



RESEARCH ARTICLE

Clinical Efficacy and Safety of *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* in the Management of Menopausal Syndrome: A Prospective Open-label Multicenter Study

¹Rinku Tomar, ²Savita Sharma, ³Indira Kumari, ⁴Vilas Gangurde, ⁵Sarada Ota, ⁶Pradeep Dua, ⁷Shruti Khanduri
⁸Babita Yadav, ⁹Rakesh Rana, ¹⁰Richa Singhal, ¹¹N Srikanth, ¹²MM Padhi, ¹³Kartar Singh Dhiman

ABSTRACT

Introduction: The menopausal period comprises about one-third of average women's life. During this period, women are vulnerable to conditions caused by estrogen deficiency from short-term discomfort to long-term health problems.

Aim: To evaluate the clinical efficacy of *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* in the management of menopausal syndrome and to evaluate changes in the quality of life in women.

Materials and methods: This trial was a multicenter single-arm study conducted at three Institutes of Central Council for Research in Ayurvedic Sciences. One hundred fifteen women aged between 40 and 55 years with Kupperman menopausal index score ≥ 15 , follicle-stimulating hormone ≥ 20 IU/L, and endometrial thickness ≤ 5 mm were included in the study. Three Ayurvedic classical formulations, viz., *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti*, were administered for 12 weeks followed by subsequent 2 weeks without intervention follow-up. Outcome measures were changes in menopausal symptoms using menopause rating scale (MRS) and improvement in the quality of life using menopause-specific quality of life (MENQOL) questionnaire and they were assessed at the baseline, 84th day, and at the end of 2 weeks after the completion of intervention period. Paired sample t-test was used to compare mean change from baseline to 84th day. A p-value < 0.05 was considered significant.

Results: The findings of the study reveal that the effect of therapy has shown statistically significant decrease in MRS total

score (p-value < 0.001). The mean MRS total score at the baseline was 22.43 and decreased to 5.29 after treatment at 84th day, and further reduced to 5.06 at the 14th week (follow-up period without trial interventions). The improvements of MENQOL in four domains, viz., vasomotor, psychosocial, sexual, and physical, at the end of 12th week and 14th week were also significant (p-value < 0.001) in comparison with the baseline. Further, all the safety parameters like liver function tests and kidney function tests remained within the normal limits throughout the trial period and no adverse events or adverse drug reaction were reported, which confirm the clinical safety of the trial drugs.

Conclusion: *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* are found to be safe and effective in the management of menopausal syndrome.

Keywords: Ashokarishta, Ashvagandha churna, Menopausal syndrome, Menopause rating scale, Menopause-specific quality of life, Pravala pishti.

How to cite this article: Tomar R, Sharma S, Kumari I, Gangurde V, Ota S, Dua P, Khanduri S, Yadav B, Rana R, Singhal R, Srikanth N, Padhi MM, Dhiman KS. Clinical Efficacy and Safety of *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* in the Management of Menopausal Syndrome: A Prospective Open-label Multicenter Study. J Res Ayurvedic Sci 2017;1(1):9-16.

Source of support: Nil

Conflict of interest: None

INTRODUCTION

Women, who constitute half of the world's population, are currently enjoying a life expectancy of 84.3 years approximately in developed countries.¹ Menopause is a natural phenomenon and mostly occurs at the age of 50 to 52 years in a woman.² Different stages, i.e., perimenopause, menopause, and postmenopause, comprise a half or a third of a woman's life, particularly in developing countries.³ It is characterized by an altered hormonal status and a subsequent decrease in quality of life, affecting each woman differently. Specifically, the decline and eventual cessation of estrogen production are associated with the appearance of uncomfortable symptoms (hot flushes, night sweats, breast tenderness, vaginal dryness, irregular menses, mood changes, and vaginal atrophy) as well as pathologies, such as osteoporosis, heart disease, hypercholesterolemia, endothelial dysfunction, vascular inflammation, hyperglycemia, and depression.⁴

^{1,6-8}Research Officer (Ayurveda), ^{2,4,5}Research Officer (Ayurveda) S-2, ³Former Research Officer (Ayurveda) S-4, ⁹Statistical Officer ¹⁰Statistical Assistant, ¹¹Deputy Director General, ¹²Former Deputy Director General, ¹³Director General

^{1,2}Regional Ayurveda Research Institute for Mother and Child Health Care, Nagpur, Maharashtra, India

³Regional Ayurveda Research Institute for Lifestyle Related Disorders, Thiruvananthapuram, Kerala, India

⁴Ayurveda Contraceptive Drug Research Institute, Ahmedabad Gujarat, India

⁵⁻¹³Central Council for Research in Ayurvedic Sciences New Delhi, India

Corresponding Author: Sarada Ota, Research Officer (Ayurveda), Central Council for Research in Ayurvedic Sciences New Delhi, India, Phone: +919810425662, e-mail: sarada_ota@yahoo.com

Clinical studies indicate that the use of hormone replacement therapy (HRT) in menopause needs to be carefully assessed and risks and benefits of the therapy should be evaluated by the clinician for each individual woman. Herbal preparations, food supplements, healthy living, and healthy mental status were mentioned as possible alternatives for managing menopausal symptoms.

