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Original Research Article

Effectiveness of the OZiva® plant-based HerBalance supplement in the management of polycystic ovary syndrome: a real-world evidence study

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ABSTRACT

Background: Polycystic ovary syndrome (PCOS) is a complex heterogeneous endocrine disorder that is characterized by polycystic ovaries, chronic anovulation, and hyperandrogenism. We evaluated the efficacy and safety of OZiva® Plant Based HerBalance for PCOS (HBPCOS) supplement therapy on females suffering from symptoms and signs of PCOS.

Methods: This study employed a retrospective, questionnaire-based design to gather real-world evidence. A total of 153 female participants between the age range of 20-50 years diagnosed with PCOS or related symptoms were enrolled in this study. Primary data was collected using an electronic diary, capturing demographic characteristics and pre-treatment and post-treatment statuses of PCOS clinical signs and symptoms.

Results: In this, Female participants, with an average age of 28.70 ± 5.34 years, years and a history of PCOS for an average duration of 3 months, were recruited. Of the female participants, >87% of those with menstrual cramps, >92% with menstrual bleeding issues, 80% with acne, 64% with excess facial hair, 74% with weight management issues, 61% with difficulty conceiving, and >68% with irregular menses experienced complete or partial resolution of their symptoms after three months of consuming OZiva® HBPCOS. There was a statistically significant improvement in symptoms across the participants.

Conclusion: This study shows that PCOS-related infertility, obesity/difficulty managing weight, menstrual issues, and dermatological symptoms/signs have been significantly reduced after consuming OZiva® HBPCOS product for 3 months.

Keywords: Infertility, Menstrual cycle, Polycystic ovary syndrome, Hyperandrogenism, Patient reported outcomes

INTRODUCTION

Polycystic ovary syndrome (PCOS) stands as the prevalent endocrine disorder among women, impacting approximately 8-13% of women in their reproductive years and persisting until menopause, with potential lifelong complications.¹⁻³ Although incredibly common, PCOS presents difficulties for both diagnosis and treatment because the primary symptoms can change depending on the patient's age and the course of treatment must be customized to meet each patient's unique needs. Due to the wide range of potential diagnostic approaches

(e.g. The Rotterdam criteria), available treatments, and frequently contradictory advice, a large international consortium was formed to rigorously examine the evidence and create evidence-based guidelines for diagnosis and treatment.⁴ According to the widely accepted Rotterdam criteria, PCOS is diagnosed when two out of the three criteria are met: hyperandrogenism, oligo-ovulation or anovulation, and polycystic ovaries on ultrasound.⁵ Women with issues of obesity, acne, amenorrhea, excessive hair growth, infertility, pelvic pain, and patches of thick, dark, velvety skin, particularly around the neck, often get a diagnosis of PCOS from

healthcare professionals. Women with PCOS exhibit elevated risks of developing endometrial cancer, cardiovascular disease, dyslipidemia, and type-2 diabetes mellitus.^{6,7} Obesity worsens the presentation of PCOS, thus weight management (weight loss, maintenance or prevention of excess weight gain) and lifestyle management are proposed as the first lines of treatment which include diet, exercise, and behavioural modification.⁸ Reducing symptoms of hyperandrogenism, restoring menstrual regularity, and achieving conception are the main goals of treatment. Treatment for PCOS frequently includes estrogen tablets, metformin, and anti-androgen therapy. Symptomatic approaches, like hair removal and acne treatment, are also common. In certain cases, surgical intervention, which may involve the removal of ovaries, could be required. Letrozole (an aromatase inhibitor), seems to be a more effective treatment for infertility resulting from PCOS than clomiphene citrate, (an anti-estrogen and reference infertility medication). Patients with better metabolism and from a multidisciplinary team may be able to sustain healthy lifestyle modifications like weight loss, increased metabolism, and improved reproductive health. The most popular type of androgen inhibitor for treating menstrual irregularities in PCOS patients who do not want to get pregnant is compound oral contraceptives.⁹

Additionally, studies have found that women diagnosed with PCOS often express notable dissatisfaction with the diagnostic process, information dissemination, and treatment recommendations, leading to sustained psychological distress post-diagnosis.^{10,11} A qualitative analysis involving 10 overweight women diagnosed with PCOS revealed that the majority encountered challenges in weight loss endeavours and perceived that PCOS hindered their ability to lose excess weight.¹² A survey conducted among women diagnosed with PCOS recruited from specialized clinics revealed that most of them expressed dissatisfaction with the effectiveness of oral contraceptives or fertility drugs as treatment options.¹³ There is a scarcity of evidence regarding the perspectives and experiences of both women and clinicians in managing the challenges associated with PCOS, including obstacles to effective management.⁴

