

## Soy and Calcium Supplementation Reduces Postmenopausal Problems

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**ABSTRACT** This was a purposive randomized intervention trial which assessed the occurrence of postmenopausal symptoms/problems and effectiveness of soy protein isolate and calcium supplementation on overcoming these symptoms in 100 postmenopausal subjects. Questionnaire cum interview schedule was used to collect required information and intervention trials were carried out for a period of 100 days each. Large number of subjects reported a variety of problems associated with menopause. Somatic complaints were reported by 49.43% to 70.78% of the women and were significantly ( $p < 0.05$ ) more prevalent than psychological complaints (17.97% to 98.87%) and urogenital problems. Majority of the subjects (83.14%) had moderate degree of problems. Soy protein isolate intervention was effective in reducing most of the somatic problems in 8.00% to 58.82% of the subjects. Maximum improvement was reported on flushes, heart problems and sleep disturbances. Calcium supplementation was effective in reducing mainly joint pain in the subjects (57.89%). Thus, dietary interventions in the form of soy protein isolate and calcium help in decreasing postmenopausal problems.

### INTRODUCTION

Many functional disturbances are noticeable in postmenopausal women. These are physiological as well as psychological in nature. Hot flushes and night sweats are the symptoms most consistently associated with menopause and are the hallmarks of postmenopausal years in 85% of women. Neurological and emotional parenthesis which takes the form of sensation of pins and needles in the extremities is common. Headache, anxiety, irritability and depression are also common features. In addition, the locomotor system is affected. Menopausal arthropathy, osteoarthritis, fibrosis, backaches and intervertebral disc lesions are other complaints at menopause (WHO 1996; Whiteman et al. 2003; Mushtaq 2011).

The role of phytoestrogens in combating postmenopausal problems has stimulated considerable interest since populations consuming a diet high in isoflavones appear to have lower rates of menopausal vasomotor symptoms, cardiovas-

cular disease, osteoporosis and cancers of the breast, colon, endometrial and ovaries (Messina and Erdman 1998; Frankhanel 1999; Adlercreutz et al. 2000; Butler et al. 2010; Li et al. 2010). Phytoestrogens are plant substances that have effects similar to those of estrogens (Burk et al. 2003; Alekel et al. 2010; Li et al. 2010). Soy foods are the richest source of isoflavones (soy phytochemicals): genistein, daidzein and glycitein are the major isoflavones in soy. Consumption of this class of phytoestrogens has documented health benefits, including reduction of hypercholesterolemia, maintenance of prostate health, and possibly increased bone density and reduction of the risk of hormone-dependent cancers (Alekel et al. 2010; Liu et al. 2010). Reduction in incidence and severity of hot flushes has also been reported in several studies (Albertazzi 1998; Nagata 1998; Potter et al. 1998; Radhakrishnan et al. 2009).

Although hormone replacement therapy confers beneficial effects to postmenopausal women, its health benefits are not completely risk free (Dixon 2002; Grady 2002; Alekel et al. 2010; Liu et al. 2010). Therefore, alternate therapies in the form of food products and nutrient supplements are important to overcome menopausal symptoms and problems. Very few studies have been published on the effect of soy protein iso-

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late supplements on the postmenopausal symptoms in Indian population. Thus, the present study was planned to find out the prevalence of postmenopausal symptoms and the effect of dietary interventions.

### Objectives

To assess the effect of dietary interventions of soy protein isolate and calcium supplementation on the bothersome symptoms of menopause in Indian population.

## METHODS

### Subjects and Sample Size

As the study was very purposive and dietary interventions were involved, the locale was selected on the basis of convenience in terms of easy access for dietary intervention as well as for monitoring the interventions. A total of 100 postmenopausal subjects on the basis of the inclusion criteria and the willingness to cooperate were selected from the north-west part of the metropolitan city of Delhi. Inclusion criteria were (i) menstrual cycle had ceased for at least one year prior to the time of study, (ii) on regular diet, (iii) not taking any cholesterol lowering drug, (iv) not on any type of supplementation, (v) not on ERT and, (vi) not suffering from any metabolic disorders. Of the 100 postmenopausal women selected, 11 dropped during the course of the study. Thus, 89 subjects were studied for postmenopausal symptoms. Further, of the 89 postmenopausal subjects, 72 agreed to take dietary interventions. These subjects were randomly divided into two groups (36 each). Some of the subjects further withdrew themselves from taking the interventions because of various reasons viz. i) Taste of the soy isolate was not liked. ii) Some of the subjects were not regularly taking soy isolate. iii) Some subjects migrated to other place without giving any information thus was beyond control. Thus, finally 30 subjects in Group I (Soy) and 29 subjects in Group II (calcium) could be covered for the purpose of determining the effect of dietary interventions.