In Ayurveda, *Rajonivritti kala* (the period of permanent cessation of menstrual cycle) is considered as 50 years^{5,6} mentioned by all classical texts without any controversy. It is a consequence of *Jaraavastha* (senility),⁷ and *Vata* remains dominant during this period.⁸ *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* are among thousands of traditional Ayurvedic formulations which are widely used to treat ailments in women. *Ashokarishta*, a polyherbal formulation, contains herbs having *Hridaya* (cardiotonic), *Balya* (immune-modulator), *Deepaniya* (carminative), *Pachaniya* (digestive), *Medhya* (brain tonic) properties. Further, Ashoka (*Saraca asoca* Roxb. willd), the principal ingredient of the formulation has the action, viz., *Daha shamak* (alleviates burning sensation in the body), *pittahara* due to its *sheeta guna*.⁹ *Ashvagandha churna* is a well-known *Balya* (immune modulator), *Vayasthapaka* (rejuvenator), and *Manastarpaka* (brain tonic). *Pravala pishti* is having *Pittahara* property and is a rich source of calcium. Due to above actions and uses and as these drugs are in use since long safely and effectively, their efficacy in the present context needs to be evaluated. Keeping this in view, the present study was designed to establish the efficacy of *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* in the management of menopausal syndrome.

OBJECTIVES

The primary objective was to assess the clinical efficacy of *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* in the management of menopausal syndrome and secondary objective was to assess the changes in the quality of life of the women with menopausal syndrome.

MATERIALS AND METHODS

Study Design and Setting

This was a multicenter single-arm study conducted at three peripheral Institutes of Central Council for Research in Ayurvedic Sciences, namely, Regional Ayurveda Research Institute for Mother and Child Health Care, Nagpur; Regional Ayurveda Research Institute for Skin Disorders, Ahmedabad; and Regional Ayurveda Research Institute for lifestyle related disorders, Thiruvananthapuram.

The study was conducted as per the existing guidelines of good clinical practices of India and Declaration

of Helsinki. The study protocol was approved by the Institutional Ethics Committee of each participating center and the study was also registered in Clinical Trial Registry of India (CTRI/2012/03/002538).

Study Participants

Total 116 menopausal women were recruited for the trial from the outpatient departments of all the participating centers after obtaining written informed consent. Patients were screened in accordance with inclusion and exclusion criteria mentioned in the protocol.

Inclusion Criteria

Women between the age of 40 and 55 years; with amenorrhea for ≥ 12 months; Kupperman menopausal index score ≥ 15 ; levels of follicle-stimulating hormone (FSH) ≥ 20 IU/L, and endometrial thickness ≤ 5 mm and who were willing to participate were included in the study.

Exclusion Criteria

Patients with evidence of malignancy, who has had surgical menopause, or those who were diagnosed with mental illness were excluded. Moreover, patients suffering from systemic diseases, such as diabetes mellitus, hypertension, rheumatoid arthritis, coronary heart disease, patients with concurrent serious hepatic disorder (defined as aspartate aminotransferase and/or alanine aminotransferase, total bilirubin, alkaline phosphatase > 2 times upper normal limit) or renal disorders (defined as serum creatinine > 1.2 mg/dL), chronic obstructive pulmonary disease, hypothyroidism, and any other major illness were also vetoed from the study. The women on prolonged (> 6 weeks) medication with corticosteroids, antidepressants, anticholinergics, or any other drugs that may have an influence on the outcome of the study; alcoholics and/or drug abusers; and those who have participated in any other clinical trial in the past 6 months of screening were also excluded.

Study Interventions

Ashokarishta,¹⁰ *Ashvagandha churna*,¹¹ and *Pravala pishti*,¹² three classical Ayurvedic formulations, were procured from Good Manufacturing Practice-certified Ayurvedic pharmaceutical industries and standardized following the standard laid in Ayurvedic Pharmacopoeia of India.¹³ *Ashokarishta* was administered orally in a dose of 25 mL twice a day with equal quantity of water after food. *Ashvagandha churna* (3 gm) and *Pravala pishti* (one capsule of 250 mg) were administered orally twice a day with milk just half an hour before food intake. These treatment schedules were continued for 12 weeks followed by sub-

sequent 2 weeks follow-up without trial interventions.

Study Procedure

On the enrollment day at baseline (visit 1), patients' demographic profile, medical history, general physical and systemic examination, assessment of clinical/Ayurvedic parameters and scoring of menopause rating scale (MRS), menopause-specific quality of life (MENQOL) questionnaire were recorded. Trial drugs and drug compliance report form was also given and the subsequent visits were planned at an interval of 2 weeks [14th day (visit 2), 28th day (visit 3), 42nd day (visit 4), 56th day (visit 5), 70th day (visit 6), and 84th day (visit 7)]. Patients were assessed and study medications were given at each subsequent visit till 84th day. In addition to 12 weeks (84 days) intervention period, a without drug follow-up at 14th week was also scheduled. Details of clinical assessment and study schedule are given in Flow Chart 1.

Data of all the patients were recorded in predesigned case report forms (CRFs) and were also entered in electronic formats (e-formats) designed in MS-Excel with many data validation checks to ensure correct data entry. The e-formats and xerox of the CRFs along with the scorings and laboratory investigation reports of the patients were sent by the participating centers to the Council's headquarters on a weekly basis for the purpose of clinical trial monitoring.

