

Original Research Article

Evaluation of the effects of *Asparagus racemosus* extract (ARova5X) supplementation on postmenopausal discomfort

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Abstract

Objective: Menopause is a critical physiological transition often associated with a spectrum of health challenges such as sexual dysfunction, vasomotor symptoms, and increased oxidative stress. This study aimed to evaluate the efficacy of a hydroalcoholic extract of *Asparagus racemosus* root (ARova5X), standardized to contain 5% shatavarins, in improving health outcomes among postmenopausal women.

Materials and Methods: A randomized, double-blind, placebo-controlled clinical trial was conducted at Apollo Hospitals, Hyderabad, India, during January 2024-2025. A total of 214 postmenopausal women were randomly assigned to receive either ARova5X (250 mg/day) or placebo for 90 days (n=107 per group). Outcome measures were assessed at baseline and post-intervention using validated tools including the Sexual Quotient-Female (SQ-F) questionnaire, the Female Intervention Efficacy Index (FIEI), oxidative stress markers, and anthropometric parameters. Primary endpoints included changes in sexual function, menopausal symptoms, oxidative stress, and weight-related measures.

Results: Participants receiving ARova5X showed significant improvements in multiple domains of sexual function including desire ($p<0.001$), foreplay ($p=0.002$), arousal ($p<0.001$), and satisfaction ($p=0.004$) compared to the placebo group. Vaginal lubrication improved by 84.11% in the intervention group compared to 13.08% in the placebo group. Oxidative stress levels were markedly reduced, with 39.25% of women in the ARova5X group reaching minimal stress levels. Clinical obesity prevalence decreased from 42.99% to 29.91%. Menopausal symptoms such as hot flashes, fatigue, and irritability were also significantly alleviated.

Conclusion: ARova5X appears to be a safe, effective natural intervention for improving sexual health, reducing oxidative stress, and supporting weight management in postmenopausal women.

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Introduction

Menopause represents a significant physiological transition in a woman's life, marked by the cessation of menstrual cycles and a decline in reproductive hormones. This natural process typically occurs between the ages of 45 and 55 years and is clinically defined as 12 consecutive months of amenorrhea not attributed to pathological causes (World Health Organization 1996). The menopausal transition is often accompanied by a constellation of symptoms that can significantly impact quality of life including vasomotor symptoms (hot flashes, and night sweats), psychological manifestations (irritability, depression, and anxiety), and sexual dysfunction (Santoro et al. 2015).

Postmenopausal sexual dysfunction, in particular, affects approximately 40-45% of women and encompasses disorders of desire, arousal, orgasm, and pain during sexual activity (Clayton et al. 2018). These sexual health challenges are primarily attributed to the substantial decline in estrogen levels, which leads to vaginal dryness, decreased lubrication, and thinning of vaginal tissue, collectively contributing to painful intercourse and diminished sexual satisfaction (Nappi and Palacios 2014). Additionally, the hormonal fluctuations during menopause are associated with increased oxidative stress, which has been implicated in the pathophysiology of menopausal symptoms and age-related complications (Sánchez-Rodríguez et al. 2012).

Adjustment disorder, characterized by emotional or behavioral symptoms in response to identifiable stressors, may be particularly relevant in perimenopausal women. The hormonal volatility during this transitional phase contributes to heightened vulnerability to stress, mood swings, and affective disturbances. Psychological and physiological stressors including changing family roles, aging concerns, and physical symptoms such as hot flashes and sexual dysfunction, can compound to increase the

risk of adjustment disorders in this population.

Current pharmacological interventions, including hormone replacement therapy (HRT) and selective serotonin reuptake inhibitors (SSRIs), often fail to adequately address the psychosomatic and sexual dimensions of menopausal distress or carry potential adverse effects that discourage long-term use (Rossouw et al. 2002; Marjoribanks et al. 2017). This underscores the need for safe, multi-targeted interventions capable of alleviating both physiological and emotional symptoms experienced during the menopausal transition.

HRT has traditionally been the primary treatment modality for addressing menopausal symptoms. However, concerns regarding potential adverse effects, including increased risks of breast cancer, cardiovascular events, and thromboembolic disorders, have prompted many women and healthcare providers to seek alternative therapeutic approaches (Rossouw et al. 2002; Marjoribanks et al. 2017). This shift has generated considerable interest in natural remedies, particularly plant-based interventions with phytoestrogenic properties, for managing menopausal symptoms (Franco et al. 2016).

