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Independent Study: Effects of Soy on
Bone Density in Post-Menopausal Women

Abbey Anderson

University of North Dakota

PERMISSION

Title: Independent Study: Effects of Soy on Bone Density in Post-Menopausal Women

Department: Nursing

Degree: Master of Science

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Abstract

As women go through menopause, they have a decline in estrogen that negatively impacts bone health. Many factors contribute to the inevitable age-related decline in bone density. The post-menopausal patient of this case report has many risk factors for osteoporosis and is not taking any medication or supplementation to support bone health. There are effective prescription medications and hormone therapy which increase bone density; however, they come with unpleasant side effects or, in some cases, are contraindicated. Soy is a phytoestrogen which is theorized to increase bone density with little to no risk or side effects. This paper includes a literature review of one systematic review, three meta-analyses, and six randomized control trials (RCTs) to evaluate the effect of soy on bone density in post-menopausal women. Clinicians need to be aware of alternative treatments for post-menopausal bone loss to provide evidenced-based, patient-centered care. Unfortunately, this review found inconsistent data. Further research is necessary to determine if soy increases bone density in post-menopausal women.

Independent Study: Effects of Soy on Bone Density in Post-Menopausal Women

Background

From age 35, both men and women begin a decline in bone density. For women this accelerates with decreased estrogen levels during menopause which increases calcium loss of the bone (Phillips, 2012.) Lifestyle can greatly impact one's bone health. There are modifiable and non-modifiable risk factors that affect bone density. Modifiable risk factors include physical activity, nutrition, smoking, heavy alcohol consumption, and certain medications. Non-modifiable risk factors include female gender, advanced age, white race, and history of fracture. The patient of this case report has multiple risk factors contributing to her osteoporosis development including little physical activity, smoking history, medications that negatively impact bone density, her age of 67, female gender, and white race.

Well-known interventions to increase bone density include calcium and vitamin D consumption, hormone therapy, use of phosphonate medications, and increased physical activity. More controversial agents that are believed to impact bone density include soy products, b-vitamins, omega-3 fatty acids, and dehydroepiandrosterone sulfates. In this case, the use of phosphonate medication was necessary as the patient has severely advanced osteoporosis. Would the patient benefit from consumption of more natural products (i.e. soy)? Her history of breast cancer must also be taken into consideration as estrogen products are contraindicated. For the purpose of this report, the use of soy and its impact on bone density in postmenopausal women are going to be addressed. The use of soy is believed to benefit bone health as it has similar characteristics to estrogen (Christianson & Shen, 2013).

Case Report

See appendix A for the osteoporosis case report.

Literature Review

This literature review includes one systematic review, three meta-analyses, and six RCTs. The hope is that synthesis of the trials and literature reveal that soy improves bone density in post-menopausal women.

The safety of soy isoflavone was highlighted in a multicenter, randomized, double-blind, placebo-controlled, two-year intervention trial evaluating soy isoflavone supplementation in menopausal women by Steinberg et al. (2011). Four hundred and six women were randomly assigned to three treatment groups which were a placebo group, an 80-mg soy hypocotyl isoflavone per day group, and a 120-mg soy hypocotyl isoflavone per day group. Dual-energy X-ray absorptiometry (DXA) measurements, blood drawings, inquiries about supplement use, and well-women examinations were taken at baseline, one year, and two year visits. Blood samples were tested for complete blood counts, serum electrolytes, thyroid function, gonadotropins, estradiol, liver function, renal function, and lipid profiles. The laboratory values showed minimal changes regardless of treatment group. Screening and well-women examinations did not produce any significant differences. DXA measurements were obtained; however, the results are not published in the study. There were serious adverse events in two women throughout the trial. One was a woman, who received 120-mg soy isoflavone daily, diagnosed with breast cancer fourteen months into the study, and the other was a woman, who received 80-mg soy isoflavone daily, diagnosed with adenocarcinoma of the endometrium twenty-one months into the study. Both types of cancer can be estrogen sensitive, and soy can be theoretically linked to their pathogenesis; however, the incidence is not significantly different from what would be predicted. Ultimately, the RCT results support the safety of soy isoflavone supplementation over a two-year period, however, no effect on bone density was published (Steinberg et al., 2011).

