Original Article

The Effect of Soy Flour Intake on Systemic Blood Pressure and Glycemic Control in Post-Menopausal Women with Pre-diabetes and Prehypertension

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ABSTRACT

Metabolic syndrome has a high prevalence & fast growing trend of cardiovascular risk factor in post-menopausal women and the prehypertension and pre-diabetes are the predictors of heart disease. In the treatment of metabolic syndrome, dietary management is one of the therapeutic approaches for the control of metabolic risk factors. In few studies the use of the soy has shown the effective results in controlling the systemic blood pressure & glycemic changes in post-menopausal women. However, the data's are contradictory. **Aim**: The present study aimed to examine the effectiveness of soy flour diet on systemic blood pressure & glycemic control, of the post-menopausal women with pre-diabetes and prehypertension. The objective of this study is to assess and compare the effect of soy flour diet with different quantity on glycemic control and systemic blood pressure. **Methods**: In this 3*3 completely randomized repeated measures design study, 75 subjects were randomly divided into three groups: study group I (n = 25), study group II (n=25) and control (n = 25). The subjects in the study group I & II were received 25 g/day and 45 g/day of soy flour respectively in the form of dosa and in control group, the subjects were received wheat flour 52g/day in the form of dosa for 12 weeks. The dosage of the diet received by subjects had not been exchanged during the study period. Before, 6 weeks and 12 weeks of the intervention, serum fasting glucose, fasting insulin, insulin resistance and systolic and diastolic blood pressure, were measured in the subjects. Insulin-resistance was calculated by using HOMA-IR formula. **Results**: There was a significant difference across the 3 time points and significant differences between control and study groups by lowered FPG, fasting insulin, insulin-resistance, diastolic blood pressure, but not had any significant different in time within group & between the three groups in reducing systolic blood pressure. Moreover, the study groups I & II is more effective in controlling diastolic blood pressure and glycemic changes. **Conclusion**: Soy flour diet intake in post Menopause with prediabetes and pre-hypertension can lead an effect in glycemic control, insulin-resistance and diastolic blood pressure, but not had any significant effect in reducing systolic blood pressure.

Key words: Metabolic syndrome, Post- menopausal women, Glycemic control, Systemic blood pressure, HOMA-IR-Homeostatic model assessment-Insulin resistance.

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INTRODUCTION

Menopause is normal physiological process and the end of women's reproductive period, all women go through this stage either just or after she stops menstruation. During this stage most of the women will experience various menopausal symptoms and health issues. In menopause ovaries stop their functioning, it leads to reduction in the estrogen and progesterone hormones in the body. In premenopausal women's estrogen act has plasma cholesterol lowering factor, which action is preventing from

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cardio vascular,[1] but in post menopausal women's body the protective action of estrogen is lost which is causing changes in lipid profile.[2] Post menopause is the years after menopause. Due to the depletion of estrogen increasing changes in the metabolic risk factors in the women body.[3] Metabolic risk factors include a pro-atherogenic lipid profile, higher prevalence of visceral obesity, insulin resistance, and hypertension.[4]

Cardio-vascular diseases (CVD), one of the main causes of death in women[5] & type II diabetes increases the risk of death from CVD by two- to four times,[6] and women with diabetes are 4 times most likely to die from CVD than men.[7] Post-menopausal low estrogen state & increased insulin resistance[8,9] may lead to increase the risk of CVD in women with diabetes.

In Andhra Pradesh the percentage of women aged 30- 49 who were menopause is 31%, out of range from the national average of around 18 % and it is high rank in India, according to the second national family health survey, a government health survey available for the 1998-99. As the population ages, estimate suggest that by the year 2016, 45% of all women's will be 45 years or older, an age often associated with the changes in the menstrual cycle.[10] Dr. S.V. Kameswari presented her case study on hysterectomies in Medak district of Andhra Pradesh and she found that increased number of cases of hysterectomy in Andhra Pradesh below the age of 40yrs. She was discussed that early hysterectomy increases the greater risk of premature menopause and its complications and she emphasized the need of research in the area of how lost ovarian function can be replaced.[11]

Moreover, more than 80% of the women experiencing less physical & mental well-being in the year approaching menopause due to lack of estrogen in the body. Hence post-menopausal woman can be considered as risk population.[12] Health issues of postmenopausal women therefore would pose a significant challenge to public health & also considering the fact that, there hasn't been a specific health program for such a menopausal women in the our country. The current old age health care services are mostly based on the general health problems of the elderly and not directed specifically to the post- menopausal health problems.[13] Hence there is an urgent need to increase knowledge, develop practice, reinforce primary gynecological care, and develop alternative methods of Hormonal Replacement Therapy for menopausal health problems.