Asparagus racemosus (commonly known as Shatavari), a plant indigenous to tropical and subtropical regions of India, has been extensively utilized in traditional Ayurvedic medicine for women's health issues (Sharma and Bhatnagar 2011). This adaptogenic herb has demonstrated multiple pharmacological properties including antioxidant, anti-inflammatory, immunomodulatory, and phytoestrogenic activities, which may potentially alleviate menopausal symptoms (Alok et al. 2013; Hayes et al. 2006). Previous preclinical studies have reported that *A. racemosus* exhibits estrogenic effects through interaction with estrogen receptors and may enhance the levels of circulating estradiol (Pandey et al. 2005). Furthermore, the steroidal saponins and isoflavones present

in *A. racemosus* have been postulated to modulate neurotransmitter systems involved in mood regulation, potentially addressing the psychological manifestations of menopause (Gautam et al. 2004).

Despite its long history of traditional use and promising preclinical evidence, there remains a paucity of robust clinical data evaluating the efficacy of *A. racemosus* extract for managing postmenopausal symptoms, particularly sexual dysfunction. Given the substantial burden of menopausal symptoms on women's quality of life and the limitations of conventional hormone therapy, there is a compelling need for evidence-based, natural alternatives.

Therefore, this study aimed to evaluate the effects of standardized *A. racemosus* extract (ARova5X) supplementation on sexual function, menopausal symptoms, oxidative stress parameters, and anthropometric measures in postmenopausal women through a randomized, double-blind, placebo-controlled clinical trial.

Materials and Methods

Study design and participants

This study was designed as a randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy of *A. racemosus* extract (ARova5X) in improving postmenopausal sexual dysfunction. The study was conducted at Apollo Hospitals, Hyderabad, between January 2024 and January 2025. The trial protocol was approved by the Institutional Ethics Committee (Approval No. AHJ-C-S-008/12-21) and adhered to the principles of the Declaration of Helsinki. The trial was registered on the Clinical Trial Registry of India (CTRI/2022/05/042463). Written informed consent was obtained from all participants prior to enrollment.

Eligibility criteria

Inclusion criteria encompassed postmenopausal women with a minimum of 12 months of amenorrhea and follicle-stimulating hormone levels above 30 mIU/ml. Participants were required to have a stable partner, be sexually active, and report postmenopausal sexual dysfunction. Exclusion criteria included the use of hormonal therapy, chronic illnesses such as diabetes, hypertension, cancers, psychiatric disorders, hepatic or renal diseases, cardiovascular diseases, cognitive disorders, or substance abuse history (alcohol, tobacco, or drugs).

Randomization and blinding

Eligible participants were randomized in a 1:1 ratio into two groups using computer-generated randomization software. Group allocations were concealed using sequentially numbered opaque envelopes. The intervention group received one capsule of ARova5X (250 mg of a hydroalcoholic Shatavari root extract), standardized to contain 5% shatavarins, in improving health outcomes among postmenopausal women daily after breakfast for 90 days, while the placebo group received an identical-looking capsule without active ingredients. Both participants and study personnel remained blinded to group allocations. An independent nurse prepared the medications to maintain allocation concealment.

Intervention

ARova5X, provided by Stiriti Ayur Therapies Pvt Ltd, contained 250 mg of *A. racemosus* root extract. Participants were instructed to take one capsule daily with breakfast for 90 days. The placebo capsules contained inert ingredients and were identical in appearance to the intervention capsules.

Outcome measures

Primary outcomes were assessed using the Sexual Quotient—Female Version (SQ-F) questionnaire (Postigo et al. 2016) and

the Female Intervention Efficacy Index (FIEI) questionnaire (Berman et al. 2001). The SQ-F consists of 10 items measuring sexual desire, foreplay, arousal, comfort, and satisfaction on a Likert scale from 0 (never) to 5 (always) (Abdo 2006). The FIEI questionnaire consists of five items assessing vaginal lubrication, sensation, arousal, sexual satisfaction, and orgasm ability (Berman et al. 2003). Both questionnaires were administered at baseline and after 90 days by the same researcher.

Oxidative stress evaluation

Oxidative stress was measured using the Osumex Free Radical Test Kit (Osumex Natural Alternatives Ltd., Canada). Fresh urine samples (5 ml) were collected, and test strips were dipped into the samples for 30 sec. The strips were then compared against a standardized color chart, with color intensity indicating oxidative stress levels from Level 1 (very low) to Level 5 (very high) (Osumex Natural Alternatives Ltd n.d.)

Anthropometric assessments

Participants' body weight and height were measured using standard methods with a Mechanical Beam Type Scale (UNICEF S0140500) and Electronic Scale (UNICEF Model 874), respectively. BMI was calculated and categorized into no obesity ($<30 \text{ kg/m}^2$), preclinical obesity ($\geq 30 \text{ kg/m}^2$ or high waist circumference without metabolic complications), and clinical obesity (metabolic complications or organ dysfunction) (World Health Organization 2000).

