ABSTRACT

A COMPARISON OF VITAMIN D PRACTICE HABITS
TO BONE MINERAL DENSITY SCORES

Vitamin D deficiency and bone metabolism are related. Vitamin D research has shown that greater than 50% of adults over age 65 in the United States (U.S.) are vitamin D deficient and as the aging population rises, osteoporosis and fractures are also rising. The National Osteoporosis Foundation has reported one out of two women over 50 years of age will have an osteoporosis related fracture in their remaining lifetime, however, research has shown that community dwelling adults who have taken vitamin D supplementation, and have higher vitamin D levels, have lower first fracture rates and lower rates for fracture occurring at the hip, wrist and vertebrae.

This non-experimental comparison research project delineated the dietary, supplement and sun intake habits of vitamin D in women age 50 plus years. Participants undergoing bone mineral density (BMD) testing for the first time had their BMD results compared to vitamin D practice habits. The theoretical framework for this research was the Health Belief Model.

Women coming for first time BMD testing completed a self-administered questionnaire packet given at two clinics in northeastern Wisconsin. Six women met all inclusion criteria. The researcher reviewed the medical record of the participants to obtain BMD scores, verified their medication list and medical diagnoses, including smoking and alcohol use. Data was analyzed using correlation and descriptive statistics. With this small study, no significant findings were obtained regarding vitamin D practice habits and BMD results.

A COMPARISON OF VITAMIN D PRACTICE HABITS TO BONE MINERAL DENSITY SCORES

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Mary J. Miller

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APPROVAL

Roxana Hnebscher PhD Advisor

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PROVOST AND VICE CHANCELLOR

L R Gun

4/26/2010

Date Approved

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Gloria Splettgerber

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Date Approved

I would like to dedicate this research project to my husband and my family.

To Jeff, thank you for supporting me and believing in me. I couldn't have done this without your love and confidence in me.

To Rob, Chris and Heather, I hope with all of my heart that your passions lead you in life to fulfill all of your dreams come true.

To my dad, thank you for years of patience, support and believing in me that I would someday reach my dreams.

In loving memory of my mom, who was my best friend, my inspiration for hard work and guided me to be a better person every day of my life. I know you would be very proud of me.

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CHAPTER I

INTRODUCTION

Osteoporosis is a major public health concern for Americans. Ten million individuals in the United States (U.S.) have osteoporosis with another 34 million individuals estimated to have low bone mass (National Osteoporosis Foundation [NOF], 2008). Approximately one out of two women over age 50 will have an osteoporosis related fracture in their remaining lifetime (NOF, 2008). As the aging population increases in the U.S., the NOF estimates osteoporosis-related fracture costs will rise from $19 billion dollars estimated in 2005 to $25.3 billion dollars by 2025 (NOF, 2008).

Certain people have risk factors that increase the likelihood of developing osteoporosis, including being small, thin, female, having a diet low in calcium and vitamin D, smoking and drinking more than the recommended amount of alcohol. Some of these people include postmenopausal women under age 65, women age 65 or older without any risk factors, women after age 50 who have a history of fracture, women going through menopause with certain risk factors and postmenopausal women who are not on any hormone replacement therapy (NOF, 2008).

Practitioners and researchers utilize BMD testing in high risk individuals with these risk factors or older adults to find low bone mass and diagnose osteoporosis. They also educate and emphasize lifestyle modification to prevent osteoporosis, including exercise, smoking cessation, limiting alcohol intake, adequate calcium and vitamin D intake and prescriptive medicine.

During the last two decades there have been important advances in vitamin D knowledge. Consensus of laboratory testing and histomorphometric analysis of adult bone samples by Parfitt in the early 1990's brought the issue of vitamin D deficiency to the forefront of research (Holick, 2006). Since that time researchers have challenged current Food and Nutrient Board recommendations for vitamin D requirements in adults. The Food and Nutrient Board recommends an adequate intake (AI) of Vitamin D3 200 international units (IU) daily for infants, children, pregnant females and all adults less than 50 years old, 400 IU for adults age 50-70 and 600 IU for all adults greater than 70 years old (Moore, 2009). The NOF recommends 400-800 IU for adults less than 50 years old and 800-1000 IU daily for adults greater than 50 years old (NOF, 2008).

In June 2008, the National Coalition for Osteoporosis and Related Bone Diseases met in Washington, D.C. to build on recommendations and findings from the 2004 Surgeon General's Report on Bone Health and Osteoporosis. One of the priorities developed was to promote adequate vitamin D and calcium intake, with a focus on re-evaluating vitamin D and revising the AI level for vitamin D in order to provide consistent education to the public. The AI recommendations made by the Food and Nutrient Board when nutritional needs cannot be precisely quantified are believed to cover the needs of most of the population (Moore, 2009). The American Medical Association and National Committee on Quality Assurance have specifically identified the need for increased counseling on vitamin D and calcium intake in their physician performance measurement set for osteoporosis (National Action Plan for Bone Health, 2008).

Significance of the Problem

Vitamin D deficiency has been found in more than 50% of adults over the age of 65, and up to 57% of general medical inpatients in the U.S. (Holick, 2006). Thomas et. al (1998) studied 290 patients admitted to a Massachusetts hospital. Researchers found deficient serum 25- hydroxyvitamin D levels less than or equal to 15 ng/ml. in 164 of these patients. In a sub-group of 77 patients less than 65 years old without known risk factors for having a vitamin D problem, 42% were found to have serum 25-hydroxyvitamin D levels less than eight ng/ml. This is concerning to healthcare professionals as older persons strive to prevent osteoporosis-related fractures. Preventative measures may be useful and nurses can educate consumers on vitamin D rich foods, fortified foods and over the counter vitamin D3 supplementation to enhance bone health.

Vitamin D3 is synthesized naturally by the skin from the ultraviolet B (UVB) rays of the sun and is typically known as the sunshine vitamin. Limited sun exposure, skin pigments, geographic location, aging and sunscreen impair vitamin D3 synthesis (Wolff, et al., 2008). Vitamin D is found in limited dietary sources of foods and fortified food products, but is essential to normal calcium metabolism. Inadequate intake of vitamin D alters absorption of calcium, thus mobilizing calcium from the skeleton to maintain a physiological acceptable range in the body (Burckhardt, Dawson-Hughes, & Heaney, 2004).

Statement of the Problem

Women vary in their dietary and supplementation intakes of vitamin D. Women who have the best vitamin D intake habits may have the best BMD scores, however, levels of vitamin D in the body vary depending on individual gut absorption, sun exposure and skin pigmentation.