Recently, the use of alternative medicine, including herbal medicine, has been gaining popularity in the management of PCOS.¹⁴ A systematic review on polycystic ovaries and herbal remedies showed that aloe vera improves fertility by increasing the number of ovarian follicles and de chiro Inositol lowers blood glucose and lipid levels to mitigate the adverse effects of PCOS-induced diabetes.¹⁵ The effect of herbs in the treatment of PCOS and regulation of menstrual cycle without changes in hormonal levels can be attributed to strengthening of the immune system.¹⁵

OZiva® HBPCOS is an herbal supplement designed to assist women with PCOS by balancing hormones and supporting menstrual health. It is formulated as a powder blend, combining inositol, chromium, two digestive

enzymes, and a proprietary blend of FertizenR™ and FertizenO. The FertizenR™ blend features key ingredients such as fennel seed extract (*Foeniculum vulgare*) standardized to 20% saponins, hibiscus extract (*Hibiscus rosa-sinensis*), flaxseed extract (*Linum usitatissimum* L.) and licorice root extract (*Glycyrrhiza glabra*). FertizenO blend consist of shatavari (*Asparagus racemosus*), ashoka (*Saraca asoca*), chaste berry (*Vitex agnus-castus*), gokhru (*Tribulus terrestris*), which offer benefits including anti-inflammatory effects, hormone regulation, and skin improvement.¹⁶⁻²¹ Despite the well-documented benefits of the individual ingredients in OZiva® HBPCOS, there remains a need for comprehensive research on the supplement's overall effectiveness. To bridge this gap, a questionnaire-based study was conducted to evaluate the impact of OZiva® HBPCOS on menstrual issues, weight management, infertility, and dermatological symptoms associated with PCOS.

METHODS

Study design

This retrospective, questionnaire-based real-world evidence study evaluated PCOS symptoms before and after three months of daily consumption of OZiva® HBPCOS. The Royal Pune Independent Ethics Committee approved the study on 14 June 2022 (IEC no.: RPIEC300622) and the protocol was also registered with the Clinical Trial Registry of India (CTRI/2022/08/044758). The study was conducted for 6 months duration, commenced on 18 August 2022, and was completed by February 2023. A structured questionnaire was employed to evaluate the signs and symptoms of PCOS. Our database contained details of the female patients who had purchased OZiva® HBPCOS for at least 3 months. These patients were contacted and the questionnaire was shared as an electronic-diary with the subjects willing to participate. Before filling in the questionnaire, the patients were required to approve the consent statement. The primary data collected via this e-diary from the subjects included their demographics (age, height, weight, BMI, location-city and state), pre and post treatment status of clinical symptoms and signs of PCOS like menstrual problems, acne, obesity, excess facial hair, etc. noted by the subjects at the same time. The clinical symptoms (pre and post treatment) were assessed on a scale from 1 to 10; scores between 1-3 were categorized as mild, 4 to 6 as moderate, and 7 to 10 as severe. The responses were submitted by the subjects after which the data was extracted for analysis.

Study participants and eligibility criteria

The study targeted female patients of reproductive age diagnosed with PCOS who experienced symptoms like irregular menstrual periods, heavy bleeding, acne, unhealthy weight gain, and infertility. A convenience sampling method was used, including participants who consented without formal sample size calculation. Participants were instructed to take 5 grams of OZiva®

HBPCOS powder daily, mixed with 150 milliliters of water, following the product guidelines for at least three months. After completing the regimen, they filled out a questionnaire to assess the severity of their PCOS symptoms. They completed a questionnaire to assess PCOS symptom severity post-regimen. Along with the supplement, they adhered to a balanced diet focused on low glycemic index foods, engaged in regular physical activity, and practiced stress management techniques like yoga and meditation. This holistic approach aimed to manage PCOS by integrating supplementation with dietary and lifestyle modifications.

Statistical methods

Descriptive statistics included mean \pm SD for continuous variables and counts/percentages for categorical data. BMI was calculated and classified per WHO guidelines. The Wilcoxon signed-rank test assessed the significance of changes in PCOS symptom severity after consuming OZiva® HBPCOS.²²

RESULTS

Demographic and other baseline characteristics

In this study, a total of 153 subjects were enrolled. Among them, the majority, comprising 109 subjects (71.24%), fell within the age range of 20-30 years. The mean age of the participants was 28.70 \pm 5.34 years. Majority of the participants were in the overweight category according to BMI (25.0–29.9 kg/m²) and 45.75% reported to have menstrual cycle intervals between 60 to 90 days (Table 1).

