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ORIGINAL ARTICLE

# OPEN LABEL SINGLE CENTRIC CLINICAL EXPLORATORY OF EFFICACY STUDY ON ASPAROSE CAPSULE, AN AYURVEDIC PROPRIETARY FORMULATION

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**ABSTRACT**

**Introduction:** Polycystic Ovarian Syndrome (PCOS) is a common endocrine disorder affecting women of reproductive age, often manifesting as irregular menstrual cycles, abnormal bleeding, and menstrual cramps. Ayurvedic medicine has been widely used for managing such conditions. This study aims to clinically validate the efficacy of the proprietary Ayurvedic Medicine, ASPAROSE Capsule, in alleviating the symptoms associated with PCOS. The primary objective of this Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial was to evaluate the effectiveness of ASPAROSE Capsule in reducing PCOS-related symptoms, such as irregular menstrual cycles, abnormal bleeding disorders, vaginal pain, and menstrual cramps. **Methods:** A total of20 female patients aged 21-40 years with clinically diagnosed PCOS symptoms were enrolled in the study. Participants were administered 1-2 ASPAROSE Capsules twice daily with lukewarm water for 30 days. Baseline and post-treatment evaluations were conducted using clinical and laboratory assessments. Ethical approval was obtained, and patient consent was secured before study participation. **Results:** At the end of the 30-day trial period: 70% (14 patients) experienced significant improvement in symptoms. 10% (2 patients) showed moderate improvement. 10% (2 patients) had mild improvement. 10% (2 patients) exhibited no significant improvement. Laboratory investigations supported these findings, demonstrating improved hematological parameters post-treatment. No severe adverse effects were reported, indicating the safety of the medication. **Conclusion:** ASPAROSE CAPSULE was found to be highly effective in managing PCOS-related menstrual irregularities, abnormal bleeding, and associated pain. The study suggests that this proprietary Ayurvedic formulation may serve as a potential therapeutic option for PCOS management. Further large-scale studies are recommended to confirm these findings.

**Keywords:** Polycystic Ovarian Syndrome, Ayurvedic Medicine, ASPAROSE Capsule

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## INTRODUCTION

Polycystic Ovarian Syndrome (PCOS) is one of the most prevalent endocrine disorders among women of reproductive age, affecting approximately 5-20% of the female population worldwide, depending on diagnostic criteria used[1]. It is characterized by a combination of symptoms such as irregular menstrual cycles, hyperandrogenism (excess male hormones leading to acne and hirsutism), and polycystic ovarian morphology observed on ultrasound[2]. These manifestations significantly impact the physical and emotional well-being of affected individuals, leading to complications such as infertility, metabolic disturbances, and increased risk of type 2 diabetes mellitus and cardiovascular diseases[3].

### Pathophysiology and Clinical Manifestations of PCOS

The pathogenesis of PCOS remains complex and multifactorial, involving genetic, hormonal, and environmental factors[4]. The hallmark of PCOS is insulin resistance, which is observed in nearly 70% of affected individuals, contributing to compensatory hyperinsulinemia. This hyperinsulinemia exacerbates ovarian androgen production, leading to disrupted folliculogenesis and anovulation[5]. In addition, low-grade systemic inflammation has been proposed as a contributing factor in PCOS pathophysiology, with elevated levels of inflammatory markers such as C-reactive protein (CRP) and tumor necrosis factor-alpha (TNF-α) noted in affected individuals[6].

Clinically, PCOS presents with a heterogeneous spectrum of symptoms. Menstrual irregularities such as oligomenorrhea (infrequent menstruation) or amenorrhea (absence of menstruation) are commonly reported due to chronic anovulation[7]. Abnormal uterine bleeding, often characterized by prolonged and heavy menstruation, is also a frequent concern[8]. Additionally, women with PCOS are at a heightened risk of developing metabolic syndrome, obesity, and impaired glucose tolerance, further complicating disease management[9].

Conventional Management Approaches and Their Limitations

Current therapeutic strategies for PCOS focus on symptom management rather than disease modification. First-line pharmacological interventions include combined oral contraceptives (COCs) to regulate menstrual cycles and anti-androgenic agents such as spironolactone to mitigate hyperandrogenic symptoms[10]. Insulin-sensitizing drugs like metformin are widely prescribed to address insulin resistance and improve ovulatory function[11]. However, these pharmacological treatments are often associated with side effects, including gastrointestinal distress, weight gain, and potential thromboembolic risks[12].

Lifestyle interventions, including dietary modifications and regular physical activity, are crucial in managing PCOS. Studies suggest that weight loss as minimal as 5% can significantly improve menstrual regularity and metabolic parameters in women with PCOS[13]. Despite these benefits, adherence to lifestyle changes remains a significant challenge,

necessitating alternative therapeutic options[14].

**Ayurvedic Medicine in PCOS Management**

The limitations of conventional therapies have led to increased interest in complementary and alternative medicine (CAM) approaches, particularly Ayurveda, for managing PCOS. Ayurveda, an ancient Indian system of medicine, emphasizes restoring balance in bodily functions through herbal formulations, dietary modifications, and lifestyle interventions. Various Ayurvedic herbs such as Ashwagandha (Withaniasomnifera), Shatavari (Asparagus racemosus), and Guduchi (Tinospora cordifolia) have demonstrated promising effects in modulating hormonal imbalances, reducing oxidative stress, and enhancing ovarian function.

ASPAROSE CAPSULE, a proprietary Ayurvedic formulation, has been developed as a potential therapeutic intervention for PCOS-related symptoms. This herbal blend is designed to regulate menstrual cycles, alleviate abnormal bleeding, and reduce menstrual pain through its adaptogenic and anti-inflammatory properties. The ingredients in ASPAROSE CAPSULE are traditionally known for their efficacy in reproductive health and hormonal balance, warranting scientific validation through clinical trials.

Need for Clinical Validation of Ayurvedic Interventions

Despite the widespread use of Ayurvedic medicine in managing gynecological disorders, scientific validation through rigorous clinical trials remains limited[19]. The absence of standardized dosing, variability in herbal composition, and a lack of large-scale studies have hindered the integration of Ayurvedic treatments into mainstream medical practice. Addressing these challenges through well-designed clinical trials can provide evidence-based support for the efficacy and safety of Ayurvedic formulations, thereby facilitating their broader acceptance in clinical settings.

