

Comparative Clinical Study on Kanashatahwadi Kashaya Ganavati and Capsule Pconidd in Artavkashaya

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ABSTRACT:

Artavakshaya is characterized by irregularity of cycles, scanty menstruation i.e.; oligomenorrhoea and hypomenorrhoea and pelvic pain due aggravation of *vatadosha*. *Anartava* is produced when *vatamarga* is obstructed by *kapha*. Due to this *vatamargaavrodha*, there will be formation of *granthi*. Polycystic Ovary Disease (PCOD) is one of the most common endocrine disorders among women with reproductive age. PCOD causes *artavakshaya*. WHO estimates that it affects 116 million women worldwide as 2010 (3.4% women). USG finding of PCO are found in 8.25% of normal women. The present study included comparison between trial groups capsule *kanashatahwadi kashaya* and capsule Pconidd for *artavakshaya lakshana* in PCOD. Trial aimed to compare the effect of capsule *kanashatahwadi kashaya* and capsule Pconidd and its combined effect on *artavakshaya lakshana* (PCOD). Objective was to evaluate effect of trial drugs on reduction of cyst, decrease of ovarian volume and regularization of menstrual cycle. Study was a randomized open labelled, three arm, comparative clinical trial among 37 subjects fulfilling criteria of diagnosis and inclusion allocated as Gp K(n=10) (*Kanashatahwadi kashaya* granules) and Gp P(n=10) as capsule Pconidd and combined Gp C(n=10) for a duration of 3 months with 7 drop outs. In Gp K 50% moderately improved, 30% patients markedly improved and 20% patients reported mild improvement. None of patient reported unchanged and complete cured. Total 10 patients completed the treatment in gp P out of which maximum i.e. 60% markedly improved, 30% patients moderate improved, 10% unchanged. Total 10 patients completed the treatment in gp C out of which maximum i.e. 50% unchanged, 30% patients moderate improved, 20% markedly improved. Trial concluded as Gp K was statistically significant in normalizing duration(45.5%)and interval of menstrual cycle(63.7%), improving the quantity of menstruation(81.8%), relieving dysmenorrhoea(59.1%) and in reducing ovarian volume(57.3%). Gp P was significant in regularizing menstrual cycle(44.8%), improving the quantity of menstruation(55.0%), relieving dymenorrhoea(59.9%), reducing ovarian volume(53.8%) and number of cysts (61.7%). Gp C had significant result in regularizing menstrual cycle(61.2%), reducing ovarian volume (50.1%) and the number of cyst(55.4%).

Keywords: *Ayurveda*, *Artavakshaya*, *Cap. Kanashatahwadi kashaya*, *Cap Pconidd*, Poly cystic ovary disease.

INTRODUCTION:

PCOD is one of the most common endocrine disorders among women with reproductive age. *Artavakshaya* refers to irregularity of cycles either as oligomenorrhoea or hypomenorrhoea due to *vata dosha*. *Anartava* is due to *vata marga* obstructed by *kapha*¹. *Vatamargaavrodha* may lead to formation of *beejakoshagranthi*. Based on the pathophysiology PCOD can be one of the leading causes for *artavakshaya*. This was a three arm clinical trial on cap. *kanashatahwadi kashaya*, cap. *pconidd* and combined use for *artavakshaya* (PCOD). *Kanashatahwadi kashaya* contains *vata kaphahara dravyas* which are also found to be *artavajanka* and is indicated in *rakta gulma*². Cap. *Pconidd*, one of the indigenous formulations, is also *vata kaphahara* and found to be beneficial in relieving the signs and symptoms of PCOD.

