ORIGINAL ARTICLE

Comparative study of gabapentin and isoflavone in menopausal vasomotor symptoms

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ABSTRACT

Objective: This study was planned to compare the effects of gabapentin and isoflavones in menopausal vasomotor symptoms.

Materials and Methods: This prospective comparative study was conducted on 100 patients with complaints of hot flashes, divided into two groups of 50 each. Group I received 900 mg of gabapentin and Group II received 60 mg of isoflavones daily for 3 months. The patients were interviewed to calculate hot flash, global and depression scores and were rescored after 2, 4, 8, and 12 weeks. The primary outcome measure was a change in the hot flash score from baseline. The secondary outcome was an improvement in sleep, depression, and lipid profile. Data were analyzed using Chi-square test and Student's *t*-test.

Results: Both groups showed significant improvement in hot flash score at the end of 12 weeks (82% Group I, 74% Group II; $P = 0.076$). Statistically significant difference was seen at 12 weeks in sleep quality in favor of gabapentin ($P = 0.011$) and in depression in favor of isoflavones (0.026). Isoflavone had significant improvement in cholesterol, high-density lipoprotein, low-density lipoprotein, and triglycerides profiles after 12 weeks ($P < 0.001$, 0.009, 0.024 and <0.001, respectively) as compared to gabapentin.

Conclusion: Isoflavone and gabapentin are equally effective in the treatment of hot flashes; however, isoflavones have better response in patients who have associated with complaints of depression and gabapentin is better who have associated sleep disturbance.

Key Words: Gabapentin, hot flashes, isoflavone, menopause

INTRODUCTION

Menopause is defined retrospectively as the time of the final menstrual period followed by 12 months of amenorrhea that occurs as a part of the normal aging process.[1] It is characterized by various symptoms that include hot flashes, vaginal dryness, mood and sleep disturbances, somatic complaints (aches and pains), anxiety, fatigue, irritability, and even panic.[2] Some women are able to weather this period in their lives with little or no intervention whereas others experience more bothersome symptoms and want treatment. The management of menopausal symptoms calls for an individualized intervention depending on the nature of her symptoms and their impact on her quality of life, her personal preferences, and efficacy profile of potential treatment options.

Hot flashes have been reported as the most bothersome symptom of menopause accounting for 75% of symptoms.[3] Both hormonal and nonhormonal treatment modalities are available. Hormonal therapy includes estrogen, combined estrogen/progestin, and concern

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regarding the adverse effects and low compliance with estrogen due to irregular bleeding, mastalgia, nausea, weight gain, etc., has led to the demand of other treatment options.[4]

Nonhormonal therapy includes isoflavones, gabapentin, clonidine, selective Serotonin reuptake inhibitors (SSRI's), black cohosh, and Vitamin E. Isoflavones are nonsteroid compounds that weakly bind to estrogenic receptors and have been demonstrated to decrease both severity and frequency of menopausal vasomotor symptoms.[5] Soy products are generally very safe. Gabapentin's role in hypothalamic calcium channel activity has been implicated as a mediator of temperature regulation, thereby helping in the treatment of hot flashes.[6,7] The reasons suggested by Yurcheshen *et al.* as to why gabapentin was responsible for a significant increase in sleep quality are a reduction of hot flashes, an increase in slow wave sleep, and a hypnotic effect.[8] The North American Menopause Society and the American College of Obstetricians and Gynaecologists recommend the use of gabapentin as an option for managing hot flashes in women who are unwilling to take estrogen-containing supplements.[3]

The present study is carried out to compare the effects of gabapentin versus isoflavones in menopausal vasomotor symptoms, especially with regards to hot flashes and sleep disturbances.

MATERIALS AND METHODS

The prospective comparative study was conducted on 100 consecutive patients in the menopausal age group (40–65 years) with complaints of hot flashes, who attended the outpatient Department of Obstetrics and Gynecology, at a tertiary care hospital in India.