Soy food is placing a new dimension in the treatment of metabolic syndrome. Soy contains complex carbohydrates, soluble fibers, vegetable protein, oligosaccharides, minerals, and phytoestrogens, mainly the isoflavones, genistein and daidzein that may be beneficial in the treatment of diabetes.[14] Soy nuts significantly control the SBP and DBP in all of the hypertensive women and 83% of the normotensive women.[15] The previous studies on the effects of a soy-based diet in persons with diabetes[15-19] have been performed on a heterogenous population using different form of soy preparations, & there are few studies focused on the effect of soy nut on diabetes and hypertension. This study was to determine the effects of two different dose of soy flour diet on glycemic control and systemic blood pressure in postmenopausal women with dysglycemia and prehypertension.

MATERIALS AND METHODS

Subjects

A total of 75 postmenopausal women with pre-diabetes and prehypertension were screened for inclusion in the study. Women aged between 40-60 years, either surgically or naturally menopause with FSH levels ≥30 m IU/ml was included. The natural menopausal group consisted of those women who had their last menstrual period at least 1 year earlier but not more than 10 years. Women with a fasting glucose concentration ≥100 mg/dl, systolic blood pressure ≥ 130 mmHg & diastolic blood pressure ≥ 85 mmHg were included for the study. Women with diabetes mellitus, undiagnosed diabetes, and hypertension, current or previous use of estrogen therapy, untreated hypothyroidism, kidney or liver diseases, smoking, breast cancer, uterine cancer & history of drug and alcohol abuse were excluded from the study. All participants provided informed consent. The present study was approved by the human ethical committee of the Saveetha University, Chennai, Tamil Nadu, India.

Study design

We used 3*3 completely randomized repeated measure design and cluster randomization followed by simple random technique was used to select the samples for the present study. Postmenopausal women were included. A total of 25 women were assigned to control group who they received wheat flour 52 g/day, 25 women were assigned as study group I who were received soy flour 25 g/day, and 25 women were assigned as study group II who were received soy flour 45 g/day in the form of dosa for 12 weeks. The soy dosa prepared with soy flour, water, little salt, coriander leaves and chillies. The proportions of genisten, diazeden, and glycetine soy flour 25 g dosa averaged 41.2 mg, 5.34 mg, 6.45 and in soy flour 45 g dosa mg averaged 69.4 mg, 8.05 mg, 9.54 mg respectively. Patients were asked to maintain an

isocaloric diet thought out the study period. The participants were instructed not to change their habitual physical activity level for the duration of the study.

Study measurements

After an overnight fast, systemic blood pressure were measured and fasting blood samples were drawn to check the fasting blood glucose and fasting at the beginning of the study, 6 weeks and 12th week. The insulin resistance was calculated using formula HOMA-IR = (Insulin × glucose)/22.5). Serum FSH was measured by enzymatic method. Routine biochemistry test was performed by using standard methods.

Statistical analysis

The data were calculated by using the SPSS version 17. Data were presented in the form of mean and standard deviation (SD). Mean changes, between the group and within the group effect on time and group and time interaction effect were calculated by using two way repeated measures ANOVA. Following up the interaction effect Dunnett t-tests was done for pair wise comparison. The significance level was considered equal when the p value is < 0.05.

RESULTS

The subjects who were selected for the study, comparable for age and time since menopause were statistically similar between the three groups (Table 1)

Table 2 shows systolic and diastolic blood pressure, fasting plasma glucose, fasting insulin and HOMA-IR mean values with standard errors in three group and it also shows the between group effect and within effect - time effect and time and group interaction effect of variables and significance level.

Serum fasting glucose, fasting insulin, HOMA-IR and systemic blood pressure levels were calculated by using two way repeated measures of Anova. We found that there was no significance difference in pretest level between the three groups.

