



## Research Article

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### A CLINICAL STUDY OF ETIOPATHOGENESIS OF OBESE (STHULA) PCOS AND ITS MANAGEMENT BY MEDOHARGUGGULA

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#### ABSTRACT

The polycystic ovarian syndrome is a hormonal disorder affecting 7% of the reproductive age of women. Women with PCOS have an irregular menstrual cycle, excess androgen, anovulation, hirsutism, and infertility. As per Ayurveda, this type of clinical feature is found in Pushpaghni Jataharini and Nashtartava. The present study provides information about some herbal plants, active plant constituents, and some formulations clinically tested in animal models that induce PCOS and humans suffering from PCOS. Aim: A clinical study of etiopathogenesis of obese (Sthula) PCOS and its management by Medoharguggula. Methodology: The two sections have made for a better understanding of the aim and objectives of the present study. The study was conducted on 30 patients. The drug Medoharguggula was given in Vati form with the dosage of 500 mg thrice a day with lukewarm water. This study was conducted at Bharati Ayurveda hospital during 2020-2022. It was a randomized, open clinical trial study. Results: A total of 35 patients were evaluated in this study. Out of which five discontinued the treatment, and 30 patients completed it. Conclusions: The herbal contents of the drug were found effective in reducing weight. It was not found effective in reducing BMI, hirsutism, acanthosis nigricans and weight reduction. Also, the menstrual cycle interval was found to be regular or at the interval of 45 days in 80% of the patients.

**Keywords:** Polycystic ovarian syndrome, Obesity (Sthaulya), Ayurveda.

#### INTRODUCTION

An introduction is a beginning section which states the purpose and goals of the following writing. The introduction describes the scope of the documents and gives a brief explanation or summary of the work.

The current study has two parts; the first part consists of the study of etiopathogenesis of obese (Sthula) PCOS and to develop the relation between Sthaulya and PCOS, and the second part was tried to see whether Medoharguggula can do the management of PCOS.

In Ayurveda, Jataharini has described by Acharya Kashyapa in Revati Kalpaadhyaya. In this Revati Vritha Pushpam (anovulation), Yathakalam Prapashyati, Sthula Ganda (a feature of obesity), and Lomasha Ganda (Hirsutism) are found.<sup>1</sup> Associated features of PCOS closely resemble Vandhya Yonivyapada, Artavavahastrotasa-Vidhha Lakshana, Nashtartava, and Ksheenaartava, described by Acharya Sushruta.<sup>2</sup>

Ayurveda describes as having an equal involvement of the Dosha, Dhatu and Upadhatu for the development of Vyadhi. Ayurveda considered Vata and Pitta Dosha as a dominant factor in the development of PCOS.<sup>3</sup>

PCOS requires a long-term committed treatment that can have serious side effects.<sup>4</sup> PCOS is the most common hormonal abnormality in reproductive-age women affecting 7% of this population.<sup>5</sup> Clinical manifestations are diverse, including

hyperandrogenism, anovulation, oligomenorrhoea, hirsutism, acne, infertility, and increased risk of metabolic diseases besides psychological dysfunction.<sup>6</sup> There are reports of incidence of PCOS in non-obese and lean women too. But the prevalence of obesity along with PCOS is higher.<sup>7</sup>

Obesity, particularly the abdominal phenotype, may be partly responsible for insulin resistance and associated hyperinsulinemia in women with PCOS.<sup>8</sup> By analysing the symptoms of both Pushpaghni Jataharini and PCOS, it is found that both are somewhat similar.

#### MATERIALS AND METHODS

##### Collection of Drugs

The raw material was brought from the local Ayurvedic store, Ekdanta Ayurvedic Store, Dhankawdi, Pune, Maharashtra, India. Dr S. S. Deokule does authentication from Savitribai Phule University, India.

Dr Swapnil Shinde prepared the drug from Ayush Ayurveda LLP pharmacy, Pune, with GMP certified Pune, Maharashtra, India.