Purpose of the Study

The purpose of this study was to study the exogenous and endogenous vitamin D intake habits of women undergoing BMD testing for the first time. The researcher compared BMD results with vitamin D intake to see if scores were higher in women who had better vitamin D intake habits.

Research Question

Do women who have the best vitamin D intake habits have the best bone mineral density scores?

Conceptual Definitions

Osteoporosis: A condition in which the bones become so porous and weak that they are likely to break from a minor injury (NOF, 2008). BMD of the hip and/or spine that lies within 2.5 standard deviations (SD) or more below the average value for young healthy women (a T-score of <-2.5 SD) (World Health Organization [WHO], 2004).

Osteopenia: Low bone mass. This means bone mass or bone mineral density is lower than normal, but not yet low enough to be considered osteoporosis (NOF, 2008). T-score at the femoral neck of between -1.0 SD and -2.5 SD below the young female adult mean [WHO, 2004].

Bone Densitometry: BMD testing is the only test used to find low bone mass and diagnose osteoporosis. A number of non-invasive methods can be used to measure bone mineral content more accurately than by observation of radiographs. These methods include radiogrammetry, radiographic absorptiometry, single-photon absorptiometry (SPA), dual-photon absorptiometry (DPA), dual-energy x-ray absorptiometry (DXA) and quantitative computed tomography (QCT) (Juhl, Crummy, & Kuhlman, 1998).

Vitamin D Sufficiency: 25(OH) D level of at least 32 ng/ml. or 80 nmol/L as supported by an expert round table panel discussion consisting of vitamin D experts Bess Dawson-Hughes, Robert P. Heaney, Michael Holick, Paul Lips, Pierre J. Meunier and Reinhold Vieth (Burckhardt, et al., 2004).

Vitamin D Insufficiency: 25(OH) D level 10-32 ng/ml or 25-75 nmol/L (Burckhardt, et al., 2004).

Vitamin D Deficiency: 25 (OH) D levels 0-10 ng/ml or 0-25 nmol/L (Burckhardt, et al., 2004), diagnosed as rickets in children and osteomalacia in adults.

Dietary history: A detailed dietary record; may include a 24-hour recall, food frequency questionnaire, food diary, and other information such as weight history, previous diet changes, use of supplements, and food intolerances (Mahan & Escott-Stump, 2008).

Operational Definitions

Osteoporosis: BMD of the hip and/or spine that lies 25 standard deviations (SD) or more below the average value for young healthy women (a T-score of <-2.5 SD) [WHO, 2004].

Osteopenia: T-score at the femoral neck of between -1.0 SD and -2.5 SD below the young female adult mean [WHO, 2004].

Bone Densitometry: Dual-energy x-ray absorptiometry (DXA). DXA is currently considered the gold standard for clinical bone mineral density measurement because of best precision (coefficient of variation, 0.5%-3%) and lowest radiation dose (Juhl, et al., 1998).

Vitamin D Sufficiency: 25(OH) D level of at least 32 ng/ml. or 80 nmol/L as supported by an expert round table panel discussion consisting of vitamin D experts Bess Dawson-Hughes, Robert P. Heaney, Michael Holick, Paul Lips, Pierre J. Meunier and Reinhold Vieth (Burckhardt, et al., 2004).

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Dietary history: A detailed record developed by the author of this paper, that includes a food frequency questionnaire on vitamin D rich foods, vitamin D fortified foods and other information such as BMI and use of vitamin supplements.

Assumptions

1. Women will be honest in sharing their knowledge related to sun exposure, dietary intake and vitamin supplementation regarding vitamin D intake.
2. Women will be honest in sharing demographic and general health information.

Chapter Summary

The author discussed the rising incidence and prediction of fractures related to osteoporosis, as well as concerns among national and international experts on the impact that osteoporosis and vitamin D will have in the future. The author outlined the purpose, significance of the problem, conceptual definitions, operational definitions and assumptions.

CHAPTER II

THEORETICAL FRAMEWORK AND LITERATURE REVIEW

Health Belief Model

The Health Belief Model (HBM) by Rosenstock was the theoretical framework used for this research study. It was initially developed by a group of social psychologists in the 1950's (Strecher & Rosenstock, 1997). The development of the model grew out of concerns regarding the limited success of the public health prevention services offered by the public health service.

Psychologists initially focused on explaining people's behavior for nonattendance at screening procedures. As time evolved, they focused on why patients did attend screenings. The HBM concepts expanded from screening to include all preventative, illness and sick-role behaviors (Strecher & Rosenstock, 1997). Concepts of the HBM include: (a) Perceived susceptibility, (b) Perceived severity, (c) Perceived benefits, (d) Perceived barriers, (e) Cues to action, and (f) Self-efficacy (Strecher & Rosenstock, 1997).

Perceived susceptibility is defined as the belief one has regarding the chances of acquiring a health issue (Strecher & Rosenstock). Women undergoing BMD for the first time may or may not perceive themselves as being at risk for osteoporosis or vitamin D insufficiency. They may be leading productive lives, be in the work force and may be generally active in their daily routine so they may not be thinking of their dietary and supplementation intake habits as having an impact on their future health.

Perceived severity is defined as the concern one has regarding the seriousness of the condition and the potential difficulties it may cause if left untreated (Strecher & Rosenstock, 1997). Women undergoing BMD may or may not be aware of the risk factors of osteoporosis, including the role of vitamin D in calcium metabolism, and that one out of two women over the age of 50 will have an osteoporosis-related fracture in their remaining lifetime that may significantly alter their quality of life.

Perceived benefits relates to the belief that changing behavior may reduce the threat to one's health (Strecher & Rosenstock, 1997). Dietary changes to enhance health are recommended such as weight control, sodium control and reducing cardiovascular and cancer risks. Women may or may not be aware of the dietary changes and supplement options available to obtain vitamin D for optimal calcium absorption.

Perceived barriers are the perceptions of the obstacles to change behavior (Strecher & Rosenstock, 1997). Women may or may not feel that a change in dietary or supplementation behavior is necessary. Lack of symptoms may or may not be a barrier to modify dietary behaviors to prevent or suppress a long term disease such as osteoporosis. Economic barriers may alter medication regimes as insurances generally do not reimburse over-the-counter minerals and vitamins.