**Objective of the Study**

The primary objective of this study is to clinically validate the efficacy of ASPAROSE CAPSULE in relieving PCOS-related symptoms, including irregular menstrual cycles, abnormal uterine bleeding, and menstrual cramps. The study aims to assess the formulation's therapeutic potential in a controlled clinical setting, evaluating patient-reported outcomes and laboratory investigations before and after treatment.

By bridging the gap between traditional knowledge and scientific research, this study seeks to provide a validated alternative for PCOS management, potentially improving patient outcomes while minimizing the adverse effects associated with conventional therapies.

**METHOD AND MATERIALS:**

**Description of the population to be studied**

The population of Salem city is more than 10,00,000, and the estimated prevalence rates of patients with "Upasravanaroha (Irregular menstrual cycle), Rakthaasravaroha (Abnormal bleeding

disorder), Yonisoola (Pain in vaginal tract), Menstrual cramps," etc. due to Polycystic ovarian syndrome (PCOS), shall be more than 30 % in the area. To recruit the participants, we had advertised in the Social media (friend's groups, Local groups, Private Siddha/Ayurveda doctor groups, and on the Facebook pages of Siddha/Ayurveda hospitals and creating awareness in public exhibitions.

**Responsibility of potential risks and benefits, if any, to human subjects**

As per Siddha/Ayurveda textual references found in First schedule (section 3a) of Drugs and cosmetic act 1940, and scientific research studies done anywhere regarding the herbal ingredients found in the formula supplied by the manufacturing unit, an Undertaking has been obtained from the Manufacturer of the product that the Sample supplied for clinical trials contains only the herbal ingredients mentioned in the references found in first schedule Siddha/Ayurveda classical texts.

The Clinical research center has recruited the patients willing for the study after obtaining their written consent and provided the medicine in the prescribed dosage indicated in the package under the supervision of qualified Siddha/Ayurveda physician.

It has been clarified to the manufacturer that any Metals if included in the formula should conduct Toxicity studies and Pre-clinical animal studies before conducting clinical trials, and it was also clarified that the Manufacturer of the product is solely responsible for potential risk - if any, to human subjects undergoing this clinical study.

**Quality control and quality assurance**

The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The label should necessarily contain the word "For Clinical studies only".

**Description of and justification for, the route of administration, dosage, dosage regimen, and treatment period**

Route of Administration Dosage - Oral usage
Dosage - 1-2 capsules bds with 100 ml lukewarm water.
Dosage regimen - Morning and night, after food. Treatment period - 30 days.

**Trial study center**

The centre of study is, Outpatient department. CRO - Ashram Siddha research institute, Swarnapuri, Salem city, Salem district.

**IEC clearance**

The prospective Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is duly approved by the Institutional Ethical Committee For Clinical Research of the CRO, Ashram Siddha Research Institute, constituted under Rule-7 and registered under Rule-8 of The Central Drugs Standard Control

Organization (CDSCO) under Directorate General of Health Services, Ministry of Health and Family welfare, Govt. of India as per Ethical guidelines for Biomedical Research on Human subjects 2006 issued by AYUSH-ICMR guidelines. All patients were obtained with written informed consent.

**Sample size and Period of study**

Enrollment: 20 patients
Study Start Date: 29.11.2024
Study Completion Date: 31.12.2024

**Screening of Patients for study:** In the present study, patients suffering from symptoms like "Upasravanaroha (Irregular menstrual cycle), Rakthaasravaroha (Abnormal bleeding disorder), Yonisoola (Pain in vaginal tract), Menstrual cramps," etc. due to Polycystic ovarian syndrome (PCOS), was taken for study. The Inclusion and exclusion were made by recording their past history and through clinical examination. After recruitment, all follow-up visits were performed at the same hospital by qualified Siddha/Ayurveda graduate investigators in keeping with the protocol.

**Obtaining patient consent:** Whenever a patient is included in the study a consent form in his mother tongue (enclosed) detailing the procedures with side effects if any, benefits from the treatment was explained and details, of the follow up visit was also explained. The procedure for referral clause, withdrawal, and adverse effects was explained thoroughly.

**Criteria for Inclusion:** Patients above 20 years and below 40 years, suffering from clinical symptoms like "Upasravanaroha (Irregular menstrual cycle), Rakthaa-sravaroha (Abnormal bleeding disorder), Yonisoola (Pain in vaginal tract), Menstrual cramps," etc. due to polycystic ovarian syndrome (PCOS), was taken for study.

**Criteria for Exclusion:** Participants will be excluded if they are above 45 years, experiencing or have a history of the following: Osteo arthritis, pregnancy, history of drug/alcohol abuse, night/shift-work employment, Diabetic complications, Psoriatic arthritis, and any endocrine disorders.

**Criteria for withdrawal:** During the course of the trial, if any serious conditions develop (or) the symptoms aggravate which require urgent treatment, such subjects may be withdrawn from the trial.

**OUTCOME MEASURE:**

**Routine Examination and assessment as per Indian Medicine Physiology:** The complete History and physical examination of the patients along with Envagaithaervu, tridoshanaadi, saptha dhatu thaervu etc., were recorded in a case sheet on first day. The second Clinical assessment was done on 30th day of treatment.

**Blood test:** Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein.

Samples were analyzed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators.

**Intervention:** The patients were provided with Proprietary Ayurvedic Medicine-ASPAROSE CAPSULE, and advised to take 1-2 capsules, Morning and evening.As Lifestyle management with diet and exercise can improve the condition and patient self- management life style changes were advised.

**Success indicators:** Reduction of minimum 10 percent in symptoms at baseline and at the completion of treatment in the words of the patient, and measured as per the phvsician's conscience, can be taken as Success indicator.

