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Original Article

A Randomized trial to investigate the effect of *Asparagus racemosus* root tablet in Relieving Postmenopausal Hot Flashes

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ABSTRACT

Background and Objectives: As per the available data, 75% peri and postmenopausal women experience hot flashes having negative effect on their quality of life. Using herbal medicines are stepping forward to alleviate hot flashes as the available hormonal medications have been reported the presence of side effects. This study was planned with the intention to investigate the effect of Asparagus racemosus root in the treatment of postmenopausal hot flashes in comparison to the placebo.

Methods: This prospective patient blinded clinical trial randomly assigned 40 postmenopausal women with symptoms of hot flashes to receive either test drug (n=20) comprising Asparagus racemosus tablet of 1g in the dosage of 2 tablet thrice in a day for the duration of 60 days continuously or to receive placebo tablet prepared from roasted wheat flour in the same dosage and duration as test drug. The efficacy was determined by reduction in the frequency and intensity of hot flashes assessed by daily diary along with the improvement in quality of life assessed through Hot Flash-Related Daily Interference Scale. Statistical analysis was accomplished by student t test and Chi-square/Fisher Exact test.

Results: Test drug significantly ($p < 0.001$) reduced the intensity and frequency of hot flashes as well as improved the quality of life without showing any side effect.

Discussion & Conclusion: According to Unani scriptures, the treatment is to treat the underlying cause, such as aberrant temperament and psychological and environmental issues. Unani drugs have emmenagogue, anti-inflammatory, analgesic, and neuroprotective qualities that can help alleviate premenstrual symptoms. Unani herbs such as *C. sativus, Vitex, agnus castus, P. vulgare, N. Jatamansi, M. officinalis*, and *Z. officinalis* have been clinically demonstrated to be effective in PMS. Thus, traditional knowledge authentication and conservation are vital for future research and appreciated for application in the modern day. Furthermore, randomised controlled trials, comprehensive reviews, and meta-analyses are suggested.

Keywords Hot flashes, *Asparagus racemosus*, phytoestrogens, quality of life

INTRODUCTION

Hot flash can be defined as sensation of penetrating heat in the face, neck and chest, typically lasts from a few seconds up to few minutes, and experienced by about two third of all women and 10-20% of them find it very distressing.[1] Among menopausal symptoms hot flashes are the primary reason that women seek medical attention.[2] Although the precise mechanisms behind the triggering of hot flashes have not yet been established, disturbance of the temperature-regulating mechanism in the hypothalamus resulted from decline in estrogen levels is accepted by most of the researchers.[3] Hot flashes critically affect quality of life of menopausal women by affecting the work capability, social life and daily activities.[4,5] Hormonal therapy is a method of relieving hot flashes, but long-term use of these hormones may accompany with grave side effects and threats such as thromboembolic events, breast cancer, and vascular diseases.[6-8] Additionally, the use of hormonal therapy to manage menopausal symptoms has not been recommended by a large multicentred trial. Therefore, use of alternative and complementary therapies is somewhat expanded. Herbal medicine containing phytestrogens (estrogen-like compounds) has gained a crucial place in treatment of menopausal symptoms.[8] Phytestrogens are the members of polyphenolic compounds synthesized by plants. They include isoflavones and other flavonoids, lignans, stilbenes and zearalenones.[9]

In Unani medicine, the entire span of life is divided into four phases; *sin-al-namu* (from birth of the child up to the age of thirty years), *sin-al-shububiyah* or *sin-alwaquf* (from thirty to forty years), *sin-al-kuhulah* (from forty to sixty years) and

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sin-al-shaykhukhah (old age). These four phases carry different temperament due to dominance of particular humour According to this classification the menopausal age group comes under *sin-al-kuhulah* which carry *barid yabis* (cold and dry) temperament due to increased production of *black bile*.[10-11] Production of *black bile* can be considered as a cause for menopausal symptoms including hot flashes.

There are several drugs mentioned in Unani text which removes *black bile* from the body including *Asparagus racemosus*.[12] Recent experiments reported estrogenic effect of *Asparagus racemosus* on female mammary glands and on genital organs due to the presence of phytestrogens.[13] The major active constituents of *Asparagus racemosus* are steroidal saponins (Shatavarins I–IV) that are present in the roots.[14] Despite the presence of phytestrogens, *Asparagus racemosus* was not investigated for its efficacy in postmenopausal hot flashes. So, we aimed to evaluate its effect in Postmenopausal hot flashes.