The cases of the study were alternatively divided into two groups of 50 each, in such a way that the first patient was enrolled into Group I, the second patient into Group II.

Group I (gabapentin group) patients received 900 mg of gabapentin for a period of 3 months (300 mg, thrice a day).

Group II (isoflavones group) patients received 60 mg of isoflavones for a period of 3 months (once daily).

Women with history of deep vein thrombosis, myocardial infarction, and chronic liver, renal, or endocrine disease, use of hormonal therapy or antiseizure medication were excluded from the study. Ethical clearance was taken from the institutional ethics committee. After informed consent, all the cases underwent a general physical and gynecological examination and were interviewed in detail regarding hot flashes, sleep disturbances, depression, and other menopausal symptoms in the form of two validated questionnaires: Pittsburgh Sleep Quality Index (PSQI) [Annexure 1] and Zung Self-rating Depression Scale [Annexure 2]. In scoring the PSQI, seven component scores were derived, each scored 0 (no difficulty) to three (severe difficulty) and the scores were summed to produce a global score (range 0–21) [Annexure 3]. The Zung Depression Scale has scored from 20 to 80.

Hot flash score was calculated as = (1 × number of mild hot flashes in a day) + (2 × number of moderate hot flashes) + (3 × number of severe hot flashes).

Lipid profile was done at the first visit and repeated at 12 weeks. She was followed after 2, 4, 8, and 12 weeks. At all the visits, the patients were reviewed and scored regarding hot flashes, PSQI score, and depression score and were also asked about any side effect of the drugs.

The primary outcome measure was a change in the hot flash scores from baseline. The secondary outcome measures were other symptoms related to sleep, depression, and change in lipid profile. Data were analyzed using Chi-square test for univariate analysis and Student's *t*-test. $P < 0.05$ was considered statistically significant.

RESULTS

The mean age was 50.9 ± 4.49 years for Group I and 50.24 ± 5.13 years for Group II, and maximum distribution (72%) was seen in the age group 46–55 years. Eight percent of the patients were perimenopausal, 2% in Group I, and 14% in Group II. The largest number of the patients was within a year of menopause at the time of enrollment (36% in Group I and 38% in Group II) and 27% were hysterectomized (32% in Group I and 22% in Group II). The results are shown in Tables 1-5. No side effect was observed in isoflavone group; however, in gabapentin group, five patients reported drowsiness at 2 weeks and ten patients at 4 and 8 weeks which subsided at 12 weeks and one patient had gastrointestinal side effects at 2 and 4 weeks follow-up, and there was no other major side effect.

DISCUSSION

Menopause is defined as the permanent cessation of menstrual periods that occurs as part of the normal aging process or as a consequence of iatrogenic (surgical) intervention.[9] Baseline hot flash score in the present study was comparable in the two groups [Table 2, $P = 0.175$]. Improvement in the hot flash score was seen as early as after 2 weeks of treatment (8%) and was durable

Table 1: Demographic details of the study groups

Parameter	Group I (gabapentin) (*n*=50)		Group II (isoflavones) (*n*=50)	
	Count	*n* %	Count	*n* %
Marital				
Married	50	100	48	96
Widows	0	0	2	4
Residence				
Urban	26	52	36	72
Rural	24	48	14	28
Education				
Uneducated	16	32	14	28
Matriculation	20	40	19	38
12th pass	3	6	0	0
Graduate	11	22	17	34
Occupation				
Employed	3	6	13	26
Homemakers	47	94	37	74

over 12 weeks (82%) in the gabapentin group [Table 2]. Guttuso *et al.* investigated gabapentin for hot flashes in 59 highly symptomatic women and found a reduced hot flash score of 54% in the gabapentin group versus 31% in the placebo group at week 12.[10] Similarly, Pandya *et al.*, studied gabapentin at doses of 300 mg/day and 900 mg/day in 420 breast cancer patients mainly on tamoxifen, found a significant 49% decrease in hot flash score in the 900 mg/day arm, compared with 21% in the placebo arm at week 4.[11] In another trial that was not placebo-controlled, Loprinzi *et al.* found that gabapentin at a dose of 900 mg/day reduced the hot flash score by 60% in breast cancer patients at week 4.[12]