Cues to action are a stimulus that triggers health-related behaviors (Strecher & Rosenstock, 1997). This may be further defined as internal or external cues to action. External cues are things such as increased education by healthcare providers and general public education through mass media commercials. BMD and vitamin D levels are

objective measurements that cue the healthcare provider and women to examine their bone health and take action to correct any abnormalities.

Self-efficacy is the belief that the person has the ability to change behavior and positively influence health (Strecher & Rosenstock, 1997). Initially the HBM was intended for preventative actions. Later, self-efficacy was added due to long term disease processes requiring modification of life-style behavior (Figure 1).

Bone peak maturity is attained by mid-thirties. Since the average life expectancy of women is beyond bone maturity, BMD screening is done around the perimenopausal age to assess bone structure .This is when women have changes in hormones that may alter bone metabolism. Self-efficacy is required for women to make dietary and supplementation changes necessary for maintaining bone health, thus helping decrease their fracture risk later in life.

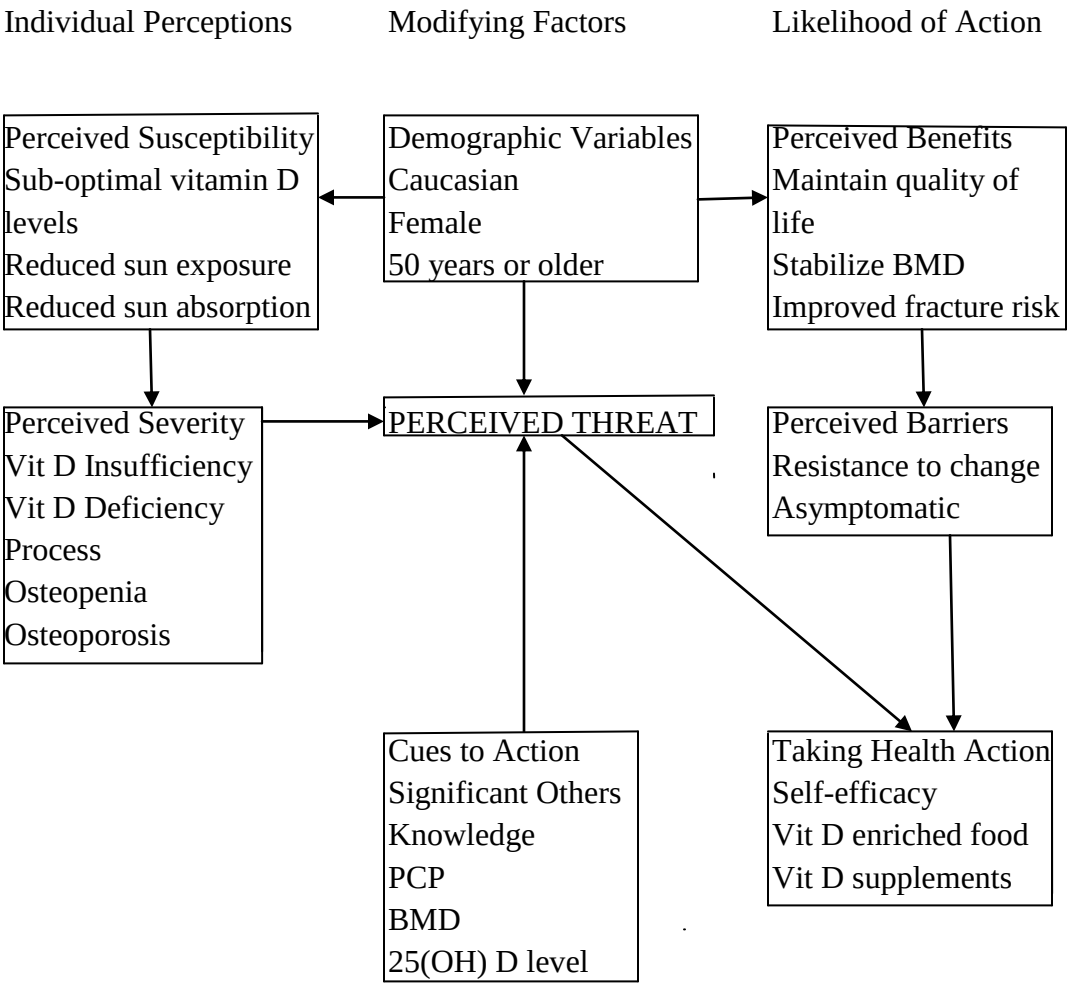

Figure 1. Application of Health Belief Model by Rosenstock for women at risk of suboptimal vitamin D.

Review of Literature

Vitamin D is a generic term that refers to cholecalciferol (vitamin D3) and ergocalciferol (vitamin D2), both of which are metabolized in the same manner in the human body. Vitamin D, a fat-soluble vitamin, is an essential component for the absorption of calcium, development of bones and maintenance of bone health (Jellin, Gregory, et al. 2009). Vitamin D is supplied from two sources: the sun and our diet. 1,25-

dihydroxyvitamin D is normally recognized as the active vitamin D metabolite, however it is the precursor, vitamin D (25(OH)D), that is absorbed from the diet and has effects of its own in regulating cell growth and calcium metabolism (Ovesen, Brot & Jakobsen, 2003).

Vitamin D3

Vitamin D3 is made naturally in the skin from absorption of ultraviolet B (UVB) rays. Sunshine is the most abundant source of vitamin D3. When skin is exposed to ultraviolet B (UVB) rays, vitamin D3 is absorbed by epidermal 7-dehydrocholesterol (Holick, 2007). Vitamin D3 also exists in rich amounts in fish liver oils, and in variable amounts in animal products such as cream, butter, egg yolk and liver.

Vitamin D2

Vitamin D2 (ergocalciferol) is found in plant sterols, such as irradiated mushrooms and yeast (Jellin, Gregory, et al. 2009). In addition, 98 percent of all fluid milk sold in the United States (U.S.) is fortified with vitamin D2. Certain cereals, margarines, yogurts, butters, tofu and all infant formula products are also fortified with ergocalciferol. Vitamin D2 does not deteriorate when stored or heated for long periods of time (Mahan & Escott-Stump, 2008). When given in high enough doses vitamin D2 can be effective in raising blood levels of 25(OH) D levels (Trang, et al., 1998). However, vitamin D2 appears to have less than one-third the potency of vitamin D3, thus making it less effective than vitamin D3 (Jellin, Gregory, et. al, 2009).

