Research Article

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AN OPEN RANDOMISED CONTROL STUDY TO EVALUATE THE COMBINED EFFECT OF SHODHANA FOLLOWED BY SHAMANA CHIKITSA OVER POLYCYSTIC OVARIAN SYNDROME

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Received on: 03/06/15 Revised on: 27/07/15 Accepted on: 07/08/15

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DOI: 10.7897/2277-4343.065116

ABSTRACT

Polycystic ovary syndrome (PCOS) is of clinical and public health importance as it is very common, affecting up to 4-12% women of reproductive age. PCOS is a syndrome having bahu doshaavasta including artava kshaya, sthoulya, youvanapidaka where involvement of kapha dosha is present along with vata dosha. Vamana karma being the important line of management in kaphaja vikara is chosen to treat this disease and administered with shaman oushadi namely shatapushpa churna and nastapushpantaka rasa. Hence it was hypothesized that vamana karma followed by nastapushpantaka rasa and shatapushpachurna may be beneficial in treating PCOS. 30 patients suffering from PCOS fulfilling the diagnostic criteria were randomly placed for study in a single group and were subjected to Vamana Karma followed by Nastapushpantaka rasa and shatapushpa churna orally after samsarjana karma. Study shows that Vamana followed by Nastapushpantaka Rasa and shatapushpa Churna orally is effective in the management of PCOS, as it has helped to initiate weight loss, normalizing the menstrual cycle, correcting the secretion of luteinizing hormone and follicular secreting hormone and brought marked change in PCO morphology in Ovary. Clinical study showed moderate improvement in PCOS by regularising the menstrual cycle, 2 patients conceived out of 3 patients who came with complains of infertility, there was no effect on patients who came with complaints of amenorrhea for more than 6 months.

Keywords: PCOS, Ayurveda, Artava kshaya, Vamana karma.

INTRODUCTION

In recent times there has been a significant change in life style with most people leading a more sedentary existence combined with an abundance of food. PCOS can be counted as one among such disease. PCOS is one of the most common reproductive endocrinological disorders in women. PCOS evolves throughout life into a series of disorders characterized by insulin resistance, premature adrenarche, infertility, hyper androgenemia, dyslipidemia, and can be related to heart disease, diabetes mellitus, endometrial hyperplasia, and endometrial cancer. Excess insulin stimulates the ovaries to produce large amounts of the male hormone, testosterone, which may prevent the ovaries from ovulating, thus causing infertility. It is the best known and most extensively studied cause of anovulatory infertility in reproductive-aged women. For the last two decades many authors have shown that insulin resistance and the consequent hyperinsulinemia is the driving factor for increased androgen production in obese as well as non-obese PCOS subjects. In the present era, the erratic Life style and diet, increased stress, strain and restlessness have resultantly expanded the spread of hormonal imbalance and menstrual disorders. PCOS is a most frequent endocrine disorder affecting 4-12%, [1-2] of all women of childbearing age. Traditional PCOS treatments are focused only on treating the symptoms not alleviating the underlying pathology of PCOS. To tackle this disorder exploring effective treatment is the need of the day. In ayurvedic perspective the PCOS mainly points out the feature of artavakshaya (oligomenorrhea) and kapha medodusti. The vamana karma (Emesis) is found to be very effective in treating both artavakshaya and kaphamedo dusti. Hence shodana (Bio purification) in the form of vamana followed by Shamana (palliative treatment) shatapushpa choorna and nastapushpantaka rasa which are yoni shukra vishodka and helps in nasta artava. Therefore current study entitled "An open randomised control study to evaluate the combined effect of shodhana followed by shamana Chikitsa over Polycystic ovarian Syndrome" is being planned.

MATERIALS AND METHODS

Null Hypothesis - H_0 = Vamana Karma followed by shatapusha churna and nastapushantaka rasa orally has no effect over the PCOS.