NEED FOR STUDY:

WHO estimates that it affects 116 million women worldwide as 2010 (3.4% women). USG finding of PCO are found in 8.25% of normal women. 14% women on oral contraceptive are found to have polycystic ovaries. Now a days incidence of this disease is increasing because of sedentary lifestyle, pollution, excessive intake of junk food.³ PCOD is one of the leading cause of infertility. A diagnosis of PCOD suggests an increased risk of Type 2 diabetes, high blood pressure, obesity, depression, miscarriages and hirsutism⁴. Numerous causes and treatment of menstrual irregularities has been given in Ayurvedic texts. But not single research has been carried out on this topic specially PCOD as one of the causes of *Artavakshaya* i.e irregular menstrual cycle, hypomenorrhoea, oligomenorrhoea and pain during menstruation. This promoted to think about the drug which is useful in *Artavakshaya* related to PCOD. In Modern science PCOD is treated by hormonal therapy along with symptomatic treatment and last option is surgery and long term use of these drugs produces many side effects. So it is very necessary to find some effective Ayurvedic medicine for this condition. PCOD being the most common diagnosis in gynaecology O.P.D., there is a need for the development of more treatment protocols which are effective, safe, palatable and economical.

Aim: Trial aimed to compare the effect of capsule *kanashatahwadi kashaya* and capsule *Pconidd* and its combined effect on *artavakshaya lakshana* (PCOD).

Objective was to evaluate effect of trial drugs on reduction of cyst, decrease of ovarian volume and regularization of menstrual cycle.

Methodology: The patients were registered from the IPD and OPD patients from Parul Ayurveda Hospital, Khemdas Ayurveda Hospital and Parul Sevashram Hospital after confirming the diagnostic and inclusion criteria.

Capsule *Kanashatahwadi kashaya*: Raw drugs were purchased and authenticated at PIA, Parul University, Vadodara and granules were prepared in the GMP certified Pharmacy of Parul Institute of

Ayurveda, Vadodara and capsules were filled in Dhanvantari pharmacy, Anand, Gujarat in a single batch.

Capsule Pconidd: It was purchased from Snehanatura Pharmacy, Bengaluru, Karnataka.

Study Design: Randomized (lottery method), open labelled three arm comparative clinical study for 3 months, among 37 subjects fulfilling the criteria of diagnosis of PCOD and *artavakshaya*, with 7 drop outs and 10 subjects completed the trial in each group.

Table No.1 Grouping, Drugs and Posology

Groups	Group-K	Group-P	Group-C
Drug	Cap. Kanashatawahadi	Cap. Pconidd	Combined drugs of both the groups
Dose	2 Capsules (500gm Each)	2 Capsules (500gm Each)	Both (500gm Each)
Route	Oral		
Anupana	Sukhoshna Jala		
Time Of Administration	Before Food –Thrice in a day		
Follow Up	1 Month		

Inclusion Criteria:

- Women aged between 20 to 35 years of age irrespective of marital status, presenting with symptoms of *artavakshaya* and *anartava* (amenorrhea) ≤ 3 months
- USG showing features of PCO, Hyperandrogenism and
- Rotterdam Criteria

Exclusion Criteria:

- Women suffering from any other diseases which may cause *anartava* and *artavakshaya* excluding PCOD on the above criteria.
- Women suffering with gross structural abnormalities of uterus and its appendages.
- Systemic illness like DM, thyroid dysfunction, HTN, renal disorders.
- Subjects suffering from menorrhagia or metrorrhagia.

Investigation:

- CBC, ESR, RBS, Urine (R/M) USG -pelvic and abdomen
- Serum testosterone level, Thyroid function test, S. LH & S.FSH

Informed Consent: The benefits and risk of the study were explained to the patients in their language and an informed written consent in bilingual form was obtained from every subject before the commencement of the trial. *Pathya* and *apathya* were also advised.