**Laboratory Investigations and discussion:**

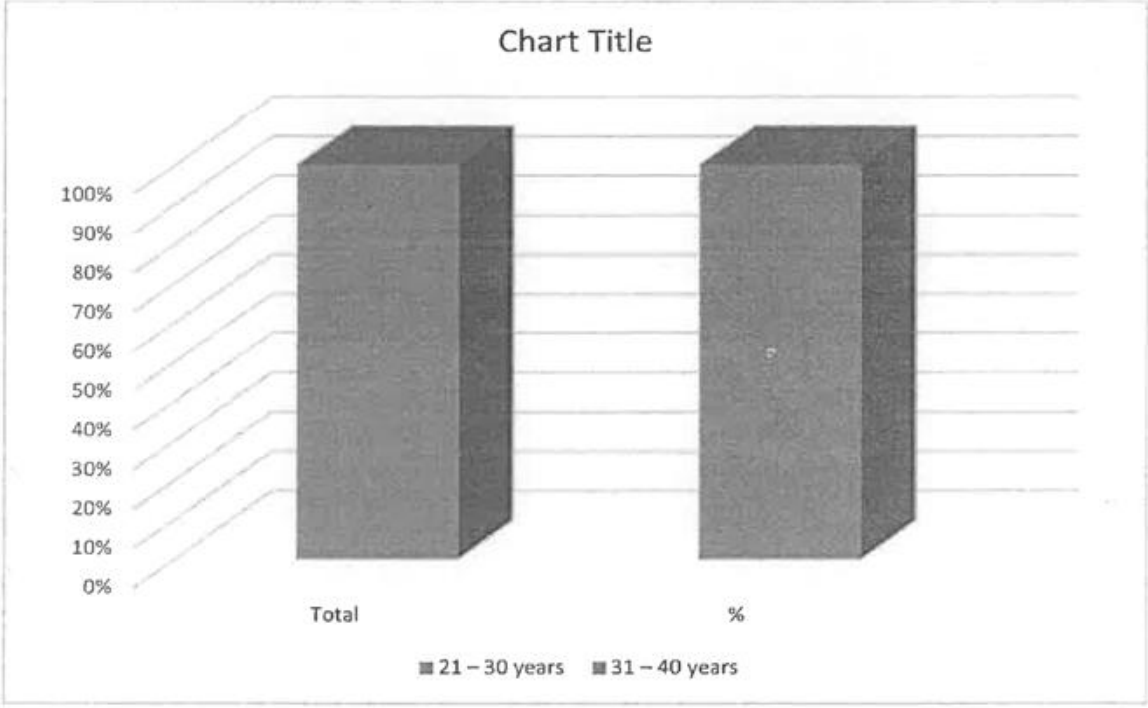
Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators.

| *SPECIMEN* | *TEST NAME* | *METHOD* | *VALUE* | *UNITS* | *REF.RANGE* |
|---|---|---|---|---|---|
| **HAEMATOLOGY** | | | | | |
| Blood | Hemoglobin | Sysmex XS 8ooi | .. | g/dl | 13.0-17.0 |
| Blood | RBC count | Sysmex XS 8ooi | .. | mil/cu.P | 4.5-6.5 |
| Blood | Haematocrit (PCV) | Sysmex XS 8ooi | .. | % | 40-54 |
| Blood | MCV | Sysmex XS 8ooi | .. | fl | 75-95 |
| Blood | MCH | Sysmex XS 8ooi | .. | picogram | 27-32 |
| Blood | MCHC | Sysmex XS 8ooi | .. | g/dl | 32-36 |
| Blood | Red cell width | Sysmex XS 8ooi | .. | % | 11-16 |
| Blood | Platelet counts | Sysmex XS 8ooi | .. | lakhs/cumm | 1.5-4.0 |
| Blood | Total WBC count | Sysmex XS 8ooi | .. | cells/cumm | 4000-11000 |
| Blood | Differential count (DC) | VESMATIC ESAY | | | |
| | Neutrophils | | .. | % | 40-80 |
| | Lymphocytes | | .. | % | 20-40 |
| | Eosinophils | | .. | % | 01-06 |
| | ESR | | .. | mm/hr | 0-10 |
| **CLINICAL PATHOLOGY** URINE COMPLETE | | | | | |
| Urine | Protein | Combur UX strip (ROCHE) | | .. | |
| Urine | Ketone | | | .. | |
| Urine | Pus cells | | | .. | /Hpf |
| Urine | Epithelial cells | | | .. | /Hpf |

## Discussion and Statistical analysis of the Results Obtained

**TABLE -1 ; Age group of Patients (20)**

| Age group | Total | % |
|---|---|---|
| 21–30 years | 12 | 60% |
| 31–40 years | 8 | 40% |

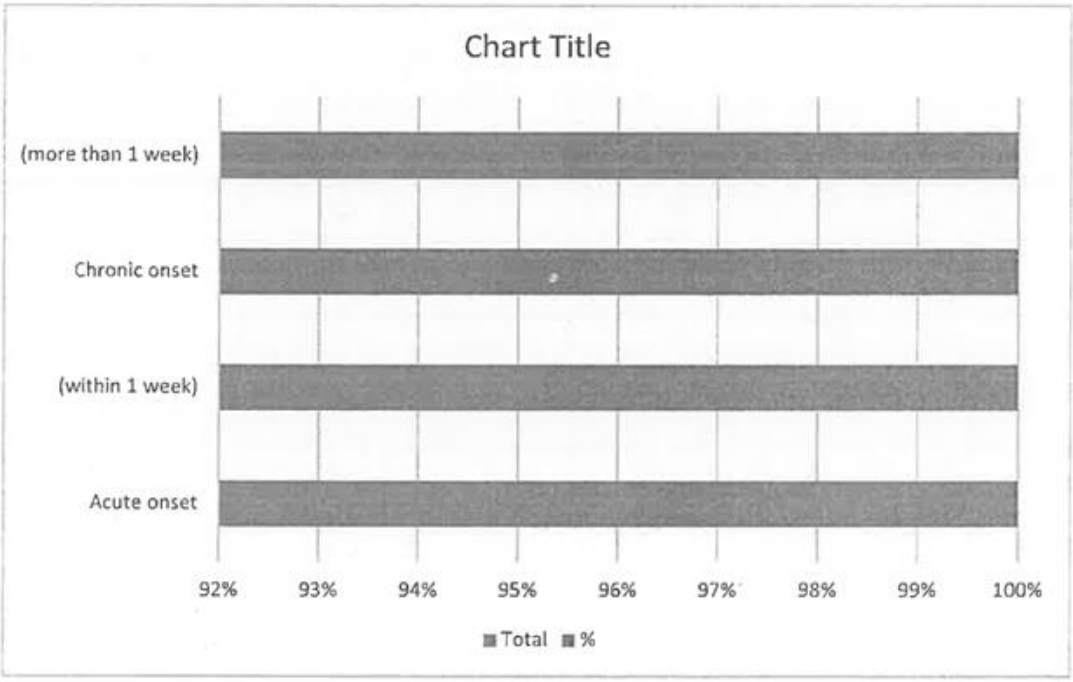



**Interpretation**

From the above chart, the sample size of the study is 20, out of which For the treatment of 30 days, 12 patients belonging to age group 21-30 years and 8 patients belonging to age group 31-40 years respectively were taken for study.