Research Hypothesis - H_R = Vamana Karma followed by shatapusha churna and nastapushantaka rasa orally has effect over the PCOS.

Research Question

Whether vamana karma followed by shatapusha churna and nastapushantaka rasa orally has role of over the PCOS?

Source of data and ethical clearance
30 patients diagnosed as PCOS were taken for the study, from the OPD & IPD of SDM Hospital Udupi, after permission is being obtained from IEC vide IEC-SDMCAU/ACA-49/EC05/13-14.

Method of collection of the data
A special proforma was prepared 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.

Research design
Interventional open randomized controlled efficacy trial.

Study population
An accessible population of PCOS in and around district of study who were representative of target population participated in the study.

Sampling
Simple random sampling technique using lottery method.

Study sample
Patients of PCOS in around region of study.

Flow chart

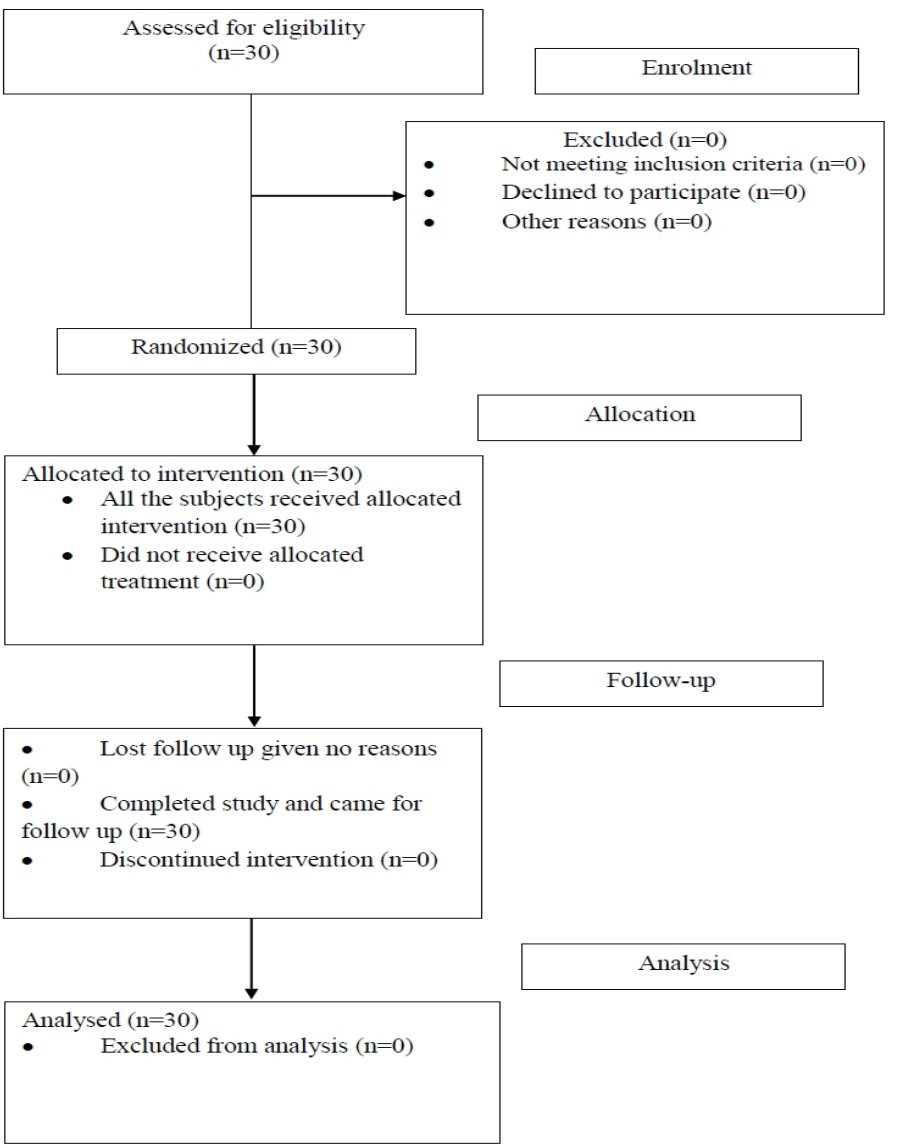

Figure 1: Schematic representation of open randomized controlled

Inclusion criteria

Female aged 15-35yrs.

