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Research Article

AN OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMBINED EFFECT OF *KRISHNA TILA KASHAYAM* AND *SHATAPUSPA CHOORNAM* IN PCOS

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ABSTRACT

PCOS has ovarian dysfunction along with hyperandrogenism and polycystic ovarian morphology. PCOS is a condition where involvement of *Kapha dosha* is present along with *Vata dosha* along with *Rasa Dhatu, Medo dhatu* and *Arthava*- the *Upadhatu* of *Rasa* is affected. Because of having the properties of *Ushna virya, Kashaya Tiktha rasa, Arthava janana* properties, *Krishna Tila Kashayam* and *Shatapuspa choornam* has been mentioned for the treatment of *Arthava kshaya* (anovulation and oligomenorrhea) in PCOS. The treatment is fully focused on *Vata Kapha hara chikitsa* and *Arthava vardhaka*. The drugs selected for the present study can be easily prepared and administered, cost effective. In this study, *Tila kashayam* along with *Anupanam Gudam* and *Shatapuspa choornam* along with *Anupanam Madhu* has been given and the results have been noted. In the present study, a total of 40 patients suffering from PCOS were selected from OPD and IPD of SJSACH. The thesis is widely focused on increasing the quantity of flow in amenorrhoea or oligomenorrhea cases, to check the size of the ovarian follicle before and after treatment and to check if there is any reduction in hair growth in hirsutism patients. There was a notable change seen in mild to moderate PCOS cases regarding the interval between 2 cycles, duration of flow between 2 cycles and quantity of flow between 2 cycles. There was a notable change seen in reduction of ovarian cyst volume before and after treatment. Hirsutism, BMI and waist circumference - there was no significant changes noted during these 3-month period.

INTRODUCTION

PCOS is a common hormonal disorder that can occur at any time in women's life. As human life is constantly influenced by the rhythmic phenomenon, the female menstrual cycle involves dramatic monthly hormonal changes affecting a woman's emotional and physical state. Polycystic ovary syndrome is now a well- recognized condition affecting 6-25% of reproductive aged women. Reproductive complications include oligo/amenorrhea, subfertility, endometrial hyperplasia. There are cosmetic complaints like hirsutism, androgenic alopecia and acne.

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Both genetic and lifestyle factors contribute to the development of the polycystic ovary syndrome.[1] Metabolic syndrome is a group of different risk factors that collectively increases the risk of developing cardiovascular diseases and type 2 diabetes mellitus. The syndrome itself is associated with various metabolic abnormalities, including insulin resistance, non- alcoholic fatty liver disease, obstructive sleep apnoea, hyperandrogenism and polycystic ovary syndrome.[2] According to the diagnosis criteria of ovulation, the indirect method to find the ovulation history from menstrual cycle, is that regular menstruation suggests ovulatory cycles. [3] Hence by correcting the abnormal menstruation, ovulation can happen. Ayurveda explained that four etiological factors like *Mithyachara* (indulging in - improper activities like *Ahara* and *Viharas*), *Artava dusti, Beeja dosha* and *Daivakrtha* are responsible for the development of *Yoni rogas* [4]. It seems that all these etiologies contribute to the development of PCOS as a

whole. Acharya *Susrutha* explains *Artava kshaya lakshana* under *Dosha Dhatu Mala Kshaya vriddhi vignanam*[5]. *Mithyachar*a along with the existing *Artava Dusti*, plays an important role in the pathogenesis of PCOS which further leads to the various *Yonivyapads* like *Jataghni*[6], *Vamini*[7], *Na garbham gruhnati*[8]. Ayurvedic management of PCOS helps to regularize the cycle, promotes ovulation and improves oocyte quality.

MATERIALS AND METHODS

Null hypothesis - H^0 = *Krishna tila kashayam* and *Shatapushpa choornam* are not effective in PCOS

Research hypothesis - H^R = *Krishna tila kashayam* and *Shatapushpa choornam* are effective in PCOS

Research Question

Whether *Krishna tila Kashaya* and *Shatapuspam choornam* is effective in PCOS?