MATERIAL AND METHODS

1. Design of the study

This was a prospective patient blinded randomized control which was carried out according to the Principles of Declaration of Helsinki at outpatient department of *Ilmul Qabala wa Amraze Niswan*, Luqman Unani Medical College Hospital and Research Centre (LUMCH) Bijapur Karnataka India from November 2017 to March 2019 after obtaining the ethical approval from the Institutional Ethics Committee of LUMCH under IEC No: BJP/LUMC/PG/IEC/2016-17/02/IQAN/01

2. Participants criteria

40 Postmenopausal women complaining hot flashes in the age group of 45-60 years having amenorrhoea of at least 1 year were enrolled in the study after obtaining informed consent. Exclusion criteria included lactating women, history of hormonal treatment or any other medications for treatment of hot flashes, history of systemic and endocrinal diseases, h/o any kind of malignancy or undiagnosed abnormal vaginal bleeding and h/o hysterectomy, oophorectomy.

3. Randomization and allocation concealment

Patients fulfilling the above criteria were allocated randomly and equally in 1:1 ratio to test or control group which was achieved by computer generated randomization table produced from www.randomization.com. The generated random number was kept hidden from the researcher enrolling the patient to achieve the allocation concealment.

4. Procedure

The pre-randomization screening visit includes detailed history particularly about onset, duration, frequency, character, severity, site of hot flashes, physical examination, hot flashes related daily interference scale (HFRDIS) score and laboratory investigations. All the information were recorded in the case record form designed for the study. The socio-economic history including monthly income, education, and occupation, assessed by Kuppuswamy's Socioeconomic Scale was also recorded. Assessment of temperament was done using temperament chart. Other clinical features associated with menopause were also recorded. For exclusion of general diseases routine investigations such as haemoglobin, random blood glucose and thyroid stimulating hormone was performed.

5. Follow up

Patients meeting the study criteria were provided hot flash daily diary for one week to collect the baseline frequency of hot flashes. After starting the therapy patients were followed at the interval of 15 days for 60 days. During follow up visits, HFRDIS were measured and the daily diary were collected (which was provided in the previous follow up visit) to assess the frequency of hot flashes. For safety assessment additional or new symptoms were enquired along with physical examination done.

6. Intervention

6.1. Selection of test drug and preparation

Asparagus racemosus root was given in test group which is selected on the basis of drug temperament and its action as mentioned in Unani classical texts.[10] Test drug was purchased from local crude drug market of Hyderabad and was identified by Professor Sayyed Saleemuddin Department of Pharmacology, Luqman Unani Medical College Hospital and Research Centre. The sample of *Asparagus racemosus* has been kept in the department for future reference. Drug was cleared from all the impurities and powdered and were converted into tablets of 1g by using tablet making machine in the pharmacy of the Luqman Unani Medical College Hospital and Research Centre. Orally 2 tablets thrice daily with plain water after food was given daily to the patients for 60 days and in control group placebo tablet of roasted wheat flour was made by using given in tablet form prepared by using tablet making machine in the same pharmacy was given to the patients of control group in the same dosage and for the same duration as the test drug.

7. Assessment tools

7.1. Frequency of hot flashes

Frequency of hot flashes were assessed by using daily diary in which patients were advised to mention the date and time of hot flashes she experienced, severity (mild, moderate, severe, very severe), diurnal variation and associated activity. Severity of hot flashes assessed by score 1(mild), 2(moderate), 3(severe), more than 3(very severe).

7.2. HFRDIS

HFRDIS is designed to measure the impact of hot flashes on overall quality of life as well as 9 specific activities including work, social activities, leisure activities, sleep, mood, concentration, relations with others, sexuality, and enjoyment of life. Total score ranged between 0-10. Scores between 0-4 considered as non-interference of the daily activities while 5-10 scores completely hamper the day today activities.