##### Standard Operative Procedure of Medoharguggula

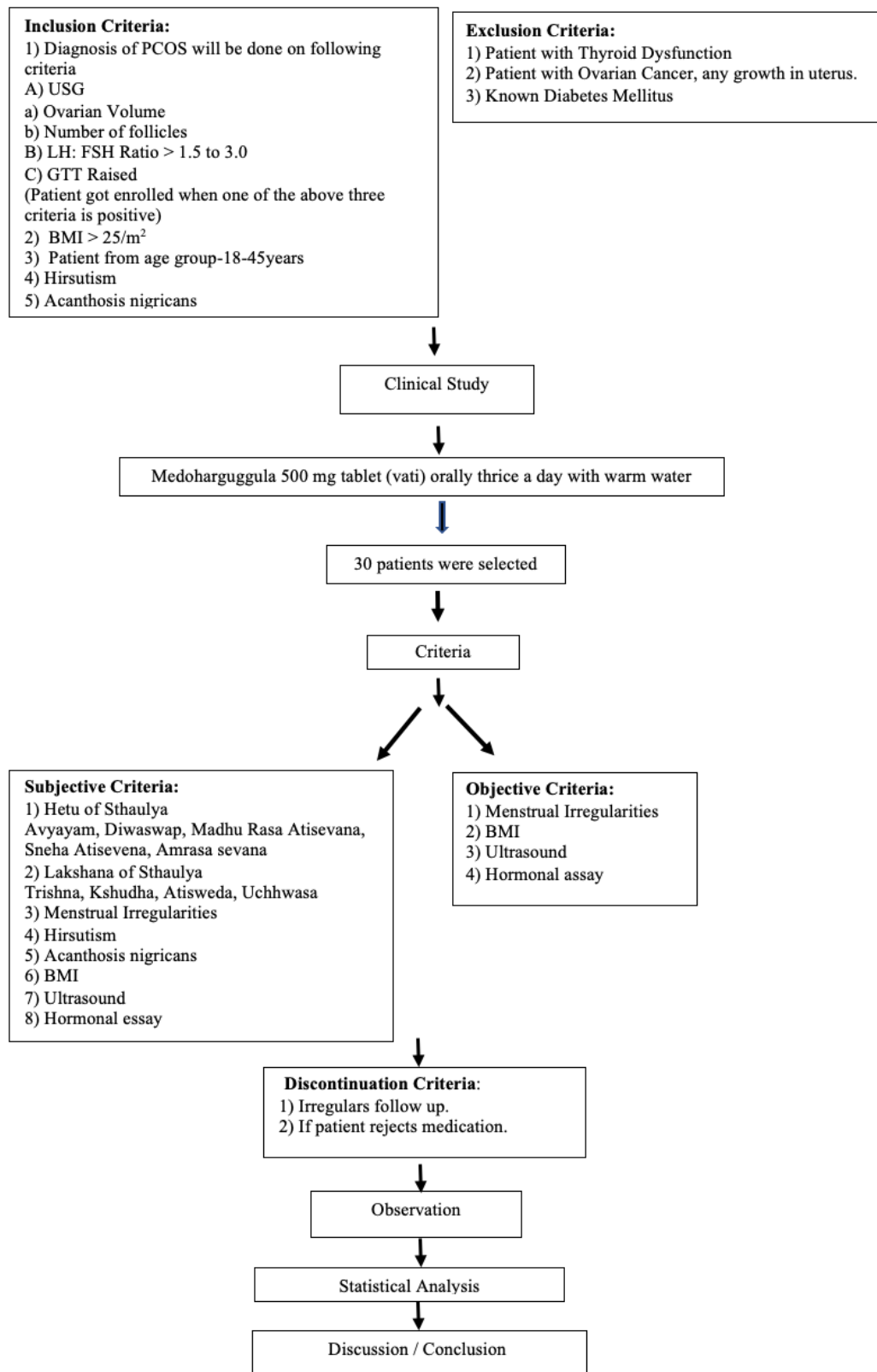
Shudhha Guggula, Shunthi, Maricha, Pippali, Amalaki, Bibhitaki, Haritaki, Chitraka, Vidanga, Mustaka each drug 450 gm. Sneha used for this is Eranda Sneha.

1) Fine powders of all ingredients except Shudhha Guggula and Eranda Taila are measured shifted through 40 number mesh. The Shudhha Guggula is dissolved in 2 litres of water, all fine powders mixed in it homogeneously.

- 2) Eranda Taila is mixed well in the bolus, and further granulation was done.
- 3) The prepared granules were dried in a tray dryer at 55 °C.

- 4) After drying, a 500 mg tablet was prepared using a rotary tableting machine.
- 5) The prepared tablets are analysed for Hardness, Disintegration time etc., as per the API guideline.

### Study Design



### Drug Authentication and Standardization

Authentication of the drug was done by using the botanical parameters such as organoleptic/ macroscopic and microscopic evaluation. The pharmacological and physiochemical methods did standardization.

Standardization as per API guidelines was done. Authentication certificate reference number: Bot/1/2020 and standardization certificate reference number: Bot/6/2020.