Table No.2 Subjective Parameter^{5,6}

Sr. No.	Symptom	Variable	Score
1.	Duration of Bleeding	3-5 Days	0
		1-2 Day	1
		Spotting	2
2.	Interval Between two Menstrual Cycle	<35 Days	0
		36-45 Days	1
		46 -60 Days	2
		>60days	3
3.	Quantity Of Menstrual Bleeding	>2 Pads	0
		2 Pads	1
		1 Pad	2
		Spotting	3
4.	Pattern Of Menstrual Cycle	Regular Cycle	0
		Irregular Cycle	1
5.	Pain During Menstrual Bleeding	No Pain	0
		Mild Pain (Daily Activities Are Not Affected)	1
		Moderate Pain (Daily Activities Affected, Need To Take Analgesics)	2
		Severe Pain Patient (Daily Activities Inhibited, Pain Continuous After Taking Analgesics)	3

Table No.3 Objective Parameters^{7,8}

Sr. No.	Symptom	Variable	Score
1.	Weight (on the basis of BMI by WHO)	18.5 TO 24.9 Kg/m ² (normal)	0
		25.00 TO 29.9 Kg/m ² (over weight)	1
		30.01 TO 34.9 Kg/m ² (class 1 obesity)	2
		35.0 TO 39.9 Kg/m ² (class 2 obesity)	3
		>40(morbidly obese)	4
2.	Acne	No	0
		Comedones, occasional papules	1
		Papules, comedones, few pustules	2
		Predominant pustules, nodules, abscesses	3
		Mainly cysts, abscesses, wide spread scarring	4
3.	Hirsutism	Normal (score less than 8)	0
		Medium coverage (score 8-15)	1
		Heavy coverage (score more than 15)	2

Table No.4 Contents of Cap. Kanashatahwadi kashaya & Cap. Pconidd

Sr.No.	Cap. Kanashatahwadi Kashaya	Cap. Pconidd
1.	<i>Kana (Piper longum)</i>	<i>Ashoka (Saraca indica)</i>
2.	<i>Shatahwa (Anethum sowa)</i>	<i>Karvella (Momordica charantina)</i>
3.	<i>Karanja (Pongamia pinnata)</i>	<i>Meshshrungi (Gymmema sylveste)</i>
4.	<i>Lata Karanja (Caesalphia crista)</i>	<i>Jambu (Eugelena jamolana)</i>
5.	<i>Devadaru (Cedrus deodara)</i>	<i>Mamejjaka (Enicostema littorale)</i>
6.	<i>Bharngi (Clerodendrum serratum)</i>	<i>Shilajit</i>
7.	<i>Kulatha (Marcotyloma uniflorum)</i>	<i>Haridra (Curcuma longa)</i>
8.	<i>Tila (Sesamum indicum)</i>	<i>Shatavari (Asparagus racemosa)</i>
9.	<i>Lashuna (Allium sativum)</i>	<i>Bilva (Aegle marmelos)</i>
10.	<i>Hingu (Ferula asafoetida)</i>	<i>Bala (Sida cordifolia)</i>
11.		<i>Guduchi (Tinospora cordifolia)</i>
12.		<i>Nimba (Azadirachta indica)</i>
13.		<i>Twak (Cinnamomum zeylanicum)</i>
14.		<i>Yashad</i>
15.		<i>Lodhra (Symplocos racemosa)</i>

Ethical clearance was obtained from institutional ethics committee of Parul Institute of Ayurved, PU, Vadodara, Ref. No. PU/PIA/IECHR/2019/56, dated 14/02/19 and study was registered in Clinical Trial Registry of India with CTRI Number CTRI/2019/10/021680.

Statistical Analysis: Non-parametric Kruskal-Wallis test.

Result:

Age: Out of 37 patients, 20 patients i.e.54.1% belongs to age group of 20-25 years, followed by age group of 26-30 years 14(37.8%) and 3 patients (8.1%) of age group 31-35 years.

Pattern, duration and interval of menstrual cycle:

Gp K showed statistically significant effect on interval between two menstrual cycle after completion of clinical trial with P value 0.024; on duration of menstruation (P value 0.029). Gp P showed statistically significant effect on pattern of menstrual cycle after completion of clinical trial with P value 0.044. Gp C had significant results on aforesaid parameters (P value 0.021).