Menstrual cramps

In the study, 32 subjects reported mild, 40 moderate, and 30 severe menstrual cramps. After three months of consuming OZiva® HBPCOS, 28 with mild, 37 with moderate, and 24 with severe cramps experienced complete or partial resolution. Overall, 87.25% of subjects had complete or partial resolution, with over 92% of those with moderate cramps seeing the highest improvement.

Menstrual bleeding

In the study, 56 subjects reported menstrual bleeding issues: 10 mild, 33 moderate, and 13 severe. After consuming OZiva® HBPCOS, 9 with mild, 32 with moderate, and 11 with severe bleeding experienced complete or partial resolution. Overall, 92.86% of subjects had complete or partial recovery, with 32.14% achieving complete resolution and 60.71% partial resolution.

Acne

In the study, 94 subjects reported acne: 17 had mild, 53 moderate, and 24 severe acnes. After consuming OZiva® HBPCOS, 14 with mild, 46 with moderate, and 16 with severe acne experienced complete or partial resolution.

Overall, 80.85% had complete or partial recovery, with 28.72% achieving complete resolution and 52.13% partial resolution.

Excess facial hair

Among 109 subjects with excess facial hair, 27 mild, 33 moderate, and 10 severe cases had complete or partial resolution after three months of consuming OZiva® HBPCOS. Overall, 55 subjects (50.46%) experienced partial recovery.

Table 1: Patient's baseline characteristics and menstrual patterns.

Patient characteristics	N (%)
Age (years)	
20-30	109 (71.24)
31-40	40 (26.13)
41-50	4 (2.61)
Mean age	28.70 \pm 5.34
BMI (kg/m²)	
Normal (18.5–24.9)	43 (28.10)
Overweight (25.0–29.9)	55 (35.95)
Obesity class 1 (30.0-34.9)	31 (20.26)
Obesity class 2 (35.0-39.9)	13 (8.50)
Obesity class 3 (\geq 40.0)	11 (7.19)
Interval between 2 menstrual cycles (days)	
15	9 (5.89)
28-35	29 (18.95)
40-45	45 (29.41)
60-90	70 (45.75)
Days of bleeding	
1-2	29 (18.95)
3-4	41 (26.80)
5-6	50 (32.68)
>6	33 (21.57)

Percentage of study subjects who achieved complete or partial resolution of menstrual problems after completion of therapy

Weight management

Among 119 participants with weight management issues, 17 mild, 49 moderate, and 37 severe cases improved after three months of OZiva® HBPCOS.

Overall, 74.79% experienced resolution of weight management issues.

Improvement in conception rates related to PCOS

Among 21 subjects with difficulty conceiving and weighing 40-119 kg, over 61% experienced resolution after three months of consuming OZiva® HBPCOS. The highest resolution was observed in subjects weighing 40-59 kg, with a 100% improvement rate.

Irregular menses

(68.94%) experienced complete or partial resolution of this issue.

Out of 153 subjects, 132 had irregular menses. After three months of consuming OZiva® HBPCOS, 91 subjects

Table 2: Symptom resolution in PCOS patients' post-therapy.

Variables	N	%	Complete or partial resolution (N)	%	% who had complete or partial resolution by issue
Severity of menstrual cramps before consuming OZiva® HerBalance					
Mild	32	31.37	28	31.46	87.5
Moderate	40	39.22	37	41.57	92.5
Severe	30	29.41	24	26.97	80
Total	102		89		87.25
Severity of menstrual bleeding before consuming OZiva® HerBalance					
Mild	10	17.86	9	17.31	90
Moderate	33	58.93	32	61.54	96.97
Severe	13	23.21	11	21.15	84.62
Total	56		52		92.86
Severity of acne before consuming OZiva® HerBalance					
Mild	17	18.09	14	18.42	82.35
Moderate	53	56.38	46	60.53	86.79
Severe	24	25.53	16	21.05	66.67
Total	94		76		80.85
Severity of excess facial hair before consuming OZiva® HerBalance					
Mild	37	33.94	27	38.57	72.97
Moderate	49	44.95	33	47.14	67.35
Severe	23	21.10	10	14.29	43.48
Total	109		70		64.22
Severity of weight management before consuming OZiva® HerBalance					
Mild	22	18.49	17	19.10	77.27
Moderate	60	50.42	4	55.06	81.67
Severe	37	31.09	23	25.84	62.16
Total	119		8		74.79
Issue faced in conceiving before consuming OZiva® HerBalance					
	N	%	Resolution (n)	%	% who had complete resolution by issue
Difficult to conceive	21	100	13	100	61.9
Total	21		13		
Irregularity of your menstrual periods before consuming OZiva® HerBalance					
	N	%	Regular (n)	%	% who had complete and partial resolution by issue
Irregular	132	100	91	100	68.94
Total	132		91		68.94

Table 3: Effectiveness of OZiva® HBPCOS symptoms: pre- and post-treatment analysis.