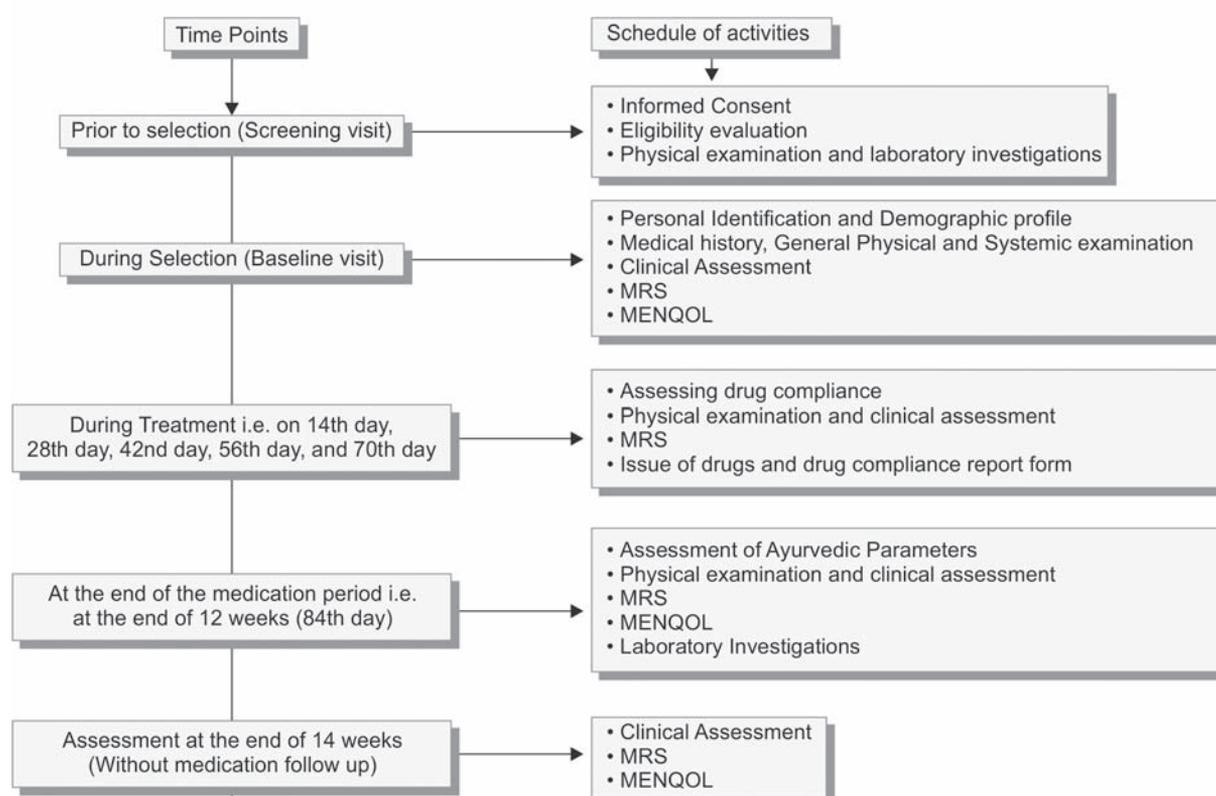
cal trial monitoring.

Out of the total 116 patients enrolled in the study, 7 dropped out during the course of the study. Intention-to-treat analysis was done and the data of all those patients who have completed at least 14th day visit were imputed by last-observation carried-forward (LOCF) method. Patients who dropped out after baseline visit only were excluded from analysis. Hence, data of a total 115 patients were used for statistical analysis. Flow Chart 2 shows the outflow of the patients in the study.

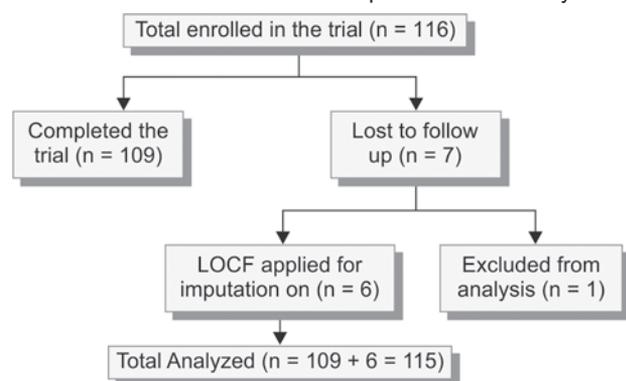
Efficacy Evaluation through Outcome

The primary outcome measure was change in menopausal symptoms using MRS score and was assessed at the baseline, end of 12th week, and the end of 14th week. The MRS has 11 symptoms, and each was rated on a 5-point scale of severity. It is also divided into three subscales: somatic, psychological, and urogenital. The secondary outcome measure was changes in the quality of life of the study participants from the baseline and assessed at the end of 12th week and 14th week by using MENQOL questionnaire. It contains 29 items with four domains: vasomotor, psychosocial, physical, and sexual scores range from 0 to 6. Lower scores indicate better quality of life.

Flow Chart 1: Study schedule



Flow Chart 2: Outflow of the patients in the study



Statistical Analysis

The efficacy and safety parameters were analyzed according to the intention-to-treat analysis. Missing values were imputed by the LOCF method. Statistical analysis was performed using Statistical Packages for Social Sciences. Statistical significance was defined as p -value < 0.05 . Primary and secondary outcome measures; changes in the scores for MRS and MENQOL questionnaire from the baseline to 12 weeks were analyzed by using paired t -test.