Graph-1 shows within group test, the interaction between the time and group is significant. The between groups test pointing out that there variable group is not significant. The graph shows at the pretest level, the mean values are similar, control group mean increasing over a time but when comparing with study groups it is far away from reducing the particular value. The mean value of study group I & II systolic blood pressure also not significant within group over time.

Table 1: Comparable clinical parameters in the study group I, II and control group

Parameters	Study group I(soy flour 25 gms) (MEAN±SEM)	Study group II (soy flour 45 gms) (MEAN±SEM)	Control group (MEAN±SEM)
Age	52.36±0.66	51.24±0.62	51.52±0.51
Time since menopause (yrs)	3.76±0.28	3.40±0.29	3.00±0.24

Table 2: Comparative effects of two different dose of soy flour on systemic blood pressure and glycemic parameters

Parameters	Groups	0 week	6 weeks	12 weeks	Time F value (2,144)	Group F value (2,72)	Time*group F value (4,144)
Systolic BP	Control Study group I Study group II	135.32±0.56 135.32±0.50 135.40±0.53	135.84±0.52 135.00±0.46 135.16±0.52	136.08±0.57 135.00±0.46 135.16±0.52	0.332 P=0.0718 η^2=0.005	0.450 P=0.64 η^2=0.005	5.984 P<0.01 η^2=0.410
Diastolic BP	Control Study group I Study group II	85.32±0.53 85.08±0.54 87.28±0.23	86.20±0.52 81.36±0.79 79.92±0.40	86.12±0.53 80.00±0.52 78.08±0.39	254.06 P<0.01 η^2=0.78	110.89 P<0.01 η^2=0.14	23.59 P<0.01 η^2=0.40
Fasting plasma glucose	Control Study group I Study group II	113.16±1.66 114.32±1.43 113.56±1.19	112.88±1.59 110.28±1.43 110.72±1.26	112.52±1.52 106.56±1.27 99.60±1.49	106.33 P<0.01 η^2=0.60	3.35 P=0.04 (P<0.05) η^2=0.09	31.98 P<0.01 η^2=0.47
Fasting Insulin	Control Study group I Study group II	29.52±0.70 29.76±0.60 30.72±0.68	29.08±0.66 28.48±0.55 27.4±0.48	29.08±0.62 24.32±0.53 25.20±0.30	111.45 P<0.01 η^2=0.61	3.13 P=0.40 (P<0.05) η^2=0.08	25.48 P<0.01 η^2=0.41
HOMA- IR	Control Study group I Study group II	8.26±0.26 8.40±0.22 8.60±0.20	8.11±0.24 7.75±0.19 7.50±0.18	8.09±0.23 6.42±0.20 6.19±0.12	197.28 P<0.01 η^2=0.73	4.19 P=0.019 (P<0.05) η^2=0.10	41.00 P<0.01 η^2=0.53

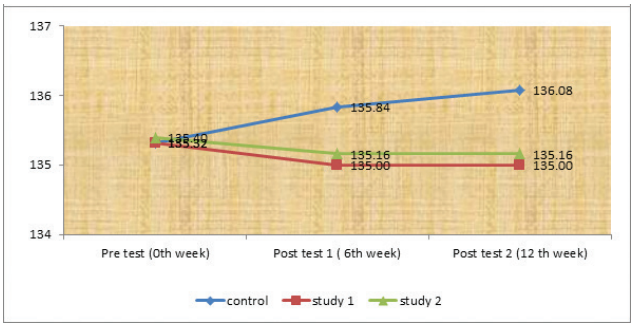
Graph-2 shows between groups test stipulate that the variable group is significant, & within subject test point out that there is a significant time effect, in other words, the groups do change over time, both study group are getting less diastolic blood pressure over time. Moreover, the interaction of time and group is significant. The graph shows at the pretest level the mean value are more or less similar, control group mean increasing over a time but in the study group I & II are significantly decreasing the diastolic blood pressure over a time.

Graph-3 shows the between group test indicates that the variable group is significant. The within group test indicates that there is a significant time effect, in other words, the groups do change in fasting plasma glucose over time. This means that the study groups are decreasing fasting blood glucose over time. Again, the within subject test point out that the interaction of time and group is significant.

