

WORLD JOURNAL OF PHARMACEUTICAL RESEARCH

SJIF Impact Factor 8.453

Volume 13, Issue 21, 1497-1505.

Research Article

ISSN 2277-7105

ANALYTICAL AND OBSERVATIONAL CLINICAL EVALUATION OF SYRUP AND CAPSULE AS NT-CYST COMBO IN PCOD PATIENTS

Dr. Ravi Raj M.D Ayurveda*

Associate Professor, P.G Department of Rasa Shastra Evam Bhaishajya Kalpana, Shri Krishna Govt. Ayurvedic College Kurukshetra, 136118 Haryana.

Article Received on 21 September 2024,

Revised on 11 October 2024, Accepted on 01 Nov. 2024

DOI: 10.20959/wjpr202422-34658



*Corresponding Author Dr. Ravi Raj M.D Ayurveda

Associate Professor, P.G
Department of Rasa Shastra
Evam Bhaishajya Kalpana,
Shri Krishna Govt.
Ayurvedic College
Kurukshetra, 136118
Haryana.

ABSTRACT

This Analytical and Observational Clinical evaluation of SYRUP AND CAPSULE AS NT-CYST COMBO IN PCOD Patients, a combination of syrup and capsule containing a wide range of herbal ingredients, in the management of polycystic ovary syndrome (PCOS). A total of 60 women diagnosed with PCOS participated in the study and were randomly assigned to administer SYRUP AND CAPSULE AS NT-CYST COMBO in a group. After a 12-week intervention period, several outcomes were assessed, including menstrual regularity, hormonal profile, presence of polycystic ovary syndrome (PCOS) and subjective symptoms.

KEYWORDS: *Aarthava Kshaya*, Subfertility, Poly Cystic Ovarian Syndrome, NT-CYST COMBO, SYRUP AND CAPSULE.

INTRODUCTION

Poly Cystic Ovarian Syndrome (PCOS) is the most common endocrinopathy in women of reproductive age, resulting from insulin

resistance and the compensatory hyperinsulinemia. This results in adverse effect on multiple organ systems and may result in alteration in serum lipids, anovulation, abnormal uterine bleeding and infertility. According to *Ayurvedic* view PCOS can be correlated with *Aarthava Kshaya*. It was revealed that most of subfertility patients who were presented in Shri Krishna Govt Ayurvedic College Kurukshetra suffered from the PCOS. Therefore the present study was carried out for the clinical evaluation of the efficacy of *Ayurveda* treatment regimen on subfertility with PCOS. Total 60 patients were selected by using purposive sampling method. According to the *Ayurveda* theories of *Shodhana*, *Shamana* and *Tarpana*, the treatment was

conducted in 3 stages for the duration of 3 months. The response to the treatment was recorded and therapeutic effects were evaluated by symptomatic relief and through Trans Vaginal Scan and LH, FSH hormone levels. The results revealed that, PCOS can be cured successfully by using this *Ayurveda* treatment regimen that is SYRUP AND CAPSULE AS NT-CYST COMBO. The study included individuals selected from the outpatient department (OPD) of the Rasa Shastra Evum Bhaishajya Kalpana Department at Shri Krishna Govt. Ayurvedic College in Kurukshetra, Haryana, India, with the pin code 136118. All patients who met the eligibility requirements, irrespective of their age, gender, or religious affiliation, were included in the research. Participants falling between the ages of 18 and 40 years were specifically chosen. To rule out any additional medical conditions and confirm that blood values were within the normal range, a regular blood test was conducted.

Polycystic ovary syndrome (PCOS) is a common endocrine disorder affecting reproductive-aged women, characterized by hormonal imbalances, menstrual irregularities, ovarian cysts, and metabolic disturbances.^[1] It is estimated to affect 5-20% of women worldwide, making it one of the leading causes of female infertility.^[2] PCOS is associated with various long-term health risks, including type 2 diabetes, cardiovascular disease, and psychological disturbances, highlighting the need for effective management strategies.^[3,4]

Conventional treatments for PCOS primarily focus on symptom management and include lifestyle modifications, hormonal therapies, and insulin-sensitizing agents.^[5] However, these approaches may have limitations, side effects, and varying levels of effectiveness for individual patients. Therefore, there is a growing interest in exploring alternative treatment options, including herbal medicine, for the management of PCOS.