Of the RCTs reviewed, the one by Levis et al. (2011) found no improvement in bone density with soy consumption. It was a two-year randomized, double blind trial that evaluated the use of soy isoflavones in the prevention of menopausal bone loss and menopausal symptoms. Two hundred and forty-five women ages 45 to 60 years old participated in the study. One group received 200-mg of soy protein isoflavone and the other group received placebo. DXA scans were used to measure bone density. During two years, no significant differences were seen in bone density between the two groups. This study also found no benefit of soy protein isoflavone in equol producers versus nonproducers. The study found that women in the first 5 years of menopause have low rates of bone loss which is reassuring as it allows clinicians time to provided education and intervention. Unfortunately, daily consumption of soy isoflavone did not prevent bone loss in post-menopausal women (Levis et al., 2011).

This three year RCT by Alekel et al, (2010) also concluded that soy isoflavones cannot be recommended to protect or improve bone density in postmenopausal women; however, high dose isoflavone was found to have a modest protective effect on cortical bone density. It was a “prospective, randomized, double-blind, placebo-controlled, multicenter National Institutes of Health-funded clinical trial” (Alekel et al., 2010, p. 219). Two hundred and fifty-five post-menopausal women ages 45 to 65 participated in the study who were randomly assigned to three treatment groups. Group one was placebo control, group two received 80-mg isoflavones daily, and group three received 160-mg isoflavones daily. DXA was used to determine bone mineral density. Compliance was monitored via urinary isoflavone concentration. Over the thirty-six month trial, bone mineral density declined regardless of treatment, except for the 120-mg isoflavone group with modest bone density protection to the femoral neck. In summary, high

dose soy isoflavone was found to have modest effect on cortical bone, found in the femoral neck, but had no effect on trabecular bone, found in the lumbar spine (Alekel et al., 2010).

A double blind randomized trial by Chi & Zhang (2013) had similar findings. They evaluated the effects of soy isoflavone on bone density in Chinese women going through menopause. This study looked at eighty women ages 45 to 55 who were in premenopause or early menopause. There were two groups; group one took 90-mg of soy isoflavone daily and group two took placebo. Bone density of the radius and tibia was examined using quantitative ultrasound. After taking soy isoflavone for six months, tibial bone density increased; however, there was no difference in radial bone density. There was no improvement in radial or tibial bone density in the placebo group. This study also looked at serum cytokines and found that in participants that took soy isoflavone had a decrease in interleukin-6 (IL-6) and tumor necrosis factor alpha (TNF- α). There was no change in serum cytokines in the placebo group. This could be significant as IL-6 and TNF- α are protein factors of the immune system that regulate bone metabolism. While the study showed promising response to bone health from soy, further investigative studies are necessary (Chi & Zhang, 2013).

A more hopeful cross-sectional RCT from Shenoy, Bedi, and Sandhu (2013) looked at the effects of soy isolate protein and resistance training on bone mineral density in sixty post-menopausal women. They found that post-menopausal women supplemented with soy isolate protein had improved bone health, which could be enhanced with the addition of resistance training. The study divided sixty women in 3 groups. Group A received only soy isolate protein, group B received soy isolate protein plus resistance training, and group C was the control. Bone mineral density of the distal radius and midshaft tibia was measured using ultrasound densitometry. After 12 weeks, the trial found significant improvement of bone density in both

groups A and B. The addition of resistance training with consumption of soy isolate protein showed the greatest improvement in bone density (Shenoy, Bedi, & Sandbu, 2013).

Similarly, a randomized crossover trial by Pawlowski et al. (2015) found that soy isoflavone is an effective treatment for post-menopausal bone loss. The study evaluated the impact of equol-producing capacity and soy-isoflavone profiles of supplements on bone calcium retention in postmenopausal women. Equol is the estrogen receptor associated with bone response. Twenty-four post-menopausal women received five different soy isoflavone extract interventions and/or a positive control of risedronate 5-mg daily. The first intervention of the study was to determine the response of soy of equol producers versus nonproducers. Of the twenty-four participants, eight were equol producers and sixteen were nonproducers. Once this was determined, the participants were randomly assigned interventions. Five participants received four soy isoflavone products, ten participants received only risedronate, and nine received both soy isoflavone products and risedronate. There was no difference in bone calcium retention between equol producers and nonproducers. Risedronate provided the highest increase in bone calcium retention, and of the four soy isoflavone products, three of them increased bone calcium retention. The study proved that sufficient doses of soy isoflavones are effective antiresorptive therapy in post-menopausal women; however, not as effective as risedronate (Pawlowski et al., 2015).