**TABLE – 2; Chronicity of the Disease (20)**

| Onset | | Total | % |
|---|---|---|---|
| Acute onset (within 3 months) | 21-30 years | 6 | 60% |
| | 31-40 years | 4 | 40% |
| Chronic onset (more than 3 months) | 21-30 years | 4 | 40% |
| | 31-40 years | 6 | 60% |

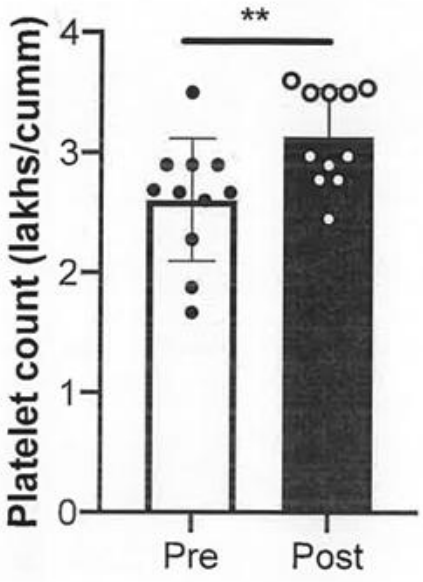



**Interpretation**

From the above chart, the sample size of the study is 20, out of which In total, 6 patients belonging to age group 21-30 years and 4 patients belonging to age group 31-40 years respectively who had been taken for study had the symptoms from within 3 months and more than 3 months.

**IMPROVEMENT IN LABORATORY FINDINGS**

**PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS**

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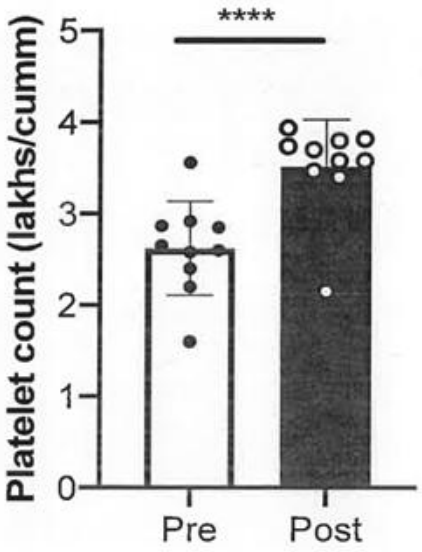


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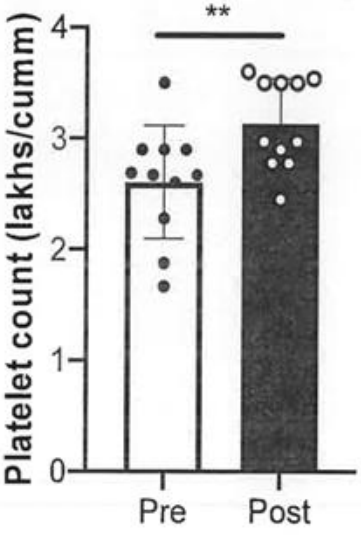


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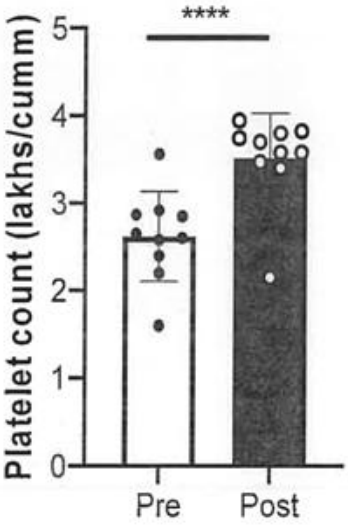


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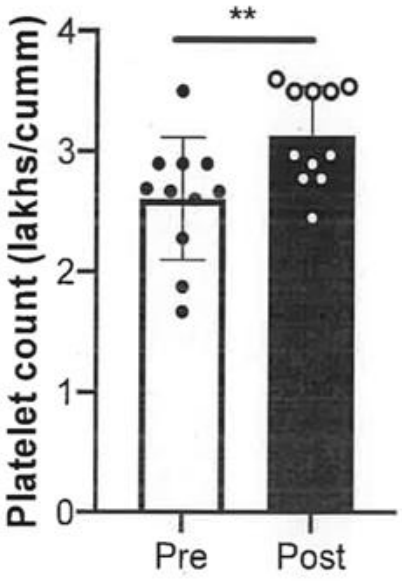


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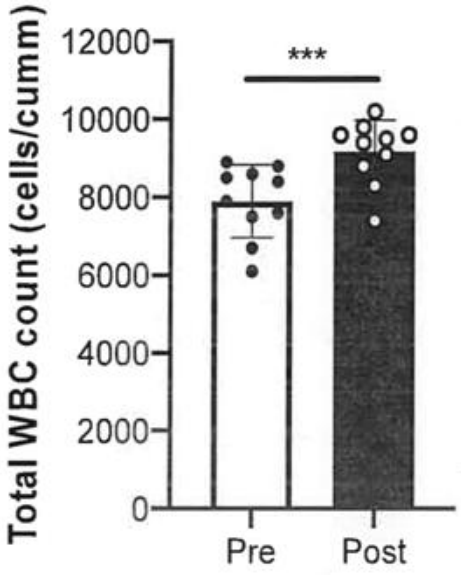


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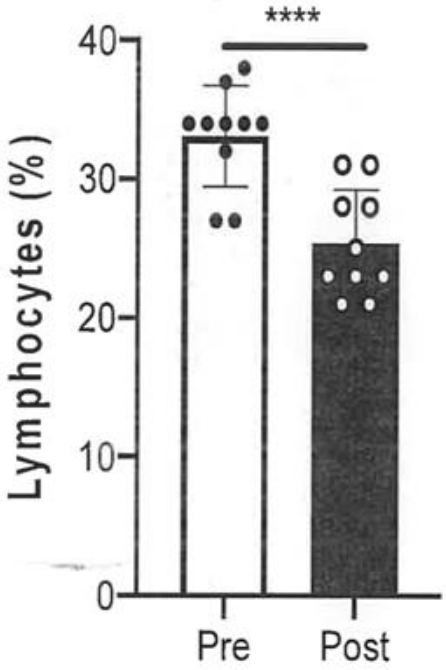