8. Blinding and compliance to treatment

The participants were blinded to the intervention provided by masking and matching the *Asparagus racemosus* tablet with placebo with respect to colour, shape and size. Additionally, the drugs were dispensed in the opaque lock bag and there was no detectable odour in any of the preparation. Compliance was assessed at every follow up by examining the lock bags in which medication was dispensed at previous visit.

9. Data analysis

0analysis has been carried out. To find the significance of study parameters on continuous scale within each group, Student t test (two tailed, dependent) has been used. To calculate the significance on categorical scale between two or more groups, Chi-square/ Fisher exact test has been used. For small samples, Fisher exact test has been used. Changes from baseline to endpoint were calculated for the test and control group at each follow-up and all changes from baseline were compared between test and placebo group at each follow-up point.

RESULTS

1. The flow of participants and socio-demographic variables

A total number of 103 women completed pre-baseline screening in which 40 women met the criteria and were included as participants in this study. Participants were randomly assigned to the *Asparagus racemosus* (n = 20) and placebo (n = 20) group **(Fig. 1)**.

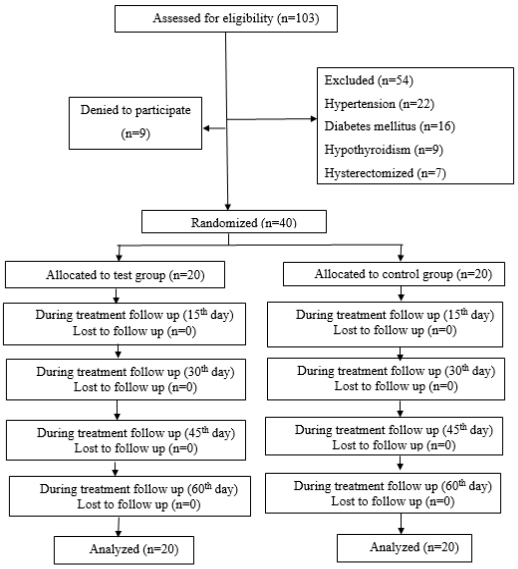

Figure 1. Flow chart showing overview of the study.

Both the groups were statistically similar with respect to age, religion, habitat, dietary habits, socioeconomic status, educational level, occupation, body mass index, age of menarche, age at menopause, postmenopausal age, temperament, parity and duration of disease with p-value >0.05. Both the groups were statistically similar at baseline regarding the age of menarche, age at menopause and postmenopausal age. In this study mean age of menarche was found 14.15±0.95 years where 40%, 27.5% and 22.5% patients attained menarche at the age of 14 years, 13 years and 15 years respectively. Only 2.5% attained menarche at the age of 12 years and 7.5% attained menarche at the age of 16 years. Mean age at menopause of the patients enrolled in this study was found 44.43±1.43 years. Mean postmenopausal age of the patients were found 7.60±5.25 years where 50% patients had postmenopausal age between 5-15 years **(Table 1)**.

Table 1. Demographic distribution of the patients in both the groups.