Statistical analysis

Sample size estimation was based on detecting a mean difference of 3 units in SQ-F scores between the intervention and placebo groups, with a standard deviation

of 6 units, 80% power, and a 5% significance level. The final sample size was 158 participants (79 per group), accounting for 20% loss to follow-up.

Descriptive statistics are presented as means, standard deviations, or percentages. Independent t-tests, chi-square tests, and Mann-Whitney U tests were used to compare baseline characteristics. The Wilcoxon Signed Rank test was applied to within-group changes in SQ-F scores, and the McNemar test was used to evaluate changes in categorical variables. A p-value of <0.05 was considered statistically significant. Data were analyzed using SPSS version 26 (IBM Corp., Armonk, NY, USA).

Results

This study evaluated the clinical and demographic characteristics, sexual function, menopausal symptoms, and adverse events among menopausal women receiving ARova5X intervention compared to a placebo group. A total of 312 participants were assessed for eligibility, with 214 participants ultimately randomized into two equal groups – ARova5X (n=107) and placebo (n=107) – as illustrated in the CONSORT flow diagram (Figure 1). The remaining 98 participants were excluded due to not meeting inclusion criteria (n=47), declining to participate (n=30), or other reasons (n=21). Follow-up data revealed that 4 participants (3.7%) from the ARova5X group and 5 participants (4.7%) from the placebo group were lost to follow-up; however, the intention-to-treat (ITT) population included all randomized participants. The demographic and clinical characteristics of the participants showed no significant differences between groups at baseline, as detailed in Table 1.

ARova5X on postmenopausal discomfort

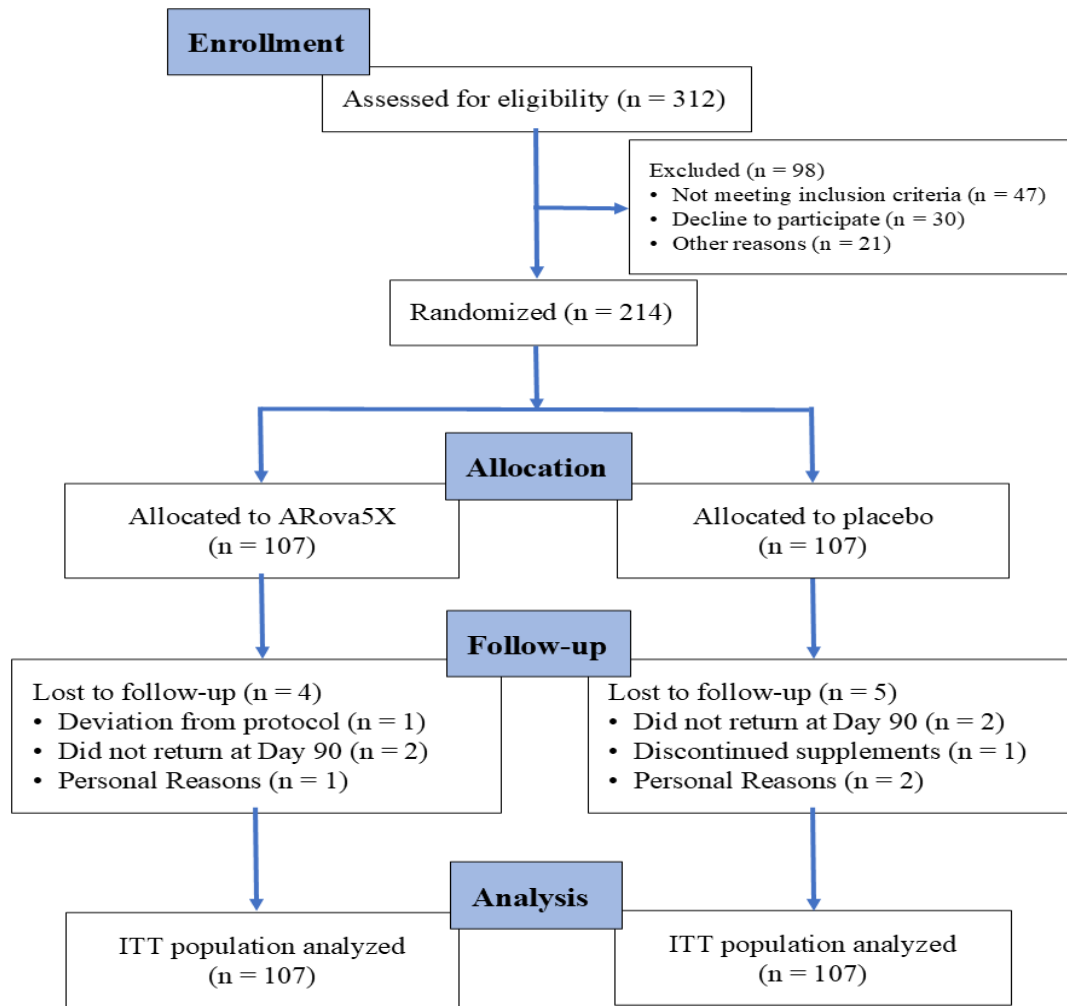


Figure 1. Flow diagram of participant enrollment, allocation, follow-up, and analysis in the present randomized controlled trial.

