana* properties of the combination might have contributed in normalising 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 cannot be taken as a conclusive statement due to insufficient sample size and follow up period.

Volume of ovary: The statistical analysis of effectiveness of treatment on criteria of volume of ovaries shows P value of BT-AT = <0.001, AT-AF= <0.001, BT-AF = <0.001 for both right and left ovary. This reveals that the treatment is effective in reducing the ovarian volume. *Vatakaphahara* and *Lekhana* properties of the combination might have contributed in reducing the ovarian volume.

BMI: The statistical analysis of effectiveness of treatment on criteria of BMI shows P value of BT-AT = <0.001, AT-AF= <0.001, BT-AF =<0.001. This reveals the effectiveness of the treatment in reducing BMI. The *deepana, pachana, srotosodhana, kaphavatahara, lekhana, medohara* properties of the combination might have contributed in reducing the weight.

Ovulation: Ovulation was absent in all the 30 patients before treatment. After three months of treatment one patient conceived which is the confirmatory sign of ovulation. After follow up of 3 months the status remains same. This reveals that the treatment was not effective in inducing ovulation. This cannot be taken as a conclusive statement because of insufficient sample size and follow up period.

CONCLUSION

Based on the results of this study, the drugs *Chitrakagrandhyadi kashayam* and *Navaka guggulu* is found to be highly effective in the management of PCOS. The combination of above drugs was effective in normalizing menstrual interval, reducing the volume of ovaries and reducing the BMI though it was not helpful in reducing the number of follicular cyst and in induction of ovulation.

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