Physiologic Effect of Vitamin D on the Skeleton

Both forms of Vitamin D from sun absorption and our diet are transported to the liver on vitamin D binding protein after being absorbed as chylomicrons into the lymphatic system and the venous circulation (Holick, 2007). The liver metabolizes both forms of vitamin D to 25-hydroxyvitamin D (25(OH) D) or calcifediol (Holick, 2007). The half-life of calcifediol is two to three weeks (Souberbielle, Friedlander, Kahan & Cormier, 2006). This form of vitamin D is a biologically inert prohormone that travels to the kidneys where it is converted to its active form, 1, 25, dihydroxyvitamin D or calcitriol (Holick, 2007). Calcitriol has a serum half-life of approximately four hours (Souberbielle et al., 2006).

Calcitriol is responsible for calcium and phosphorus homeostasis. When the body does not absorb enough calcium or ingest enough calcium, a decrease in ionized calcium is recognized by the parathyroid gland. In the presence of low plasma concentrations of calcium, the parathyroid gland signals an increase in the production of calcitriol (Mahan & Escott-Stump, 2008). Calcitriol maintains calcium homeostasis by three different ways: (a) enhancing active transport of calcium across the small intestine, (b) moving calcium and phosphorus from the bone to maintain normal blood levels, and (c) increasing renal tubular reabsorption of calcium and phosphorus (Mahan & Escott-Stump). Thus, 25 (OH) D, the circulating form of vitamin D, is the major determinant of maintaining serum calcium in a physiological acceptable range (Burckhardt et al., 2004).

Consequences of Vitamin D Deficiency

Rickets is a deficiency of vitamin D and was discovered in the late 1600's when Northern European people migrated into industrialized cities. Buildings in the cities caused less sun exposure and children developed a crippling bone disease causing growth retardation and deformity of the long bones of the legs (Holick, 2005). By the turn of the century, more than 80% of the children living in cities in North America and Europe suffered from rickets.

In 1921, radiological proof showed that when children with rickets were exposed to the ultraviolet rays of sunlight, the disease resolved (Hess & Unger, 1921). Improvement of rickets from exposure to ultraviolet B (UVB) rays from the sun led to ultraviolet irradiation food research. Steenbock (1924) applied this research by irradiating milk as a means of preventing rickets in children. This research led to the fortification of milk with vitamin D, which helped to eradicate rickets in the U.S. and other countries utilizing the fortification process.

Fortification of foods with vitamin D is done to correct an environmental deficit of UVB exposure (Vieth, 1999). Northern European countries except for Sweden and Finland forbid fortification of milk but do allow it in margarine and some cereals (Holick, 2007).

Currently, rickets is primarily seen in underdeveloped areas of the world and in immigrants coming to developed countries. However, it is seen in the U.S. in people who have inadequate exposure to sun, inadequate dietary intake of vitamin D and infants that

have prolonged breast-feeding without vitamin D supplementation and the use of commercial alternative milks that are not fortified (Porth, 2005).

Osteomalacia

Osteomalacia is the adult form of rickets, resulting from inadequate mineralization of bone due to a calcium or phosphorus deficiency. The two main causes of osteomalacia include: (a) insufficient calcium absorption from the intestine because of a lack of calcium or resistance to the action of vitamin D, and (b) phosphate deficiency due to increased renal losses or decreased intestinal absorption (Porth, 2005).

Parfitt (1990) further expanded on the concept of bone disease attributed to vitamin D deficiency. Based on histomorphometric analysis of adult bone samples, he identified three stages of disease related to increasing degrees of vitamin D deficiency. In stage one hypovitaminosis D, pathophysiology revealed reduced intestinal absorption of calcium with diminishing skeletal calcium reserves and accompanying osteoporosis. Stage two hypovitaminosis D exhibited changes seen in stage one but also identified early osteomalacia as described by mineralization defects in the skeletal matrix. Patients in this stage did not exhibit any clinical signs of osteomalacia. Stage three hypovitaminosis D exhibited hypoabsorption of calcium and osteomalacia was evident clinically, biochemically and histologically. Parfitt's research identified that 200 IU of vitamin D was sufficient enough to prevent clinical osteomalacia, but was not a sufficient dose to protect against stage one or stage two hypovitaminosis D osteopathy.

Treatment of osteomalacia is directed at treating the underlying cause of the disease. Restoring adequate amounts of calcium and vitamin D to the diet may be sufficient.

Osteoporosis

Bone maturation occurs at approximately 30 years of age. After maturation, the rate of bone loss for both sexes is approximately 0.7% per year. Bone loss accelerates to 1% or more per year in women after menopause (Porth, 2005). Osteoporosis is a skeletal disorder that decreases bone strength and increases risk of fracture. The process of osteoporosis involves an increase in bone resorption over bone formation. Major risk factors for osteoporosis include: age, female gender, inadequate intake of calcium and vitamin D, inactive life style, small bone/low body weight, smoking, alcohol abuse, menopause, low sex hormones, Caucasian, Asian, Latino, family history of osteoporosis, history of one or more fractures as an adult, certain medications (Table 1) and certain diseases (Table 2) .

Table 1: Medications That may Cause Bone Loss

Antiseizure medications such as Dilantin or Phenobarbitol

Aromatase inhibitors

Cancer chemotherapy drugs

Glucocorticoids

Gonadotropin releasing hormone

Heparin

Lithium

Medroxyprogesterone acetate for contraception

Methotrexate

Proton pump inhibitors

Selective serotonin reuptake inhibitors

Tamoxifen

Thiazolidenediones

Thyroid hormones in excess

(NOF, 2008).

Table 2: Diseases and Conditions That Cause Bone Loss

Anorexia Nervosa and other eating disorders

Depression

Hyperparathyroidism

Hyperthyroidism

Inflammatory Bowel Disease or Celiac Disease

Loss of Height

Multiple Myeloma

Organ Transplants

Rheumatoid Arthritis

Weight Loss/Poor diet

AIDS/HIV

Cancer

Ankylosing spondylitis

Cushing's syndrome

Kidney disease

Severe liver disease

Parkinson's disease

Post Polio Syndrome or Multiple Sclerosis

Spinal cord injuries

(NOF, 2008).

Osteoporosis was responsible for more than two million fractures in 2005. Those statistics are expected to rise to more than three million fractures by 2025 (NOF, 2008). Hip fracture ranks as one of the top six discharge diagnoses from acute care facilities (Ferrucci, Guralnik, Pahor, Chiara, & Havlik, 1997). Often, rehabilitation occurs in the nursing home setting after fracture reduction. At 6 months post-fracture only 15% of the patients rehabilitating from these fractures can ambulate across a room independently (NOF, 2008). This poses significant challenges for patients, healthcare providers and healthcare systems as the elderly population increases.