In the present study, fall in the mean hot flash score was also seen in the isoflavone group in the 2nd week (3%) which increased to 74% at 12 week [Table 3]. Albertazzi *et al.*, in their study using 90 mg/days of genistein aglycone, found that soy isoflavones were significantly superior to

Table 2: Comparison of hot flash score in two groups

Hot flash score (weeks)	Group I (gabapentin) (*n*=50)		Group II (isoflavones) (*n*=50)		*P* (intergroup, between percentage fall)
	Mean±SD	Percentage reduction from baseline	Mean±SD	Percentage reduction from baseline	
0	1.86±0.53	0	2.10±0.54	0	0.175
2	1.70±0.61	8	2.04±0.57	3	0.056
4	1.04±0.69	44.67	1.36±0.72	36	0.110
8	0.70±0.58	64.33	0.78±0.67	62	0.356
12	0.34±0.47	82	0.52±0.50	74	0.076

SD: Standard deviation

Table 3: Comparison of the Pittsburgh Sleep Quality Index (global score)

Global score (weeks)	Group I (gabapentin)		Group II (isoflavones)		*P* (intergroup, between percentage fall)
	Mean±SD	Percentage fall from baseline	Mean±SD	Percentage fall from baseline	
0	2.96±1.48	0	2.70±2.37	0	-
2	2.74±1.58	7.43	2.56±2.29	3.77	0.08
4	1.84±1.44	37.83	1.80±2.30	29.72	0.247
8	1.18±1.24	60.12	0.86±1.48	60.77	0.238
12	0.90±1.18	69.58	0.86±1.48	60.77	0.011

SD: Standard deviation

Table 4: Comparison of the Self-rating Depression Scale

Weeks	Group I (gabapentin)		Group II (isoflavones)		*P* (intergroup, between percentage fall)
	Mean±SD	Percentage fall from baseline	Mean±SD	Percentage fall from baseline	
0	23.3±2.67	-	24.86±6.41	-	-
2	23.2±2.62	0.42	24.86±6.41	0	0.02
4	22.7±2.51	2.57	23.92±5.32	3.77	0.360
8	21.8±1.82	6.43	21.88±2.72	11.9	0.030
12	21.7±1.82	6.86	21.72±2.68	12.62	0.026

SD: Standard deviation

Table 5: Lipid profile of the study groups

Weeks	Group I (gabapentin) (n=50)			Group II (isoflavones) (n=50)			P (inter group)
	Mean±SD	Percentage change	P	Mean±SD	Percentage change	P	
Cholesterol							
0	165.78±29.30	-	-	165.30±31.89	-	-	-
12	165.32±28.72	0.002	0.143	163.98±39.36	0.79	0.567	<0.001
HDL							
0	41.02±4.75	-	-	39.46±2.93	-	-	-
12	41.32±4.80	0.73	0.454	41.26±2.75	4.53	<0.001	0.009
LDL							
0	99.90±23.35	-	-	98.40±27.08	-	-	-
12	99.36±23.05	0.54	0.482	93.08±24.72	5.37	<0.001	0.024
VLDL							
0	24.86±9.13	-	-	27.44±8.83	-	-	-
12	24.64±10.15	0.88	0.665	26.86±8.67	2.11	0.255	0.484
TGL							
0	121.8±54.39	-	-	124.82±43.97	-	-	-
12	121.1±52.99	0.54	0.311	118.00±39.01	5.46	0.002	<0.001

HDL: High-density lipoprotein, LDL: Low-density lipoprotein, VLDL: Very low-density lipoprotein, TGL: Triglyceride, SD: Standard deviation

placebo in reducing the mean number of hot flashes after 4, 8, and 12 weeks.[13] Crisafulli observed a 24% reduction in daily flushes after 12 months with a daily dose of 54 mg of genistein.[14] These results are similar to that found the isoflavone group in the present study.