### Treatment Details

Dose	500 mg
Form	Vati (Tablet)
Time	8am – 2pm – 8pm
Anupana	Warm water
Pathya	Laghu, Ruksha Gunatmaka, Ushna Viryatmaka Ahara
Follow up	Three months
Route	Oral

### Selection Criteria

#### Inclusion Criteria

- Diagnosis of PCOS was made on the following criteria:
- USG – Ovarian Volume and Number of follicles, LH:FSH ratio >1.5-3.0, Raised GTT. (If one of the above three criteria is positive, then the patient was enrolled)
- BMI > 25/m<sup>2</sup>
- Patients from the age group 18-45 years
- Hirsutism
- Acanthosis nigricans

#### Exclusion Criteria

- Patients with thyroid dysfunction
- Patient with ovarian cancer, any growth in the uterus
- Known Diabetes Mellitus

#### Discontinue Criteria

- Irregulars follow up
- If the patient rejects medication

#### Assessment Criteria

This study has two parts: Part A and Part B

### The Clinical Study of Etiopathogenesis of Obese (Sthula) PCOS

Ethical clearance number: BVDU/COA/2437/2020-21, dated 11/07/2020.

### Following observations are done to develop the relation between Sthaulya & PCOS

- Age, Occupation
- Weight
- BMI
- Dietary timings
- Hetu of Sthaulya
- Avyayam, Diwaswapa, Madhur Rasa Atisevana, Sneha Atisevena, Amrasa sevana
- Lakshana of Sthaulya
- Trishna, Kshudha, Atisweda, Uchhwasa

### Following parameters are assessed to see whether Management of PCOS can be done by Medoharguggula, which is mentioned in Sthaulya Chikitsa

- Menstrual Irregularities
- Hirsutism
- Acanthosis nigricans
- BMI
- Ultrasound
- Weight
- Hormonal assay

### DISCUSSION

#### Age and Occupation

The maximum number of patients is from 18-28 years of age. The changing lifestyle and stress are common factors in this age group. So, most of the patients are found in this age group.

It was observed in history taking those 17 patients in the working group were in IT (Information Technology) firms. So, during this pandemic of Covid-19, they all got the work-from-home pattern. The stress of work and lack of physical activity was observed in all patients. This stress may be the cause of PCOS.

Five patients were housewives. It was noted that they had an irregularity in their dietary and sleep pattern. They were taking a rest after lunch, which resulted in Kaphasanchaya. So, Kapha Vriddhi is also the cause of Sthaulya in Ayurveda which ultimately leads to the development of PCOS.

#### Marital Status and Infertility

The average marriage age in India is 18-24. So, most of the patients are found married. PCOS is one of the major causes of infertility, so the maximum group visited the hospital with the complaint of difficulty in conception. In these patients, the sonography reports showed polycystic ovaries.

#### Assessment of Weight

A difference of 1 kg weight loss was observed in 30 patients. This is due to the Lekhana activity of Medoharguggula. It helps to treat obesity by promoting fat loss. In this study, the Hetu of Sthaulya, i.e., Avyayam, Diwaswap, Madhu Rasa Atisevana, Sneha Atisevena, and Amrasa sevana were observed in almost all patients. It may promote weight loss by inducing the breakdown of fat, thus reducing the volume of fatty tissue. The correction in Hetu significantly reduces weight loss and improves fat metabolism.

#### BMI

No significant change was seen in BMI. This may be due to short-term treatment. For this, the treatment could be continued for more than three months along with strict Nidana Parivarjana, i.e., avoiding the causes of Sthaulya.

#### Dietary Timings

The timings of meals are irregularly irregular in the patients observed in this study. It was observed that all patients were having late-night dinners. So, the Agni is not functioning correctly. The food not adequately digested yields improperly formed Rasa in Amashaya, and Rasa being retained undergoes fermentation. This state is called "Ama". This causes the Rasa Dhatu Dushti. Due to the hampered function of Rasa Dhatu, the

further Dhatus don't get nourished and leads to various symptoms like Agnimandya, Gauravata, etc.

The Rajapavrutti is not regular in PCOS patients. This is due to the Rasadushti as Raja is the Upadhatu of Rasa. One research aims to study the lifestyle to find the pathogenesis.

### Hetu of Sthaulya

Hetusevan of Sthaulya, i.e., Avyayam, Diwaswap, Madhu Rasa Atisevana, Sneha Atisevena, and Amrasa sevana are observed in all patients. In obese PCOS patients, these Hetus are the cause of PCOS. So, these hetus must be taken into consideration when treating PCOS.

### Lakshana of Sthaulya

#### Assessment of Trishna

Trishna is the sign of Rasa Dhatu Dushti and a symptom of Sthaulya. This is observed in 56% of patients with PCOS. This is the sign of Apachita Kleda, so, Medodushti is observed in all PCOS patients.