RESULTS

Data of 115 women fulfilling the inclusion criteria were used for statistical analysis. The baseline demographic data and outcome measures of the participants are summarized in Table 1. Data revealed that the mean [standard deviation (SD)] age of the participants was 49.24 (3.64) years; 85.2% of the participants were married, and 78.3% were housewives; 64.3% of the participants belonged to urban area, and 75.7% of patients had sleep disturbances.

Table 1: Baseline characteristics of study participants (n = 115)

Variables	Mean (SD)	n (%)
Age (years)	49.24 (3.643)	
Marital status		
Married		98 (85.2%)
Widow		15 (13.0%)
Educational status		
Illiterate		10 (8.7%)
Read and write		104 (90.4%)
Occupation		
Desk work		6 (5.2%)
Field work		19 (16.5%)
Housewife		90 (78.3%)
Socioeconomic status		
Above poverty line		73 (63.5%)
Below poverty line		42 (36.5%)
Habitat		
Urban		74 (64.3)
Semiurban		23 (20.0)
Rural		18 (15.7)

Effect of the Trial Drugs on the Score of MRS

At baseline, the MRS total score was 22.43 (8.24) and 36.82% reduction was seen after 4 weeks, 63.31% after 8 weeks, 76.41% after 12 weeks, and 77.44% after 14 weeks. The effect of therapy has shown statistically significant (p -value < 0.001) decrease in MRS total score (Table 2).

The test formulations also showed statistically significant ($p < 0.001$) improvement in all the three MRS subscale scores (somatic, psychological, and urogenital symptoms) at all time intervals when compared with their respective baseline score. In somatic subscale, at the end of 12 weeks, the score was 2.45 (3.21) and 72.87% reduction was seen. At the end of 14th week, the score was 2.23 (1.67) and 75.3% reduction was seen. Further, in psychological and urogenital subscales, the effect of the treatment was 74.17% (2.58 ± 2.01) and 85% (0.51 ± 1.13) respectively, at the end of 12 weeks and 75.87% (2.41 ± 2.09) and 87.35% (0.43 ± 0.98) at the end of 14 weeks respectively (Graph 1).

Effects of Trial Drugs on Total and Different Domains of MENQOL Score

The effect of treatment on MENQOL is shown in Graph 2 and Table 2. A significant reduction in total MENQOL scores was observed after the treatment of 12 weeks and also at the end of 14 weeks (2-week follow-up period) in comparison to the baseline. Further, in vasomotor domain, the reduction in the symptoms at the end of 12 weeks was 2.3 (2.79), i.e., 77.84%, and 14 weeks 1.91 (2.5), i.e., 81.6% in comparison to baseline score, i.e., 10.38 (4.9); on psychosocial domain the reduction in the symptoms at the end of 12 weeks was 8.75 (6.54), i.e., 60.8% in comparison with baseline score, i.e., 21.0 (7.54). Similarly, in physical domain, the reduction in the symptoms at the end of 12 weeks was 18.2 (11.8), i.e., 57.7%, and at the end of 14 weeks 16.9 (11.8), i.e., 60.8% in comparison with baseline, i.e., 42.98 (13.1). In sexual domain, the reduction of symptoms from baseline score was 3.6 (5.1) to 0.8 (2.33), i.e., 78.1% at the end of 12 weeks and 0.7 (2.2), i.e., 80.6% at the end of 14 weeks.

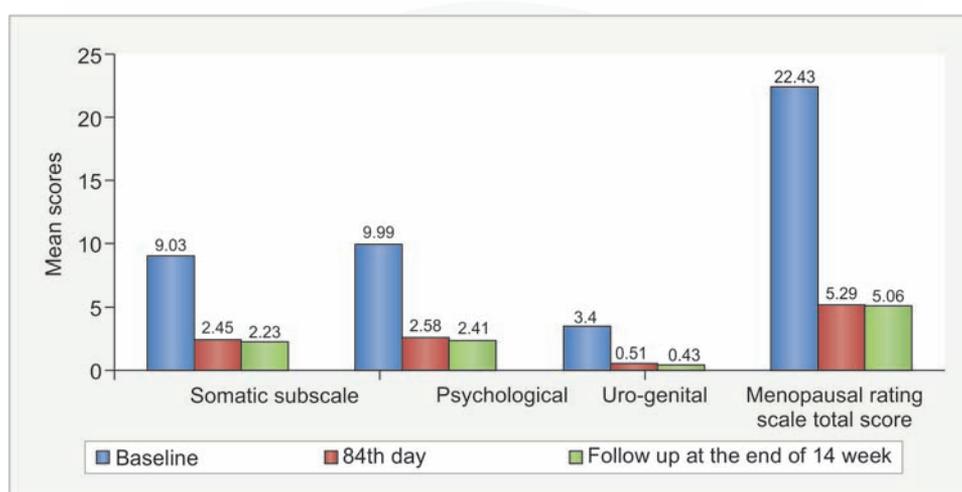
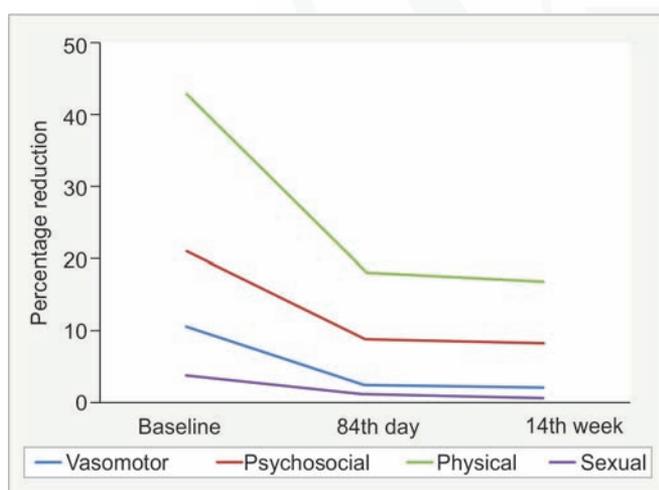
Effect of the Drugs on Safety Parameters