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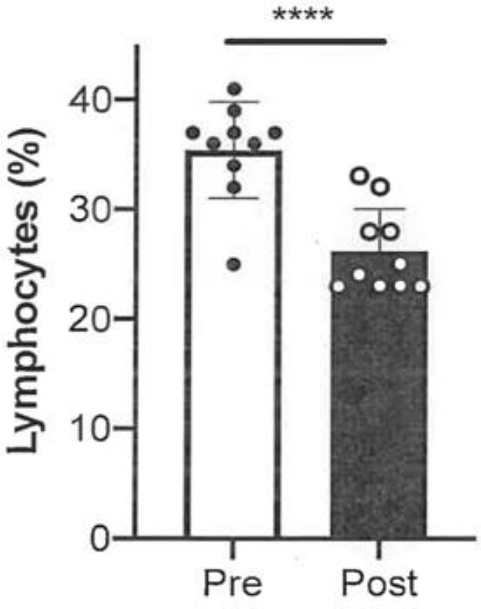


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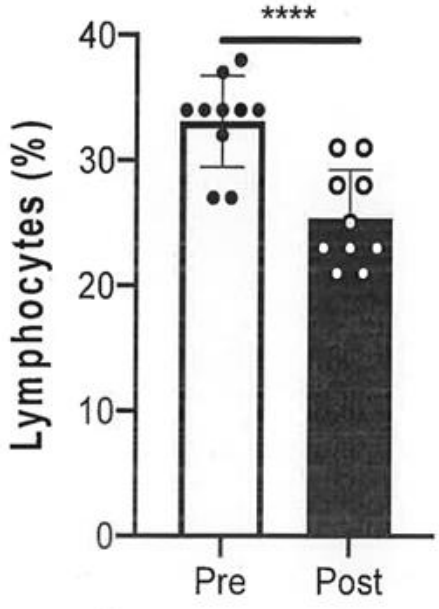


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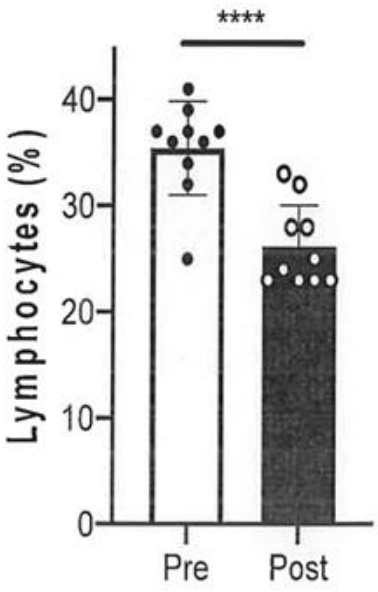


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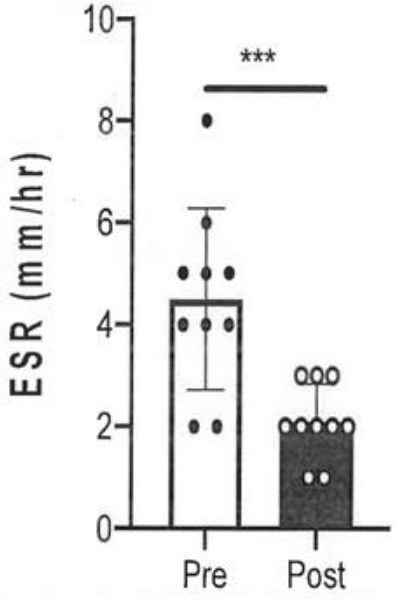


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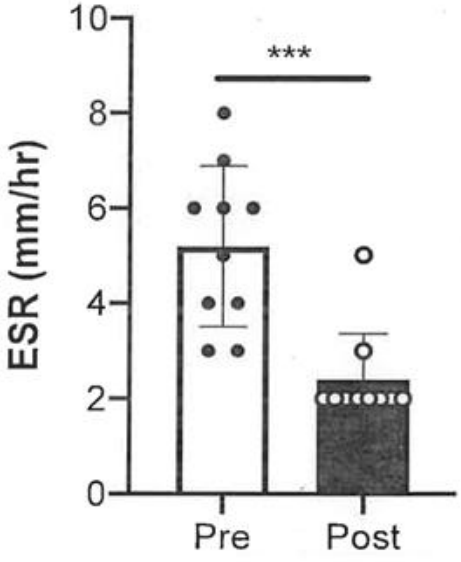


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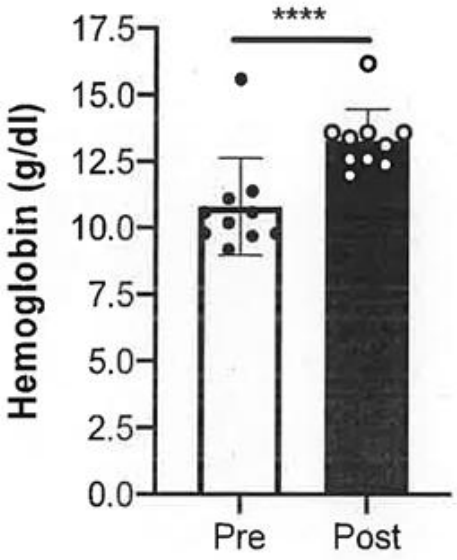


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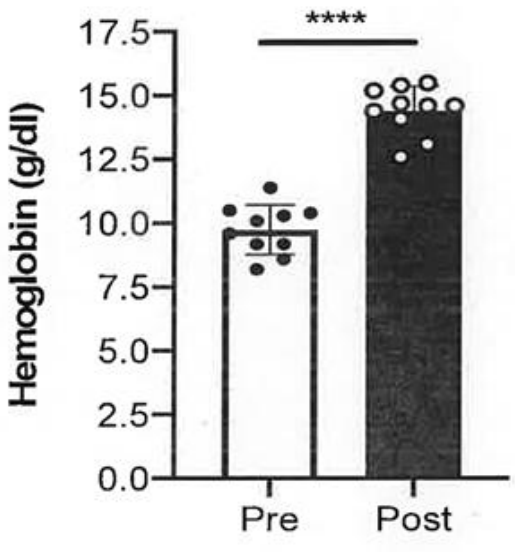