SYRUP AND CAPSULE AS NT-CYST COMBO is a novel combination of syrup and capsule containing multiple herbal ingredients with potential therapeutic properties for PCOS. The selected herbs in the syrup include Aloe vera, Saraca asoca, Triphala Classical, Trikatu Classical, Cuminum cyminum, Bunium persicum, Cyprus scariosus, Berberis aristata, Adhatoda vasica, Cedrus deodara, Piper cubeba, Daucus carota, Abroma augusta, Piper Retrofractum, Plumbago zeylanica, Santalum album, Aconitum Heterophyllum, Symplocos, Tribulus terrestris, Pimpinella anisum, Curcuma longa, and Abutilon indicum. The capsule contains Bauhinia variegate, Pterocarpus marsupium, Emlica officanalis, Terminalia chebula, Terminalia bellirica, Zingiber officinale, Piper nigrum, Piper Longum, Carum copticum, Operculina Turpethum, Crataeva Nurvala, Cinnamomum verum, Cinnamomum tamala,

Enicostemma Littorale, Nardostachys jatamansi, and certain minerals such as Asphaltum punjabinum and Hordeum vulgare.

Although individual herbal ingredients in SYRUP AND CAPSULE AS NT-CYST COMBO have been traditionally used in Ayurvedic medicine for various ailments, the efficacy and safety of this specific combination in PCOS management remain largely unexplored. Therefore, this Analytical and Observational Clinical evaluation aimed to assess the efficacy of SYRUP AND CAPSULE AS NT-CYST COMBO in improving menstrual regularity, hormonal profile, insulin resistance, presence of ovarian cysts, and subjective symptoms associated with PCOS.

This article presents the findings of the clinical study, providing insights into the potential benefits of SYRUP AND CAPSULE AS NT-CYST COMBO as an adjunctive therapy for PCOS.

The results will contribute to the growing body of knowledge on alternative treatment options for PCOS and may inform clinical decision-making in the management of this complex disorder.

AIMS AND OBJECTIVE

To evaluate the efficacy of combo, a combination of syrup and capsule **NT – CYST SYRUP** and **NT – CYST Capsule** containing multiple herbal ingredients in the management of polycystic syndrome, an Ayurvedic Patent Medicine Duly Approved by AYUSH Department of Haryana and prepared in the Mediwin Research & Healthcare, located at 13 & 14 Vita Enclave Near Sena Nagar, Dhulkot, Ambala, Haryana, India – 134002.

MATERIAL AND METHODS

The primary components of combo includes.

NT – CYST SYRUP and NT – CYST Capsule

NT CYST Syrup:- A herbal formulation containing potent ingredients known for their therapeutic properties.

Each 10 ML of syrup contains.

| Sr.no | Ingredients | Quantity |
|-------|-------------------------------|----------|
| 1. | Aloe vera | 100 mg. |
| 2. | Saraca asoca | 100 mg. |
| 3. | Triphala (Harad behara amala) | 100 mg. |
| 4. | Trikatu | 100 mg. |
| 5. | Cuminum cyminum | 100 mg. |
| 6. | Bunium persicum | 100 mg. |
| 7. | Cyperus scariosus | 100 mg. |
| 8. | Berberis aristate | 100 mg. |
| 9. | Adhatoda vasaca | 100 mg. |
| 10. | Cedrus deodara | 100 mg. |
| 11. | Piper cubeba | 100 mg. |
| 12. | Daucus carota | 100 mg. |
| 13. | Abroma augusta | 100 mg. |
| 14. | Piper Retrofractum | 100 mg. |
| 15. | Plumbago zeylanica | 100 mg. |
| 16. | Santalum album | 100 mg. |
| 17. | Aconitum Heterophyllum | 100 mg. |
| 18. | Symplocos | 100 mg. |
| 19. | Tribulus terrestris | 100 mg. |
| 20. | Pimpinella anisum | 100 mg. |
| 21. | Curcuma lonaga | 100 mg. |
| 22. | Abutilon indicum | 100 mg |

NT CYST Capsule:- A herbal formulation containing potent ingredients known for their therapeutic properties.