Pain during menstrual cycle:

Both Gp K and Gp P, individually showed statistically highly significant effect on reduction in pain during menstrual cycle (P values 0.007) respectively.

Weight:

Gp K and Gp C reduced body weight in subjects. But this may be influenced by the life style i.e. *ahara- vihara and pathya and apathy* also.

S.LH, S.FSH: Among all the 3 groups no significant effect was found on S. LH:S.FSH ratio.

Ovarian volume:

Gp K had statistically significant effect on right ovarian volume (P value 0.021) while Gp P had significant effect on both ovarian volume (P values 0.016 in left ovary and 0.037 in right ovary). Gp C had significant effect on left ovarian volume (P value 0.005).

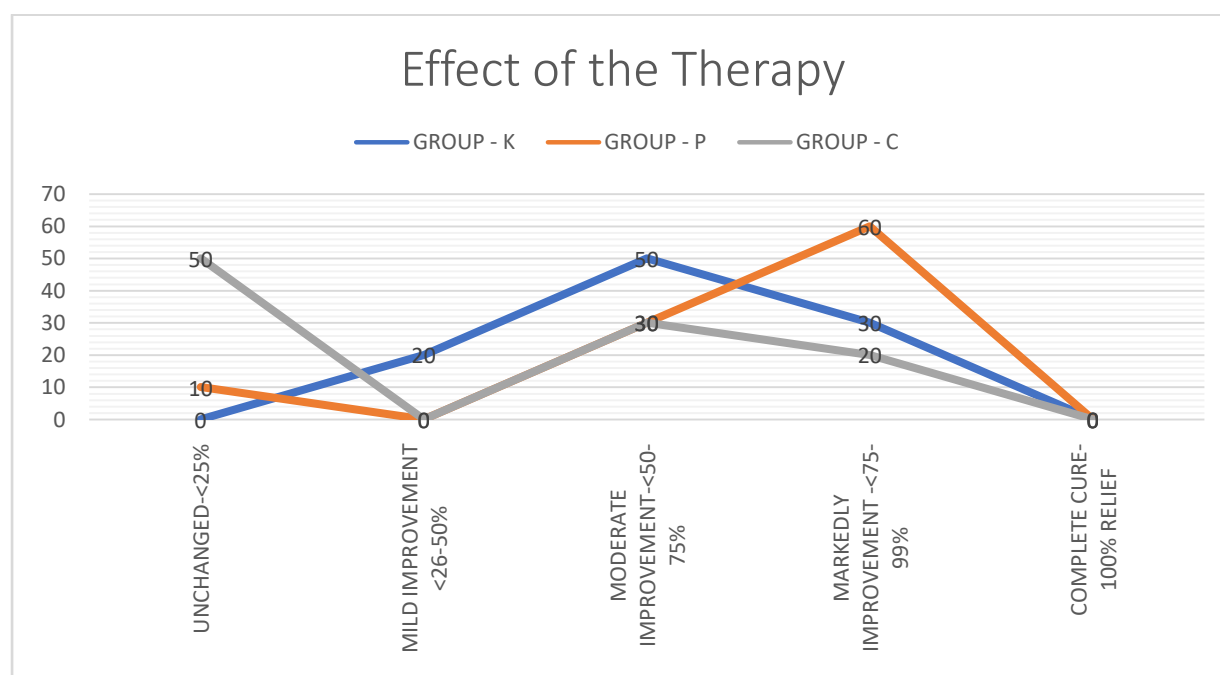
Ovarian cyst

Gp P had significant effect on both ovarian cyst(P values 0.046 in left ovary and 0.008 in right ovary).Gp C had significant effect on bilateral ovarian cyst (P values 0.046 in left ovary and 0.025 in right ovary).