Table 1. Clinical and demographic characteristics of menopausal women in the ARova5X group and the placebo group.

Characteristics	Total (n = 214)	ARova5X (n = 107)	Control (n = 107)	p-value
Age (years)	54.24 ± 6.74	55.47 ± 6.72	53.98 ± 6.61	0.38
Weight (kg)	52.19 ± 7.11	52.51 ± 8.12	51.79 ± 8.19	0.19
Height (cm)	155.83 ± 7.19	155.42 ± 7.31	155.13 ± 7.09	0.84
BMI (kg/m ²)	21.70 ± 2.38	22.02 ± 2.84	21.54 ± 2.17	0.18
Marital Status				
Unmarried (%)	5 (2.34)	3 (2.80)	2 (1.87)	0.89
Married (%)	159 (74.30)	81 (75.70)	78 (72.90)	
Divorced (%)	16 (7.48)	7 (6.54)	9 (8.41)	
Widowed (%)	34 (15.89)	16 (14.95)	18 (16.82)	
Menopausal age (years)	52.28 ± 3.91	52.49 ± 3.07	52.06 ± 3.53	0.49
Years since menopause	2.01 ± 1.12	2.85 ± 1.83	1.83 ± 1.64	0.77
Occupation				
Employed (%)	67 (28.76)	34 (28.81)	33 (28.70)	0.14
Homemaker (%)	143 (61.37)	68 (57.63)	75 (65.22)	
Retired (%)	23 (9.87)	16 (13.56)	7 (6.09)	
Socio-economic status				
Upper (%)	3 (1.40)	1 (0.93)	2 (1.87)	0.78
Upper middle (%)	21 (9.81)	13 (12.15)	8 (7.48)	
Lower middle (%)	91 (42.52)	44 (41.12)	47 (43.93)	
Upper lower (%)	42 (19.63)	20 (19.63)	22 (20.56)	
Lower (%)	57 (26.64)	29 (27.10)	28 (26.17)	

Initial analysis of the SQ-F questionnaire indicated no significant difference between the ARova5X and placebo groups at the study's commencement. However, after 90 days of intervention, significant differences emerged between the groups across multiple domains as shown in Table 2. These included desire and sexual interest

(10.32±3.97 vs 5.67±3.19, $p<0.001$), foreplay (3.51±1.43 vs 1.56±1.75, $p=0.002$), arousal and partner interaction (7.26±2.18 vs 3.86±2.42, $p<0.001$), comfort during sexual intercourse (8.02 ± 1.76 vs 3.06±1.69, $p=0.01$), and orgasm and sexual satisfaction (7.51± 2.67 vs 3.43 ± 2.18, $p=0.004$).

Table 2. Domains evaluated according to the Sexual Quotient—Female Version questionnaire at Day 0 and Day 90 of the intervention (ARova5X and placebo).

Domains Evaluated	ARova5X (n = 107)		Placebo (n = 107)		p-value	
	Day 0	Day 90	Day 0	Day 90	Day 0	Day 90
Desire	5.14 ± 2.52	10.32 ± 3.97	5.35 ± 2.68	5.67 ± 3.19	0.46	<0.001*
Foreplay	1.01 ± 1.43	3.51 ± 1.43	1.27 ± 1.38	1.56 ± 1.75	0.22	0.002*
Arousal	3.37 ± 2.06	7.26 ± 2.18	3.82 ± 2.11	3.86 ± 2.42	0.19	<0.001*
Comfort	3.16 ± 1.29	8.02 ± 1.76	3.99 ± 1.32	3.06 ± 1.69	0.57	0.01*
Orgasm	3.77 ± 2.43	7.51 ± 2.67	3.65 ± 2.64	3.43 ± 2.18	0.83	0.004*

* $p<0.05$. The p -values refer to the outcome of Wilcoxon Signed Rank test

The FIEI questionnaire results demonstrated substantial improvements in the ARova5X group compared to the placebo. Vaginal lubrication during sexual activity improved in 84.11% of the ARova5X group versus 13.08% in the placebo group ($p < 0.001$). Genital sensation during sexual stimulation improved in 79.44% of women in the ARova5X group compared to only 6.54% in the placebo group ($p < 0.001$). Perception of arousal improved in 94.39% of the ARova5X group, with the remaining 5.61% reporting no change. Sexual satisfaction showed improvement in 71.03% of the ARova5X group versus 8.41% in the placebo group ($p < 0.001$). The ability to reach orgasm improved in 32.71% of the ARova5X group compared to just 0.93% in the placebo group ($p < 0.001$). Figure 2

illustrates these differences in the FIEI questionnaire between ARova5X and placebo on Day 90 of intervention.