The effect of this treatment on liver function tests and renal function tests was assessed at baseline and at 84th day. The values were within range during the entire period (Table 3, Graphs 3 to 5). These observations validate that these classical drugs are safe for human use. Further, no adverse drug effect or adverse events were reported during the treatment period. The adverse drug reactions (e.g., headache, dizziness, nausea, vomiting)/ events if any were also recorded during study period in a prescribed format.

Table 2: Effect of trial drugs on outcome parameters (serum hormones, MRS, and MENQOL)

Outcome parameters (n = 115)	Baseline	84th day	Follow-up at the end of 14th week	t-value [§]	p-value
Hormonal assay					
Follicle-stimulating hormone	86.67 (32.22)	83.38 (30.88)		2.41	0.02*
Luteinizing hormone	40.67 (15.070)	40.80 (15.39)		0.18	0.86
Estradiol	24.16 (18.52)	28.94 (44.02)		1.30	0.196
Menopause rating scale					
Somatic subscale	9.03 (3.290)	2.45 (3.207)	2.23 (1.670)		
Psychological subscale	9.99 (3.068)	2.58 (2.013)	2.41 (2.094)		
Urogenital subscale	3.40 (3.125)	0.51 (1.135)	0.43 (0.981)		
Total MRS score	22.43 (8.243)	5.29 (3.962)	5.06 (4.020)		
Menopause-specific quality of life					
Vasomotor	10.38 (4.920)	2.30 (2.795)	1.91 (2.515)	16.825	<0.001
Psychosocial	21.00 (7.542)	8.75 (6.54)	8.23 (6.734)	15.285	<0.001
Physical	42.98 (13.935)	18.18 (11.771)	16.86 (11.805)	18.872	<0.001
Sexual	3.61 (5.105)	0.79 (2.334)	0.70 (2.240)	6.667	<0.001

Values are reported as mean (SD); [§]compared using paired t-test; *p-value < 0.05 considered as significant

**Graph 1:** Effect on MRS score in study participants**Graph 2:** Effect of therapy on MENQOL

DISCUSSION

In this study, *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* in a combination have shown significant efficacy to reduce the signs and symptoms in menopausal women.

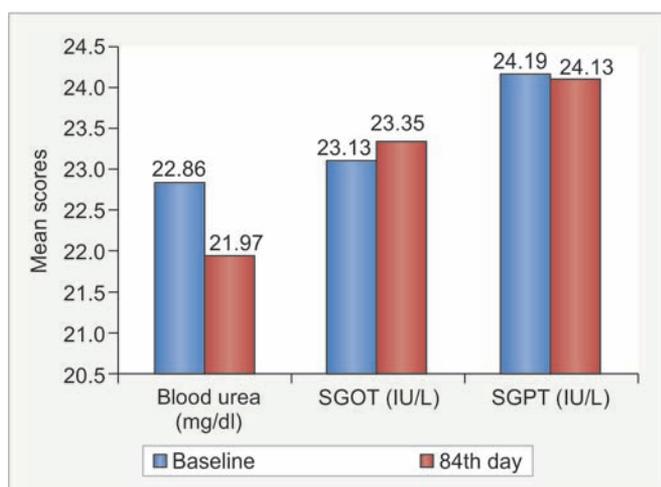
The total MRS score and scores of three subscales have been significantly decreased at 12th week (84th day) and at 14th week as compared with the baseline score. Further, there was significant improvement in the MENQOL scales at the end of 12th week in comparison to initial values.

Oxidative stress plays an integral part of the ageing process and results from the overproduction of free radicals, which overwhelm the body's antioxidant defense mechanisms. The decline in antioxidant level combined with a gradual loss of estrogens in the female body is highly associated with the various sequel of menopausal syndrome.^{14,15} *Ashvagandha* is well known for its antioxidant, adaptogenic, rasayana (rejuvenating), and antistress effects and thus help in improving MRS total score and MENQOL score in the present study.¹⁶⁻¹⁸ Earlier studies suggest the potential role of *Withania somnifera* (*Ashvagandha*) in improving the quality of life in breast cancer patients and related problems.¹⁹ The menopause-induced hormonal deficit has been linked to

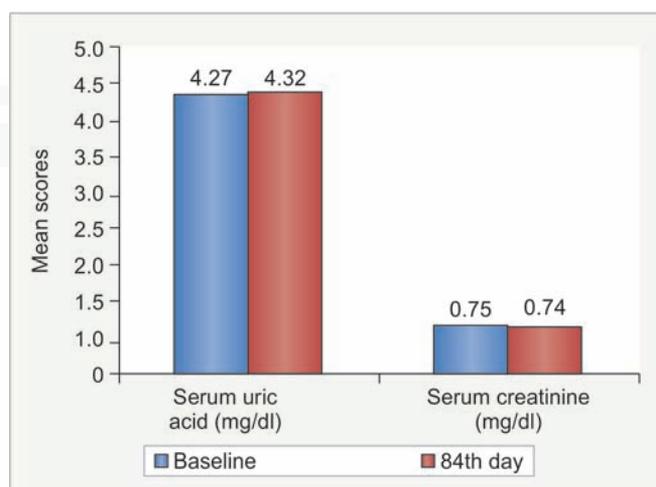
Table 3: Effect of trial drugs on safety parameters