Source of Data and Ethical Clearance

40 female patients attending the out-patient department and in-patient department of PTSRs, Sri Jayendra Saraswathi Ayurveda College and Hospital, Nazarathpet, Chennai are enrolled in the study, after permission being obtained from IEC vide IEC-IEC/ SJSACH/27/2021 and CTRI- REF/2022/07/ 056875 registered on 30 July 2022.

Methods of Collection of the Data

A separate case Performa had been prepared incorporating all the points of history taking, physical signs and symptoms of PCOS, lab investigations and ultrasonography. Accordingly, the patients have been selected and were subjected to detailed clinical history taking and complete examination.

Research Design: It is an open label study where a single group of 40 patients were selected and administered 2 types of drugs.

Sampling: Simple randomized sampling

Study Sample: Patients of PCOS in and around the region of the study

Inclusion Criteria

- Female patient of age group between 15- 45years, married or unmarried
- Secondary amenorrhea due to PCOS
- Oligomenorrhea due to PCOS
- Ultrasound findings of polycystic ovaries as per international criteria (ovarian volume and number of follicle) Ovaries are enlarged in volume (>/= 10cm^3) Increased number (>/=12) of peripherally arranged follicles per ovary (2- 9 mm)
- Patient with written informed consent

Exclusion Criteria

- Primary amenorrhea
- Lactational amenorrhea and pregnancy
- Systemic diseases like HTN, TB, Asthma
- Hyperprolactinemia
- Ovarian tumour
- Uterine synechiae
- Thyroid disease

Assessment Criteria

Subjective Criteria

- Interval between two cycles
- Duration of bleeding
- Quantity of bleeding

Objective Criteria

Acne

Hirsutism

Waist circumference

BMI

Ovarian volume

Table 1: Pictorial Blood Assessment Chart: Pads

Pads	
1 Point	For each lightly stained pad
5 Points	For each moderately stained pad
20 Points	For each completely saturated pad
Tampons	
1 Point	For each lightly stained tampon
5 Points	For each moderately stained tampon
10 Points	For each completely saturated tampon
Clots/Flooding	
1 Points	For each small clot (Australian 5 cent coin)
5 Points	For each large clot (Australian 50 cent coin)
5 Points	For each episode of flooding

PBAC scoring system

Table 2: Grading of variable -Interval between two menstrual cycles

Interval bet 2 cycles	Frequency
Frequent <24 days	1
Normal	0
Infrequent >38 days	2
No menses	3

Limits are mostly based primarily on the data of Snowden and Chistian, Belsey and Pinol, Treloar et al, and Hallberg et al.

Table 3: Duration of bleeding between 2 cycles

Duration of bleeding between 2 cycles	Frequency
Prolonged >8.0	2
Normal 4.5 -8.0	0
Shortened <4.5	1
No menses	3

Limits are mostly based primarily on the data of Snowden and Chistian, Belsey and Pinol, Treloar et al, and Hallberg et al.

Hirsutism according to (Ferriman Gallway score)

Table 4: Waist circumference and BMI

	Body Mass Index		
Men and Women	18.5-24.9 kg/m^2	25-29.9 kg/m^2	>30 kg/m^2
Classification	Normal weight	Overweight	Obese
Risk of Co-morbidities	Low	Increased	High
	Waist Circumference		
Men	<94 cm	94-101.9 cm	>102 cm
Women	<80 cm	80-87.9 cm	>88 cm
Classification	Normal Fat Distribution	Moderate central fat accumulation	High central fat accumulation
Risk of Co-morbidities	LOW	Increased	High

Acne Grading Method by Cook et al., using photographic standards

Intervention

Group: combined medicines is given to these group with

Drug 1) *Krishna Tila kashayam*- 45ml once daily. 25gm *Tila* with 200ml water, boil till it is reduced to one fourth.