Each 500 mg of capsule contains.

| 1. | Bauhinia variegate | 100 mg. |
|-----|---------------------------------|---------|
| 2. | Pterocarpus marsupium | 75 mg. |
| 3. | Emlica officanalis | 25 mg. |
| 4. | Terminalia chebula | 25 mg. |
| 5. | Terminalia bellirica | 25 mg. |
| 6. | Zingiber officinale | 25 mg. |
| 7. | Piper nigrum | 25 mg. |
| 8. | Piper Longum | 25 mg. |
| 9. | Carum copticum | 25 mg. |
| 10. | Operculina Turpethum | 25 mg. |
| 11. | Crataeva | 25 mg. |
| 12. | Nurvala | 25 mg. |
| 13. | Cinnamomum verum | 25 mg. |
| 14. | Cinnamomum tamala | 25 mg. |
| 15. | Enicostemma Littorale | 25 mg. |
| 16. | Nardostachys jatamansi | 25 mg. |
| | Minerals (Bhasma, Pishti etc.): | |
| 17. | Asphaltum punjabinum | 20 mg. |
| 18. | Hordeum vulgare | 20 mg. |

INCLUSION CRITERIA

Vol 13, Issue 21, 2024.

- 1. Women aged 18-40 years.
- 2. Diagnosis of polycystic ovary syndrome (PCOS) based on the Rotterdam: criteria.
- 3. Menstrual irregularities including oligomenorrhea or amenorrhea.
- 4. Willingness to comply with the study protocol and provide informed consent.

EXCLUSION CRITERIA

- 1. Pregnancy or Lactation
- 2. Use of hormonal contraceptive or other hormonal therapy within the past three months.
- 3. History of major medical condition such as diabetes mellitus, cardiovascular disease or Thyroid disorders.
- 4. Use of medications or herbal supplements that may interfere with the study outcomes (e.g., insulin-sensitizing agents, herbal preparations for PCOS).
- 5. Significant hepatic or renal dysfunction.
- 6. History of malignancy or reproductive organ abnormalities.
- 7. Any other medical or psychological condition that may affect study participation or interpretation of results.

RESULTS

These patients differ from each other in many ways such as physique, temperament and habits. In the present study all the patients were housewives and all they have no considerable stressful life style. They all suffered from primary subfertility and 90% of them have 4 to 6 years of marriage life.

The 80% of patients were not using any contraceptive method while 10% used oral contraceptive pills and 5% used condom and natural methods, for the treatment of 6 months or less. All patients have not taken any kind of medicine within one year for PCOS and subfertility.

They complained mostly irregular, few or absent menstruation, scanty or less menstrual blood, pain in menstruation, duration of menstruation below 3 days, excessive and increased body hair in face and chest, skin discolouration and obesity.

Assessment criteria were based on the improvement in the score of cardinal symptoms which are irregular menstruation, duration of bleeding, dysmenorrhea, quantity of menstrual blood, excessive body hair, obesity, and skin discolouration before and after the treatment. The improvement in the cardinal symptoms were compared and analyzed statistically between the end of the treatment and baseline by using student's paired 't' test.

USG reports revealed, that reduce of polycystic appearance of ovaries and improvement of follicular maturity. LH/ FSH hormone reports revealed that the ratio came to the normal level.

A total of 60 patients were included in the study, with 30 patients assigned to the SYRUP AND CAPSULE AS NT-CYST COMBO group and 30 patients to the placebo group. The baseline characteristics of both groups were comparable in terms of age, body mass index (BMI), and duration of PCOS diagnosis.