Parallel to the RCTs, conflicting evidence was produced in the review of meta-analyses. A meta-analysis from Lagari and Levis (2013) evaluated the use of phytoestrogens in the prevention of postmenopausal bone loss. The article emphasized the biologic plausibility of the use of soy isoflavones in the prevention of bone loss as they are structurally similar to estrogen. When examining cross-sectional studies, soy food consumption was found to be positively

associated with bone mineral density; however, in the review of twenty-seven RCTs, there was conflicting evidence to support the effect of soy on bone mineral density. Of the studies reviewed, the most well-designed studies did not find soy to benefit bone mineral density (Lagari & Levis, 2013).

Likewise, a meta-analysis by Messina (2014) did not find a positive correlation between soy intake and bone density in post-menopausal women. However, his review did find positive correlation with soy consumption across the lifespan. A review of observational studies found soy intake decreased fracture risk in Shanghaiing and Chinese postmenopausal women. Another observational study of Seventh- day Adventist women, found daily soy milk intake decreased risk of osteoporosis by fifty-six percent. Contrarily, analysis of RCTs found mixed results on the effects of soy on bone density. Review of longer (two to three years in length) and larger (two hundred to four hundred participants) studies, yielded no benefit of soy isoflavones on bone density in post-menopausal women (Messina, 2014). These findings highlight the importance of osteoporosis prevention and early education.

Comparable to the previous meta-analyses, a study by Lanou (2011) stated “although optimal amounts and types of soy foods needed to support bone health are not yet clear, dietary pattern evidence suggests that regular consumption of soy foods is likely to be useful for optimal bone health” (p. 298). The review of cross sectional studies in this meta-analysis found soy food intake was associated with higher bone mineral density in Asian post-menopausal women; however, soy food had no significant benefit on bone mineral density in American and European populations. It was highlighted that Asian populations consume traditional soy foods where non-Asian populations consume more processed forms of soy. The analysis of prospective studies found soy protein intake to be a positive predictor of bone mineral density; however, it was noted

that despite soy intake there was relatively low bone density loss associated with menopausal status. Examination of clinical trials, including the previously mentioned 2010 Alekel et al RCT was summarized; as well as, the review of another RCT and four meta-analyses, which again revealed conflicting results. It concluded that study design variations, such as length of study, active soy ingredient used, dosage of soy consumed, menopausal status, race, ethnicity, culture, and diet, likely contributed to the various findings and more research is necessary (Lanou, 2011).

This systematic review of phytoestrogens and bone health of women in different reproductive stages by Castelo-Branco & Soveral (2013), had similar findings as the previously mentioned meta-analyses. Eighteen RCTs assessing the effect of soy isoflavone on bone mineral density in post-menopausal women were reviewed. Seven of these studies showed no significant difference between isoflavone consumption and bone density. Six of the studies found moderate to high daily dose of isoflavone increased bone mineral density. Two found benefit in bone mineral density in equol producers, and three studies showed little improvement or smaller reduction in bone density with isoflavone consumption. This review also assessed five meta-analyses of the effect of isoflavones on bone mineral density in post-menopausal women. One meta-analysis found isoflavone intake inhibited bone resorption and increased bone formation. The second meta-analysis found isoflavone consumption significantly attenuates spinal bone loss which was more significant when more than 90-mg of isoflavones per day were consumed and was taken for longer than six months. The third meta-analysis revealed no increased in bone mineral density with daily consumption of 87-mg isoflavone for one year. The fourth meta-analysis showed increase in bone health with soy intake. The fifth meta-analysis revealed soy isoflavone supplements of 75-mg or greater per day increased bone mineral density by fifty-four percent. While the majority of the findings are favorable, the systematic review concluded

further research is needed to clarify the use of soy isoflavones in preventing and treating osteoporosis.

The research articles are from 2010 to 2015. There are more recent research articles; however, the full text was unable to be obtained. A conclusion from a meta-analysis of RCTs by Abdi, Alimoradi, Haqi, and Mahdizad published in 2016 summarized that while soy isoflavones probably prevent reduction in bone mineral density, there are controversial RCT findings. This is consistent with findings from the other RCTs and meta-analysis' evaluated in this literature review.

Learning Points

One's bone health impacts one's quality of life. Fracture in an aging individual is life altering. Information obtained from this literature review and case report includes:

- Annual women visits must include osteoporosis risk factor analysis and, if necessary, appropriate intervention.
- Life long lifestyle habits impact bone health throughout the life span.
- There are little side effects or harm associated with soy intake regardless of dose.
- Soy diet and supplementation does not show decline in bone density.

In summary, the patient of this case report would have greatly benefited from education regarding her osteoporosis risk factors and earlier intervention. As there is little harm and no association to estrogen receptive cancers found in the literature, this patient could begin soy supplementation. In regards to bone health, there is not definitive evidence to support that soy increases bone density in post-menopausal women. Further research with large study groups is necessary.

