EPH- International Journal of Biological & Pharmaceutical Science
ISSN (Online): 2208-2166
Volume 11 Issue 01 March 2025

DOI: https://doi.org/10.53555/eijbps.v11i1.59

OUTCOMES OF SOY PROTEIN CONSUMPTION ON THE BIOCHEMICAL PARAMETERS OF PLASMA IN HUMAN VOLUNTEERS - POSTMENOPAUSAL WOMEN

Dr.A.Helah Kiranmai[1]*, Ms.C.Vanisree[2], Mrs. N.Swathisree[3], Ms. B.Maheswari[4]

[1]Assistant Professor, Department of Biochemistry, St.Pious X Degree &PG College for Women, Hyderabad, Telangana State, drhelahkiran7@stpiouscollege.org*
[2]Head of the Department, Department of Biochemistry, St.Pious X Degree &PG College for Women, Hyderabad, Telangana State. vanisree3108@gmail.com
[3]Assistant Professor, Department of Biochemistry, St.Pious X Degree &PG College for Women, Hyderabad, Telangana State, swathisree1213@gmail.com
[4]Assistant Professor, Department of Biochemistry, St.Pious X Degree &PG College for Women, Hyderabad, Telangana State, maheshwaribathula.mb@gmail.com

Corresponding Author: Dr.A.Helah Kiranmai
**E-mail address: drhelahkiran7@stpiouscollege.org*

ABSTRACT :
In the recent decade the pre and post menopausal complications and symptoms are increasing alarmingly posing a multidisciplinary intervention. Various chronic & temporary diseases in postmenopausal women are caused by rapid changes in hormones and stressful conditions and are accompanied by rapid changes in body composition (muscle, bone, and fat). In order to maintain a healthy body composition and overall well being the post menopausal women in the ageing society are ingesting high quality protein foods these days. Literature is proving the beneficial effects of soy protein in post menopausal women as soy proteins are rich in isoflavones. Nutrigenomics and personalized nutrition are taking big seat in treating the subjects. But there is is limited /no public data available on the consumption of soy protein – and its impact on various plasma parameters. In conjunction with this, the present study was aimed at the impact of various types of soy proteins on the plasma parameters of female human volunteers aged 45± 7 years mean age being 45 years for a period of 12 weeks. The present study is showing hypoglycemic effect and has impact on lipid profile with less significant changes on proteins, but much intensive research has to be done to establish the results

Keywords: *Plasma, Pre menopause, Post menopause, Soy proteins, Isoflavones, plasma parameters , glycemic index, lipid profile*

Introduction

he findings of the Women's Health Initiative resulted in a sharp decline in the use of estrogen therapy to treat menopause transitional phase and menopausal women. In the recent past it was observed that the menopausal women were interested in ingestion of soya meal as it was considered as an alternative to estrogen therapy for the treatment of menopausal symptoms. The evaluation of the effectiveness of soy foods / textured soy protein to ease the vasomotor and urogenital symptoms analysis studies are scarce, and a small number of them are presented in this article. Due to marginal number of trials detailing the disputing results, the substantiation of the effectiveness of Glycine max protein to ameliorate menopausal symptoms is limited.