All evaluated menopausal symptoms including hot flashes, weight gain, fatigue, insomnia, sweating, irritability, and depression showed significant improvement following 90 days of ARova5X intervention compared to placebo, as summarized in Table 3. Oxidative stress levels also changed significantly in the ARova5X group, with 39.25% of participants reporting minimal stress (level 1) on day 90 compared to only 8.41% at baseline. The percentage of participants experiencing severe oxidative stress (level 5) decreased by 18.69% in the ARova5X group ($p=0.03$), while it increased by 0.94% in the placebo group, as depicted in Figure 3.

Table 3. Frequency of response to the symptoms evaluated on day 0 and day 90 of intervention

Symptoms Evaluated	ARova5X (n = 107)			Placebo (n = 107)		
	Day 0	Day 90	p-value	Day 0	Day 90	p-value
Flashes	43 (40.19)	20 (18.69)	<0.001*	48 (44.86)	46 (42.99)	0.78
Sweating	25 (23.36)	13 (12.15)	0.03*	22 (20.56)	25 (23.36)	0.62
Weight Gain	59 (55.14)	27 (25.23)	<0.001*	61 (57.01)	66 (61.68)	0.48
Irritability	63 (58.88)	31 (28.97)	<0.001*	59 (55.14)	57 (53.27)	0.78
Depression	12 (11.21)	4 (3.74)	0.03*	13 (12.15)	15 (14.02)	0.68
Poor Sleep	57 (53.27)	24 (22.43)	<0.001*	59 (55.14)	61 (57.01)	0.78