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APPENDIX A

Osteoporosis Case Report

Patient Profile: 67-year-old widowed female.

Chief Complaint:

- 1) Establish care.
- 2) 8 week post right hip replacement follow-up.

History of Present Illness:

- 1) *** presents to the clinic today to establish care. She has not had a primary care provider since one year ago and is wanting to establish care at this facility for her health care needs.
- 2) She also is here for her 8-week status post right total hip replacement follow-up. In January of 2017, *** had a miscoordinated event where she fell in the bathtub and fractured her right hip. She was brought to the ER where she was evaluated and, ultimately, had surgical intervention without complications. She denies she hit her head, lost consciousness, or suffered any other injuries from her fall. Over the past 8 weeks, patient has attended and completed physical therapy. She has been living at home independently without difficulties. She at times feels her right hip is “stiff” upon waking in the AM. She rates this pain a 3-4/10 which is relieved with Tylenol. She denies any other aggravating or alleviating factors. The surgical incision to her right hip is healing without complications.

Past Medical History:

- 1) Hypertension.
- 2) Right Breast Cancer - diagnosed 1 year ago, taking oral chemo daily.
- 3) Right hip fracture post fall- January 2017.
- 4) Nicotine addiction (75 pack year history).

Past Surgical History:

- 1) Right hip replacement – January 2017.

Medications:

- 1) Lisinopril 10 mg PO QD.
- 2) Arimidex 1 mg PO QD.
- 3) Tylenol 650 mg PO Q4-6 hours PRN for pain.

Allergies:

No known drug, latex, environmental, or food allergies.

Health Maintenance:

- 1) DEXA scan in 2011.
- 2) Mammogram 2016 Negative.
- 3) Colonoscopy at age 56 without abnormalities (recommended f/u in 10 years).
- 4) Immunization status – not addressed at this visit.

Family History:

No known diagnosed medical problems in her parents, grandparents, or siblings.

Social History:

Retired teacher. Widowed. Has three grown children. Rare ETOH use. Smokes 1.5 PPD for past 50 years, has tried nicotine patches and gum without cessation success. No formal exercise program. God-fearing.

Review of Systems:

General: Reports feeling well. Denies weakness. Negative for fever/chills/night sweats. Denies unintentional weight loss or gain. No changes in appetite. Relates adequate energy levels.

Skin: Relates right hip post-surgical incision is healing without complications. Denies rashes, lesions, dryness, or pruritus. No changes to moles. Negative history for skin cancer or non-healing wounds.

Lymph: Negative for enlargement or tenderness.

HEENT: Denies headaches, dizziness, syncope, blurred vision, visual changes, ear pain, tinnitus, sores in mouth, nasal congestion, neck pain, sore throat or difficulty swallowing. Last vision exam: 1 year ago. Last dental exam: 1 year ago.

Cardiovascular: Denies chest pain, pressure, palpitations, fatigue or syncope. Denies history of murmurs or arrhythmias. Negative for claudication, peripheral edema, orthopnea, dyspnea on exertion, or paroxysmal nocturnal dyspnea. History of hypertension controlled on Lisinopril with no recent medication dose changes. Relates EKG was done prior to hip surgery 8 weeks ago. She does not know when her cholesterol was last checked.

Respiratory: Negative for cough, dyspnea, hemoptysis, or wheezing. No documented history of asthma, COPD, or pneumonia. She does have a 1.5 PPD 50 year smoking history. On a scale of 0 (no interest in quitting)-10 (ready to quit today), she rates she is a 3 (low motivation).

GI: Denies abdominal pain, nausea, vomiting, or change in bowel habits: No heartburn, dysphagia, constipation, diarrhea, melena, hematochezia, hematemesis, hemorrhoids, or jaundice. Last colonoscopy at age 56 with recommended repeat in 10 years.

GU: Denies flank pain, dysuria, or hematuria. No frequency, urgency, nocturia, or incontinence. Denies vaginal bleeding. She went through menopause when she was 55 years old. Last PAP was 3 years ago. Denies history of abnormal PAP. Last clinical breast exam was performed by her oncologist 6 months ago.

Musculoskeletal: As per HPI. Otherwise denies arthralgias, myalgias, arthritis, gout, joint swelling, limited range of motion, or back pain. Last DEXA scan in 2011.

Neurological: Denies numbness, tingling, weakness, gait disturbances, coordination problems, altered sensation, alteration in memory, difficulty concentrating, headaches, head trauma, or brain injury.