Variables	Test Group	Control Group	Total	P-value
Age in years				
45-50	11(55%)	9(45%)	20(50%)	0.396[b]
51-60	9(45%)	9(45%)	18(45%)	
61-65	0(0%)	2(10%)	2(5%)	
Mean ± SD	51.25±5.66	52.80±5.75	52.03±5.69	
Religion				
Hindu	2(10%)	1(5%)	3(7.5%)	1[b]
Muslim	18(90%)	19(95%)	37(92.5%)	
Diet				
Mixed	19(95%)	19(95%)	38(95%)	1[b]
Veg	1(5%)	1(5%)	2(5%)	
Socio Economic Status				
Lower Middle	7(35%)	6(30%)	13(32.5%)	1[b]
Upper Lower	4(20%)	4(20%)	8(20%)	
Upper Middle	8(40%)	8(40%)	16(40%)	
Upper	1(5%)	2(10%)	3(7.5%)	
Habitat				
Rural	12(60%)	11(55%)	23(57.5%)	0.749[b]
Urban	8(40%)	9(45%)	17(42.5%)	
Education				
Illiterate	7(35%)	5(25%)	12(30%)	0.949[b]
Primary	7(35%)	6(30%)	13(32.5%)	
Secondary	3(15%)	5(25%)	8(20%)	
Higher secondary	2(10%)	2(10%)	4(10%)	
Graduate	1(5%)	1(5%)	2(5%)	
Post graduate	0(0%)	1(5%)	1(2.5%)	
Occupation				
House wife	14(70%)	11(55%)	25(62.5%)	0.727[b]
Teacher	4(20%)	7(35%)	11(27.5%)	
Labourer	1(5%)	1(5%)	2(5%)	
Made	1(5%)	0(0%)	1(2.5%)	
Nurse	0(0%)	1(5%)	1(2.5%)	
Parity				
1	2(10%)	0(0%)	2(5%)	0.583[c]
2	7(35%)	6(30%)	13(32.5%)	
3	3(15%)	3(15%)	6(15%)	
4	6(30%)	8(40%)	14(35%)	
5	0(0%)	0(0%)	0(0%)	
6	1(5%)	2(10%)	3(7.5%)	
7	0(0%)	1(5%)	1(2.5%)	
8	1(5%)	0(0%)	1(2.5%)	
BMI Kg/m^2				
20-25	6(30%)	3(15%)	9(22.5%)	0.195[c]
26-30	7(35%)	10(50%)	17(42.5%)	
31-35	3(15%)	2(10%)	5(12.5%)	
36-40	4(20%)	5(25%)	9(22.5%)	
Mean ± SD	10.92±13.88	12.95±14.86		
Age of menarche (Year)	14.30±0.98	14.40±0.92	14.15±0.95	0.324[a]
Age at menopause (Year)	44.20±1.54	44.65±1.31	44.43±1.43	0.326[a]
Postmenopausal age (Year)	7.05±4.89	8.15±5.65	7.60±5.25	0.514[a]

[a]Student t test, [b]Fisher Exact Test, [c]Chi-Square Test

2. Parameters of efficacy

At baseline, there was no significant difference found in the frequency of hot flashes between the groups. In test group significant reduction in the frequency of hot flashes was reported on 15th, 30th, 45th and 60thday of treatment. When these observations were compared with control group

statistically highly significant difference was noted with a p-value <0.001 **(Table 2) (Fig 2)**.

Table 2. Frequency of hot flashes comparison in two groups at various timepoints.

Timepoint	Test Group	Control Group	P-value
Results			
Baseline	8.05±0.83	8.10±0.64	0.832
15th Day	6.70±0.80	7.20±0.70	0.042*
30th Day	5.0±0.73	6.60±0.60	<0.001**
45th Day	3.35±0.81	6.10±0.85	<0.001**
60th Day	2.05±0.76	5.45±0.83	<0.001**
Difference from baseline to 60th day	6.00	2.65	
P-value	<0.001**	<0.001**	-

Student t test *Moderately significant (P value: 0.01<P ≤ 0.05) **Strongly significant (P value: P≤0.01)

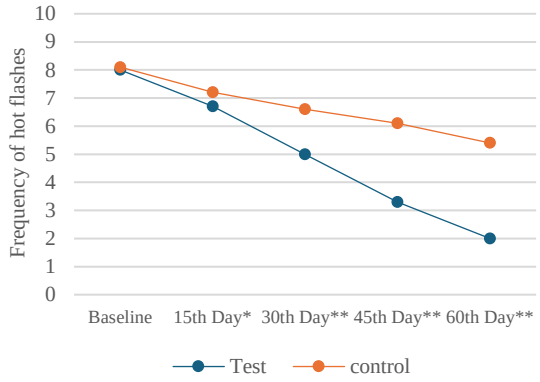

Figure 2. Comparison of mean hot flash frequency (*Moderately significant (P value: 0.01<P ≤ 0.05) **Strongly significant (P value: P≤0.01)

At baseline, there was no significant difference found in the HFRDIS score between the groups. In test group significant reduction in HFRDIS score was reported on 15th, 30th, 45th and 60thday of treatment. When these observations were compared with control group highly significant difference was noted with a p-value <0.001. Also, in control group the HFRDIS score was significantly decreased from baseline to 60th day with a mean difference of 17.000 **(Table 3) (Fig 3)**.

Table 3. HFRDIS score in two groups of patients at different timepoints.