Diagnosed with PCOS with complaints of disordered or absent menstrual cycle and ovulation.

Exclusion criteria

Abnormal menstrual cycle not due to PCOS confirmed by USG studies.

Amenorrhoea, hirsutism and obesity not due to PCOS.

Systemic illness.

Assessment Criteria[3]

Subjective criteria

Menstrual cycle

Interval between two cycles

Duration of bleeding

Quantity of bleeding

Acne

Hirsutism

BMI

Objective Criteria

Ovulation

Table 1: Grading of variable interval between two menstrual cycles

Interval between two menstrual cycles	
Variable	Score
30-45 days	0
46-90 days	1
More than 90 days	2

Table 2: Grading of variable duration of bleeding

Duration of bleeding	
Variable	Score
3-5 days	0
<3 days	1
>5days	2

Table 3: Grading of variable amount of bleeding

Amount of bleeding	
Variable	Score
Normal flow	0
Spotting /scanty menstruation	1
Excessive	2

Table 4: Grading of variable body weight

Body weight	
Variable	Score
No reduction	0
Reduced by 1 kg	1
Reduced by 2kg	2

Table 5: Grading of variable Acne

Acne	
Variable	Score
comedones, occasional papules	1
papules, comedones, few pustules	2
predominant pustules, nodules, abscesses	3
Mainly cysts, abscesses' caring	4

Hirsutism

Ferriman – gallwey scoring system (total score of 8 accepted as hirsutism)

(0=absence of terminal hair to 4=extensive terminal hair growth)

Intervention

These patients were administered with Deepana Pachana followed by phalaghrita snehapana (internal oleation) in increasing dosage till samyag snigda lakshana is achieved then vamana karma was done. After samsarjana karma (post purification diet) administration of shatpushpa choorna 12 grams with madhu in divided dosage and nastapushpantaka rasa 125 mg bid with honey for 3 months.

RESULTS

Effect of Treatment

In the present study, 30 patients of PCOS were registered and were randomly selected. The effect of treatment on the subjective and objective parameters was analysed by using Statistical Package for social science (SPSS) version 20, Paired t Test was used to analyze the significance of change in objective parameters normally distributed. However Friedman's test with Bonferroni correction was used to analyze the significance of change in Subjective parameters. Wilcoxon signed rank test is done for post Hoc with Bonferroni correction on parameters which show significance in Friedman's test, to interpret the time of significant change.

Table 6: Effect of treatment over Body Weight

Pairs	Variables	Mean	Std. Deviation	Std. Error Mean	t	df	P Value	Remarks	% Change
Pair 1	wtbt - wtav	3.63333	.99943	.18247	19.912	29	.000	HS	5.5
Pair 2	wtbt - wtfu	3.56667	1.52414	.27827	12.817	29	.000	HS	5.75
Pair 3	wtav - wtfu	-.06667	.86834	.15854	-.421	29	.677	NS	-0.11

Table 7: Effect of treatment over Bod mass index (BMI)

Pairs	Variables	Mean	Std. Deviation	Std. Error Mean	t	df	P Value	Remarks	% Change
Pair 1	bmiabt - bmiav	2.50333	5.56277	1.01562	2.465	29	.020	S	9.02
Pair 2	bmiabt - bmifu	1.58333	7.92803	1.44745	1.094	29	.283	NS	5.7
Pair 3	bmiav - bmifu	-.92000	5.57781	1.01836	-.903	29	.374	NS	-3.5