Parameters (n = 115)	Baseline	84th day	t-value [§]	p-value
Blood urea (mg/dL)	22.86 (6.270)	21.97 (4.991)	1.684	0.095
Serum uric acid (mg/dL)	4.27 (0.895)	4.32 (0.746)	0.560	0.577
Serum creatinine (mg/dL)	0.75 (0.150)	0.74 (0.135)	1.049	0.297
Serum calcium (mg/dL)	9.22 (1.223)	9.45 (0.751)	1.878	0.063
SGOT (IU/L)	23.13 (7.569)	23.35 (7.274)	0.331	0.742
SGPT (IU/L)	24.19 (9.486)	24.13 (11.308)	0.065	0.948
Total protein (g/dL)	7.08 (0.624)	7.34 (0.453)	4.001	<0.001*
Serum albumin (g/dL)	4.24 (0.516)	4.37 (0.435)	3.021	0.003*
Serum globulin (g/dL)	2.86 (0.636)	2.99 (0.563)	2.502	0.014*
Conjugated bilirubin (mg/dL)	0.38 (0.236)	0.36 (0.236)	1.245	0.216
Unconjugated bilirubin (mg/dL)	0.21 (0.121)	0.37 (1.943)	0.895	0.373
Serum alkaline phosphatase (U/L)	162.46 (44.73)	154.37 (45.66)	1.937	0.055

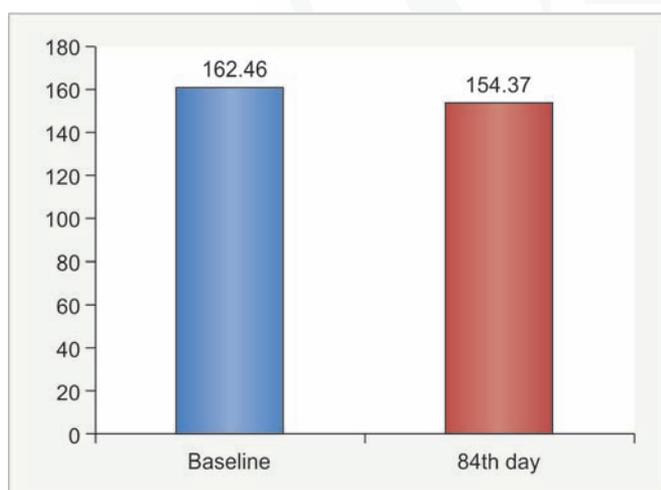
Values are expressed as mean (SD); [§]Compared using paired t-test at baseline and 84th day; *p-value <0.05 has been considered as significant; SGOT: Serum glutamic oxalocetic transaminase; SGPT: Serum glutamic pyruvic transaminase



Graph 3: Effect of the trial drug on safety parameters [blood urea, serum glutamic oxalocetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT)]



Graph 4: Effect of the trial drug on safety parameters (serum uric acid and serum creatinine)



Graph 5: Effect of the trial drug on safety parameters (serum alkaline phosphatase)

an increase in inflammatory cytokines within the serum, such as tumor necrosis factor- α , interleukin (IL)-4, IL-10, and IL-12. Ashvagandha and its constituents have potent anti-inflammatory activity,^{20,21} which may be helpful in

relieving the inflammation, pain, and associated symptoms during menopausal syndrome. Further, withanolides and active constituents of Ashvagandha serve as an important hormone precursor that can convert the hormones as needed. It is reported that Ashvagandha can regulate important physiological processes,²² which are supposed to be beneficial in improvement of various parameters in the present study. *Ashokarishta* is one of the Ayurvedic polyherbal-fermented liquid formulations known to cure gynecological disorders. It is considered as an ideal rejuvenator. *Ashokarishta* has good free radical scavenging, reducing power, and superoxide scavenging activity.²³

The test drugs significantly decreased the FSH level, while showing nonsignificant increase in estradiol content as compared with the baseline values. Previous studies suggest that serum estrogen concentration decreased significantly with the increase in age and a steeper decline was observed at higher age, while FSH concentration increased significantly with advancement of age and a steeper increase was observed at higher

age.²⁴ *Pravala pishti* has *pittahar* property and is also a rich source of calcium. In the present study, *Pravala* is used with herbal phytoestrogen for better result in menopausal syndrome.

The study conducted earlier on the above formulations also showed a significant result in both somatic and psychological complaints in women.²⁵ But in that study, the sample size was less in comparison to the present study.

Further, it is observed that all the test drugs are clinically safe to use as no significant changes were seen in any of the safety parameters, i.e., kidney function and liver function. No adverse drug reaction or events were also reported during the treatment period.

Hence, it is suggested that *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* are clinically safe.