Review of the Literature

The soya bean protein and the flavones contained in soy proteins can enhance muscle and bone density and quality and lower the body weight. The soy protein was found to be productive in preventing low bone mass and low muscle mass and a rise in BMI that may occur after menopause. (1) , Soya protein has significant effect on lipid profile(2) it decrease cholesterol and triglyceride levels, which is beneficial for systemic metabolism and cardiovascular health. Recent epidemiological evidences and experimental data from animal studies strongly support the useful outcomes of isoflavones in averting various chronic diseases (3,4).Soybeans contain 12 types of isoflavones (5,6) and the content of soy isoflavones can vary from 50mg/100g to 300 mg/100 g of Glycine max seed protein (7). Soy phytoestrogens have been reported to lessened the bone density loss from the lower part of the spinal column in perimenopausal women (8), to lower blood cholesterol levels (9, 10, and 11) and to have antioxidant properties *in vivo* and *in vitro* experiments (12, 13).Attributable to these potential of edible bean isoflavones ,it is mentioned in a few studies that it has the helpful results on averting and attenuation in chronic diseases such as cancers (14) cardiovascular diseases (15), osteoporosis (16) and menopausal symptoms (17, 18). soya bean oils are rich with poly unsaturated fatty acids predominantly with the essential fatty acid – linoleic acid and smaller amounts of α- linoleic acid (19)The unsaturated fatty acid of soy, such as n-3 long-chain polyunsaturated fatty acids, enables improvement in blood glucose level and insulin resistance (20). The research studies also established the consequences of soy foods on the endocrine status of the post menopausal women.(21) Soy can also improve the metabolic health of postmenopausal women(22) In laboratory animals, dietary soy protein intake is associated with obesity, decreased blood glucose and insulin, and improved lipid distribution and insulin sensitivity, so this shows that soy isolates are effective in improving obesity (23,24,25) Despite of the reality that the studies on soy bean meal remains at issue (26) as a source of protein rich food , it is important for maintaining bone density in postmenopausal women. Soya meal has cholesterol reduction function and effectively balance gut microbiome, shifting the gut microflora constitution towards an augmentation in Lactobacilli, Bifidobacterium, and Firmicutes to Bacteroidetes ratio (27) Soy isoflavone intake led to a reduction in both the transaminases - Alanine trasminase and Aspartate transaminase (28)

Menopausal symptoms

In the process of the commencing years of menopause women many a time experience episodes of temperature dysfunction leading to nocturnal hyperhidrosis, somatic indicators such as weariness, myalgia, and vulvovaginal atrophy, and emotional signs such as irritability, impatience, unhappiness, low libido, and insomnia. The prevalence, rigorousness, and the time span of changes in gonadal hormone features vary according to the population (29).The manifestations can begin during the menopausal transformation up to two years before the cessation of menstruation. The mean time scale of hot flashes is six months to five years, although 20% of females go on with symptoms into their 70s and 80s.Chronic sleep insufficiency, constantly recurring fatigue and impulsive were found to occur due to the horning in night flashes with sleep. Estrogens were productive in lowering the frequency and criticality of these indicators and are commonly used as positive controls in clinical trials. Nevertheless the handling of climacteric symptoms has changed considerably since the publication of the WHI results in 2002 (30). Fair segments of Post menopausal women now report of holistic approach; four score percentage of women aged 45–60 old announce the usage of nonprescription therapies to get along the menopausal symptoms (31). Soya trading in US has expanded from 300 million dollars in 1992 to 4.5 billion dollars in 2009 (32) designating its significance. The substantial growth was seen in soy-based meat alternatives like soymilk and tofu.Soy Protein is currently the subject of extensive research, mainly because it is a unique and abundant source of isoflavones. There is no public data available on the soy protein – and its impact on the plasma parameters that in turn may have positive effects to combat the post menopausal symptoms. Soyprotein often exhibits a beneficial outcome on the bone health.

Subjects for the study

A 12 weeks preliminary study has been conducted on two groups (sample size of 24 subjects) of human female post menopausal volunteers, were considered for the analysis each group consisting of twenty four members (Group I was used as controls who doesn't use soy protein , Group II were Soy food users). All volunteers, were of 43-50 years old (mean age 45±3 years) residing in Hyderabad, Telangana state who have attained menopause and are showing one or few symptoms of post menopause have showed that the ingestion of soja in systematic basis had a potential effect on various parameters of plasma.

TABLE1: CHARACTERISTIC FEATURES OF STUDY PARTICIPANTS

Parameter	Group	
	Control	Soy protein users
Number (n)	24	24
Age (years) & Gender	45 ±3 (female)	45 ±3 (female)
Soy protein (gm/day)	Not used	15-20 gm
Period of Soy protein use in diet	Not applicable	60 days
Subjects suffering from any Chronic diseases/illnesses	Nil	Nil

Values are expressed as Mean ± SEM, n=24 Data were subjected to student't' test
* Values represent the differences between groups which are statistically striking at $P \leq 0.05$.