Table 8: Effect of treatment over Follicle stimulating hormone (FSH)

Pairs	Variables	Mean	Std. Deviation	Std. Error Mean	t	df	P Value	Remarks	% Change
Pair 1	fshbt - fshfu	1.37667	2.97561	.54327	2.534	29	.017	S	18.5

Table 9: Effect of treatment over Luteinizing Hormone (LH)

Pairs	Variables	Mean	Std. Deviation	Std. Error Mean	t	df	P Value	Remarks	% Change
Pair 1	lhbt - lhfu	1.78267	3.84495	.70199	2.539	29	.017	S	22.6

Table 10: Effect of treatment over interval between two cycles (IBTC)

Friedman Test

Variable	Mean Rank	N	Chi-Square	df	p value
IBTC_BV	1.82	30	19.000	1	.000
IBTC_FU	1.18				

Post hoc test – Wilcoxon signed rank test with Bonferroni correction (p=0.50)

Levels	Ranks	N	Mean Rank	Sum of Ranks	Z	p value	Remarks	% change
IBTC_FU - IBTC_BV	NR	19a	10.00	190.00	-4.359b	.000	HS	39.08
	PR	0b	0.00	0.00				
	Ties	11c						
	Total	30						

Table 11 - Effect of treatment over duration of bleeding (DOB)

Friedman Test

Variable	Mean Rank	N	Chi-Square	df	p value
DOB_BV	1.72	30	13.000	1	.000
DOB_FU	1.28				

Post hoc test – Wilcoxon signed rank test with Bonferroni correction (p=0.50)

Levels	Ranks	N	Mean Rank	Sum of Ranks	Z value	P Value	Remarks	% change
DOB_FU - DOB_BV	NR	13a	7.00	91.00	-3.286b	.001	HS	39.2
	PR	0b	0.00	0.00				
	Ties	17c						
	Total	30						

Table 12: Effect of treatment over Amount of bleeding (AOB)

Friedman Test

Variable	Mean Rank	N	Chi-Square	df	p value
AOB_BV	1.73	30	12.250	1	.000
AOB_AV	1.27				

Post hoc test – Wilcoxon signed rank test with Bonferroni correction (p=0.50)

Levels	Ranks	N	Mean Rank	Sum of Ranks	Z value	P Value	Remarks	% change
AOB_AV - AOB_BV	NR	15a	8.57	128.50	-3.398b	.001	HS	34.7
	PR	1b	7.50	7.50				
	Ties	14c						
	Total	30						

Table 13: Effect of treatment over Acne

Friedman Test

Variable	Mean Rank	N	Chi-Square	df	p value
acne_fu	1.68	30	27.125	2	.000
acne_av	1.83				
acne_bv	2.48				

Post hoc test – Wilcoxon signed rank test with Bonferroni correction (p=1)

Levels	Ranks	N	Mean Rank	Sum of Ranks	Z value	P Value	Remarks	% change
ACNE_av - acne_bv	NR	13a	7.00	91.00	-3.606b	.000	HS	34.3
	PR	0b	0.00	0.00				
	Ties	17c						
	Total	30						
acne_fu - acne_bv	NR	16d	8.50	136.00	-4.000b	.000	HS	17.6
	PR	0e	0.00	0.00				
	Ties	14f						
	Total	30						
acne_fu - ACNE_av	NR	3g	2.00	6.00	-1.732b	.083	NS	-56.7
	PR	0h	0.00	0.00				
	Ties	27i						
	Total	30						

Table 14: Effect of treatment over Hirsutisum

Friedman Test

Variable	Mean Rank	N	Chi-Square	df	p value
hirsutisum_bv	1.52	30	1.000	1	.317
hirsutisum_fu	1.48				

Post hoc test – Wilcoxon signed rank test with Bonferroni correction (p=0.50)