CONCLUSION

From the present study, it is concluded that *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* are effective in the treatment of menopause-associated symptoms and can promote the quality of life of menopausal woman. Hence, these Ayurvedic formulations can be used effectively for the management of menopausal symptoms in place of HRT and other therapies. Further, it is suggested that a randomized clinical trial may be conducted to corroborate the result of this study.

ACKNOWLEDGMENTS

The authors are thankful to all the patients for their participation in the study and all the in-charges and staff of participating centers for providing logistic and technical support for data collection.

REFERENCES

1. Abdollahi AA, Qorbani M, Asayesh H, Rezapour A, Noroozi M, Mansourian M, Soleimani MA, Ansari H. The menopausal age and associated factors in Gorgan, Iran. *Med J Islam Repub Iran* 2013 May;27(2):50-56.
2. Rotem M, Kushnir T, Levine R, Ehrenfeld M. A psycho-educational program for improving women's attitudes and coping with menopause symptoms. *J Obstet Gynecol Neonatal Nurs* 2005 Mar-Apr;34(2):233-240.
3. Pérez-López FR. An evaluation of the contents and quality of menopause information on the World Wide Web. *Maturitas* 2004 Dec;49(4):276-282.
4. Cicero AFG, Tartagni E, Ferroni A, De Sando V, Grandi E, Borghi C. Combined nutraceutical approach to postmenopausal syndrome and vascular remodeling biomarkers. *J Alter Complement Med* 2013 Jun;19(6):582-587.
5. Shastri, AD.; editor. *Maharshi Sushrut, Sushruta Samhita, Sutra Sthana, Shonitavarnaniya Adhyaya, 14/6*. 2nd ed. Varanasi: Chaukhamba Samskrit Samsthan; 2006. p. 48.
6. Acharya, V. *Asthanga Hridaya, Sharira Sthana, 1/7*. Commentary by Kaviraj Atridev Gupta, Reprinted. Varanasi: Chaukhamba Surbharti Prakashan; 2007. p. 170.
7. Shree, B. Bhavaprakasha, PurvaKhanda 3/1. In: Mishra PSBS, editor. 9th ed, Varanasi: Chaukhamba Samskrit Samsthan; 2005. p. 204.
8. Santwani K, Shukla VD, Santwani MA, Thaker G. An assessment of *Manasika Bhavas* in menopausal syndrome and its management. *Ayu* 2010 Jul;31(3):311-318.
9. Vaidya, SBG. Nighantu Adarsha (Purvardha). 1st ed. Varanasi: Chaukhamba Vidya Bhawan; 2013. p. 484.
10. Anonymous. Ayurvedic formulary of India. Part-I, 2nd ed. New Delhi: Department of AYUSH, Ministry of Health and family welfare, Government of India; 2003. p. 8.
11. Anonymous. Ayurvedic pharmacopeia of India. Part-I, Vol-I. 1st ed. New Delhi: Department of AYUSH, Ministry of Health and family welfare, Government of India; 2001. p. 19-20.
12. Bhat A. A comparative pharmaceutico clinical study of *Pravala Pishti* and *Pravala Bhasma* in special reference of management of Hyperacidity. MD thesis. Jamnagar: Rasa Shastra and Bhaishajya Kalpna Department, IPGT and RA; 2003.
13. Anonymous. The Ayurvedic Pharmacopoeia of India. Part II, Vol I. 1st ed. New Delhi: Department of AYUSH, Ministry of Health and Family Welfare, Government of India; 2007. p. 136-161.
14. Agarwal A, Aponte-Mellado A, Premkumar BJ, Shaman A, Gupta S. The effects of oxidative stress of female reproduction: a review. *Reprod Biol Endocrinol* 2012 Jun;10:49.
15. Ruder EH, Hartman TJ, Bumberg J, Goldman MB. Oxidative stress and antioxidants: exposure and impact on female infertility. *Hum Reprod Update* 2008 Jul-Aug;14(4):345-357.
16. Archana R, Namasivayam A. Anti-stressor effect of *Withania somnifera*. *J Ethnopharmacol* 1999 Jan;64(1):91-93.
17. Singh N, Bhalla M, de Jager P, Gilca M. An overview on ashwagandha: a Rasayana (rejuvenator) of Ayurveda. *Afr J Tradit Complement Altern Med* 2011 Jul;8(5 Suppl):208-213.
18. Abbas SS, Singh N. Anti-stress agents (herbs) of Indian origin - herbal drugs, a twenty first century perspective. Institute of Nuclear Medicine and Allied Sciences, Defence Research and Development Organization (DRDO), Govt. of India, Delhi; 2006. pp. 578-591.
19. Biswal BM, Sulaiman SA, Ismail HC, Zakaria H, Musa KI. Effect of *Withania somnifera* (Ashwagandha) on the development of chemotherapy-induced fatigue and quality of life in breast cancer patients. *Integr Cancer Ther* 2013 Jul;12(4):312-322.
20. Sivamani S, Joseph B, Kar B. Anti-inflammatory activity of *Withania somnifera* leaf extract in stainless steel implant induced inflammation in adult zebrafish. *J Genet Eng Biotechnol* 2014 Jun;12(1):1-6.
21. Budhiraja RD, Sudhir S. Review of biological activity of withanolides. *J Sci Ind Res* 1987;46:488-491.
22. Verma SK, Kumar A. Therapeutic uses of *Withania somnifera* (Ashwagandha) with a note on withanolides and its pharmacological actions. *Asian J Pharm Clin Res* 2011 Jul;4(Suppl 1):1-4.
23. Dushing YA, Laware SL. Antioxidant assessment of *Ashokarishta* – a fermented polyherbal ayurvedic formulation. *J Pharm Res* 2012 Jun;5(6):3165-3168.
24. Randolph JF, Zheng H, Sowers MR, Crandall C, Crawford S, Gold EB, Vuga M. Change in follicle-stimulating hormone and estradiol across the menopausal transition: effect of age at the final menstrual period. *J Clin Endocrinol Metab* 2011 Mar;96(3):746-754.
25. Modi MB, Donga SB, Dei L. Clinical evaluation of *Ashokarishta*, *Ashvagandha Churna* and *Pravala Pishti* in the management of menopausal syndrome. *Ayu* 2012 Oct;33(4):511-516.