Both groups showed statistically significant improvement in hot flash score at the end of 12 weeks 82% in Group I and 74% in Group II; however, on comparing the two groups, the difference was statistically insignificant at all the visits [P = 0.056, 0.11, 0.356, and 0.076, Table 2]. Although no head-to-head trial comparing the two drugs has been made, placebo-based studies showed that gabapentin at doses of 900 mg/day was similar to estrogens in the control of hot flushes.[15] In a head-to-head comparative design, Crisafulli *et al.* evaluated the efficacy and safety of hormonal therapy versus a genistein concentrate in the reduction of menopausal hot flushes and found a significant difference in the magnitude of the effect between both treatments, which favored hormonal therapy.[14]

Sleep disturbance and insomnia are common symptoms of menopause. In the present study, analysis of the PSQI showed significant improvements in the global score in both the groups, 69.5% in Group I and 60.77% in Group II at 12 weeks, and sleep quality was significantly better with gabapentin at 12 weeks [P = 0.011, Table 3]. Placebo-controlled studies by Yurcheshen *et al.* have shown that gabapentin caused a significant improvement in the PSQI score as compared to placebo.[8] A number of studies have been conducted to evaluate the effect of isoflavones on sleep-related disorders in menopause though no study has used the PSQI as an analytic tool. Hachul *et al.* examined the effect of isoflavones on hot flashes and insomnia using the Kupperman Index and polysomnography (PSG). They found that isoflavones decreased the frequency of moderate/severe insomnia related to menopause and increased sleep efficiency according to PSG.[16] Although their study did not show any correlation between insomnia and hot flashes, other studies such as that by Erlik *et al.* showed that insomnia may be related to the severity of hot flashes.[17] Whether the improvement of the PSQI score in our study was due to the symptomatic improvement in hot flashes with isoflavones remains unclear. On comparing the two groups, statistically significant difference was seen at 12 weeks in the global score in favor of gabapentin [P = 0.011, Table 3].

Studies have shown an association between hot flashes and depression.[18-20] Analysis of the Zung Self-rating Depression Scale in the present study showed improvement in the mean value in both the groups which persisted throughout till 12 weeks [6.86% in Group I and 12.62% in Group II, Table 4]. Reddy *et al.*, however, reported no significant difference in the Zung Depression Score between patients in either the gabapentin, estrogen, or placebo groups.[15] Studies on the effect of isoflavones in depression associated with menopause have been very few. Lipovac *et al.* studied the effect of isoflavone extracts and reported that the Zung Depression Score scorings were significantly decreased (improvement) in comparison to placebo.[21] In another placebo-controlled, double-blind randomized study, de Sousa-Muñoz and Filizola evaluated the effect of soy isoflavones on depressive symptoms using the Center of Epidemiologic Studies of Depression

scale and found a significant reduction in the depressive symptoms in the experimental group; however, the response was not higher than that of the control group.[22] There was an earlier response (at 2 weeks) on depression symptoms, to the treatment with gabapentin as compared with isoflavone in which case improvement started from week 4 and the percentage fall in depression score from baseline at 4, 8 and 12 weeks favored isoflavones [Table 4]. A statistically significant difference was observed between the two groups at week 8, and 12 weeks [Table 5, $P = 0.02$, 0.03, and 0.026, respectively], thus favoring isoflavone.