Levels	Ranks	N	Mean Rank	Sum of Ranks	Z value	P Value	Remarks	% change
hirsutisum_fu - hirsutisum_bv	NR	1a	1.00	1.00	-1.000b	.317	NS	0.98
	PR	0b	0.00	0.00				
	Ties	29c						
	Total	30						

Table 15: Effect of treatment overAcanthosisNigrans (AN)

Friedman Test

Variable	Mean Rank	N	Chi-Square	df	p value
AN_BT	1.50	30	1.000	1	1.000
AN_AV	1.50				

Post hoc test – Wilcoxon signed rank test with Bonferroni correction (p=1)

Levels	Ranks	N	Mean Rank	Sum of Ranks	Z value	P Value	Remarks	% change
AN_AV - AN_BT	NR	0a	0.00	0.00	.000b	1.000	NS	0
	PR	0b	0.00	0.00				
	Ties	30c						
	Total	30						

Table 16: Effect of treatment over PCO morphology (USG)

Friedman Test

Variable	Mean Rank	N	Chi-Square	df	p value
usgbt	1.35	30	9.000	1	.003
usgfu	1.65				

Post hoc test – Wilcoxon signed rank test with Bonferroni correction (p=0.50)

Levels	Ranks	N	Mean Rank	Sum of Ranks	Z value	P Value	Remarks	% change
usgfu - usgbt	NR	0a	0.00	0.00	-3.000b	.003	S	
	PR	9b	5.00	45.00				
	Ties	21c						
	Total	30						

Table 17: Effect of treatment over Volume of ovaries (USG)

Friedman Test

Variable	Mean Rank	N	Chi-Square	df	p value
usgvolbv	1.87	30	22.000	1	.000
usgvolfu	1.13				

Post hoc test – Wilcoxon signed rank test with Bonferroni correction (p=1)

Levels	Ranks	N	Mean Rank	Sum of Ranks	Z value	P Value	Remarks	% change
usgvolfu - usgvolbv	NR	22a	11.50	253.00	-4.690b	.000	HS	
	PR	0b	0.00	0.00				
	Ties	8c						
	Total	30						

DISCUSSION

Effect on body weight of Treatment

There was significant decrease in body weight before Vamana and after vamana followed by shamana oushadi with 5.75% whereas the change in weight before vamana and after vamana was only 5.5%. No significant change in weight was noticed after vamana and after shamana oushadi. This is due to fact that there is a negative calorie balance during the process of snehapana as stomach is filled with ghrita, which is high in fat. This causes the utilization of fat for energy.

Effect on BMI of Treatment

There was significant decrease of 9.02% in BMI after vamana with p value .020. Whereas the change in BMI after vamana followed by shamana oushadi was not significant.

Effect on Follicle stimulating hormone and Luteinizing Hormone of treatment

There was significant increase in secretion of Follicle stimulating hormone level, after the treatment with p=0.17 with 18.5% percentage of change. There was significant correction in the level of Luteinizing Hormone after the treatment with p=0.17 with 22.6 % percentage of change. This is because of combined effect of vamana karma and shaman oushadi where vamana acts on stabilizing at the cellular level. The shamana oushadi increases / improves the metabolization of hormones by acting on liver thereby enhancing metabolism of hormones, having hepatoprotective and regulates the hormones, by stimulating the follicle, hypoglycaemic action of the oushadi may indirectly corrects insulin insensitivity. Thereby correcting HPO axis secretion of testosterone and synthesis of androgen.[4]

Normal pattern of menstruation was attained after vamana followed by shaman oushadi in terms of interval between two cycles was reduced by 39.08% with p=0.17. Duration of bleeding was normalised with p=0.001 with 39.2% and amount of bleeding was normalised with p = 0.001 with 34.7% change.

This may be due to the action of shodhana and shamana on HPO axis and by regulation hormonal secretion. Nastapushpantaka rasa has property effect on condition of nasta pushpa, shatapushpa churna is rutu pravartini, clears the rajoroda, and it is yoni shodhana.