The 12 week design comprised of subjects consuming a controlled diet containing the assigned 20 gms of textured protein in their daily breakfast indifferent edible forms, the miracle bean was supplied to subjects as per nutritional guide lines and assessed for plasma parameters where as Controls (age, sex and diet matched) who did not use any soy protein in their were selected for the study. A written consent form was secured from the study subjects selected for the study after explaining to them the experimentation procedure thoroughly. This study was approved by the institutional ethical committee. Blood samples from overnight fasted subjects were used for the study. It was also ensured that all the participants in the current study did not suffer from any chronic disease or illness and is teetotalers with no smoking habit and free from use of any tranquillizers, drugs and anesthetics.

TABLE: 2 TYPES SOY PROTEINS GIVEN TO THE SUBJECTS

S.No	Week	Type of Glycine max
1	1 &7	Boiled & seasoned soy seeds
2	2 &8	Soya milk
3	3&9	Soya chunks curry
4	4&10	Tofu
5	5 &11	Soya nuts
6	6& 12	Soya sprouts

Methodology:
Blood collection
Blood was drawn from human female volunteers by venipuncture between 7 to 10 AM into heparinized test tubes and was analyzed immediately for plasma, red cell and platelet analysis. Biochemical studies using plasma included mainly determining the concentration of glucose, amino acids, triglycerides, cholesterol, HDL, LDL, VLDL, phospholipids, glycolipids, nitrites, nitrates, plasma lipid peroxidation, iron, proteins, albumins, globulins, A/G, C/P ratios, SGOT, SGPT. Plasma glucose was estimated by using Monozyme diagnostic kit, originated from the method of Tinder, (1969). Free amino acids in plasma were estimated by using the method of Moore and Staein, (1948) Total protein content in the plasma was estimated by using Biuret method of Reinhold, (1953). Plasma albumin and globulin were estimated by the method described by Wotton, (1974).Lipid Profile by Kit method

Table- 3: Levels of glucose, HbA_{1C}, Cholesterol, Transaminases, Iron, Hb, Nitrite and Nitrates in plasma of controls and Soya food Users.

Parameter	Group	
	Control	Soy protein users
Glucose (mg/dL)	91.09±2.68	78.03±1.95*
HbA_{1C}	5.80±0.21	5.22±0.19*
Cholesterol (mg/dL)	217.50±4.25	195.78±5.20*
GOT (IU/L)	31.13±3.10	40.18±1.85*
GPT (IU/L)	34.09±2.55	45.30±3.28*
Iron (µg/dL)	118.32±4.66	104.81±3.98*
Hb (gm/dL)	15.40±1.40	14.90±1.28
Nitrite (µmoles/L)	3.09±0.08	3.81±0.05*
Nitrate (µmoles/L)	33.59±0.11	38.69±0.40*

Values are expressed as Mean ± SEM, n=24 Data were subjected to student't' test

* Values represent the differences between groups which are statistically notable at $P \leq 0.05$.