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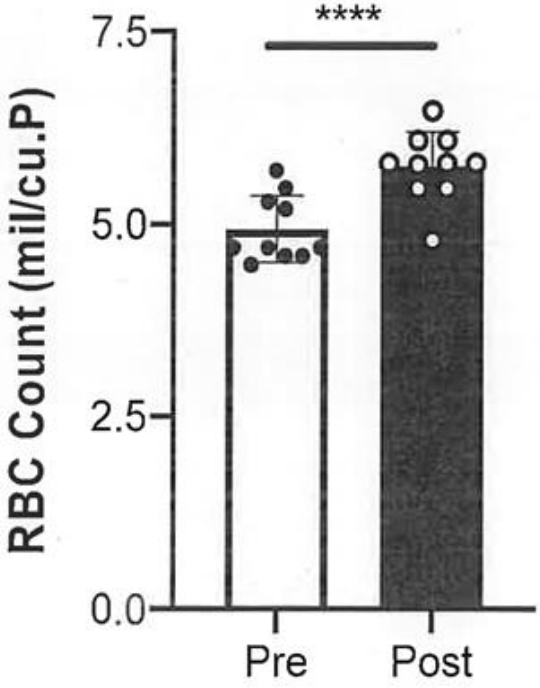


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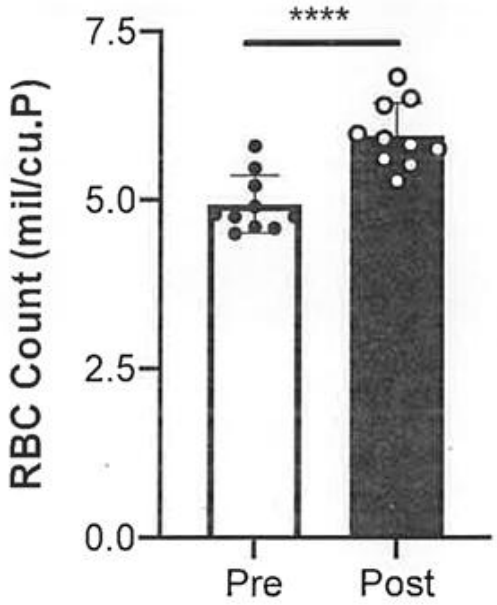
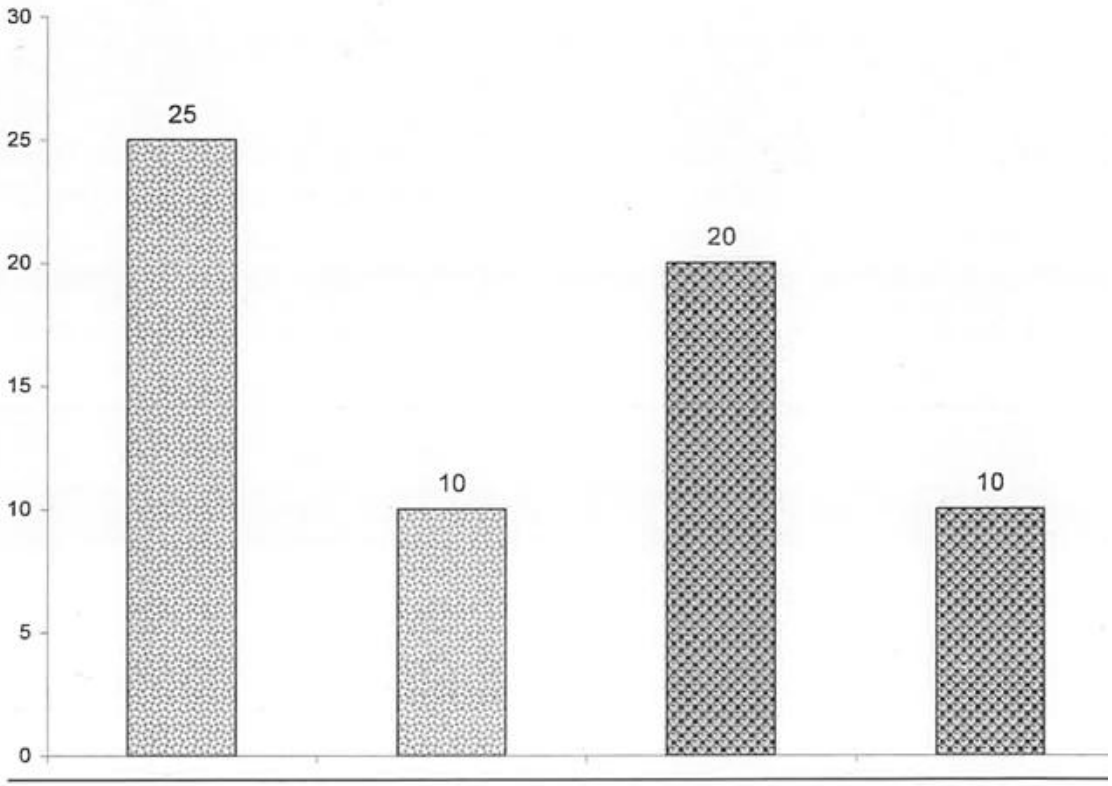



Cohort B

**TABLE – 3; Improvement of Upasravana roha (Irregular menstrual cycle) in One month (20)**

| Age group | Improvement in Criteria Before tmt, | After tmt. | % of Improvement |
|---|---|---|---|
| 21–30 years | 3 | 2 | 75 % |
| 31–40 years | 4 | 2 | 50 % |