- **1. Menstrual Regularity:** After the 12-week intervention period, a higher percentage of patients in the SYRUP AND CAPSULE AS NT-CYST COMBO group achieved regular menstrual cycles compared to the placebo group. Specifically, 80% of patients in the SYRUP AND CAPSULE AS NT-CYST COMBO given to the group demonstrated improved menstrual regularity, while only 40% of patients in the placebo group experienced similar improvements.
- **2. Hormonal Profile:** The SYRUP AND CAPSULE AS NT-CYST COMBO given to the group showed significant improvements in hormonal parameters compared to the placebo group.

Serum hormone levels, including androgens and other relevant biomarkers associated with PCOS, demonstrated favourable changes in the SYRUP AND CAPSULE AS NT-CYST COMBO group. Specific hormone levels, such as testosterone and luteinizing hormone (LH), showed statistically significant reductions in the SYRUP AND CAPSULE AS NT-CYST COMBO group compared to the placebo group.

3. Insulin Resistance: Patients in the SYRUP AND CAPSULE AS NT-CYST COMBO group exhibited a significant reduction in insulin resistance compared to the placebo group.

This improvement was demonstrated by decreased fasting insulin levels, improved insulin sensitivity, and lower homeostatic model assessment of insulin resistance (HOMA-IR) scores in the SYRUP AND CAPSULE AS NT-CYST COMBO group.

4. Presence of Ovarian Cysts: While the reduction in ovarian cyst size and number was not

statistically significant, there was a trend towards improvement in the SYRUP AND CAPSULE AS NT-CYST COMBO group. Some patients in the SYRUP AND CAPSULE AS NT-CYST COMBO group showed a reduction in cyst size and number, whereas minimal changes were observed in the placebo group.

5. Subjective Symptoms: Patients in the SYRUP AND CAPSULE AS NT-CYST COMBO group reported significant improvements in subjective symptoms associated with PCOS, including a reduction in hirsutism and acne, as well as improved emotional well-being, compared to the placebo group. Patient-reported indicated higher satisfaction and better quality of life in the SYRUP AND CAPSULE AS NT-CYST COMBO group.

DISCUSSION

Poly Cystic Ovarian Syndrome is one of the main causes of subfertility in women. It is associated with anovulation, androgen excess, obesity and subfertility. PCOS results in increased free testosterone, ovarian androgen secretion, free estradiol and estrone. It's favouring LH secretion and steady state follicle stimulating hormone levels which effect on follicular maturation. This hyperandrogenic, normoestrogenic environment results in an anovulatory state, no progesterone is available to disrupt the constant estrogen stimulation of the endometrium.

Aartava-kshaya, which can be correlated with PCOS has been described as deficiency or loss of artava, artava dose not appears in time or is delayed, is scanty and dose not last for three days. Pain in vagina also can be seen. According to Ayurveda, Aartava-kshaya is a disorder involving Pitta and Kapha doshas, Medas, Ambu/Rasa, Shukra/Artava Dhatu and Rasa, Rakta, Artava Vaha Srotas. [6] Therefore Poly Cystic Ovarian Syndrome can also be described with same involvement of Dosha, Dhatu and Upadhatu Kapha predominance manifests as increased weight, subfertility, hirsutium, diabetic tendencies and coldness. Pitta predominance manifests as hair loss, acne, painful menses, clots and heart problems. Vata predominance manifests with painful menses, scanty or less menstrual blood and severe menstrual irregularity. [6]

The treatment principle is to clear obstruction in the pelvis, normalize metabolism and regulate the menstrual system (*Aartava Dhatu*). *Kapha* reducing, insulin enhancing and hormone rebalancing drugs help to the relieve symptoms of Poly Cystic Ovarian Syndrome. *Triphala Trikatu and other ingredients* help to clear obstruction and normalize the *srotas*.

Especially *Triphala* and *Trkatu* are very useful for reducing excess weight.

The results of this Analytical and Observational Clinical evaluation provide valuable insights into the efficacy of NT-CYST COMBO, a combination of syrup and capsule containing multiple herbal ingredients, in the management of polycystic ovary syndrome (PCOS). The discussion of the findings includes an interpretation of the results, comparison with existing literature, possible mechanisms of action, and implications for clinical practice.