Fig 1

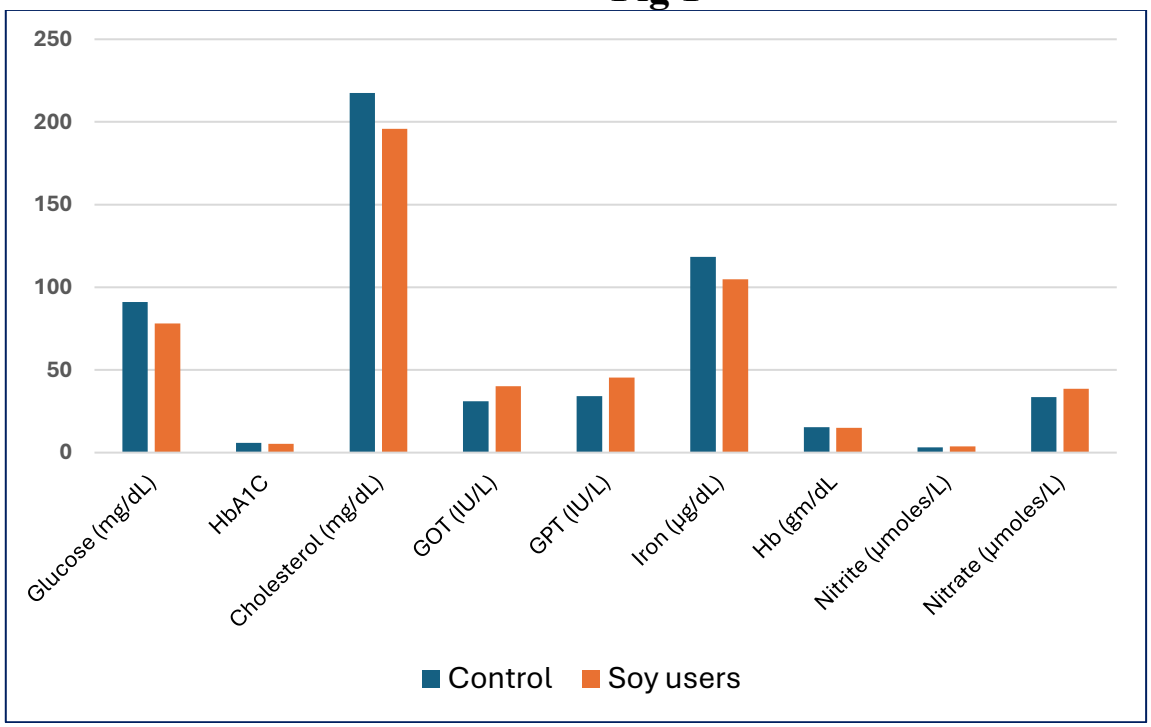


Figure-1 Levels of glucose, HbA_{1C}, Cholesterol, Transaminases, Iron, Hb, Nitrite and Nitrates in plasma of controls and Soy protein Users.

Soy protein use in postmenopausal female human volunteers on the concentrations of plasma glucose, $HbA1_C$ Cholesterol, Iron, Hb and activities of GOT and GPT and the concentrations of nitrite and nitrate in plasma of soy protein users and control subjects who do not use Soyprotein at all. There has been a reduction in the concentration of glucose (14.33%), HbA_{1C} (10%), Cholesterol (9.98%), Iron (14.1%), and Hb (9.2%) followed by an increment in the levels of plasma nitrite (18%) and nitrate (15%) in soy protein using subjects when compared to controls. Increased activities of plasma GOT (22%) and GPT (32.88%) in soy protein users were also observed in the present work.

Table-4 Results of Soy proteins use on plasma lipids, lipoprotein patterns and LPO

Parameter	Group	
	Control	Soy protein users
Cholesterol (mg/dL)	217.50±4.25	195.78±5.20*
HDL-C (mg/dL)	47.23±2.93	56.17±2.46*
LDL-C (mg/dL)	67.48±3.67	56.78±3.32*
VLDL-C (mg/dL)	13.42±1.84	31.73±2.14*
Triglycerides (mg/dL)	147.60±6.32	173.40±5.26*
Glycolipids (mg/dL)	322.09±4.25	303.35±4.58*
Phospholipids (mg/dL)	245.10±3.38	266.08±4.21*
Atherogenic index	4.41±0.75	3.48±0.54*
Lipid peroxidation (µmoles of MDA/L)	5.11±0.32	5.97±0.12

Values are expressed as Mean ± SEM, n=24 Data were subjected to student't' test

* Values represent the differences between groups which are statistically significant at $P \leq 0.05$.