Symptoms	Before treatment	After treatment	Wilcoxon signed-rank test
	Mean±SD	Mean±SD	P value
Menstrual cramps	2±0	0.85±0.62	<0.0001
Menstrual bleeding	2±0	0.75±0.58	<.00001
Irregular menses	2±0	0.62±0.93	<0.0001
Infertility related to PCOS	2±0	1.05±0.86	0.0002
Acne	2±0	0.9±0.69	<0.0001
Excess facial hair	2±0	1.22±0.67	<0.0001
Weight management	2±0	1.03±0.69	<0.0001
Abdominal bloating	2±0	0.86±0.62	<0.0001

N=Number of subjects, p=level of significance, SD=standard deviation; before treatment, for subjects with symptoms, the score given was 2; after treatment, the score for subjects with complete recovery was 0, partially recovered=1, not recovered=2

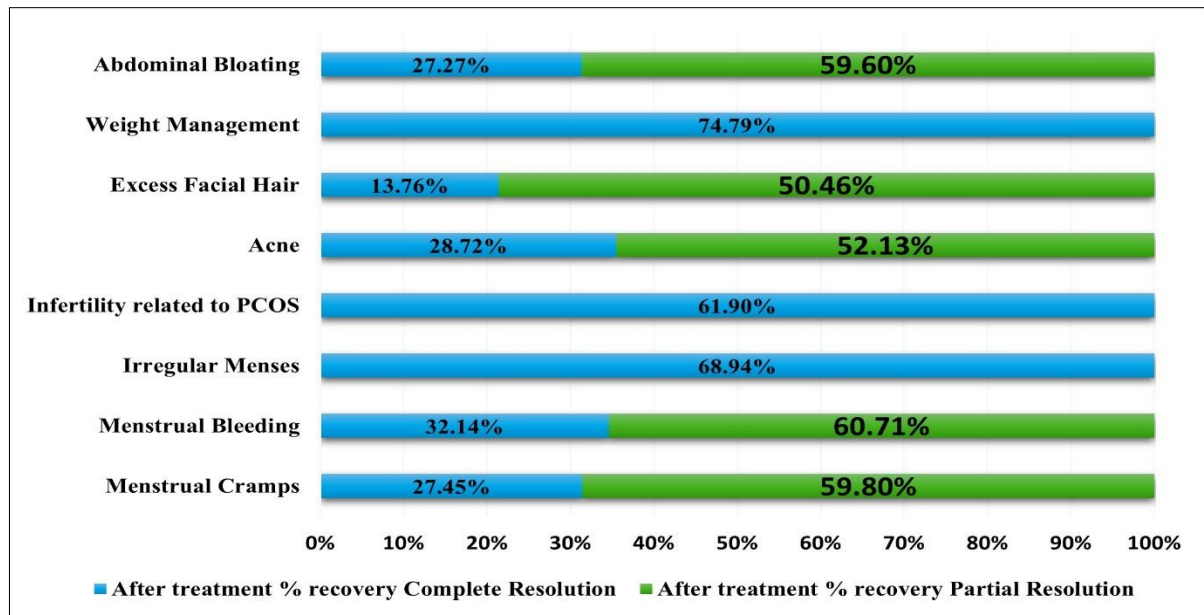


Figure 1: Outcomes of treatment: complete and partial recovery rates among subjects.

Overall feedback and safety of OZiva® HBPCOS

Out of 153 subjects, 136 (88.89%) were satisfied with OZiva® HBPCOS. During the study, 35 subjects reported issues: 6 had irregular periods and weight management problems; 5 had excess unwanted hair; 4 experienced hair fall; 3 had mood swings; and other minor issues included less bleeding, bloating, pigmentation, excess bleeding, fibroids, nausea, acne, and loss of appetite. No serious adverse events were reported.

DISCUSSION

Approximately 1 in 10 women are affected by PCOS. Oral contraceptives are considered as the standard treatment of choice for PCOS in women not seeking to get pregnant. However, it can be associated with potential metabolic and cardiac side effects. The OZiva® HBPCOS are designed to aid women in achieving hormonal balance and promoting a regular menstrual cycle.