HFRDIS	Test Group	Control Group	P-value
Results			
Baseline	67.60±6.74	68.45±4.29	0.637
15th Day	60.60±5.73	64.85±4.02	0.010**
30th Day	50.90±5.60	60.10±5.03	<0.001**
45th Day	41.95±4.89	55.30±8.12	<0.001**
60th Day	31.55±3.61	51.45±8.64	<0.001**
Difference			
60th Day	36.05	17.00	-
P-value	<0.001**	<0.001**	

Student t test *Moderately significant (P value: 0.01<P ≤ 0.05), **Strongly significant (P value: P≤0.01)

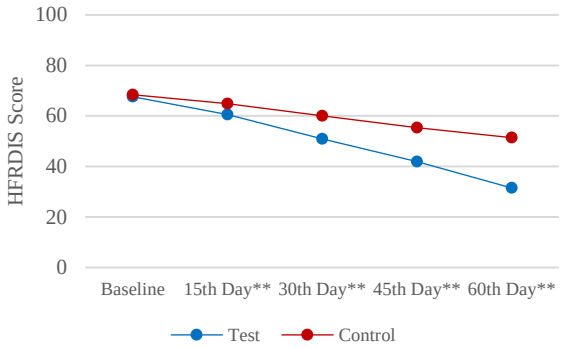

Figure 3. Comparison of mean HFRDIS score (**Strongly significant (P value ≤0.01)

DISCUSSION

The effect of *Asparagus racemosus* in postmenopausal hot flashes has not been studied before. The reduction in the frequency of hot flashes as well as improvement in the HFRDIS score in test group can be attributed to the phytestrogens present in the test drug which are plant compound having estrogen-like properties.[15,16] The isoflavones and lignans are the two major classes of phytestrogens.[15] Preliminary study suggests that phytestrogens can alter serum hormones levels, increase the menstrual cycle length, diminish hot flashes and improve vaginal dryness in healthy women.[17] The major active constituents of *Asparagus racemosus* are steroidal saponins (shatavarins I-IV), isoflavones, asparagamine (an alkaloid substance similar to aspirin) and polysaccharides.[18,19] Although the mechanism of action is not clear, because of structural similarity with the natural ligand and oestradiol, the phytestrogens can bind to alpha and beta estrogen receptors and show their effects in human.[20,21,22] A meta-analysis of 10 randomized controlled trials by *Chen et al* reported that phytestrogens significantly reduced the hot flash frequency compared to placebo.[15] Daily consumption a milk product enriched with soy isoflavones caused improvement in vasomotor symptoms in Spanish postmenopausal women.[23] It has been observed significant improvement in all 4 quality of life subscales (vasomotor, psychosexual, physical, and sexual) among the women taking isoflavones, compared to placebo where no changes were seen.[24] Regular consumption of ViveSoy (a commercially available soy drink) containing high concentration of isoflavones, improved the symptoms of menopause, as well as health-related quality of life in peri- and postmenopausal women.[25]

No adverse effect was noted in both the groups showing that the drug is safe. Similar to this several clinical trial on *Asparagus racemosus* did not observe any adverse effect.[26,27] Combined therapy of ethanolic extract of *Asparagus racemosus* either with gliclazide or pioglitazone significantly decreased hepatic enzyme levels when compared to disease control rats, gliclazide treated rats and pioglitazone treated rats indicated improvement in liver dysfunctions[28] indicating the hepatoprotective activity of the drug. *Asparagus*

racemosus extract prevented isoniazid-induced hepatotoxicity.[29]

CONCLUSION

The present study reported significant efficacy of *Asparagus racemosus* root tablet in alleviating the postmenopausal hot flashes in comparison to placebo tablet without causing any adverse effects and it could be a safe and better alternate for postmenopausal hot flashes. However, some limitation in this trial is present including small sample size, lack of long-term follow-up and determination of the efficacy of the tested drug based on subjective parameters. So, authors recommended a confirmatory double-blind study on large sample size with long term follow along with some laboratory parameters for the testing of efficacy.

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Nil

CONFLICT OF INTEREST

None to declare

CONTRIBUTION OF THE AUTHOR

All authors contributed equally to this manuscript.

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