Figure-2 Results of Soy proteins use on plasma lipids, lipoprotein patterns and LPO

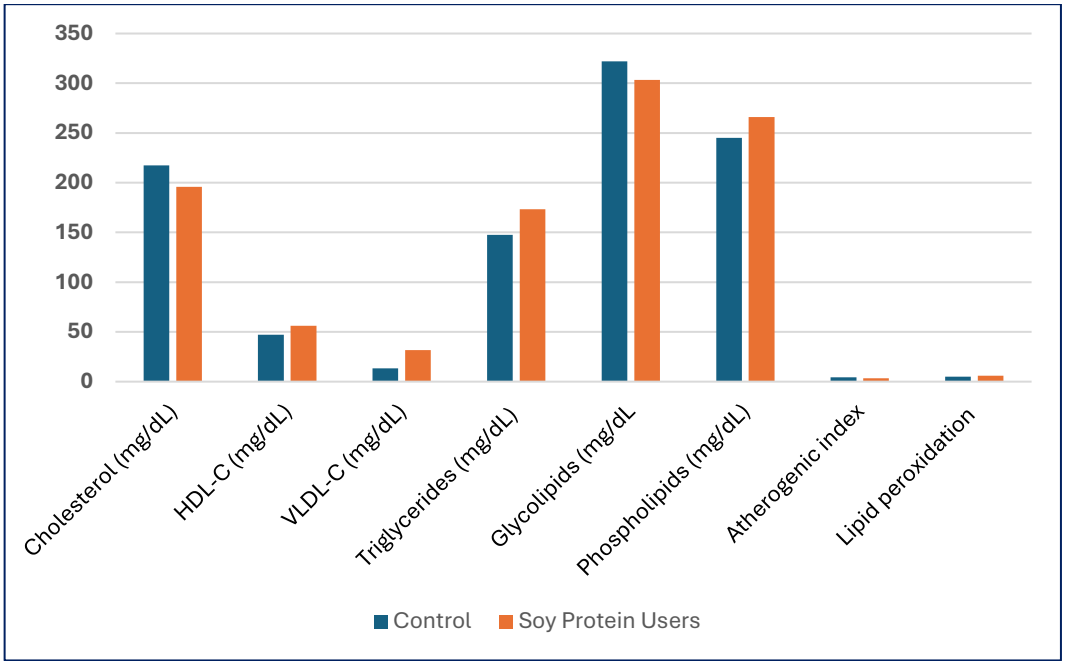


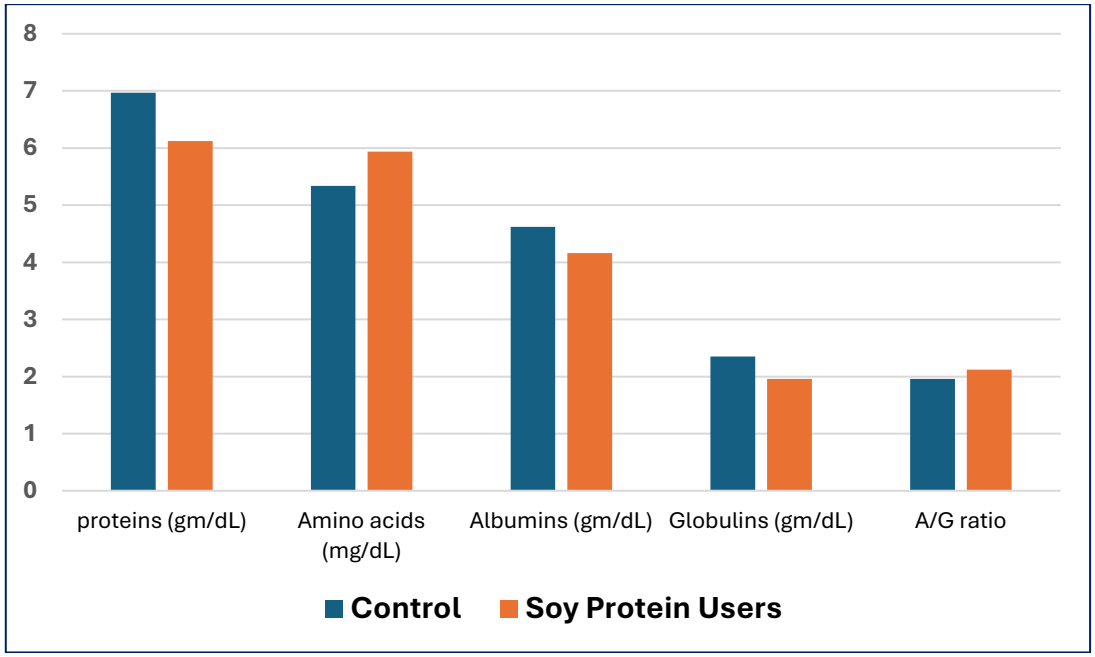
Table- 5 Outcomes of Soya use on plasma proteins and amino acid content