Soy isoflavones have been associated with a favorable effect on lipid profile. In our study, we found that there was a significant difference in the lipid profiles between the two groups which favored isoflavones [Table 5]. The isoflavone group had significant improvement in cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL), and triglycerides (TGLs) profiles after 12 weeks [$P < 0.001$, 0.009, 0.024, and < 0.001, respectively, Table 5]. In a meta-analysis of 11 randomized trials, Taku *et al.* found that soy isoflavones significantly reduced serum total and LDL cholesterol but did not change HDL cholesterol and triglyceride.[23]

In the present study, none of the drugs caused any major side effect and were well tolerated by the patients. Drowsiness was the main complaint that was seen in the gabapentin group that started at 2 weeks and persisted till week 8. This side effect has been reported in many studies involving gabapentin.[10,15,24]

CONCLUSION

Both isoflavone and gabapentin are equally efficacious in the treatment of hot flashes, but in patients who have associated complaints of depression isoflavones have better response. Gabapentin has better results in patients who have associated sleep disturbance with hot flashes. Both drugs are well tolerated. Isoflavones have a favorable effect on lipid profile with decrease in cholesterol, LDL, and TGL and an increase in HDL and also have added advantage of once daily dosage.

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Conflicts of interest
There are no conflicts of interest.

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Annexure 1: Pittsburgh Sleep Quality Index (PSQI)

1. During the past month, what time have you usually gone to bed at night? _____
2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?
3. During the past month, what time have you usually gotten up in the morning?
4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed)

Question number	During the past month, how often have you had trouble sleeping because you	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
	a. Cannot get to sleep within 30 min				
	b. Wake up in the middle of the night or early morning				
	c. Have to get up to use the bathroom				
	d. Cannot breathe comfortably				
	e. Cough or snore loudly				
	f. Feel too cold				
	g. Feet to hot				
	h. Have bad dreams				
	i. Have pain				
	j. Other reason (s), please describe				
6.	During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?				
7.	During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
		No problem at all	**Only a very slight problem**	**Somewhat of a problem**	**A very big problem**
8.	During the past month, how much of a problem has it been for you keep up enough enthusiasm to get things done?				
		Very good	**Fairly good**	**Fairly bad**	**Very bad**
9.	During the past month, how would you rate your sleep quality overall?				

Annexure 2: Zung Self-rating Depression Scale

Parameters	Scoring			
	A little of the time	Some of the time	Good part of the time	Most of the time
I feel down-hearted and blue	1	2	3	4
Morning is when I feel the best	4	3	2	1
I have crying spells or feel like it	1	2	3	4
I have trouble sleeping at night	1	2	3	4
I eat as much as I used to	4	3	2	1
I still enjoy sex	4	3	2	1
I notice that I am losing weight	1	2	3	4
I have trouble with constipation	1	2	3	4
My heart beats faster than usual	1	2	3	4
I get tired for no reason	1	2	3	4
My mind is as clear as it used to be	4	3	2	1
I find it East to do the things I used to	4	3	2	1
I am restless and can't keep still	1	2	3	4
I feel hopeful about the future	4	3	2	1
I am more irritable than usual	1	2	3	4
I find it easy to make decisions	4	3	2	1
I feel that I am useful and needed	4	3	2	1
My life is pretty full	4	3	2	1
I feel that others would be better off if I were dead	1	2	3	4
I still enjoy the things I used to do	4	3	2	1

Key to scoring the self-rating depression scale: Total maximum score=20×4=80, total minimum score=1×20=20. Add up the numbers for a total score. Most people with depression score between 50 and 69

Annexure 3: Scoring the PSQI

In scoring the PSQI, seven component scores are derived, each scored 0 (no difficulty) to 3 (severe difficulty). The component scores are summed to produce a global score (range 0 to 21). Higher scores indicate worse sleep quality.

Component 1: Subjective sleep quality – question 9 Component 1 score: _____

Component 2: Sleep latency – questions 2 and 5a Component 2 score: _____

Component 3: Sleep duration – question 4 Component 3 score: _____

Component 4: Sleep efficiency – question 1, 3, and 4 Component 4 score: _____

Component 5: Sleep disturbance – questions 5b-5j Component 5 score: _____

Component 6: Use of sleep medication – question 6 Component 6 score: _____

Component 7: Daytime dysfunction – question 7 to 8 Component 7 score: _____

Global PSQI Score: Sum of seven component scores: _____