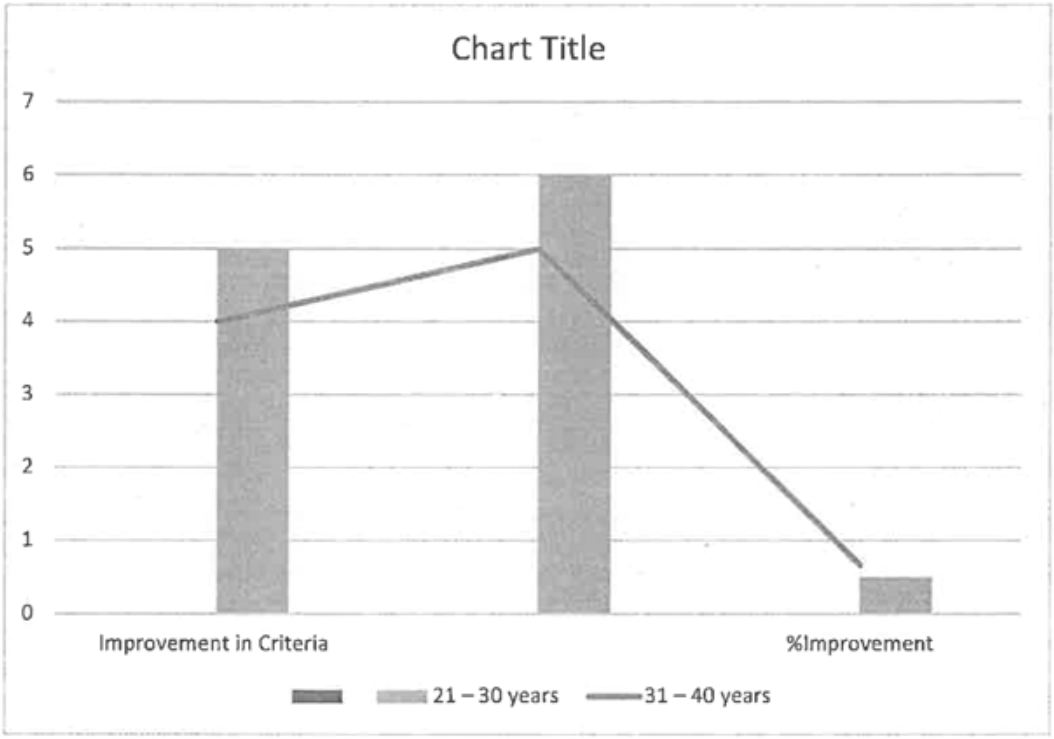



**Interpretation**

From the above chart, the sample size of the study is 20, out of which after the treatment of 30 days, 75% belonging to age group 21-30 years and 50% belonging to age group 31-40 years respectively had significant improvement of *symptoms*.

**TABLE – 4; Improvement of Rakthaasrava roha (Abnormal bleeding disorder) in One month (20)**

| Age group | Improvement in Criteria Before tmt, After tmt. | | %Improvement |
|---|---|---|---|
| 21–30 years | 2 | 4 | 50 % |
| 31–40 years | 3 | 4 | 74.6 % |

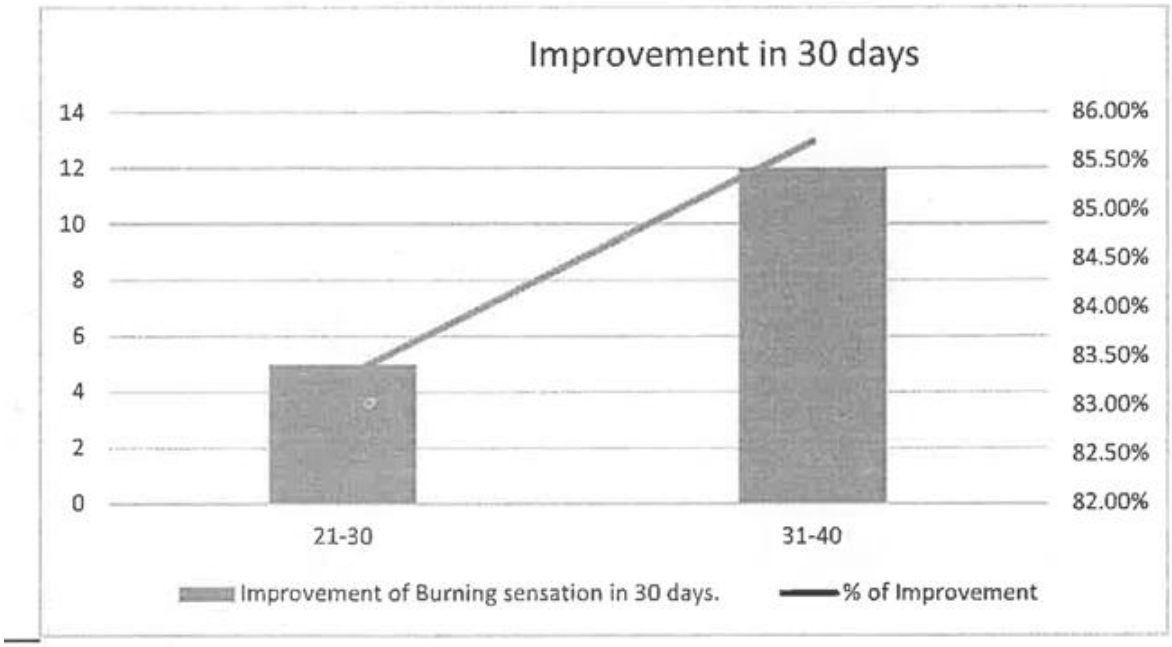



**Interpretation**

From the above chart, the sample size of the study is 20, out of which after the treatment of 30 days, 50% belonging to age group 21-30 years and 75% belonging to age group 31-40 years respectively had significant improvement of symptoms.

**TABLE – 5; Improvement of Yonisoola (Pain in vaginal tract), Menstrual cramps, in One month (20)**

| Age group | Improvement in 30 days. | % of Improvement |
|---|---|---|
| 21-30 | 4 | 83.3 % |
| 31-40 | 3 | 85.7 % |



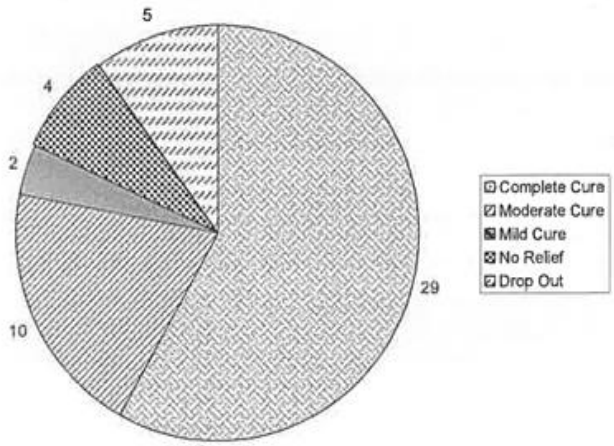

**Interpretation**

From the above chart, the sample size of the study is 20, out of which after the treatment of 30 days, 83% belonging to age group 21-30 years and 86% belonging to age group 31-40 years respectively had significant improvement of symptoms.