* $p<0.05$. The p -values refer to the outcome of McNemar test

ARova5X on postmenopausal discomfort

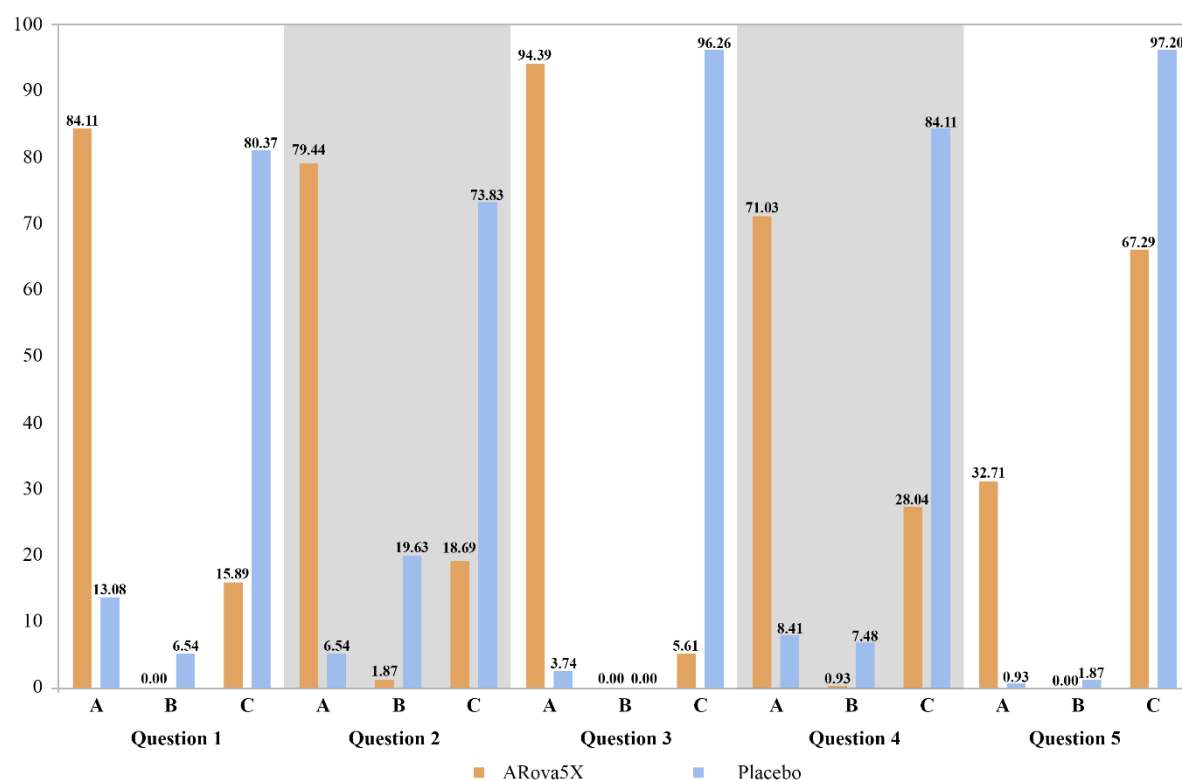


Figure 2. Female intervention efficacy index: frequency of response to the items as improved (A), worsened (B), indifferent (C) on Day 90 of intervention. **Question1:** Did vaginal lubrication during sexual activity or stimulation (e.g., foreplay) change after taking the medication? **Question2:** Did genital sensation (vagina, labia majora, clitoris) during sexual activity or stimulation change after taking the medication? **Question 3:** Did you notice any change in genital sensation after the study? **Question 4:** Did your experience of sexual activity or stimulation change after taking the medication? **Question 5:** Did your ability to achieve orgasm change after taking the medication?.

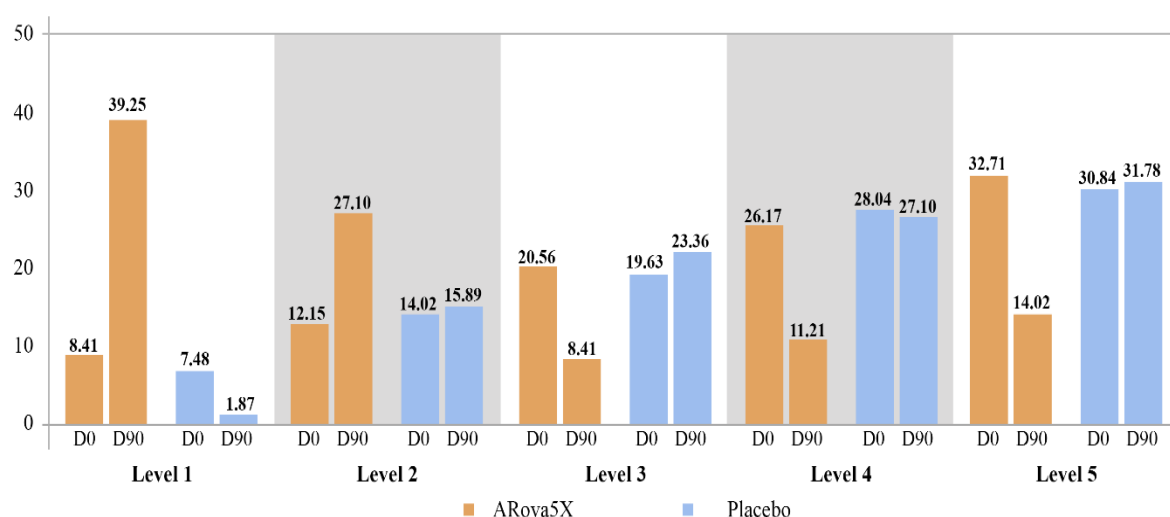


Figure 3. Frequency of participants in different levels of oxidative stress on day 0 and day 90 of intervention. D0 – Day 0; D90 – Day 90. **Level 1:** Very Low Oxidative Stress; **Level 2:** Low Oxidative Stress; **Level 3:** Moderate Oxidative Stress; **Level 4:** High Oxidative Stress; **Level 5:** Very High Oxidative Stress

Weight management outcomes also improved in the ARova5X group, with the number of clinically obese participants decreasing from 42.99% to 29.91% ($p=0.01$). The proportion of non-obese participants increased by 19.63% in the ARova5X group, while no changes were observed in the placebo group. These weight classification changes are illustrated in Figure 4, showing the positive impact of ARova5X on weight management compared to placebo.

Regarding safety, no significant differences in adverse effects were noted between the groups, with the most common side effects being nausea (5.14%), vomiting (3.74%), and gastroesophageal reflux (3.74%), as detailed in Table 4. Overall, the results suggest that ARova5X offers significant benefits for menopausal women across multiple domains including sexual function, menopausal symptom management, oxidative stress reduction, and weight management, with a favorable safety profile comparable to placebo.

Table 4. Number and percentage of adverse events attributable to intervention and control

	Total (n = 214)	ARova5X (n = 107)	Control (n = 107)	p-value
Fever	7 (3.27)	3 (2.80)	4 (3.74)	0.70
Nausea	11 (5.14)	5 (4.67)	6 (5.61)	0.75
Vomiting	8 (3.74)	3 (2.80)	5 (4.67)	0.47
Diarrhea	7 (3.27)	5 (4.67)	2 (1.87)	0.24
Abdominal Pain	4 (1.87)	3 (2.80)	1 (0.93)	0.31
Gastroesophageal Reflux	8 (3.74)	2 (1.87)	6 (5.61)	0.14