Biphosphonates are prescribed to treat osteoporosis. A systematic review conducted by the Agency for Healthcare Research and Quality (AHRQ) found evidence that the biphosphonates alendronate, etidronate, ibandronate and risedronate prevent vertebral, nonvertebral or hip fractures in patients with osteoporosis (MacLean et al., 2008). Muneaki et. al (2009), studied post-menopausal women on alendronate and the effects of vitamin D with biphosphonate therapy. They found that a 25(OH) D concentration of 25 ng/ml. was the minimum level required for alendronate to have an optimal response in improving lumbar spine bone mineral density.

Cutaneous Synthesis of Vitamin D

Many factors such as geographic location, sunscreen use, skin pigment, aging and limited sun exposure affect vitamin D absorption through the skin. Casual sun exposure of the face, arms and hands causing light erythema is approximately equal to 200 IU of vitamin D (Haddad, 1992). Action spectra data indicates that UVB rays of 295-315

nanometers are responsible for vitamin D3 production. This is also the peak region of UVB rays responsible for sunburn and non-melanoma skin cancer (Wolff et al., 2008).

In temperate regions above 45 degrees latitude, there are insufficient UVB rays during October through March to synthesize adequate vitamin D3 (Wolff, et al. 2008). A general urban population was studied in 20 French cities located between the latitude of 43 degrees and 51 degrees in winter from November to April. Twenty-five (OH) D values of less than or equal to 12 ng/ml. were found in 14% of the population studied. In the population studied, a rise in serum parathyroid hormone level was seen when serum 25(OH) D levels were equal to or less than 31 ng/ml. (Chapuy et al., 1997).

Binkley, Novotny, et. al (2007) studied sun exposure of adults in Hawaii at a latitude of 21 degrees. In a convenience sampling of 93 adults, self-reported sun exposure was 28.9 hours/week. Mean circulating 25(OH) D levels were 31.6 ng/ml. 51% of the sample population had serum 25(OH) D levels below 30 ng/ml. Data from this study suggests UVB radiation responsiveness varies among individuals, causing variable serum 25(OH) D levels in individuals despite sun exposure at latitudes where UVB rays are abundant.

One of the variables in individuals affecting UVB absorption is the melanin in the skin. Melanin is the natural skin pigment built into humans designed to protect the skin. People of color are more deficient in vitamin D than whites. Exposure to the sun's UVB rays increases the production of melanin, causing tanning to occur (Porth, 2005). African-Americans have higher total body calcium and bone mass than whites. Burckhardt, et al. (2004) explains this difference is not due to vitamin D sufficiency, but

due to higher calcium absorption efficiency and lower urinary calcium excretion. African-American women have a lower rate of osteoporosis (Dawson-Hughes, 2004). Yet there is a rising incidence of rickets in African-American children who receive their total nutrition from breastfeeding (Kreiter et al., 2000).

Aging also reduces the amount of 7-dehydrocholesterol in the skin, thus decreasing vitamin D absorption in the epidermis (Holick, 2007). Lips (2001) confirmed this through his research. Irradiation from artificial ultraviolet lighting increased serum vitamin D levels four times more in young adults age 20-30 than in elderly adults age 62-80 with the same skin type.

Dietary Supplementation and Benefits of Vitamin D

When vitamin D synthesis through sun exposure is impaired, dietary ingestion is required to ensure adequate vitamin D. Ingestion of vitamin D can normalize serum 25(OH) D levels and may prevent fractures in humans. For 5 years, Trivedi, Doll and Khaw (2003) studied 2686 community dwellers age 65-85 years old in Britain using a double blind controlled trial of oral vitamin D3 vs. placebo. Participants received one dose of 100,000 IU oral vitamin D3 every 4 months or placebo. At the end of the study, vitamin D concentrations were 40% higher in the active treatment group than the placebo group. Those participants also had 22% lower first fracture rate and a 33% lower rate for fracture occurring at the hip, wrist, or vertebrae. Mean calcium intake did not differ between groups averaging 742 mg. /day. These findings were confirmed in a meta-analysis (Bischoff-Ferrari, Dawson-Hughes, et. al, 2004). Researchers included only double-blind random controlled trials that studied any type of vitamin D. Their primary

outcome was to assess the relative risk of having one fall in community-dwellers or institutionalized people on vitamin D, compared to those not taking any vitamin D. The mean age of community-dwellers studied was 60 years old. Analysis revealed that a person taking vitamin D supplementation reduced their fall risk by 22%. Taking into account the pooled risk differences, this indicated that 15 people would need to be treated with vitamin D to prevent one person from falling. They also found doses of at least 700-800 IU of vitamin D3 were necessary for fracture reduction. A secondary analysis found that calcium 1200 mg. plus vitamin D 800 IU reduced the rate of falls by 60% compared to 1200 mg. of calcium supplementation alone (Bischoff-Ferrari, Conzelmann, et al., 2006).

A study was conducted on vitamin D dosing in nursing home residents to assess doses adequate to reduce falls (Broe, et al., 2007). Dosing of 200 IU, 400IU, 600 IU, 800 IU or placebo was randomly administered to 124 residents with the average age being 89. Vitamin D doses at 800 IU had a lower number of residents who fell and a lower incidence of falls over 5 months. This was less than any other group taking the vitamin or placebo.

Older adults in a nursing home ages 58-89 years old living at 47 degrees N latitude were given one bun daily fortified with 5000 IU vitamin D3 and 320 mg. elemental calcium. Initial serum 25(OH) D concentrations ranged from 7.08 ng/ml. to 15.72 ng/ml. After 12 months, 25(OH) D concentrations rose to levels ranging from 34.72 ng. /ml. to 65.76 ng/ml. Ninety-two percent of the participants achieved a level of 29.6 ng/ml. No changes in serum calcium or hypercalcemia were observed. Z scores for

mean BMD at the lumbar spine in women were increased 4.6%, a statistically significant difference. Hip BMD measures were not statistically significant between the sexes. However, overall Z scores for hip BMD at 12 months increased 23.4% from initial baseline measurements. This study showed bone responsiveness in adults lacking adequate vitamin D (Mocanu, et al., 2009). This study reflects similar results obtained by Heaney, Davies, Chen, Holick and Burger-Lux, (2003) who concluded that healthy men ages 27.5 to 50 living at 41.2 degrees latitude require approximately 3000-5000 IU daily of vitamin D3 in the absence of substantial cutaneous synthesis of vitamin D.