Parameter	Group	
	Control	Soy protein users
proteins (gm/dL)	6.12±0.27	6.97±0.31
Amino acids (mg/dL)	5.94±0.22	5.34±0.18
Albumins (gm/dL)	4.16±0.14	4.62±0.16
Globulins (gm/dL)	1.96±0.11	2.35±0.12
A/G ratio	2.12	1.96

Values are expressed as Mean ± SEM, n=24 Data was subjected to student't' test

* Values represent the differences between groups which are statistically important at $P \leq 0.05$.

Figure-3 Outcomes of Soya use on plasma proteins and amino acid content



Discussion

The present study is showing hypoglycemic effect and has impact on lipid profile with less significant changes on proteins, but much intensive research has to be done to establish the results.

The limitations of the present study comprise diminutive sample size, minimal duration, and the usage of discrete soya foods that carry varied portions of soy phytoestrogens, and the study subjects are in the age range or who vary in the amount and severeness of menses cessation manifestations therefore, the study has to be ratified and should be extended more than 12 weeks to assess the conservational consequences on plasma parameters.

To conclude, it can be acknowledged that post menopausal signs are frequent, despite the fact that their prevalence differs based on the population under study. The facts of the ongoing research can lessen the usage of hormone replacement therapy among post menopausal females which own lot of side effects as per the various published reports. An escalation in the eating of soya and soya supplements rich with Genistein,Daidzein,Glycitein isoflavones for handling the menopausal issues is encouraging as per current study.

But few works appraised the efficacy of soya in the improvement of vasomotor and genital signs have been piloted globally and have employed a diverse soya foods holding distinct amounts of isoflavones have shown denial outcomes .To deduce and taking into consideration of the contradictory consequences provided by insignificant number of studies, the virtue of soya isoflavones in the betterment of menopausal symptoms remains ambiguous.

References

1. Sijia Tang, Yang Du, Chorong Oh, and Jaekyung No. Effects of Soy Foods in Postmenopausal Women: A Focus on Osteosarcopenia and Obesity. J Obes Metab Syndr. 2020 Sep 30; 29(3): 180–187. Published online 2020 Aug 26. doi: 10.7570/jomes20006 PMCID: PMC7539339 PMID: 32843586
2. Jee-youn Shim, Yoo Jung Kim, and Hye-Sung Lee. Effects of soybean isoflavone extract on the plasma lipid profiles and antioxidant enzyme activity in streptozotocin-induced diabetic rats. Nutr Res Pract. 2008 Winter; 2(4): 218–226. Published online 2008 Dec 31. doi: 10.4162/nrp.2008.2.4.218PMCID: PMC2788194 PMID: 20016722
3. Anderson JW, Smith BM, Washnock CS. Cardiovascular and renal benefits of dry bean and soybean intake. *Am J Clin Nutr.* 1999;70:464S–474S. [PubMed] [Google Scholar] [Ref list]
4. Setchell KDR, Cassidy A. Dietary isoflavones: Biological effects and relevance to human health. *J Nutr.* 1999;129:758S–767S. [PubMed] [Google Scholar] [Ref list]
5. Wang HJ, Murphy PA. Isoflavone content in commercial soybean foods. *J Agric Food Chem.* 1994;42:1666–1673. [Google Scholar] [Ref list]
6. Anderson JJ, Anthony MS, Cline JM, Washburn SA, Garner SC. Health potential of soy isoflavones for menopausal women. *Public Hearth Nutr.* 1998;2:489–504. [PubMed] [Google Scholar] [Ref list]
7. Kuiper JM, Carrison B, Grandien K, Enmark E, Haggblad J, Nilsson S, Gustafsson JA. Comparison of the ligand binding specificity and transcript tissue distribution of estrogen receptors alpha and beta. *Endocrinology.* 1997;139:4252–4257. [PubMed] [Google Scholar] [Ref list]
8. Eldridge AC, Kwolek WF. Soybean isoflavones: Effect of environment and variety on composition. *J Agric Food Chem.* 1983;31:394–396. [PubMed] [Google Scholar] [Ref list]