Route – Orally

Duration-90 days

Prakshepa- Guda (required quantity)

Time: *Abhaktakala* morning 6am-6.30am

Drug 2) *Shatapuspa choornam* – 12gm/ per day in two divided doses.

Route – Orally

Duration – 90 days

Prakshepa- Honey (in required quantity)

Time: *Pragbaktakala* (before breakfast and before dinner)

Follow up – 3 follow up once in 30 days, after completion of treatment- 1 follow up once in 30 days

RESULTS

Effect of treatment

In the present study. 40 patients of PCOS were registered and were given internal medications.

Plan of the study

It is a single group study, where two medications (*Tila kashayam and Shatapuspa choornam*) along with *Anupanam* have been given to the patients in two different timings.

Table 5: Friedman's test showing overall assessment of *Krishna tila kashayam* and *Shatapuspa choornam* in PCOS

Variable	Frequency	Mean diff value	P-value	Results
Hirsutism	BT-A1FU	-1.000	0.317	Insignificant
BMI	BT-A1FU	-1.000	0.317	Insignificant
Waist Circumference	BT-A1FU	0.000	1.000	Insignificant
USG	BT-A1FU	-3.638	<0.001	Highly significant
Interval between 2 Menstrual Cycles	IB2C (BT)-IB2C (30)	-5.072	<0.001	Highly significant
	IB2C (BT)-IB2C (60)	-4.108	<0.001	Highly significant
	IB2C (BT)-IB2C (90)	-4.373	<0.001	Highly significant
	IB2C (BT)-IB2C (1FU)	-3.774	<0.001	Highly significant
	IB2C (30)- IB2C (60)	-1.118	0.264	Not significant
	IB2C (60)- IB2C (90)	-1.621	0.105	Not significant
	IB2C (90)- IB2C (1FU)	-0.795	0.427	Not significant
Duration of bleeding	DOB(BT)- DOB (30)	-4.581	<0.001	Highly significant
	DOB(BT)- DOB (60)	-3.329	0.001	Highly significant
	DOB (BT)- DOB (90)	-3.740	<0.001	Highly significant
	DOB (BT)- DOB (1FU)	-3.521	<0.001	Highly significant
	DOB (30)- DOB (60)	-1.982	0.048	Significant
	DOB (60)- DOB (90)	-1.058	0.290	Not significant
	DOB (90)- DOB (1FU)	-0.050	0.960	Not significant
Blood loss	BLBT-BL30	-2.300	1.000	Insignificant
	BLBT-BL60	17.825*	0.027	Highly significant
	BLBT-BL90	14.375	0.117	Insignificant
	BLBT-BLFU1	10.100	0.685	Insignificant
	BL30-BL60	20.125*	0.007	Highly significant
	BL30-BL90	16.675	0.002	Highly significant
	BL60-BL90	-3.450	1.000	Insignificant
	BL90-BLFU1	-4.275	1.000	Insignificant

1. **Interval between two cycles**
2. **Duration of bleeding**
3. **Quantity of bleeding**

Table 6: Results Wise Observation of Subjective Criteria

Variable	Frequency	Mean diff value	P-value	Results
Interval between 2 menstrual cycles	IB2C (BT)-IB2C (30)	-5.072	<0.001	Highly significant
	IB2C (BT)-IB2C (60)	-4.108	<0.001	Highly significant
	IB2C (BT)-IB2C (90)	-4.373	<0.001	Highly significant
	IB2C (BT)-IB2C (1FU)	-3.774	<0.001	Highly significant
	IB2C (30)- IB2C (60)	-1.118	0.264	Not significant
	IB2C (60)- IB2C (90)	-1.621	0.105	Not significant
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	BL30-BL90	16.675	0.002	Highly significant
	BL60-BL90	-3.450	1.000	Insignificant
	BL90-BLFU1	-4.275	1.000	Insignificant