**Table – 6; Overall results of Treatment in reduction of Clinical symptoms in patients treated (Total 20 patients)**

| Results | No. of patients | Percentage |
|---|---|---|
| Very good improvement | 14 | 70 % |
| Moderate improvement | 02 | 10 % |
| Mild improvement | 02 | 10% |
| No significant relief | 02 | 10 % |
| Drop out | 0 | 0 % |

CHART - 10
OVERALL RESULTS OF TREATMENT




**Interpretation**

After the treatment of 30 days, 14 patients (70%) had very good improvement of symptoms, 2 patients (10%) had moderate improvement, 2 patients (10%) had mild improvement and 2 patients (10%) had no significant improvement from the study.

**Direct access to source data/documents**

We hereby agree that the investigator(s)/institution will permit trial-related monitoring, audits, institutional review board/independent ethics committee review, and regulatory inspection(s), by the Research Council/Department of AYUSH providing direct access to source data/documents.

**Quality control and quality assurance**

The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The table should necessarily contain the word “For Clinical studies only”.

**Compensation to the Participant**

As per GCP guidelines the subjects were compensated for the inconvenience and time present in connection with their participation in this clinical trial,by signing a Voucher after payment of compensation.

**Participant protections and ethics**

To protect human participants, the protocol was written according to general ethical guidelines, such as the Declaration of Helsinki and Good Clinical Practice and was approved by the institutional ethical committee of the organization. The study participant consent process includes information about potential risks, benefits, alternatives, and responsibilities during the trial.

Before participants agree to participate in this trial, researchers will explain this information in detail in person.

**Data and safety monitoring**

Regular monitoring that will be clarified in a standard operating procedure will be conducted to ensure good data quality. Monitors from IEC will evaluate whether the case report forms are properly written and whether the recruiting and treatment procedures are adequately performed according to the protocol. Investigators will be contacted to discuss whether it is necessary to revise the study protocol or inclusion criteria and other important issues. The investigators and independent researchers will assess the progress of the clinical trial and severe adverse events and determine whether they are acceptable and whether it will be necessary for the trial to be modified or stopped.

Case Sheets prepared for each patient and all the records and vouchers will be retained with the treatment centre for Three years.

**CONCLUSION**

Phase-II-A, Single center, Open label, Therapeutic exploratory clinical validation The current Phase-II-A, Single center, Open label, Therapeutic exploratory clinical validation is designed to evaluate the efficacy of Proprietary Ayurvedic Medicine - ASPAROSE CAPSULE, Manufactured by Vijayani Nutraceuticals P. Ltd, No.2B/1,2B/2, 6th street, 3rd Main road, Ambattur Industrial estate South,

Ambattur, Chennai-600058 on patientssuffering from clinical symptoms of “Upasravanaroha (Irregular menstrual cycle), Rakthaasravaroha (Abnormal bleeding disorder), Yonisoola (Pain in vaginal tract), Menstrual cramps,” etc. due to Polycystic ovarian syndrome (PCOS).

By consolidating the results obtained in the clinical investigations and laboratory investigations, it is hereby concluded that the Proprietary Ayurvedic Medicine - ASPAROSE CAPSULE, is highly effective in controlling Clinical symptoms of “Upasravanaroha (Irregular menstrual cycle), Rakthaasravaroha (Abnormal bleeding disorder), Yonisoola (Pain in vaginal tract), Menstrual cramps,” etc. due to Polycystic ovarian syndrome (PCOS),in the recruited patients.

**REFERENCES**


1. Teede HJ, Misso ML, Costello MF, et al. Recommendations from the international evidence-based guideline for the assessment and management of polycystic ovary syndrome. Hum Reprod. 2018;33(9):1602-1618.
2. Azziz R, Carmina E, Chen Z, et al. Polycystic ovary syndrome. Nat Rev Dis Primers. 2016; 2:16057.
3. Lizneva D, Suturina L, Walker W, Brakta S, Gavrilova-Jordan L, Azziz R. Criteria, prevalence, and phenotypes of PCOS. Fertil Steril. 2016; 106(1):6-15.
4. Goodarzi MO, Dumesic DA, Chazenbalk G, Azziz R. Polycystic ovary syndrome: Etiology, pathogenesis and diagnosis. Nat Rev Endocrinol. 2011; 7(4):219-231.
5. Diamanti-Kandarakis E, Dunaif A. Insulin resistance and the polycystic ovary syndrome revisited: An update on mechanisms and implications. Endocr Rev. 2012;33(6):981-1030.
6. Escobar-Morreale HF. Polycystic ovary syndrome: definition, aetiology, diagnosis and treatment. Nat Rev Endocrinol. 2018; 14(5):270-284.
7. Norman RJ, Dewailly D, Legro RS, Hickey TE. Polycystic ovary syndrome. Lancet. 2007;370(9588):685-697.
8. Dokras A, Clifton S, Futterweit W, Wild R. Increased risk for abnormal depression scores in women with polycystic ovary syndrome: a systematic review and meta-analysis. Obstet Gynecol. 2011; 118(3):583-592.
9. Moran LJ, Misso ML, Wild RA, Norman RJ. Impaired glucose tolerance, type 2 diabetes and metabolic syndrome in PCOS: A systematic review and meta-analysis. Hum Reprod Update. 2010;16(4):347-363.
10. Hoeger KM, Dokras A, Piltonen T. Update on PCOS: Consequences, challenges, and guiding treatment. J Clin Endocrinol Metab. 2021;106(3):e1071-e1083.
11. Legro RS, Arslanian SA, Ehrmann DA, et al. Diagnosis and treatment of polycystic ovary syndrome: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2013; 98(12):4565-4592.
12. Palomba S, Santagni S, Falbo A, La Sala GB. Complications and challenges associated with polycystic ovary syndrome. Expert Rev Obstet Gynecol. 2015;10(1):97-118.
13. Lim SS, Hutchison SK, Van Ryswyk E, Norman RJ, Teede HJ, Moran LJ. Lifestyle interventions in polycystic ovary

syndrome. Hum Reprod Update. 2019;25(2):259-282.
14. Thakker D, Raval A, Patel I. Study of lifestyle modification on PCOS patients. Indian J Endocrinol Metab. 2014; 18(2):299-301.
15. Sharma S, Saxena A, Mishra A, et al. Herbal interventions in PCOS: Evidence-based review. J Ethnopharmacol. 2020; 260:113099.

**S. Suman, P. Karthikeyan, S. Moulishankar, et.al (2025).** Open Label Single Centric Clinical Exploratory Of Efficacy Study On Asparose Capsule, An Ayurvedic Proprietary Formulation, ijmaes; 11(1); 2030-2048.