### Study Design

The study was a purposive randomized intervention trial conducted in three phases:

**Phase I (Pre intervention):** Data was collected with suitable questionnaire cum interview schedules for all conceptualized variables of sociodemographic profile, dietary information and for problems of postmenopause. This included information on age, marital status, type of family, educational qualification, occupation and income. Data regarding the problems/complaints relating to postmenopause was collected and studied using a rating scale developed for the present study based on a scale used by Heinemann et al (2003). As per the rating scale, various problems/complaints of postmenopause were grouped as somatic, psychological and urogenital domains. The somatic domain had five sub-domains viz. hot flushes, heart problems, sleep problems, joint pains and skin problems. The psychological domain included depression, irritability, anxiety and exhaustion. The urogenital domain included problems like sexual urge, bladder complaints and vaginal dryness.

**Phase II (Intervention):** Dietary interventions were given to the postmenopausal subjects. These interventions were soy protein isolate and calcium supplementation. The soy protein isolate (Supro 670) was partially donated by Solae LLC. Seventy-two participants who agreed to take dietary interventions were randomly divided into two groups (36 in each). Group I was given 40g of soy protein isolate (containing approximately 35g of soy protein) per day for 100 days and Group II was given 500mg of elemental calcium supplement for 100 days. Some of the subjects further withdrew themselves from taking the interventions. Thus, finally 30 postmenopausal subjects in Group I (soy supplementation) and 29 in Group II (calcium supplementation) could be covered for the purpose of determining the effect of dietary interventions.

**Phase III (Post Intervention):** Data regarding postmenopausal complaints was again collected in this Phase so as to study the effect of dietary interventions.

## RESULTS

Table 1 shows the socio-demographic profile of the subjects. Majority of the subjects were married (83.1%) and living in a nuclear family set up (88.8%). Most of the subjects were undergraduates and graduates (60%). While 57.2% were employed in government or private jobs, a fairly large number were housewives (42.7%).

**Table 1: Socio-demographic profile of the postmenopausal subjects (N=89)**

Profile		N (%)
Age(yrs)	Mean ± SD	50.24.42
	Age range	39 – 60
Marital Status	Married	74 (83.14)
	Divorced	4 (4.49)
	Widow	8 (8.98)
	Unmarried	3 (3.37)
	Total	89 (100)
Type of Family	Nuclear	79 (88.76)
	Joint	10 (11.24)
	Extended	-
	Total	89 (100)
Educational Qualification	Under graduate	33 (37.07)
	Graduate	23 (25.84)
	Post graduate and Higher Studies	33 (37.07)
	Total	89 (100)
Occupation	Government	20 (22.47)
	Private	31 (34.83)
	House wife	38 (42.69)
	Total	89 (100)

**Problems of Menopause**

The average age of menopause was 46.71±3.74 years, ranging from 38 to 54 years. Majority of the subjects, regarding the general characteristics of menstrual cycle before the onset of menopause (Table 2), reported commencement of menstruation at or above 12 years of age. For almost all the subjects, menstrual cycle lasted for 4 to 5 days or more and most of them reported having regular menstruation and a moderate blood flow during their menstrual period.

Data regarding the various complaints/problems associated with menopause was also obtained. The responses were categorized into somatic, psychological and urogenital domains. Each of these domains was further classified into sub-domains/complaints (Table 3). In the somatic category, sub-domain of hot flushes was reported by 49.43% of the subjects, joint and muscle pain by as high as 68.53%, sleep disturbances by 66.29% and 60.67% reported palpitation and suffocation. In the psychological domain, while almost all subjects reported on the sub-domain exhaustion (98.87%), a fairly large number also reported depression and irritability. Regarding urogenital problems, 55.05% of the subjects reported decrease in sexual urge. While none of them reported any complaints related to bladder functioning (incontinence), vaginal dryness was reported by a fairly large number (53.93%) of the subjects.