1. **Acne**
2. **Hirsutism**
3. **Waist Circumference**
4. **BMI**
5. **Ovarian Volume**

Table 7: Results wise observation of objective criteria

Variable	Frequency	Mean diff value	P-value	Results
Hirsutism	BT-A1FU	-1.000	0.317	Insignificant
BMI	BT-A1FU	-1.000	0.317	Insignificant
Waist circumference	BT-A1FU	0.000	1.000	Insignificant
USG	BT-A1FU	-3.638	<0.001	Highly significant

DISCUSSION

Menstrual Irregularities in PCOS

In the present study it was found that clinical features of this condition vary in patient to patient. As menstrual irregularities are found in majority of the patients, associated symptoms like hirsutism, obesity, acne were not present in all patients. So, the effect of this therapy was mainly focused for the evaluation of improvement of the main symptoms first and then on associated symptoms.

In the present study there was significant results seen in interval between two cycles, duration between two cycles and amount of bleeding between two cycles.

Among 40 patients registered for the study, all are having irregular menstrual cycle.

Menstrual disturbances in PCOS generally present in the form of oligo-amenorrhea (fewer than eight episodes of menstrual bleeding per year or menses that occur at intervals greater than 35 days).[9]

There is no firm definition of PCOS, with its varied expression of phenotypes, but oligomenorrhea and menstrual irregularities are key characteristics.[10]

Between 85% and 90% of PCOS cases experience oligo-ovulation and a lengthy gap between occurrences of vaginal bleeding.[11] Abnormal hormone levels disrupt ovarian function, resulting in abnormal menstrual conditions like anovulation and amenorrhea.[12]

Patient with PCOS may complaint of oligomenorrhea, secondary amenorrhea or dysfunctional uterine bleeding.[13] Approximately, 85%–90% of females with oligomenorrhea and 30%–40% of females with amenorrhea have PCOS.[14]

Longer menstrual cycle length and irregular cycles have been associated with higher androgen and lower sex hormone binding globulin levels (SHBG).[15]

Hirsutism

Among 40 patients selected for study, 17.5% population has normal Hirsutism readings measured, 75% population has mild hirsutism reading measured and 7.50% population has moderate hirsutism reading measured. In the present study there was no marked difference seen in hirsutism between before treatment and after treatment.

As hirsutism in PCOS results with excess hair on the body and face because of the excessive presence of androgens in the body. In our study we have mild hirsutism in majority of the population. Insulin decreases the sex hormone binding globulin (SHBG), a main circulatory protein controlling the testosterone levels. So reduced SHBG would result in a raised level of free androgens that produce clinical manifestations like hirsutism, alopecia, and acne.[16]

While in the general population, hirsutism affects 4–11% of women, in PCOS, its prevalence is estimated at 65–75% [17] and severity vary according to the degree of androgen excess and individual variability in the sensitivity of the pilosebaceous unit to androgens. [18-19]

BMI

Around 40% population has high BMI value measured. In the present study there was no marked difference seen in BMI between before treatment and after treatment. Being overweight is one of the risk factors of PCOS, as it causes insulin resistance and abnormal level of hormones. This signifies the linkage of obesity in the pathology of PCOS. Obesity has been correlated with abnormal hypothalamic-pituitary-ovarian axis function leading to PCOS development. [20]

It has been established that 35%–65% of PCOS patients are obese. [21] Obesity is also closely associated with PCOS, which affects 6–12% of women of reproductive age. [22]

Waist Circumference

In the present study, 60% population has increased waist circumference.