सारांश

रजोनिवृत्ति जन्य लक्षणों के प्रबंधन में अशोकारिष्ट, अत्र्वगंधा चूर्ण और प्रवाल पिष्टि की नैदानिक प्रभावकारिता का मूल्यांकन – एक प्रत्याशित बहुकेन्द्रीय ओपन लेबल अध्ययन

¹रिंकू तोमर, ²सविता शर्मा, ³इंदिरा कुमारी, ⁴सारदा ओता, ⁵प्रदीप दुआ, ⁶श्रुति खंडूड़ी, ⁷बबीता यादव
⁸राकेश राणा, ⁹ऋचा सिंघल, ¹⁰एन श्रीकांत, ¹¹एम एम पाढी, ¹²करतार सिंह धीमान

भूमिका: एक महिला के जीवन काल का औसतीय तृतीयोश वय रजोनिवृत्ति काल में व्यतीत होता है। इसी काल में इस्ट्रोजन की कमी के परिणामस्वरूप महिलाएँ नाना प्रकार के रजोनिवृत्ति जन्य लक्षणों से ग्रसित हो जाती हैं।

उद्देश्य: चिकित्सीय मूल्यांकन द्वारा रजोनिवृत्ति जन्य लक्षणों में अशोकारिष्ट, अत्र्वगंधा चूर्ण और प्रवाल पिष्टि (आयुर्वेदिक औषधियों) की नैदानिक प्रभावकारिता के साथ-साथ ग्रसित महिलाओं के जीवन की गुणवत्ता में परिवर्तन का अध्ययन करना।

साधन एवं विधि: यह एक बहुकेन्द्रीय अध्ययन है जो कि केन्द्रीय आयुर्वेदीय अनुसंधान परिषद् द्वारा तीन संस्थानों में किया गया था। इस अध्ययन में कुल 115 प्रतिभागी महिलाएँ; जिनकी वय 40-55 वर्ष; कूपरमेन मेनोपोसल इंडेक्स स्कोर ≥ 15 ; FSH $20 \geq 20$ IU/L और एंडोमेट्रीयल मोटाई ≤ 5 mm थी, को अध्ययन में सम्मिलित किया गया है। अशोकारिष्ट, अत्र्वगंधा चूर्ण एवं प्रवाल पिष्टि जैसे तीन आयुर्वेदीय शास्त्रीय योगों को 12 सप्ताह तक रोगियों को दिया गया था एवं आगामी 2 सप्ताह में बिना औषध दिए केवल देखरेख किया गया था। इस अध्ययन के प्रभावस्वरूप मेनोपोसल रेटिंग स्कोर (MRS) से रजोनिवृत्ति जन्य लक्षणों एवं मेनोपोस स्पेसिफिक क्वालिटी ऑफ लाईफ (MENOL) प्रश्नावली द्वारा ग्रसित महिलाओं के जीवन की गुणवत्ता में बदलाव देखे गए।

परिणाम: इस अध्ययन के निष्कर्षानुसार, उपचार के प्रभावस्वरूप MRS कुल स्कोर (p-value < 0.001) में सांख्यिकीय रूप से महत्वपूर्ण कमी देखी है। शुरुआत में अंकित औसतीय (MRS) कुल स्कोर 22.43 था जो कि 12 सप्ताह के बाद घट के 5.29 हो गया एवं आगामी 2 सप्ताह में स्कोर 5.06 हो गया था। संपूर्ण रूप से चिकित्सा के अंत में कुल MRS स्कोर में 77.4 % प्रभाव/कमी देखी गई। प्रतिभागी महिलाओं के जीवन की गुणवत्ता में 4 क्षेत्रों जैसे कि वेसोमोटर, मनोसामाजिक अवस्था, यौन प्रक्रिया एवं शारीरिक प्रक्रिया में सुधार पाया गया था, जो कि चिकित्सा के शुरुआत से 12 एवं 14 सप्ताह में तुलनात्मक महत्त्वपूर्णता दर्शाता है (p-value < 0.001)। चिकित्सा के उपरान्त इन औषधिय योगों का रोगियों के शरीर में कोई भी दुष्प्रभाव के लक्षण नहीं पाए गए थे।

निष्कर्ष: इस अध्ययन के निष्कर्ष से यह स्पष्ट होता है कि अशोकारिष्ट, अत्र्वगंधा चूर्ण एवं प्रवाल पिष्टि औषधियों को रजोनिवृत्ति जन्य लक्षणों में प्रभावी ढंग से प्रयोग किया जा सकता है तथा यह जीवन की गुणवत्ता में सुधार हेतु भी अति लाभदायक हो सकती है।

आयुष
ayush