9. Alekel DL, Germain A, Peterson CT, Hanson HB, Stewart JW, Toda T. Isoflavone-rich soy protein attenuates bone loss in the lumber spine of premenopausal women. *Am J Clin Nutr.* 2000;72:844–852. [PubMed] [Google Scholar] [Ref list]
10. Jenkins DJ, Kendall CW, Jacson CJ, Connelly PW, Parker T, Faulkner D, Vidgen E, Cunnane SC, Leiter LA, Josse RG. Effects of high- and low-isoflavone soyfoods on blood lipids, oxidized LDL, homocysteine, and blood pressure in hyperlipidemic men and women. *Am J Clin Nutr.* 2002;76:365–372. [PubMed] [Google Scholar] [Ref list]
11. Kirk EA, Sutherland P, Wang SA, Chait A, LeBoeuf RC. Dietary isoflavones erduce plasma cholesterol and atherosclerosis in C57BL/6 mice but not LDL receptor-deficient mice. *J Nutr.* 1998;128:954–959. [PubMed] [Google Scholar] [Ref list]
12. Raines EW, Ross R. Biology of atherosclerotic plaque formation possible role of growth factors in lesion development and the potential impact of soy. *J Nutr.* 1995;125:624S–630S. [PubMed] [Google Scholar] [Ref list]
13. Wei H, Wei L, Frenkel K, Bowen R, Barnes S. Inhibition of tumor promoter-induced hydrogen peroxide formation in vitro and in vivo by genistein. *Nutr Cancer.* 1993;20:1–12. [PubMed] [Google Scholar] [Ref list]
14. Wei H, Cai Q, Rahn RO. Inhibition of UV light- and Fenton reaction-induced oxidative DNA damage by the soybean isoflavone genistein. *Carcinogenesis.* 1996;17:73–77.
15. Zhang M, Xie X, Lee AH, Binns CW. Soy isoflavone intake are associated with reduced risk of ovarian cancer in southeast China. *Nutr Cancer.* 2004;49:125–130. [PubMed] [Google Scholar] [Ref list]
16. Teede HJ, Dalais FS, Kotsopoulos D, Liang YL, Davis S, McGrath BP. Dietary soy has both beneficial and potentially adverse cardiovascular effects: a placebo-controlled study in men and postmenopausal women. *J Clin Endo Metab.* 2001;86:3053–3060. [PubMed] [Google Scholar] [Ref list]
17. Arjmandi BH, Alekel L, Hollis BW, Amin D, Stacewicz-Sapuntzakis M, Guo P, Kukreja SC. Dietary soybean protein prevents bone loss in an ovariectomized rat model of osteoporosis. *J Nutr.* 1996;126:161–167. [PubMed] [Google Scholar] [Ref list]
18. Somekawa Y, Chiguchi M, Ishibashi T, Aso T. Soy intake related to menopausal symptoms, serum lipids, and bone mineral density in postmenopausal Japanese women. *Obst Gynecol.* 2001;97:109–115. [PubMed] [Google Scholar] [Ref list]
19. Slavin M, Kenworthy W, Yu LL. Antioxidant properties, phytochemical composition, and antiproliferative activity of Maryland-grown soybeans with colored seed coats. J Agric Food Chem, 57 (2009), pp. 11174-11185
20. Agnieszka Barańska,[1,*] Agata Błaszczuk,[2] Małgorzata Polz-Dacewicz,[2] Wiesław Kanadys,[3] Maria Malm,[1] Mariola Janiszewska,[1] and Marian Jędrych[1.] Effects of Soy Isoflavones on Glycemic Control and Lipid Profile in Patients with Type 2 Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Nutrients. 2021 Jun; 13(6): 1886. Published online 2021 May 31. doi: 10.3390/nu13061886. PMCID: PMC8229139 PMID: 34072748 Ahmad Al-Mrabeh, Academic Editor Review Hum Reprod Update. 2009 Jul-Aug;15(4):423-40. doi: 10.1093/humupd/dmp010. Epub 2009 Mar 19.