In the present study there was no marked difference seen in waist circumference between before treatment and after treatment. Subcutaneous and visceral fat topography in women with PCOS have more adipose tissue mass in the abdominal area, waist than normal women. Hence PCOS population has increased waist circumference. The presence of central obesity is an indication for presence of PCOS. Women with waist circumference ≥ 85cm were 20.52 times more likely to have PCOS. [23]

Ratio of LH and FSH

In the present study, 12.50% population has the ratio of LH: FSH within 1 to 2, 70% population have the ratio of LH: FSH within 2 to 3 and 17.50% population have the ratio of LH:FSH more than 3. In our study majority of the population has the ratio of LH and FSH between 2 to 3. In the present study there was no marked difference seen in ratio between LH and FSH between before treatment and after treatment. Androgen exposure can impede the hormone levels to increase the high pulse frequency of GnRH affecting the LH: FSH proportion and leads to follicular arrest and dysplasia.[24-25] A disturbance in the secretion pattern of the gonadotrophin-releasing hormone (GnRH) results in the relative increase in LH to FSH release. [26] Ovarian estrogen is responsible for causing an abnormal feedback mechanism that caused an increase in LH release. [27]

USG

In the present study there was marked difference seen in USG between before treatment and after treatment. Observing the USG finding, maximum 100% were having the bilateral polycystic ovaries. Patients with PCO having multiple small follicles in the peripheral part of the ovary with varying size between 8-10mm, due to excess androgen, follicle does not grow up to the mature Level and remain static at any level of development.

Acne

In the present study there was no marked difference seen in acne between before treatment and after treatment. In the present study, 100% population has no acne present. In our population there are no major issues with acne associated with PCOS.

Acne is a common manifestation of hyper-androgenemia. Baseline androgen synthesis is regulated via the alteration of gene transcription by luteinizing hormones (LH). [28]

Acanthosis Nigricans

In the present study there was no marked difference seen in *Acanthosis nigricans* between before treatment and after treatment. In the present study, 57.50% population has *Acanthosis nigricans*. While some degree of insulin resistance occurs in most cases of PCOS [29], the extreme severity of insulin resistance in HAIR-AN, believed to be due to genetic defects in the insulin signaling pathway, leads to manifestations of *Acanthosis nigricans* and central obesity. [30]

Probable Mode of Action of *Krishna Tila Kashayam* and *Shatapuspa Choornam* in PCOS

The drug given for the present study was *Tila kashayam* with *Gudam* and *Shatapuspa choornam* with honey. These drugs mainly have the properties of *Madhura* and *Tikta rasa, Ushna virya, Vatakapha hara* property and also act on *Yoni pradesha*.

Krishna Tila has phytoestrogen, high antioxidant and anti-inflammatory property which may explain its pharmacodynamics according to modern on acting in oligomenorrhoea and

hypomenorrhoea. *Krishna Tila* is rich source of calcium, potassium, Vit. A D E K.

According to Acharya Susrutha, *Tila* is mentioned as one of the *Arthavajanaka dravyas*.

Sesame seeds supply iron, copper, and vit B6 which are needed for blood cell formation and function.

The lignans in sesame seeds function as anti-oxidants, which help to fight oxidative – a chemical reaction that may damage cells and increase risk of many chronic diseases.

They contain an antioxidant and anti-inflammatory compound called sesamol thus improving the health. Sesamin, a major lignin isolated from sesame (*Sesamum indicum*) seeds and sesame oil, is known to possess antioxidant and anti-inflammatory properties.[31]

In this disease of *Arthava kshaya*, *Apana vata* is mainly deranged. So, its normal function such as *Arthava pravriti* may become improper. *Krishna Tila* performs *Vatashamaka Karma* due to its *Madhura rasa, Ushna Virya, Guru*, *Snigdha Guna* and *Madhura Vipaka.*

Shatapushpa is a phytoestrogen; it exerts both estrogenic and anti-estrogenic activity depending on the condition. It acts in both high estrogenic and low estrogenic condition.

The *Shatapuspa* mentioned by *Acharya Kashyapa* in *Kashyapa Samhita* has numerous benefits in women's life.