The results of these studies are consistent with current speculation that the daily AI of 400-600 IU is inadequate to meet the needs of adults. It also provides evidence that the upper level intake of 2000 IU daily of vitamin D may be inadequate to meet the needs of an aging population and that optimal vitamin D supplementation could reduce falls experienced by older adults, particularly nursing home residents.

Toxicity and Measurement of Serum Concentrations of Vitamin D

Measuring serum 25(OH) D is considered the gold standard for determining the vitamin D status of humans (Holick, 2005). Controversy has surrounded laboratory measurements of 25(OH) D due to variation in results from lab to lab. Radioimmunoassay (RIA) measurements of 25(OH) D levels are often higher than high-performance liquid chromatography (HPLC) measurements due to lack of discrimination between 25(OH) D and other hydroxylated metabolites of vitamin D (Holick, 2007). Liquid chromatography tandem mass spectroscopy (LCMSMS) and HPLC have been considered the best technology developed to determine 25(OH) D levels (Holick, 2007).

Binkley, Krueger, Gemar and Drezner, (2008) studied between-laboratory differences of HPLC, RIA and LCMSMS methodologies among four labs. They utilized 15 healthy individuals, age 20-60 years old, using standard calibration to enhance between-lab agreement. Between laboratory comparisons revealed that 80% of the sample was appropriately categorized between optimal and vitamin D insufficiency, but between-laboratory systematic bias determined the mean bias to range from +2.9 to +5.1 ng/ml. Standard calibration technique improved between-laboratory variation but did not resolve variation. This variability highlighted the importance for clinicians to recognize the importance of lab variability surrounding human samples and instrumentation limitations related to treatment choices, particularly when their patients are close to the lower 25(OH) D cutoff level of 32 ng/ml.

UVB Exposure

Ultraviolet exposure with more than a mild erythematic response does not increase vitamin D production. Production of vitamin D is counterbalanced by degradation of the vitamin and its precursors (Vieth, 1999).

Toxicity

Pharmacologic Vitamin D toxicity has been rare and has not shown lasting effects on humans (Veith, 1999). Adams and Lee (1997) cited four subjects presenting with hypercalciuria. One subject was consuming vitamin D 1200 IU/day. When the study was later questioned, Adams and Lee stated that the subjects had indeed consumed doses greater than 1200 IU/day, but accurate doses were never able to be attained. Veith (1999) summarized documented accounts of serum 25(OH) D levels associated with

pharmacologic or toxic vitamin D intake. Prolonged pharmacologic dosing of vitamin D can produce hypercalcemia. Analysis of hypercalcemia due to vitamin D intoxication was always accompanied by serum 25(OH) D concentrations greater than 88 ng/ml. To attain this level, a person would have to consume at least 40,000 IU vitamin D daily (Veith, 1999). Hypercalcemia should always be investigated, as there are other reasons for the calcium imbalance. Other causes include: excess dietary calcium, milk-alkali syndrome, primary hyperparathyroidism, malignant neoplasms, prolonged immobilization, thiazide diuretics and lithium therapy (Porth, 2005).

In order to maintain a normal serum 25(OH) D concentration of 30-88 ng/mL., a homeostatic mechanism exists. Pharmacologic intake can consist of greater than or equal to 200 IU/day whereas, UVB exposure can consist of 10,000-20,000 IU/day. Vitamin D is stored in body fat for use during periods when sun exposure is inadequate (Jellin et al., 2009). Mechanisms where metabolism of vitamin D is regulated include the concentration of 25-hydroxylase in the liver, catabolism of 25(OH) D by the liver into products excreted in bile, and catabolism of 25(OH) D by the side-chain cleavage pathway initiated by 24-hydroxylase present in other tissues throughout the human body (Veith, 1999). Given the wide margin of safety reported for vitamin D and laboratory variation, a target for an acceptable 25(OH) D level is approximately 40 ng/ml. (Binkley et al., 2008).

Barriers to Adequate Vitamin D

Human behavior plays an important role in health and adherence to healthy lifestyle habits. Studies done by Ford, Bass, and Keathley (2007) on college-age women

revealed they had a moderate level of knowledge regarding osteoporosis. Despite having knowledge of the disease and dietary intake to decrease their risk of disease, they did not modify their dietary habits to maintain a healthier lifestyle for their bones. Johnson, McLeod, Kennedy and McLeod (2007) confirmed the same behavior patterns in their study of osteoporosis beliefs among men and women, both young and old. Susceptibility scores of both genders were significantly lower in young adults age 18-25 compared to the adults greater than and equal to 30 years of age. Despite older adults scoring higher in susceptibility scores, no significant differences were measured in their perceived seriousness of the disease or health motivation to take preventative action.

Factors associated with higher vitamin D status reflected healthier body habitus and more active lifestyles. Behavior and physical traits studied in 861 community-dwelling women age 20-92 years old participating in the Geelong Osteoporosis Study in Australia showed excessive weight and smoking were associated with lower 25(OH) D concentrations (Pasco, Henry, Nicholson, Brennan, Kotowicz, 2009).

Segal, Zinman, Raz and Ish-Shalom (2009) studied compliance of 122 patients ages 62.5- 82-5 after they underwent surgical hip fracture correction. At three months post-surgery 23.8% were fully compliant taking a calcium and vitamin D supplement of 1200 mg. / 800 IU. At 12 months a 55.7% drop out rate occurred with the major reason being non-compliance to taking supplementation.

CHAPTER III

METHODOLOGY

The purpose of this study was to examine the exogenous and endogenous intake habits of women undergoing initial BMD and compare results to see if BMD scores were higher in women who had better vitamin D intake habits. This chapter provides an overview of the research design and methodology used for the study.

Research Design

This was a non-experimental comparison research project that examined the vitamin D dietary, supplement and sun intake habits of women age 50 plus years and compared their intake to their BMD. Participants who were having their first BMD test, completed questionnaires on vitamin D intake, demographic information and their health history.