#### Assessment of Kshudha

This is the sign of Vata Dosh and Medo Dhatu Dushti. The repeated feeling of hunger is observed in maximum patients. Kshudhaadhikya is the symptom as well as a cause of Sthaulya. While treating PCOS, this cause shall be corrected. This is the abnormal feeling as per the Samhita.

#### Assessment of Atisweda

Sweda in Ayurveda is considered as Mala or excreted product of Meda Dhatu or fat. Among Medo Pradoshaja Vikarasa (diseases caused due to morbid fat), Charaka has mentioned Nindita Purushas. Among the eight Ninditasa, Ati Sthula (obese) is one, and Ati Sweda is one of the Lakshana of Medo Vriddhi, i.e., Ati Sthula.

#### Assessment of Uchwasa

Uchwasa is the Lakshana found in the Medo Roga. Medo Dhatu Vriddhi is found in Sthaulya Vyadhi, which causes difficulty in fat metabolism. This causes the Dushti of Pranavaha Strotasa, which develops difficulty breathing, i.e., Uchwasa. This leads to difficulty in treating PCOS. Similarly, this leads to scanty or heavy menstrual bleeding as Raja is a Upadhatu of Rasa.

### Objective Criteria

#### Menstrual Cycle

The pattern observed in 66% of patients is irregular and irregularly irregular, which is the peculiar sign of PCOS. This pattern is due to all Dosh and Dhatu Dushti. The menstrual bleeding becomes regular or at the interval of 45 days seen in 24 patients, i.e., 80% during treatment. This is due to the Medopachana and Agnivaradhana action of Medoharguggula. This may be due to the reduction of Avarana of Dushita Medo Dhatu.

#### Hirsutism

Hirsutism means abnormal hair growth. Medo Dhatu is the precursor of Asthi Dhatu. Also, hair is a Mala of Asthi Dhatu. In 90% of the patients, the hair feel was smooth. This remained the same at the end of the study. The overall Rasa of Dravyas in Medoharguggula is Madhura and has Ushna Veerya, which keeps the hair smooth.

#### Acanthosis nigricans

Acanthosis nigricans occurs due to a high level of insulin. The Medoharguggula did not show any effect on the discolouration of

the skin. This may be due to the inadequate action of Medoharguggula on insulin levels.

### Ultrasound- Ovarian Volume

The ovary is a site of Teja. An increase in the Aapa, i.e., Kapha due to Medodushti and Kleda, decreases the Teja. This increased ovarian volume. In this study, the ovarian volume remained the same during the treatment. It may be due to the inadequate insulin sensitivity action of Medoharguggula. This may be improved by increasing the dose of Medoharguggula as all the herbs in this medicine are anti-hyperglycaemic, anti-inflammatory, and antioxidant properties.

### Hormonal Assay

#### Assessment of LH

The LH levels were reduced by 2nmol/dL in the ten patients. A high level of insulin results in a high level of LH. Lowering the inflammatory conditions to some extent may reduce the LH level. The herb Haritaki in Medoharguggula has anti-inflammatory action.

#### Assessment of FSH

The FSH levels were reduced by 0.34 nmol/dL in the ten patients. This effect is because of the breakdown of cholesterol. The guggulu has hypolipidemic and thyroid stimulant action.

#### Assessment of Testosterone

The ten patients reduced testosterone levels by 7.3 nmol/dl. This effect is because of the breakdown of cholesterol. The Triphala and Trimada in Medoharguggula have anti-inflammatory and antioxidant properties, so that these properties may decrease the androgen levels.

### CONCLUSION

The two sections have made for a better understanding of the aim and objectives of the present study. The first section has made for the study of etiopathogenesis of obese (Sthula) PCOS by observing the age and occupation, weight, BMI, dietary timings, Hetu of Sthaulya, i.e., Avyayam, Diwaswap, Madhu Rasa Atisevena, Sneha Atisevana, Amrasa sevana, etc. and Lakshana of Sthaulya, i.e., Trishna, Kshudha, Atisweda, Uchwasa, etc.

According to the above observations, the relation between Sthaulya Vyadhi mentioned in Ayurveda classics and PCOS is well developed by comparing the cause and the pathogenesis, i.e., Samprapti of Sthaulya with PCOS. So, it can be concluded that they both are like some extent because all the Hetu and Lakshana of Sthaulya were observed in PCOS. The drug was not very effective in reducing BMI range, hirsutism, and acanthosis nigricans. It was not effective in the reduction of ovarian volume.

The drug Medoharguggula was found effective in the reduction of weight. Also, the menstrual cycle interval was found to be regular or at the interval of 45 days in 80% of the patients. Medoharguggula was found to be effective in the reduction of average values of LH, FSH and testosterone to some extent due to the action of lipolysis of fat cells and breakdown of cholesterol.

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