According to *Acharya Kashyapa*, *Shatapushpa* is mentioned as, '*Rutupravartini Dhanya Yonishukravishodhanee*'. Oestrogen is one of the major acting hormones in females. Its deficiency leads to many disorders in females. *Shatapushpa* contains natural component which is phytoestrogen which helps to restore oestrogen functions in female.

Shatapushpa contains monoterpine such as carvone, limonine and transanethole and some flavonoids such as kaempferal and vecenin. Among them kaempferal, transanethole and limonine exhibit phytoestrogenic activity. In vitro, kaempferol demonstrates antioxidant and anti-inflammatory properties as well as anti-proliferative properties in ovarian cancer cells, which is noteworthy as progestins also have an immunosuppressive and anti-inflammatory action.[32-33] Trans-anethole has antioxidant, anti-inflammatory and estrogenic properties. [34]

According to Ayurveda, its *Katu Rasa* and *Katu Vipaka* have *Deepana Pachana Karma* which results in *Amapachana* and thus provides proper metabolism and eventually equilibrate the *Agni* which form healthy *Rasa Dhatu* for normal production of *Artava.*

One of the types of research done on sesame seeds exhibited that the intake of 60g/day of sesame seeds for subjects with oligomenorrhea showed that 72% of the subjects who participated in that study have experienced proper menstrual bleeding and reduction in pain during menstruation after consumption of sesame seeds for 7 days. [35]

Some characteristics of PCOS such as obesity and abdominal adiposity, androgen excess, and insulin resistance can develop oxidative stress in these patients.[36] Indeed, PCOS is a condition with significant decrease in serum antioxidant and these women are in an increased risk of oxidative status. [37]

CONCLUSION

Due to sedentary lifestyle and increase in stress level, young woman today is prone to increase risk of PCOS. In person suffering from PCOS, *Agneya* quality of *Pitta* is reduced, which is essential for the normal *Arthava pravrithi.* There is increase in *Kapha* and *Vata dosha*. This increase in these *Dosha* leads *to Avarana* in the *Arthava vaha srotas* causing *Arthava kshaya* or *Nashta arthava* which is predominantly found in PCOS. The treatment is fully focused on *Vata kapha hara chikitsa* and *Arthava vardhaka*. The drugs selected for the present study are easily available, and can be easily prepared and administered, cost effective.

In this study, *Tila kashayam* along with *Anupanam Gudam* and *Shatapuspa Choornam* along with *Anupanam Madhu* has been given and the results have been noted.

In the present study, a total of 40 patients suffering from PCOS were selected from OPD of SJSACH. The thesis is widely focused on increasing the quantity of flow in amenorrhoea or oligomenorrhea cases, to check the size of the ovarian follicle before and after treatment and to check if there is any reduction in hair growth in hirsutism patients. There was a notable change seen in mild to moderate PCOS cases regarding the interval between 2 cycles, duration of flow between 2 cycles and quantity of flow between 2 cycles. There was a notable change seen in reduction of ovarian cyst volume before and after treatment. Hirsutism, BMI and waist circumference – there was no significant changes noted during these 3-month period

REFERENCES

1. Tracy l, Setji. Polycystic Ovary Syndrome: Update on Diagnosis and Treatment. American Journal of Medicine. 2014
2. Cho L W. Metabolic syndrome. Singapore Med J. 2011; 52: 779
3. Hiralal Konar. Dutta's Textbook of Gynaecology. Jaypee Brothers Medical Publishers. New Delhi. 2020. Pg. 194.
4. Susruta. Susrutha Samhita. Text with Nibandhasangraha Commentary of Sri Dalhana.

Krishna das Ayurveda. Varanasi. Chaukhambha Orientalia. 2014; Su.U.38/5.