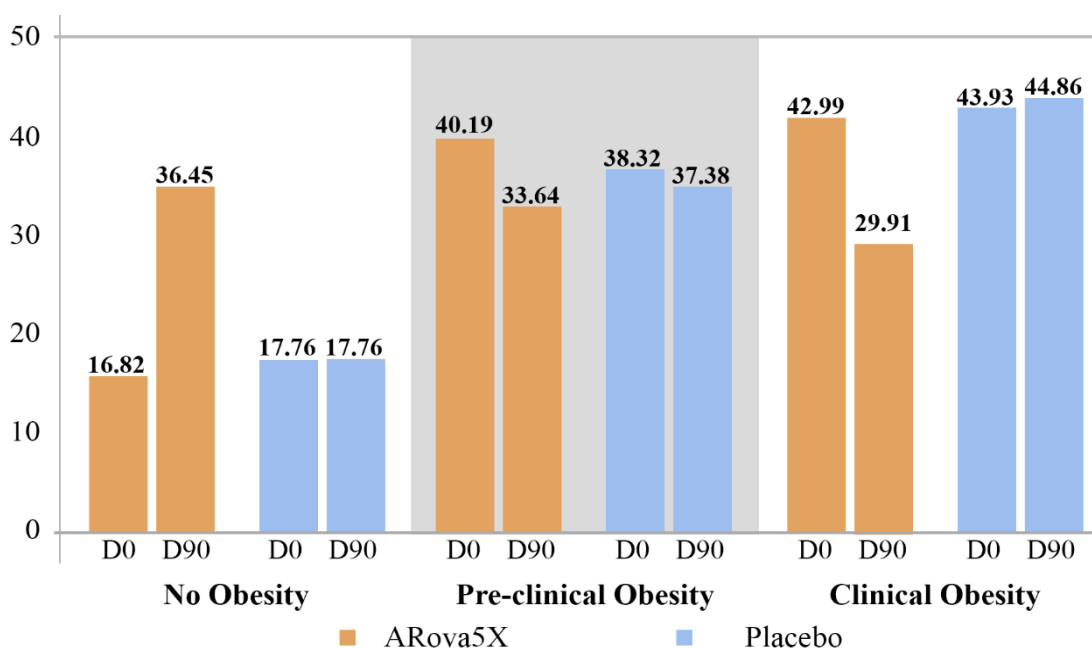


Figure 4. Frequency of participants in different categories of obesity on Day 0 and Day 90 of intervention. D0 – Day 0; D90 – Day 90

Discussion

This randomized, double-blind, placebo-controlled clinical trial demonstrated that daily supplementation with ARova5X (250 mg of *A. racemosus* extract) for 90 days significantly improved sexual function, alleviated menopausal

symptoms, reduced oxidative stress, and favorably impacted anthropometric parameters in postmenopausal women compared to placebo.

Sexual dysfunction is a prevalent concern among postmenopausal women, substantially impacting quality of life and interpersonal relationships (Palacios et al.

2018). Our findings revealed significant improvements across all domains of sexual function including desire, foreplay, arousal, comfort, and orgasm, as measured by the SQ-F questionnaire. These results align with an earlier study which reported improvements in sexual function following administration of *A. racemosus* in combination with other herbal compounds (Nasimi Doost Azgomi et al. 2018). However, our study is the first to demonstrate the efficacy of *A. racemosus* extract as a standalone intervention for postmenopausal sexual dysfunction.

The improvements in sexual function observed with ARova5X supplementation may be attributed to its phytoestrogenic properties. *A. racemosus* contains steroidal saponins and shatavarin which have demonstrated estrogen-like effects in preclinical studies (Visavadiya and Narasimhacharya 2009). These phytoestrogens may ameliorate vaginal atrophy and enhance lubrication, potentially explaining the significant improvement in vaginal lubrication during sexual activity reported by 84.11% of women in the intervention group compared to just 13.08% in the placebo group. Furthermore, the phytoestrogenic compounds in *A. racemosus* may modulate neurotransmitter systems involved in the regulation of sexual desire and arousal, including dopamine, serotonin, and norepinephrine (Singh et al. 2009).

The significant reduction in menopausal symptoms including hot flashes, sweating, irritability, depression, and sleep disturbances, following ARova5X supplementation corroborates findings from previous studies on phytoestrogen-containing botanicals (Chen et al. 2015). Notably, the frequency of hot flashes decreased from 40.19% to 18.69% in the intervention group, representing a clinically meaningful improvement for this often debilitating symptom. These effects may be mediated through multiple mechanisms including modulation of hypothalamic thermoregulatory centers,

optimization of neurotransmitter balance, and anti-inflammatory properties of *A. racemosus* (Umadevi et al. 2013; Sekine et al. 1994).