Hirsutism and Acne:

Hirsutism and Acne score remained unchanged. No significant effect in Hirsutism and Acne score was observed in any of the groups.

Chart No.1 -Total Effect Of The Therapy



Discussion:

Table No. 5 Mode of action of Drugs in Artavkshaya (PCOD)^{9 to 25}

Formulation	Drug	Properties	Mode of action
Pain during menstruation			
Capsule kanashatahwadi Kashaya	All drugs	vatahara	As vata is main factor for vedana, vatahara, vatanulomana drugs normalize the function of
	shatahwa, hingu, lashuna, kana	Vatanulomana	
	latakarnaja, hingu	Vedanasthapaka	
	karanja, latakarnaja, shatahwa, bharngi, kulatha and lashuna	Analgesic effect	
	karanja, devadaru , hingu	Antispasmodic	

Capsule Pconidd	meshshrungi, shatavari, bilva	Vatahara	apanavata. vedanasthapaka, analgesic and antispasmodic property helps to relieving the pain during menstrual cycle.
	guduchi, meshshrungi,	Vatanulomana	
	karavellaka, bala guduchi	Analgesic effect	
	Shatavari	Antispasmodic	
Weight Reduction			
Capsule kanashatahwadi Kashaya	kana, shatahwa, kulatha, latakaranja, bharngi, hingu	medohara, lekhana, dipana, pachana	dipana, pachana properties increases agni which helps to ampachana and uttarotaradhatu utpatti- poshana leads to normalized BMI. ushna virya, lekhana karma helps to treat medodushti and decrease weight.
	All drugs	ushna virya	
	kana, kulatha and hingu	Anti-Obesity	
Capsule Pconidd	guduchi, nimba, mamejjaka, bilva, karvellaka, haridra, and shilajita	medohara, lekhana, dipana	
	ashoka, jambu, haridra, bilva, bala, lodhra, shilajita	Anti-obesity	
PCOD			
Capsule kanashatahwadi Kashaya	tila	Decreasing the androgen levels by increasing SHBG. Stimulates ovulation.	Work as antiandrogen, balance the hormones, enhance folliculogenesis and ovulation helps to cure PCOD and related symptoms.
	shatahwa	Enhance implantation and fertility	
	hingu	Increase the secretion of progesterone	
Capsule pconidd	ashoka	Regulate ovulation & menstrual cycle	Cap. Pconidd mainly works to balance hormones, enhance folliculogenesis, ovulation and helps to cure pcod and related symptoms.
	lodhra	Prevent ovarian cell dysfunction, stimulate fsh and enhance folliculogenesis and fertility.	
	guduchi	Lowering the serum testosterone and regulates the menstrual cycle.	
Both capsules	All drugs	Medohara, Dipana, Agnivardhaka, Aampachanna Lekhana	1.Removes the Srotosana and normalize the function of the Artavvahasrotas. 2.Due to removal of Srotosanga, aggravated Apanavata normalized, which expelled Artava in proper interval with duration in normal Rutuchakra. 3.As there is normal function of Apanavata and Artvavhasrotasa, normalize the development of follicles and ovulation occurs.

Conclusion:

Capsule Kanashatahwad individually was found statistically significant in normalizing duration (45.5%) and interval of menstrual cycle (63.7%), improving the quantity of menstruation (81.8%), relieving the pain during menstruation (59.1%) and in reducing ovarian volume (57.3%). *Capsule Pconidd* individually was found statistically significant in regularizing menstrual cycle (44.8%), improving the quantity of menstruation (55.0%), relieving pain during menstruation (59.9%), reducing ovarian volume (53.8%) and number of cysts (61.7%). Both the drugs had significant result in regularizing menstrual cycle (61.2%), reducing ovarian volume (50.1%) and number of cyst (55.4%). Thus both the drugs either individually or in combination were highly effective in relieving *artavakshaya lakshana* of PCOD.

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