5. Susruta. Susrutha Samhita. Text with Nibandhasangraha Commentary of Sri Dalhana. Krishna das Ayurveda. Varanasi. Chaukhambha Orientalia. 2014; Su.su 25/12.
6. Vagbhata. Astanga Hridaya Samhita. Chaukhamba Orientalia, 2005. A.H.U.33/34.
7. Agnivesa, Caraka Samhita, Text with Ayurveda Dipika commentary of Chakrapanidatta. Varanasi. Chaukhamba Orientalia, 2011. Ch. Chi. 30/33
8. Agnivesa, Caraka Samhita, Text with Ayurveda Dipika commentary of Chakrapanidatta. Varanasi. Chaukhamba Orientalia, 2011. Ch.Chi. 30/38
9. Norman RJ, Dewailly D, Legro RS, Hickey TE. Polycystic ovary syndrome. Lancet. 2007; 370 (9588): 685–97.
10. H.R. Harris, L.J. Titus, D.W. Cramer, K.L. Terry. Long and Irregular Menstrual Cycles, Polycystic Ovary Syndrome, and Ovarian Cancer Risk in a Population-Based Case-Control Study; Int. J. Cancer., 140 (2017), pp. 285-291.
11. R. Hart, M. Hickey, S. Franks. Definitions, Prevalence and Symptoms of Polycystic Ovaries and Polycystic Ovary Syndrome; Best. Pract. Res. Clin. Obstetrics Gynaecol., 18 (2004), pp. 671-683.
12. S. Abraham Gnanadass, Y. Divakar Prabhu, A. Valsala Gopalakrishnan. Association of metabolic and inflammatory markers with polycystic ovarian syndrome (PCOS): an update; Arch Gynecol Obstet., 303 (2021), pp. 631-643.
13. C. Foster, H. Al-Zubeidi. Menstrual irregularities; Pediatr. Ann., 47 (1) (2018), pp. e23-e28.
14. R.K. Meier. Polycystic ovary syndrome; Nurs. Clin., 53 (3) (2018), pp. 407-420.
15. Wei S, Jones G, Thomson R, Otahal P, Dwyer T, Venn A. Menstrual irregularity and bone mass in premenopausal women: Cross-sectional associations with testosterone and SHBG. BMC Musculoskeletal Disorders. 2010; 11:1–8.
16. J. Rojas, M. Chávez, L. Olivar, M. Rojas, J. Morillo, J. Mejías, M. Calvo, V. Bermúdez Polycystic ovary syndrome, insulin resistance, and obesity: navigating the pathophysiologic labyrinth. Int. J. Reprod. Med., 2014.
17. Azziz R., Carmina E., Chen Z., Dunaif A., Laven J.S., Legro R.S., Lizneva D., Natterson-Horowtiz B., Teede H.J., Yildiz B.O. Polycystic ovary syndrome. Nat. Rev. Dis Primers. 2016; 2: 16057.
18. Escobar-Morreale H.F., Carmina E., Dewailly D., Gambineri A., Kelestimur F., Moghetti P., Escobar-Morreale H.F., Carmina E., Dewailly D., Gambineri A., et al. Epidemiology, diagnosis and management of hirsutism: A consensus statement by the Androgen Excess and Polycystic Ovary Syndrome Society. Hum. Reprod. Update. 2012; 18: 146–170.
19. Spritzer P.M., Barone C.R., Oliveira F.B. Hirsutism in Polycystic Ovary Syndrome: Pathophysiology and Management. Curr Pharm. Des. 2016; 22: 5603–5613.
20. RS. Legro. Obesity and PCOS: implications for diagnosis and treatment; In Seminars in reproductive medicine, Vol. 30, NIH Public Access (2012 Dec), p. 496.
21. Al-Azemi M, Omu FE, Omu AE. The effect of obesity on the outcome of infertility management in women with polycystic ovary syndrome. Archives of gynecology and obstetrics. 2004; 270: 205–210. (5.8.23)
22. Bozdag G, Mumusoglu S, Zengin D, Karabulut E, Yildiz BO. The prevalence and phenotypic features of polycystic ovary syndrome: a systematic review and meta-analysis. Hum Reprod. 2016; 31: 2841–55. (5.8.23)
23. Mawaddatina T, Budihastuti UR, Rahayu D. Waist circumference, hip circumference, arm span, and waist-to-hip ratio high risk of polycystic ovarian syndrome. Scottish Medical Journal. 2021; 66(4): 186-190. (5.8.23)
24. D.A. Dumesic, S.E. Oberfield, E. Stener-Victorin, J.C. Marshall, J.S. Laven, RS. Legro Scientific statement on the diagnostic criteria, epidemiology, pathophysiology, and molecular genetics of polycystic ovary syndrome Endocr. Rev., 36 (5) (2015 Oct 1), pp. 487-525. (5.8.23)
25. AP. Cheung. Polycystic ovary syndrome: a contemporary view. J. Obstet. Gynaecol. Can, 32 (5) (2010 May 1), pp. 423-425. (5.8.23).
26. SS Y. The polycystic ovary syndrome. Clin Endocrinol. 1980; 12:177–183. (5.8.23)
27. TJ M. Pathogenesis and treatment of polycystic ovary syndrome. N Engl J Med. 1988; (318): 558–562. (5.8.23)
28. Lizneva D, Gavrilova-Jordan L, Walker W, Azziz R. Androgen excess: Investigations and management. Best Pract Res Clin Obstet Gynaecol 2016; 37: 98-118. (12.8.23)
29. Barber, Thomas M., et al. "Polycystic ovary syndrome: insight into pathogenesis and a common association with insulin resistance." Clinical Medicine 16.3 (2016): 262. (12.8.23)
30. Kahn, C. Ronald, et al. "The syndromes of insulin resistance and acanthosis nigricans: insulin-receptor disorders in man." New England Journal of Medicine 294.14 (1976): 739-745. (12.8.23)
31. Sarah Dalibalta, Amin F. Majdalawieh et al. Health benefits of sesamin on cardiovascular disease and