Oxidative stress has been implicated in the pathophysiology of menopause-related symptoms and complications (Doshi and Agarwal 2013). Our study demonstrated a significant reduction in oxidative stress markers following ARova5X supplementation, with a notable shift toward lower levels of free radical activity. This antioxidant effect aligns with preclinical evidence indicating that *A. racemosus* contains racemofuran, asparagamine, and polyphenols with potent free radical scavenging capabilities (Wiboonpun et al. 2004; Kamat et al. 2000). The antioxidant properties of ARova5X may contribute to its broad therapeutic effects observed in this study, as oxidative stress is associated with various menopausal symptoms and age-related disorders (Borrelli and Ernst 2010).

An interesting finding in our study was the significant impact of ARova5X on anthropometric parameters, with a reduction in clinical obesity from 42.99% to 29.91% in the intervention group. This effect may be attributed to multiple mechanisms including modulation of adipokine secretion, enhanced insulin sensitivity, and regulation of lipid metabolism (Singh 2016). Moreover, the adaptogenic properties of *A. racemosus* may optimize hypothalamic-pituitary-adrenal axis function, potentially mitigating stress-induced weight gain (Rege et al. 1999). These findings suggest that ARova5X may offer comprehensive benefits for postmenopausal women beyond symptom relief, potentially addressing the increased cardiometabolic risk associated with menopause (El Khoudary et al. 2020).

The safety profile of ARova5X was comparable to placebo, with no significant differences in adverse events between the groups. The most common adverse effects were mild gastrointestinal disturbances,

which is consistent with previous safety assessments of *A. racemosus* preparations (Palanisamy and Manian 2012). The favorable safety profile, coupled with the significant efficacy demonstrated across multiple parameters, positions ARova5X as a promising natural alternative for managing postmenopausal symptoms.

The major strengths of this study include its rigorous randomized, double-blind, placebo-controlled design, adequate sample size, comprehensive assessment of multiple health parameters, and use of validated instruments to evaluate outcomes. The study provides robust evidence on the standalone efficacy of *A. racemosus* extract, contributing to the limited literature on natural interventions for postmenopausal health.

However, several limitations warrant consideration. First, the follow-up duration was limited to 90 days, which restricts the evaluation of long-term safety and efficacy. Second, no hormonal or biochemical biomarkers were assessed to objectively evaluate physiological changes. Third, the absence of an active comparator arm limits the ability to compare ARova5X with existing pharmacological treatments such as hormone therapy. These limitations highlight the need for longer, biomarker-integrated trials with active control groups to better understand the therapeutic role of ARova5X.

Future research should focus on evaluating the long-term effects of ARova5X supplementation, exploring dose-dependent responses, and investigating potential synergistic effects with other botanicals. Further studies should include diverse populations to enhance the generalizability of findings and incorporate comprehensive hormonal profiling and cardiovascular markers to elucidate the underlying mechanisms of action. Additionally, randomized controlled trials with extended follow-up durations would be valuable in assessing the sustained benefits and safety profile of ARova5X.

This study provides compelling evidence that ARova5X supplementation significantly improves sexual function, alleviates menopausal symptoms, reduces oxidative stress, and favorably impacts anthropometric parameters in postmenopausal women. The favorable safety profile and multifaceted therapeutic effects of *A. racemosus* extract highlight its potential as a natural, effective alternative for managing the diverse manifestations of menopause.

Further research is warranted to confirm these findings and explore the broader applications of ARova5X in promoting women's health during the menopausal transition.

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Conflicts of interest

The authors declare that they have no conflicts of interest. The authors are not affiliated with the company in any way.

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Ethical Considerations

The study was conducted at Apollo Hospitals, Hyderabad, India. The trial protocol was approved by the Institutional Ethics Committee (Approval No. AHJ-C-S-008/12-21) and adhered to the principles of the Declaration of Helsinki. The trial was registered on the Clinical Trial Registry of India (CTRI/2022/05/042463). Written informed consent was obtained from all participants prior to enrollment.

Data Availability

The datasets produced and/or assessed in this study are not currently accessible to the public; however, they can be obtained from the corresponding author upon reasonable request.

Authors' Contributions

K.G.M. and N.P. conceptualized the study; K.G.M. and N.R.P. developed methodology; K.G.M., A.M. and N.R.P. were responsible for software; K.G.M., A.M. and N.P. validated the data; K.G.M., N.R.P. A.M. and N.P. performed formal analysis; K.G.M. and N.R.P. investigated the data; K.G.M., N.R.P. and N.P. were responsible for resources and curated the data; K.G.M. prepared the original draft; K.G.M., N.R.P., A.M. and N.P. reviewed and edited the manuscript; K.G.M., and N.P. visualized the study; K.G.M., A.M. and N.P. were involved in project administration; N.P. supervised the study. All authors have read and agreed to the published version of the manuscript. All participants involved in the study provided fully informed written consent.

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