Population, Sample and Setting

The target population was women age 50 plus years undergoing BMD for the first time. The sample was women age 50 and over coming for first time BMD to a clinic in a northeastern Wisconsin healthcare system. After 1 month of study, an appeal was made to the university and healthcare system institutional review boards due to limited numbers of participants. The study was opened up to a second site doing BMD in the same healthcare system. Two sites conducted the study for a total of 1 month. A convenience

sample of six participants was utilized in the research study. Exclusion criteria included participants with the following medical diagnoses: anorexia nervosa, GI malabsorption syndrome, depression, hyperparathyroidism, hyperthyroidism, inflammatory bowel disease, multiple myeloma, organ transplant, rheumatoid arthritis, sex hormone disorders and renal disease. Exclusion criteria also included participants taking the following medications: antiepileptic medications, aromatase inhibitors, cancer chemotherapy drugs, steroids, cyclosporine A, tacrolimus, gonadotropin releasing hormone, heparin, lithium, medroxyprogesterone acetate, methotrexate, proton pump inhibitors, selective serotonin reuptake inhibitors, tamoxifen, thiazolidenediones and thyroid hormones.

Data Collection Instruments

The research study included two questionnaires developed by the researcher. A Vitamin D questionnaire asked participants about their dietary intake of vitamin D rich and fortified foods. A demographic/health questionnaire asked participants about their dietary history of supplements, demographic data, activity pattern, sun exposure pattern, history of fracture and current medication list.

Data Collection Procedure

The receptionist checking women into the clinic where BMD was done asked potential participants registering for their first bone densitometry test if they would like to voluntarily participate in a research project on vitamin D conducted by a graduate nurse practitioner student from the University of Wisconsin-Oshkosh College of Nursing. If the

participant replied affirmatively, they were given the self-administered questionnaires: vitamin D (Appendix A) and demographic/health information (Appendix B). They filled out the questionnaires in the reception area while they were waiting for their BMD. Once completed, participants sealed the questionnaires in an envelope provided and placed it in a sealed box. The researcher picked up questionnaires from the box at the end of each week. The researcher obtained electronic access to each participant's medical record following written consent (Appendix C). The researcher obtained approval from the university and the IRB at the healthcare system prior to the study. Once the questionnaires were obtained, the researcher conducted a chart review of each participant to obtain bone densitometry results, review medications, and medical history. Appendix A, B and C were numbered so names did not appear on Appendix A and B. Appendix C was kept by the researcher in a locked box to insure anonymity. Only the researcher and chairperson for the research study knew the names of the participants. No names were used in reporting of the study. Only aggregate data was reported. All research data was stored in a lockbox in the researcher's home. All computer information will be deleted upon completion of the research study.

Data Analysis Procedure

Analysis was done utilizing SPSS analysis at the University of Wisconsin Oshkosh. Descriptive and correlation statistics were analyzed. Research assistants helped with data entry and ran the program for the study.

Limitations

Limitations of the study included:

1. The vitamin D questionnaire made by the author lacked reliability and validity testing.
2. Self-reporting on food frequency questionnaires focuses on consumption of food groups. Participants may consciously or unconsciously not remember their intake, alter their intake to simplify recording the data, or alter their data to impress the researcher on their eating habits.
3. Size of the sample does not permit any generalization of the study.

Chapter Summary

In this chapter, design, sample, setting, data collection instruments and method of collection was discussed in detail. Exclusion criteria and limitations of the study were also listed.

CHAPTER IV

FINDINGS AND DISCUSSION

The researcher conducted this study to examine exogenous and endogenous vitamin D intake habits of women undergoing BMD testing for the first time. The following question was posed: Do women who have the best vitamin D intake habits have the best bone mineral density scores?

Many factors contribute to changes in bone density. There are lifestyle changes that can enhance bone health. Demographics, an analysis of vitamin D intake, and health information pertaining to life style choices, both positive and negative related to the risk of osteoporosis, will be described using descriptive statistics. Correlation statistics comparing bone mineral density results to total vitamin D intake, age, exercise and fractures will also be measured.

Women undergoing BMD testing for the first time in a northeastern Wisconsin healthcare system were asked by receptionists to voluntarily participate in filling out self-questionnaires regarding demographic, health and vitamin D intake information. In mid-October 2009, 25 questionnaires were delivered to one clinic site where BMD was done 1 to 2 days every week. After 3 weeks of data collection, only two questionnaires were obtained. A written request was submitted to both the university IRB and the healthcare system IRB for expansion to another clinical site. At week four, 50 questionnaires were delivered to a second clinic site where BMD testing was done daily. The study was completed in mid-December.

A total of eleven women volunteered to participate in this research project. Six women met all of the inclusion criteria for the study of vitamin D practice habits and the correlation of their BMD results. Five of the eleven women filling out questionnaires were excluded due to prescribed SSRI medications. Descriptive statistics of the participants are presented in Table 3.

Table 3 Sample Demographics

Demographic and Health Characteristics of Sample n=6

Participant	Age	Ht (in)	Wt (lbs)	BMI	Ex*(min/week)	Fx*	Sun Ex*(min/week)
1	51	61	100	18.9	60	Yes	NA
2	60	66	120	19.4	450	Yes	10
3	52	64	130	22.4	105	No	0
4	65	67	209	32.8	0	No	900
5	59	65	199	33.2	105	No	NA
6	74	53	192	34.1	60	Yes	0
Mean	60.17	62.67	158.33	26.80	130.00		

* Ex=exercise Fx = previous fracture Sun Ex = sun exposure
NA= Patient did not quantify minutes of exposure

All women in the research confirmed they were having BMD testing done for the first time. All participants were white ranging in age from 51 to 74 years old with the mean being 60 years old. All the participants had acquired at least 12 years or equivalent

of education. One of the six participants had acquired a general education degree (GED), with the mean educational level being 13.83 years of education preparation.

The minimum height for women was 61 inches and minimum weight 100 pounds, with the maximum being 67 inches and 209 pounds respectively. Body mass index (BMI) ranged from 18.9 to 34.1 with the mean BMI equal to 26.8. Three of six (50%) female participants had already had some type of fracture in their lifetime. Two participants had a history of elbow fracture and one had a leg fracture.

Five of the six participants engaged in an exercise routine. Exercise ranged from 15 minutes four times a week to 75 minutes six times a week. The average number of minutes exercising per week was 130 minutes total. Only one participant out of six acknowledged that she lifted weights.

One participant acknowledged she was a current smoker and had a smoking history for 25 years, but did not list how many packs per day smoked. Three out of six participants drank alcohol. Only one participant consumed more than the recommended amount for women according to the United States (U.S.) government dietary guidelines 2005, by drinking 120 ounces beer/week.