**Table 2: General characteristics of menstrual cycle reported by postmenopausal women**

Characteristics	Category	Postmenopausal subjects N= 89
Age at Start of Menstruation (years)	11	2 (2.24)
	12	38 (42.69)
	13	27 (30.33)
	14 and above	22 (24.71)
Duration of Menstrual Cycle (days)	3	4 (4.49)
	4	39 (43.82)
	5	26 (29.21)
	> 5	20 (22.47)
Regularity of Menstruation	Regular	80 (89.88)
	Irregular	9 (10.11)
Flow of Blood	Mild	15 (16.85)
	Moderate	59 (66.29)
	Heavy	15 (16.85)
	Any other	-
Age of Menopause (years)	Mean ± SD	46.71± 3.74
	Range	38 to 54

**Table 3: Percentage prevalence of menopausal complaints reported by postmenopausal subjects**

Domain	Sub. domain/ complaints	Postmenopausal subjects N = 89	
		Yes N (%)	No N (%)
Somatic	Flushes	44 (49.43)	45 (50.56)
	Heart problem	54 (60.67)	35(39.32)
	Sleep disturbance	59 (66.29)	30 (33.70)
	Joints and muscle pain	61 (68.53)	28 (31.46)
Psychological	Skin	63 (70.78)	26 (29.21)
	Depression	34 (38.20)	55 (61.79)
	Irritability	41 (46.06)	48 (53.93)
	Anxiety	16 (17.97)	73 (82.02)
	Exhaustion	88 (98.87)	1 (1.12)
Urogenital	Change in sexual urge	49 (55.05)	40 (44.94)
	Bladder	-	89 (100)
	Dryness	48 (53.93)	41 (46.06)

To study more precisely the health related quality of life during postmenopause, a scoring pattern was used for responses to the complaints in the three domains viz. somatic, psychological and urogenital. Each of the twelve complaints / sub-domains reported as ‘Yes’ or ‘No’ by the subjects were given a score of 1 for ‘No’ and 2 for ‘Yes’. Accordingly, total scores and mean scores were calculated for each sub domain. Further, the total scores and mean scores of each sub domain were added up to get a composite total and composite mean score for each corresponding domain (Table 4).

In the somatic category, the mean score was highest for the sub-domain of skin problems followed by joint and muscle pain. Exhaustion

**Table 4: Composite total and composite mean score of the complaints of postmenopausal subjects in the three domains (N = 89)**

Domains	Sub- domain/complaints	Scores**		Total score	Mean score
		Yes	No		
Somatic	Flushes	88	45	133	1.49
	Heart	108	35	143	1.60
	Sleep disturbances	118	30	148	1.66
	Joint and Muscle pain	122	28	150	1.68
	Skin	126	26	152	1.70
<i>Composite Total and Composite Mean Score</i>		562	164	726	1.63*
Psychological	Depression	68	55	123	1.38
	Irritability	82	48	130	1.46
	Anxiety	32	73	105	1.17
	Exhaustion	176	01	177	1.98
<i>Composite Total and Composite Mean Score</i>		358	177	535	1.5*
Urogenital	Sexual	98	40	138	1.55
	Bladder	-	89	89	1.00
	Dryness	96	41	137	1.53
<i>Composite Total and Composite Mean Score</i>		194	170	368	1.38*

\*Significantly different at  $p < 0.05$  as tested by ANOVA and Tukey's HSD

\*\*Scoring pattern: Yes - '2' and No - '1'

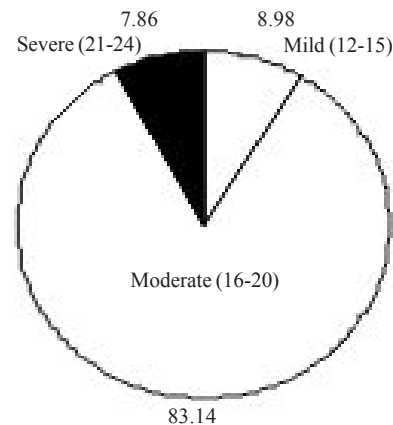
and irritability were the problems with higher mean scores in case of psychological domain. Change in sexual urge and vaginal dryness were more frequent than bladder problems in case of urogenital problems.

The composite mean score for somatic domain was highest being 1.63 and the least was 1.38 for urogenital. When ANOVA was applied to see the significance of difference between the domains, somatic problems were significantly higher than psychological and urogenital problems. Further, psychological problems were significantly more than the urogenital problems as tested by Tukey's HSD ( $p < 0.05$ ) (Table 4).