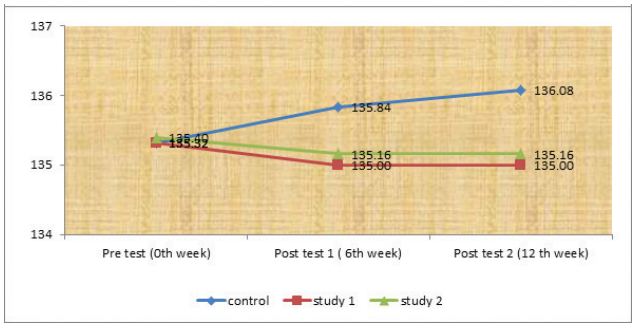
Graph-4 shows the between groups test indicates that there the variable group is significant. The within subject test stipulate that there is a significant time effect, in other words, the study groups are decreasing fasting insulin over time. Again, the within subject test indicate that the interaction of time and group is significant.

Graph-5 shows the between groups test indicates that there the variable group is significant. The within subject test point out that there is a significant time effect, in other words, the study groups are decreasing HOMA-IR over time groups do change in HOMA- IR over time. Again, the within subject test indicate that the interaction of time and group is significant. In FPG, insulin, HOMA – IR was no significant difference between the groups at baseline and study group I & II significantly decreasing within group over time.

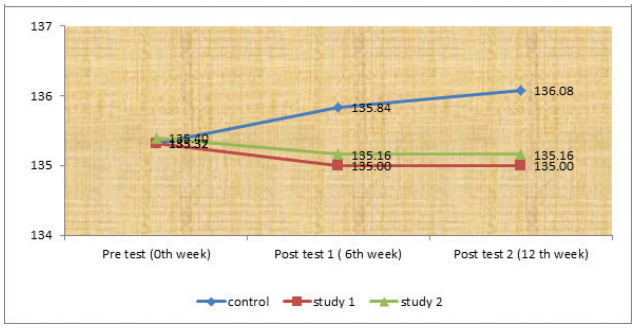
In systolic blood pressure there was no significant change within the study groups over time. But the diastolic blood pressure was significantly decreased over time. Since, the interaction between group and time was significant in diastolic blood pressure, Fasting plasma glucose, Fasting insulin and HOMA- IR, follow up test were also conducted to evaluate the groups in pair wise differences. The test revealed that the study group II (45 g soy flour) had significantly improvement in reducing diastolic blood pressure, fasting blood glucose, fasting insulin and HOMA-IR values, when compare to control group. Study group I (25 g soy flour) also had significant difference with control group in reducing diastolic blood pressure, fasting insulin and HOMA-IR levels. Further, it shows both the study group I and II statistically more or less similar effect on reducing the fasting glucose, fasting insulin and HOMA- IR and diastolic blood pressure.



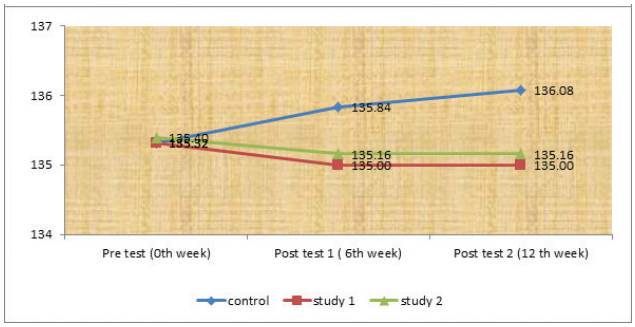
Graph-1: Comparison of systolic blood pressure mean values over time periods by group wise



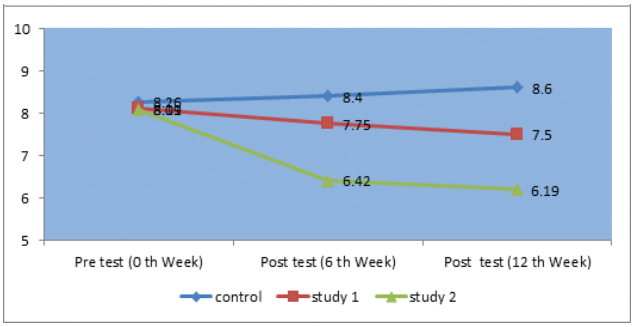
Graph-2: Comparison of diastolic blood pressure mean values over time periods by group wise



Graph-3: Comparison of fasting glucose mean values over time periods by group wise



Graph-4: Comparison of fasting insulin mean values over time periods by group wise



Graph-5: Comparison of homa-ir mean values over time periods by group wise

DISCUSSION

Above results revealed that intake of soy flour diet is placing a role in controlling the diastolic blood pressure, fasting glucose, fasting insulin and HOMA insulin-resistance. But, it did not have a significant effect on systolic blood pressure.