21. L Hooper [1], J J Ryder, M S Kurzer, J W Lampe, M J Messina, W R Phipps, A Cassidy. Effects of soy protein and isoflavones on circulating hormone concentrations in pre- and post-menopausal women: a systematic review and metaanalysis.PMID: 19299447,PMCID: PMC2691652,DOI: 10.1093/humupd/dmp010.
22. Messina M. Soy and health update: evaluation of the clinical and epidemiologic literature. *Nutrients.* 2016;8:754. doi: 10.3390/nu8120754. [PMC free article] [PubMed] [CrossRef] [Google Scholar] [Ref list]
23. Chen JR, Zhang J, Lazarenko OP, Cao JJ, Blackburn ML, Badger TM, et al. Soy protein isolates prevent loss of bone quantity associated with obesity in rats through regulation of insulin signaling in osteoblasts. *FASEB J.* 2013;27:3514–23. doi: 10.1096/fj.12-226464. [PubMed] [CrossRef] [Google Scholar] [Ref list]
24. Torre-Villalvazo I, Tovar AR, Ramos-Barragán VE, CerbónCervantes MA, Torres N. Soy protein ameliorates metabolic abnormalities in liver and adipose tissue of rats fed a high fat diet. *J Nutr.* 2008;138:462–8. doi: 10.1093/jn/138.3.462. [PubMed] [CrossRef] [Google Scholar]
25. Lavigne C, Marette A, Jacques H. Cod and soy proteins compared with casein improve glucose tolerance and insulin sensitivity in rats. *AmJ Physiol Endocrinol Metab.*2000;278:E491500.doi:10.1152/ajpendo.2000.278.3.E491 . [PubMed] [CrossRef] [Google Scholar]
26. Glisic M, Kastrati N, Musa J, Milic J, Asllanaj E, Portilla Fernandez E, et al. Phytoestrogen supplementation and body composition in postmenopausal women: a systematic review and meta-analysis of randomized controlled trials. *Maturitas.* 2018;115:74–83.doi: 10.1016/j.maturitas.2018.06.012. [PubMed][CrossRef] [Google Scholar] [Ref list]
27. Huang H., Krishnan H.B., Pham Q., Yu L.L., Wang T.T. Soy and gut microbiota: Interaction and implication for human health. *J. Agric. Food Chem.* 2016;64:8695–8709. doi: 10.1021/acs.jafc.6b03725. [PubMed] [Cross Ref] [Google Scholar] [Ref list]
28. Aida Zarei,[1,2] Cristina Stasi,[3] Marzieh Mahmoodi,[1] Seyed Jalil Masoumi,[2,*] Morteza Zare,[2] and Mohammad Jalali,Effect of soy consumption on liver enzymes, lipid profile, anthropometry indices, and oxidative stress in patients with non-alcoholic fatty liver disease: A systematic review and meta-analysis of clinical trials.2020 Oct; 23(10):1245–1250.doi: 10.22038/ijbms.2020.46854.10797 ,PMCID: PMC7585529, PMID: 33149855 Author information Article notes Copyright and License information PMC Disclaimer Sturdee DW. The menopausal hot flush: anything new? *Maturitas*. 2008;60:42–9

29. Rossouw JE, Anderson GL, Prentice RL, LaCroix AZ, Kooperberg C, Stefanick ML, Jackson RD, Beresford SA, Howard BV, et al. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. *JAMA*. 2002;288:321–33
30. Bair YA, Gold EB, Zhang G, Rasor N, Utts J, Upchurch D, Chyu L, Greendale GA, Sternfeld B, et al. Use of complementary and alternative medicine during the menopause transition: longitudinal results from the Study of Women's Health Across the Nation. *Menopause*. 2008;15:32–43 [PubMed] [Google Scholar] [Ref list]