The chemical constituents of drugs possess activities like hypolipedemic, hypoglycemic, ani-cytotoxic, immunomodulatory, anti-oxidant, folliculogenesis. These might act as insulin sensitizers and may help in regulation of HPO axis and in correction of menstrual cycle. When variable acne assessed between the intervals before vamana and after vamana there was highly significant 34.3% improvement with P=0.00 and, before vamana and after shamana oushadi the result was highly significant with 17.6% improvement. When assessed between after vamana and shaman oushadi there was no significant change for the variable acne.

In PCOS acne is seen because of reduced level of SHBG hormone from liver, the treatment administered possess maximum action at the level of hepatic cells. So this might be the probable cause to cure Acne. Furthermore the drugs administered possess hypoglycemic activity which may act on hyperinsulemia and corrects the secretion of SHBG.

Effect on ovary of treatment

There was significant difference seen in number of cyst in ovary after vamana followed by shaman oushadi with P=0.003 for the variable number of cyst in ovary. There was highly significant decrease in volume of polycystic

ovary seen after vamana followed by shaman oushadi with P=0.005 for variable volume of polycystic ovary.

The large dose of sneha was administered during snehapana phala ghrita that consists drug possessing deepana activity, lekhaniya property, yonidosha hara property. Shaman oushadhi has property like rutupravartini, artavajana which helps in conditions like nastapushpa.[5]

Shodanga sneha performs apatarpana effect in patient which reduces body weight during snehapana kala, Phala ghrita having hypolipidemic activity also helps in the reduction of body weight. Increase in body weight adds up to excess production of androgens from peripheral fat, decrease in body weight decreases the peripheral fat conversion of androgens. Androgens are said as main responsible factor for hyperthecosis[6] and this might be probable mode of action of Vamana karma.

Shamana oushadhi which was administered as shatapushpa churna is proven as folliculogenesis and aids in ovulation, Nastapushpantaka rasa ingredients exhibit hypoglycemic activity, hypolipidemic, immunomodulatory, anti-oxidant which has been proved through research. Where as in granti Vamana is advised as line of management.[7]

All these factors might have led to decrease in the increased surface area and thickness with lekaniya property and number of polycystic ovary which was evident in USG.

In the present study out of 30 patients

3 patients came with complains of infertility out of which 2 patients conceived.

3 patients came with complains of amenorrhea out of which all 3 patients also didn't gain results. These patients were consuming hormonal preparations for inducing menstruation since 3-5 years. Probably these patients may require repeated shodhana followed by shaman oushadi.

Probable mode of action of Vamana karma [8]

Vamaka Dravyas have following properties-

1. Ushna
2. Tikshna
3. Sukshma
4. Vyavayi
5. Vikasi
6. Urdhwa Bhagahara

Vamaka Dravya work in collaboration with each other to produce emesis. Ushna Guna, produces Pachana, Deepana, Svedana and spreading of the drug at sukshma srotas agneya property of the vamaka dravya produces Vishyandana in the body and does the vilayana of doshas. Tikshna Guna of Vamaka Dravya does china (detaches from the srotas and brings to the kostha) i.e. helps to mobilize from sukshma strotas / shaka to koshta/ Because of anu bhava, doshas enter anu srotas and due to pravana bhava it is brought to kostha for expulsion. The virtue of the prabhava of the drug udana vayu prerana is attained, due to agni and vayu mahabhuta, & hence doshaharana is achieved. The action of the drug is exhibited on urdhwa adho & tiryak gata dhamanis. With the help of Sukshma Guna, the Vamaka Dravya enters at the level of micro circulatory channels (Srotas as) and leads to Pachana and Vishyandana of Doshas and ultimately directs Doshas towards Koshtha, from where they are eliminated easily. Due to Vishyandi and Vikasi Gunas, the Vamaka Dravya reaches at the cellular level (all Dhatus) without being digested and produces Sandhi Shaithilya i.e. Doshas Lina in Dhatus are mobilised by the Vamaka Dravya and migrated to Koshtha for its elimination. Vamaka Dravyas produce Vamana due to its "Urdhwa Bhagahara Prabhava".