The data was also analyzed for all the problems in the three domains for each subject individually. As per the scoring pattern of 1 for a 'No' response and 2 for a 'Yes' response to each complaint / sub domain, the total scores were computed for each subject for all the twelve complaints in the three domains. The total scores ranged from a minimum of 12 to a maximum of 24 for the twelve complaints. The subjects were accordingly classified as having mild (Scores 12-15), moderate (16-20) and severe (21-24) degree of complaints. While majority of the subjects had problems of moderate severity, 7.8% were found to have a severe degree of combination of various complaints during postmenopause (Fig. 1).

### Effect of Dietary Interventions

Table 5 depicts the effect of dietary interventions on the postmenopausal symptoms. In the



**Fig. 1. Percentage of severity of postmenopausal problems reported by the subjects**

somatic domain, 50-58% of the subjects showed a decrease in the sub-domains of flushes, heart problems and sleep disturbances as a result of soy protein isolate supplementation. In case of joint pain, there was a 30% decrease. However, only 8% reported a positive effect of soy protein isolate supplements in reducing skin problem. Regarding the effect of calcium supplementation on the complaints of somatic domain, 14-28% of the subjects reported reduction in flushes, heart problems and sleep disturbances. As compared to the responses for soy protein isolate supplementation, the percentage reduction in these problems was lesser with calcium supplementation. However, in case of joint and muscle

**Table 5: Effect of dietary supplementation of soy isolate and calcium on the complaints of the subjects**

Sub domain/complaints	Soy isolate (N = 30) N (%)		% decrease	Calcium (N = 29) N (%)		% decrease
	Before	After		Before	After	
<i>Somatic Domain</i>						
Flushes	17 (56.66)	7 (23.33)	58.82	14 (48.27)	11 (37.93)	21.42
Heart problem	12 (40)	6 (20.0)	50	21 (72.41)	15 (51.72)	28.57
Sleep disturbances	17 (56.66)	7 (23.33)	58.82	21 (72.41)	18 (62.66)	14.28
Joint pain	23 (76.66)	16 (53.33)	30.43	19 (65.51)	8 (27.58)	57.89
Skin problem	25 (83.33)	23 (76.66)	8	13 (44.82)	10 (34.48)	23.07
<i>Psychological Domain</i>						
Depression	14 (46.66)	12 (40)	14.28	11 (36.66)	10 (33.33)	9.09
Irritability	10 (33.33)	8 (26.66)	20	19 (63.33)	17 (56.66)	10.50
Anxiety	4 (13.33)	4 (13.33)	0	7 (23.33)	7 (23.33)	0
Exhaustion	30 (100)	24 (80)	20	28 (93.33)	28 (93.33)	0
<i>Urogenital Domain</i>						
Sexual urge	12 (40)	9 (30)	25	21 (72.41)	21 (72.41)	0
Bladder function	-	-	-	-	-	-
Vaginal dryness	10 (33.33)	4 (13.33)	60	19 (65.51)	19 (65.51)	0

pains, a fairly larger number of subjects reported a decrease as a result of calcium supplementation (57.89%) as compared to 30.43% with soy supplementation.

Regarding the effect on psychological complaints, supplementation with soy protein isolate showed a decrease of 14 to 20% in cases of depression, irritation and exhaustion. Irritation and exhaustion showed better improvement as compared to depression. The effect of calcium supplementation on depression and irritability showed a reduction of 9 to 10%.

In the urogenital domain, 60% of the subjects reported a decrease in vaginal dryness and 25% reported improvement in sexual behavior after soy protein isolate supplementation. Calcium supplementation showed no change for the better on urogenital symptoms.

## DISCUSSION

In the present study, a large number of subjects reported menopausal problems/symptoms after one year of menopause. The study reflected that in postmenopausal women, somatic problems like hot flushes, sleep disturbances, muscle and joint pain were highly prevalent. According to WHO (1996), hot flushes and night sweats are the symptoms most consistently associated with menopause, although their prevalence varies in different cultures. These findings are also supported by the studies of Dennerstein et al. (2004), Kronenberg (1990), and Krebs (2004), summary of a National Institute of Health (NIH) workshop (2004), which showed that vasomotor symptoms, including hot flushes and night

sweats are the most frequently reported symptoms of menopausal transition and postmenopause. In India, very few studies are available on the prevalence of menopausal and postmenopausal problems. A study by Mushtaq (2011) in Srinagar city concluded that hot flushes were more commonly experienced by postmenopausal women in comparison to other symptoms of menopause.