Subroto Acharjee *et al.*[20] studied that the soy diet had significant reductions in diastolic BP (7.7%; P = 0.02), TG (22.9%; P = 0.02), C-reactive protein (CRP) (21.4%; P = 0.01) [25] among equol producers compared with control group (TLC diet). But it did not have a significant effect on systolic blood pressure. This is similar to our study result in the point of systemic blood pressure.

Afsaneh Bakhtiary *et al.*[21] studied that the soy-nut (35g/d), TSP (35g/d) two different form of soy effect on lipid profile, and the study explored that soy does not had a significant effect on the blood pressure among the elderly women with metabolic syndrome.

Azadbakht L *et al.*[22] studied that both soy-protein & soy-nut consumption had no significant effects on systolic or diastolic blood pressures compared with the control diet. Future they examined the soy intake improved glycemic control. Compared with the soy-protein and control diets, the soy nut diet significantly decreased HOMA-IR at the end of the soy-nut diet. However, the present study examined that soy flour diet intake improves the glycemic control including HOMA- IR and diastolic blood pressure, not in the systolic blood pressure.

Alireza Sedaghat *et al.*[23] studied the Soy nuts on lipid Profile, glycemic control and Insulin-Resistance in Type 2 Diabetic Patients. Soy consumption significantly lowered FPG, HbA1c, plasma insulin levels, insulin-resistance, total cholesterol and LDL-c, but did not have any significant effect on systolic blood pressure, diastolic blood pressure, HDL-c and TG. The present study also supports the significant effect of soy on fasting glucose and insulin, and not significant effect on systolic blood pressure.

Further, Welty *et al.*[24] reported in a study of 56 menopausal women with hypertension or normal blood pressure, In the case of hypertension that intake of 56 g of soy nuts for 8 weeks decreased systolic blood pressure and diastolic blood pressure by 9.9% and 6.8%, respectively and 5.2% and 2.7% in individuals with normal blood pressure. Nasca *et al.*[25] also studied that taking 25 g of soy for 8 weeks in hypertensive post-menopausal women is followed by an average decline of 9.9% and 6.6% respectively in both systolic and diastolic blood pressure. Our study result showed that whole soy flour diet for 12 weeks significantly reduced only diastolic blood pressure not systolic blood pressure.

Zhao-min Liu, *et al.*[26] conducted a study with soy on glycemic control, a meta-analysis of randomized controlled trials point out that soy intake did not show a markedly favorable effect on the decrease of fasting glucose and insulin, even though subgroup analyses indicated a positive change in fasting glucose concentrations in trials that used whole soy foods or a soy diet. In our study we used whole soy flour for study groups as a treatment, and the result showed significant effect on fasting blood sugar, fasting insulin and HOMA-IR.

CONCLUSION

In summary, these data showed that short-term dietary soy flour diet reduces systemic blood pressure & improves glycemic control in post-menopausal women with pre-diabetes and prehypertension. Studies of longer duration are needed to decide whether these effects are sustained & have a beneficial effect on controlling the metabolic risk factors.

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CONFLICT OF INTEREST

None of the authors have any personal or financial conflicts of interest.

ABBREVIATIONS USED

SBP: Systolic blood pressure; **DBP:** Diastolic blood pressure; **TSP:** Textured soy protein; **FSH:** Follicular stimulating hormone; **HOMA-IR:** Homeostatic Model Assessment of Insulin Resistance; **TG:** Triglyceride;

TLC: Therapeutic Lifestyle Changes; **FPG:** Fasting Plasma Glucose; **HbA1:** Haemoglobin A1c; **LDL-c:** Low-density lipoprotein cholesterol; **HDL-c:** High-density lipoprotein cholesterol.

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SUMMARY

- 12 weeks of soy flour diet intake reduced the systemic blood pressure in Post-menopausal women
- 12 weeks of soy flour diet intake improved the glycemic control in Post-menopausal women.
- 12 weeks of 45g soy flour diet was more effective in controlling glycemic factors and systemic blood pressure in Post-menopausal women.

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