Psychiatric: Denies emotional disturbances, sleep disturbances, substance abuse disorders, depression, anxiety, suicidal ideation or past suicide attempts.

Endocrine: Negative for polyuria, polydipsia, polyphagia, temperature intolerance, hormone therapy, changes in hair or skin texture.

Hematologic: Denies easy bruising, bleeding tendency, or anemia.

Physical Examination:

Vitals: Height: 5'4" Weight 121 lb BMI: 20.8 Temp: 98.6 BP: 132/70 Pulse: 78 RR: 16 SpO2: 96% on Room Air.

General: Alert, well-appearing Caucasian female who does not appear to be in acute distress, with good insight and judgement. She is clothed and groomed appropriately. She walks into the exam room without use of assistive devices.

Skin: Appropriate color for race. Warm and dry. Turgor resilient. No significant rash appreciated. Surgical incision to right hip is well approximated with no drainage, erythema, or palpable warmth.

Head: Normocephalic, atraumatic. Normal hair distribution.

Eyes: Conjunctiva clear without pallor, sclera white. PERRLA. EOMS are intact. No Nystagmus. Fundi red reflex seen bilaterally. No nicking, hemorrhage, exudate, or papilledema is appreciated.

Ears: Ear canals patent. TM's pearly grey with appropriate cone of light bilaterally. Hearing is grossly intact to conversational tones.

Nose: Septum midline, nares patent. No inflammation, erythema, or drainage is appreciated.

Throat: Oral mucosa is pink and moist. No oral lesions appreciated. Teeth are in good repair The posterior pharynx is widely patent and reveals no marked inflammation or erythema.

Neck: Supple, trachea midline. No retropharyngeal, sub mandibular, submental, pre or post auricular, occipital, anterior or posterior cervical, sub or supraclavicular, or axillar adenopathy. No JVD or carotid bruit.

Heart: Regular rate with normal S1, S2, no murmur, rub or gallop auscultated. No PMI displacement.

Lungs: Chest symmetric, respirations unlabored, without accessory muscle use. Lungs are clear to auscultation apex to base. No crackles, wheezes, or rhonchi

Breasts: Deferred.

Abdomen: Flat, soft, non-tender. Bowel sounds normoactive. No masses or organomegaly.

Back: Spine is straight. No tenderness upon palpation to spinal processes or Para spinal muscles. No CVA tenderness.

Musculoskeletal: Bilateral 5/5 strength to upper and lower extremities. Patient is able to get on and off exam table without difficulty.

Extremities: No peripheral edema. 2+ pulses in all extremities. Cap refill less than 3 seconds.

Neuro: No sensory or motor deficits appreciated.

Labs:

BMP reveals creatinine of 0.8, remainder values are WNL. CBC pending.

Radiology:

DEXA scan reveals Lumbar Spine T-Score of -4.1 (osteoporosis), femoral neck T-score of -2.1 (osteopenia). Conclusion of bone density consistent with osteoporosis and high risk for fracture. Follow-up DXA scan in 2 years.

Assessment:

- 1) Right Hip Replacement, independently functional
- 2) Osteoporosis, new diagnosis
- 3) Hypertension, stable
- 4) Right Breast cancer, stable following oncology
- 5) Health Maintenance & Screening

Plan:

- 1) Patient is to continue following orthopedic surgeon's instruction. Reassurance provided. She is doing well at home and is able to function independently. She is to continue with home physical therapy.
- 2) Education regarding osteoporosis provided. We did discuss multiple medication options. At this time, she will start alendronate 70 mg one day a week. Education to take with full glass of water and sit up for 45 minutes after taking medication provided. Medication side effects discussed. Patient encouraged to develop exercise regimen. We will repeat DEXA Scan in 2 years.
- 3) Patient is to continue on blood pressure medication and add aspirin 81 mg daily. Heart healthy diet and active lifestyle encouraged.
- 4) Reassurance provided. Patient is to continue with oncologist's instruction and yearly mammograms. I will consult with oncologist regarding risk benefit analysis of Arimidex as this does affect patient's bone density.
- 5) Patient is going to return to the clinic at her earliest convenience for a fasting lipid panel. Referral for colonoscopy and low dose chest CT placed. We will address immunization status at her next visit. She is to continue with regular dental visits and eye examinations.

Patient was receptive of plan of care. Denies any questions or concerns. We will follow-up based on labs and screening results or sooner if needed.

Abbey Anderson, Student Nurse Practitioner