Few studies have explored the effects of various herbal preparations in women with PCOS. A recent randomised controlled trial (RCT) compared lifestyle modifications with herbal supplement (preparation 1: *Glycyrrhiza glabra*, *Cinnamomum verum*, *Paeonia lactiflora* and *Hypericum perforatum*; preparation 2: *Tribulus terrestris*) in overweight PCOS patients. A significant improvement in oligomenorrhea, weight management, certain biochemical parameters, quality of life and pregnancy rates were observed.²³ In 2021, Ishaq et al conducted an RCT among 48 women to study the effect of the combination of *Saraca indica* L., *Vitex agnus castus* L., *Embellica officinalis* L., and *Symplocos racemosa* Roxb.²⁴ The study reported that the above combination helped in normalising the menstrual cycles, and a complete recovery was observed in 6 patients, based on the ovarian size and

morphology.²⁴ In 2019, Ainehchi et al compared herbal mixture of *Mentha spicata*, *Zingiber officinale*, *Citrus sinensis*, *Cinnamomum zeylanicum*, alone and in combination with clomiphene citrate. The findings revealed that a synergistic effect between the herbal mixture and clomiphene citrate that can improve the menstrual outcome and pregnancy rate and improve the serum antioxidant levels.²⁵

This PCOS supplement has main ingredients such as shatavari, chasteberry, aloe vera, gokhru, ashoka, amla, and fennel. Where shatavari (*Asparagus racemosus*) is found to be very effective to manage PCOS, improve follicular growth, development, and ovulation, preparing the womb for conception and prevent abortions, increase fertility and alleviate stress.²⁶ Chasteberry (*Vitex agnus-castus*) is one of the oldest herbal remedies used for addressing menstrual disorders and female infertility. It lowers the level of prolactin, improves progesterone levels, and reduces facial hair.

Chasteberry contains dopamine and estrogen receptor ligands, which regulates sex hormones primarily by influencing the pituitary gland and luteinizing hormone (LH) production.²⁷ The pharmacological functions of aloe vera encompass antibacterial and anti-inflammatory effects, as well as promotion of wound healing, facilitating acne control and skin cleansing.²⁸ Gokhru possesses aphrodisiac properties and is primarily utilized for treating sexual disorders such as infertility and leucorrhea in females. *Tribulus terrestris*, commonly known as "chota gokhru" in Indian culture, is employed to address female sexual disorders and menstrual cycle irregularities.²⁹ *Saracia asoca* also known as Ashoka, has been used in Indian medicinal system to treat uterine, genital, and other reproductive disorders in women.²⁰ Fennel seed extract helps in primary dysmenorrhea and lowers menstrual

duration.³⁰ Pomegranate extract acts as a strong antioxidant and is used as an uterine stimulant.³¹ A recent in vitro study on rat uterine smooth muscle horn strips reported that 1.5 to 5 mg/ml of pomegranate juice concentrate significantly reduced uterine concentration that could help with dysmenorrhea.³² OZiva® HBPCOS is a unique blend of these herbs and herbal extracts which can regulate menstrual cycles and women health. The limitations of our study include the small size, and the nature of study design (questionnaire based). A more comprehensive trial design would provide more insight into effects of OZiva® HBPCOS management. Nevertheless, our results show that women with PCOS symptoms (menstrual problems, weight management, infertility related to PCOS and the dermatological sign and symptoms) experience a significant improvement with OZiva® HBPCOS. Hence, by incorporating nine standardized herbal extracts such as chasteberry, shatavari, and ashoka, this PCOS supplement aids in balancing testosterone and estrogen levels. When coupled with a clean, holistic lifestyle, and regular exercise, it can alleviate PCOS symptoms, menstrual cramps, and hormonal imbalances. This PCOS supplement is gluten-free, soy-free, non-genetically modified organism (GMO), and have no artificial sweeteners.

CONCLUSION

Our study, despite its limitations of small sample size and questionnaire-based design, shows that OZiva® HBPCOS significantly improves symptoms related to menstrual problems, weight management, infertility, and dermatological issues like acne and facial hair. The supplement, with its blend of standardized herbal extracts, aids in balancing testosterone and estrogen levels, regulating menstrual cycles, and managing PCOS symptoms. Coupled with a holistic lifestyle and regular exercise, OZiva® HBPCOS offers a promising alternative for managing PCOS symptoms. The supplement is gluten-free, soy-free, non-GMO, and contains no artificial sweeteners. This study supports the effectiveness of OZiva® HBPCOS in alleviating various PCOS-related symptoms and contributing to overall women's health.

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