A high prevalence rate of bothersome hot flushes has also been reported by several other studies across different population groups. Guthrie and co-workers (2003) in their study found a prevalence rate of hot flushes in 50% of women after one year of their final menstruation. Yahya and Rehan (2002) reported hot flushes in 32% Pakistani women; while a study by Mckinlay et al. (1992) reported it in 45% of women in North America. An Indian study by Sidhu et al. (2005) showed the prevalence of hot flushes in 55.08% of women, sleep problems in 53% and headache and body aches in 38.28% of postmenopausal women. A study by Kaulagekar (2011) on Indian postmenopausal women in Pune, Maharashtra reported 35.80% prevalence of hot flushes. The prevalence of hot flushes reported in the present study (49.43%) goes with the findings of Sidhu et al. (2005) but is higher than the prevalence reported in the study by Kaulagekar (2011). Prevalence of aching and joint pain was also higher in the present study (68.53%) as compared to the one reported by Kaulagekar (2011) that is 35.80%. This difference may be due to the different techniques followed for the collection of information regarding prevalence of menopausal problems.

The statistics regarding occurrence of psychological problems were different from Sidhu et al. (2005). While fatigue was reported by 42.18% of the subjects in Sidhu's study, exhaustion was reported by 98.8% in the present study. These differences may be attributed to the difference in the terminology and their interpretation by the subjects. In the present study, the word 'exhaustion' as per the rating scale, included not only fatigue and decreased energy but also memory loss, forgetfulness and decreased concentration. Similarly, as compared to prevalence of 'depression' in 8.2% of the subjects in Sidhu's study, it was 38.2% in the present study. This difference again may be because a variety of encounters like feeling low, sadness and mood swings were included in this category in the present study. Psychological problems like irritability, anxiety and nervousness have also been reported by Kaulagekar (2011) which is similar to the findings of the present study.

In the present study soy protein isolate supplementation showed maximum improvement on postmenopausal complaints of flushes, palpitation and sleep disturbances. It was also effective in reducing psychological problems like irritation, exhaustion and urogenital problems like sexual urge and vaginal dryness. Several other studies across the world have shown the beneficial effects of soy protein isolate on postmenopausal symptoms. Albertazzi et al. (1999) in a study on 104 postmenopausal women showed that with consumption of 40 grams of isolated soy protein, there was 33% reduction in flushes at the end of 12 weeks. Consumption of 60gms of soy protein isolate for twelve weeks showed 45% reduction in hot flushes while as much as 26% reduction in a time period of 3 weeks. Murkies et al. (1995) found 40% decrease in hot flushes, when the diet was supplemented with soy flour. In an Indian study, 25 gm soy supplementation showed significantly higher number of cases reporting reduction in hot flushes, joint pain and vaginal dryness (Radhakrishnan 2009). Thus, the findings of the present study are consistent with the findings of similar studies done to assess the effect of soy protein isolate supplementation on postmenopausal symptoms.

When the effect of soy protein isolate supplementation was compared with that of calcium supplementation, soy protein isolate was found to be more effective in reducing the problems of hot flushes, heart problems, and sleep distur-

bances whereas calcium supplementation showed marked effect in reducing somatic problems like joint pain and skin problems. Calcium supplementation did not show any improvement in psychological and urogenital problems. Soy isolate supplementation was effective in reducing some of the psychological (irritability, exhaustion) and the urogenital problems like sexual urge and vaginal dryness.

### CONCLUSION

The present study reveals that postmenopausal women experience a variety of symptoms related to menopause whether somatic, psychological or urogenital. The prevalence of somatic problems (hot flushes, skin problems, muscle and joint pain, sleep disturbances) was significantly higher than the psychological and urogenital problems. Majority of the women suffer from moderate degree of severity of the problems. The study exhibits a favourable effect of dietary measures in the form of soy and calcium supplementation in reducing postmenopausal problems. Soy protein isolate was more effective in reducing problems like hot flushes, heart problems and sleep disturbances where as calcium supplementation was effective in reducing more of muscle and joint pain and skin problems.

### RECOMMENDATIONS

1. Women should be made aware of the different kind of problems associated with menopause and also about their prevalence during postmenopausal years.
2. Results of the present study suggest that soy protein isolate should be included in the diet of postmenopausal women for relief of problems related to menopause.
3. As there are increased chances of osteoporosis, calcium supplementation is beneficial for bone health during postmenopausal phase of life.

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