The main action of Vamaka Dravya is on amashaya of the individual. In the amashaya it acts on the very root cause of the vitiation of Kapha. The vitiated Kapha present in entire body is expelled out through the mechanism of Vamana and intensity of the disease process is controlled to the maximum level. The Snehana and Svedana therapy does the vriddi & vishyandana, paka & srotomukha vishodhana of the doshas. Ushna and Tikshna Gunas of Vamaka Dravyas are responsible for mobilization of the doshas. Sneha is brought from the sukshma srotas to the Koshtha from Rasadi Dhatus (tissues and cells) and finally is thrown out of the body.

As per the mode of action of Vamana Karma, as described above, it clears the channels (Srotasas) from the Sanga, created by vitiated Kapha, Meda and Ama. Maximum Doshas are thrown out from the body by this process, thus detoxifying the body up to a certain level. The remnant Doshas are controlled by Shamana therapy which includes, Rakta Prasadana, Kapha-Vatahara, artava janana, rutu pravartini properties. Because it is much easier to pacify the remnant Doshas with Shamana therapy which remain after Shodhana.

Probable mode of shamana yoga

Shatapushpa churna

Madhura, kashaya, snigdha, rushya, its bruhmana, property increases bala of patient. Does shodhana of yoni, it is patya, artava janaka, Shatavari is said as putra prdayini, and pushpa utpanna kari, rutu pravartini. Shatavari is vata prashamani. With all this actions shatavari might correct Artava kshaya and cause normalcy in menstrual cycle. 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.[9]

Nastapushpantaka Rasa

The phala shruti of Nastapushpantaka rasa states that it is given in condition of nastapushpa, which may be considered as amenorrhea or anovulation. Nastapushantaka rasa contains mineral drug which has activity like rasayana, yogavahi, artava janana properties along with tridosha hara and kapha vata hara property. The herbal drugs bear the properties like anuloma,vajikara. yonivyapad hara , kapha vata , hara, artava janana , rakta shodaka, rajorodha and jeevaniya .[10]

The chemical ingredients of drugs possess hypolipidemic, hypoglycemic, Folliculogenesis, anti-oxidant, hepato protective, anti-cancerous, immunomodulatory and anti-tumour activity.[11-12]

CONCLUSION

The syndrome PCOS cannot be co related to any one particular disease in Ayurveda. 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. Vamana karma followed by Nastapushpantaka rasa and shatapushpa churna helps in regularising the menstrual cycle, correcting the secretion of Luteinising hormone and follicular stimulating hormone. However it is a known fact that shodananga snehapana initiates in loosing body weight, this factor will add up to improvement in condition by decreasing in body mass. In this study two patients with more than 6 months amenorrhea showed no improvement. These patients were consuming hormonal preparations for inducing menstruation since 3-5 years. Probably these patients may require repeated shodhana followed by shaman oushadi.

Study concluded that Role of Vamana Karma followed by Nastapushpantaka rasa and shatapushpa churna is effective in the management of PCOS as it initiates in decreasing body weight, normalises the menstrual cycle, and regulates ovulation. A longer observation period may be taken as there will be scope to analyse the effect comprehensively. A comparative study may be taken between Vamana and virechana modalities of treatment.

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Cite this article as:

C Swathi, M Suchetha Kumari, Rajlaxmi, Chaturvedi Ashutosh. An open randomised control study to evaluate the combined effect of shodhana followed by shamana chikitsa over polycystic ovarian syndrome. Int. J. Res. Ayurveda Pharm. 2015;6(5):621-628 http://dx.doi.org/10.7897/2277-4343.065116

Source of support: Nil, Conflict of interest: None Declared