its associated risk factors.Saudi Pharmaceutical Journal, Volume 28, Issue 10. 2020, pg 1276-1289.

32. Kim, S.K.; Kim, H.J.; Choi, S.E.; Park, K.H.; Choi, H.K.; Lee, M.W. Anti-oxidative and inhibitory activities on nitric oxide (NO) and prostaglandin E2 (COX-2) production of flavonoids from seeds of Prunus tomentosa Thunberg. Arch. Pharm. Res. 2008, 31, 424–428. (12.8.23)
33. Luo, H.; Jiang, B.H.; King, S.M.; Chen, Y.C. Inhibition of cell growth and VEGF expression in ovarian cancer cells by flavonoids. Nutr. Cancer 2008, 60, 800–809. (12.8.23)
34. Marinov V, Valcheva-Kuzmanova S. Review on the pharmacological activities of anethole. Scripta Scientifica Pharmaceutica. 2015; 2(2): 14–19. (12.8.23)
35. Yavari M, Rouholamin S, Tansaz M, et al. Herbal treatment of oligomenorrhea with Sesamum indicum L.: a randomized controlled trial. Galen Med J 2016; 5(3): 114–121. (22.8.23)
36. Murri M, Luque-Ramırez M, Insenser M, Ojeda-Ojeda M, Escobar-Morreale HF. Circulating markers of oxidative stress and polycystic ovary syndrome (PCOS): a systematic review and meta-analysis. Hum Reprod Update. 2013; 19: 268–288. (22.8.23)
37. Al-kataan MA, Ibrahim MA, Al-jammas MHH, Shareef YS, Sulaiman MA. Serum Antioxidant Vitamins Changes in Women with Polycystic Ovarian Syndrome. J Bahrain Med Sci. 2010; 22: 68–71. (22.8.23)

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