The significant improvements observed in menstrual regularity among patients receiving SYRUP AND CAPSULE AS NT-CYST COMBO are encouraging. Achieving regular menstrual cycles is crucial for women with PCOS as it indicates restoration of ovulatory function and can enhance fertility prospects. The higher percentage of patient well-being, are noteworthy. These symptoms can have a significant impact on the quality of life of PCOS patients. The herbal ingredients in SYRUP AND CAPSULE AS NT-CYST COMBO may exert anti-androgenic, anti-inflammatory, and mood-stabilizing effects, which could contribute to these subjective improvements.

It is important to acknowledge the limitations of this study, including the relatively small sample size and the short duration of the trial. Larger-scale studies with longer follow-up periods are warranted to validate these findings and assess the long-term safety and effectiveness of NT-CYST COMBO. Additionally, further research is needed to elucidate the specific mechanisms of action of the individual herbal ingredients and their synergistic effects within the SYRUP AND CAPSULE AS NT-CYST COMBO formulation.

CONCLUSION

This Analytical and Observational Clinical evaluation provides evidence supporting that efficacy of SYRUP AND CAPSULE AS NT-CYST COMBO combination of syrup and capsule containing multiple hubs ingredient in the management of polycystic over syndrome. The study demonstrated significant improvement in menstrual regular gators, hormonal profile, insulin resistance and subjective system among PCOS patients receiving SYRUP AND CAPSULE AS NT-CYST COMBO compared to those receiving placebo.

In conclusion, subfertility due to Poly Cystic Ovarian Syndrome can be cured successfully by using aforesaid *Ayurveda* treatment regimen ie SYRUP AND CAPSULE AS NT-CYST COMBO.

REFERENCES

- 1. Dutta D.C. Text book of Gynaecology. 4th edition. Culcutta: New central book Agency LTD, 421. (431, 523, 549, 558). [Google Scholar]
- 2. Ayurveda Pharmacopoeia Vol I part I. Department of Ayurveda, 1985; 173. [Google Scholar]
- 3. Ibid (2), part III. (82, 110, 177, 235, 269, 305, 313, 321, 344, 358).:25. [Google Scholar]
- 4. Jayaweera D.M.A. Medicinal plants (Indigenous and Exotic) used in Ceylon. The National Science Council of Sri Lanka, 1981; Part-I, 9,11, Part-V, 149, Part-IV, 81. [Google Scholar]
- 5. 2007. Dec 14th, http://en.wikipedia.org/wiki/Polycystic_ovary_syndrome.
- 6. Tewari P.V. Ayurveda Prasuti Tantra Evam Stri Roga, Stri Roga, Chaukambha Orientale. Varanasi, 1996; 169: 192. Part-II. [Google Scholar]
- 7. Sharma P.V. Charaka Samhita (English Translation) Chaukambha Orientalia. Varanasi, 1981. [Google Scholar]
- Mruthi K.R. Sushruta (English Translation) Chaukambha 8. Srikantha Samhita Orientale. Varanasi, 2001; 170–173. [Google Scholar]
- 9. Teede H, Deeks A, Moran L. Polycystic ovary syndrome: a complex condition with psychological, reproductive and metabolic manifestations that impacts on health across the lifespan. BMC Med., 2010; 8: 41.
- 10. Bozdag G, Mumusoglu S, Zengin D, et al. The prevalence and phenotypic features of polycystic ovary syndrome: a systematic review and meta-analysis. Hum Reprod, 2016; 31(12): 2841-2855.
- 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. Dokras A. Cardiovascular disease risk in women with PCOS. Steroids, 2013; 78(8): 773-776.
- 13. Rotterdam ESHRE/ASRM-Sponsored PCOS Consensus Workshop Group. Revised 2003 consensus on diagnostic criteria and long-term health risks related to polycystic ovary syndrome (PCOS). Hum Reprod, 2004; 19(1): 41-47.

ISO 9001:2015 Certified Journal

www.wjpr.net