Two out of six participants did not utilize sunscreen when being outdoors. Outdoor sunshine exposure varied from never being outside in the sun to 300 minutes three times per week.

Vitamin D Intake

Vitamin D enriched foods were listed on the questionnaire based on those foods highest in vitamin D as listed in Krause's *Food and Nutrition Therapy* and the United States Department of Agriculture (USDA) National Nutrient Database. Participants were asked to check how often they consumed each food listed on the questionnaire. When fortified foods such as margarine, cheese, butter, yogurt and tofu were listed, the participant was asked to indicate the brand of the item. There were inconsistencies in participants listing the brand of food items, so in order to calculate vitamin D amounts, items were taken from the USDA National Nutrient Database based on what type of cheese or butter the participant listed. Margarines are fortified with 0-20% of the daily recommended intake of vitamin D so a mean of 10% was used to calculate the vitamin D intake per serving of margarine. Frequency of consuming the foods ranged from zero to six or more times per day. When participants checked that they consumed food one to three times a month, two to four times per week, five to six times per week, two to three times daily or four to five times daily, an average mean was calculated to total vitamin D intake into IU.

Half of the participants consumed some type of multivitamin on a daily basis. Multivitamins were listed on their medication list so each brand could be researched to attain the actual amount of vitamin D per pill. Only one participant took vitamin D 2000 IU on a daily basis.

The daily recommended intake (DRI) of vitamin D recommended is an AI of 400-800 IU or 12,000-24,000IU/month. The NOF recommends 800-1000 IU daily equating to

24,000-30,000IU/month, based on a 30-day month. Upper level intake recommended is 2000 IU daily or 60,000IU/month. In this study, total vitamin D intake was calculated on a monthly intake in IU/month. Total vitamin D intake ranged from 4723 IU/month to 72,292 IU/month, with the mean monthly intake of vitamin D equal to 28,027 IU. Based on a 30 day/month calendar, this ranges from 157 IU/day to 2409 IU/day (Table 4). With this small group of women, BMD results had no relationship to total vitamin D intake, age, or exercise when analyzed using Pearson Correlation (Table 5).

Table 4 Vitamin D Table

Smoking, Vitamin D and BMD Results n=6

Participant	Age	Smoker	Vitamin D (IU)*	BMD	Fx**	Sun Ex**
1	51	Yes	24969	Normal	Yes	NA
2	60	No	25089.5	Osteoporosis	Yes	10
3	52	No	4723	Normal	No	0
4	65	No	33083	Osteopenia	No	900
5	59	No	8006.5	Normal	No	NA
6	74	No	72292	Osteopenia	Yes	0
Mean	60.17		28027.17			

* Estimated monthly intake by food and oral supplementation

** Fx = previous fracture Sun Ex = sun exposure (min/week)

NA = Patient did not quantify minutes of exposure

Table 5

Correlation of Total Vitamin D Intake, Age, Exercise, Fracture to BMD Result

		Total Vitamin D	BMD Result
Total Vitamin D	Pearson Correlation	1	.438
	Sig. (2-tailed)		.385
BMD Result	Pearson Correlation	.438	1
	Sig. (2-tailed)	.385	
		Age	BMD Result
Age	Pearson Correlation	1	.524
	Sig. (2-tailed)		.286
BMD Result	Pearson Correlation	.524	1
	Sig. (2-tailed)	.286	
		Exercise	BMD Result
Exercise	Pearson Correlation	1	.200
	Sig. (2-tailed)		.704
BMD Result	Pearson Correlation	.200	1
	Sig. (2-tailed)	.704	

CHAPTER V

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

Summary

Receptionists at two northeastern Wisconsin clinics distributed questionnaires to women undergoing BMD testing for the first time to determine if BMD was related to vitamin D. The HBM was the theoretical framework for this research study. Participation was voluntary and conducted over a period of 2 months. Exclusion and inclusion criteria were utilized from the NOF criteria. Data obtained did not reveal any statistical significance in findings. Even though there was no significance shown in this small study, conclusions, recommendations and implications reached from the literature address some important factors regarding vitamin D and bone health.

Conclusions

Current vitamin D research reveals that more than 50% of adults in the U.S., over the age of 65, have vitamin D deficiency. Furthermore, people in northern latitudes do not absorb enough vitamin D in the intense summer hours of sunshine to maintain adequate stores of vitamin D through the winter months, and there are insufficient UVB rays during October through March to synthesize vitamin D3 in regions above 45 degrees latitude (Wolff et al., 2008). In order to maintain adequate stores in the body all year in the northern latitudes, oral vitamin D supplementation may be necessary since foods rich in vitamin D may not be sufficient to maintain adequate stores in the body. Vitamin D is

found in limited amounts in food and fortified products in the U.S. and people living in northeastern Wisconsin are at risk of low vitamin D intake during low level sunshine months.

In this study, people varied in the amount of summer sun exposure they received, the amount of vitamin D enriched foods they consumed on a routine basis and the amount of supplementation with vitamin D3 they consumed.

The use of food frequency questionnaires may have affected the accuracy of self-reporting vitamin D intake. Food frequency questionnaires provide an overall picture of intake, but do not, at times, provide meal pattern data or specific portion sizes (Mahan & Escott-Stump, 2008).

Total monthly vitamin D intake varied in individuals from 4,723 IU/month to 72,292 IU/month. This study measured vitamin D intake but did not measure absorption of vitamin D by the individual. Actual serum vitamin D levels were not obtained in this study due to financial constraint, but would have been useful.

The size of this study was smaller than anticipated. Many diseases and medications prescribed for disease processes alter absorption of calcium and vitamin D, thus affecting bone metabolism and thus five of the total of eleven participants were excluded from the study due to being on SSRI medications. A low number of women undergoing BMD for the first time were encountered at these clinic sites. Low numbers of initial BMD patients may have been due to the timing of collection in the calendar year, the short length of time research was collected, lack of patient willingness to

participate in research or low numbers of referrals for BMD screening to these clinic sites by practicing providers in the healthcare system.

Recommendations for Further Research

Several changes to strengthen this study include:

1. Revision of the vitamin D questionnaire to eliminate specific butter (salted vs. unsalted) and just state butter. Eliminate type of cheese and just state how many slices of cheese consumed.
2. Validity testing of the vitamin D questionnaire after revising it.
3. Retesting for reliability of the vitamin D questionnaire after revisions.
4. Reproducing the study utilizing the power analysis showing that a total of 70 participants are needed to conduct a study and using the number of participants as an endpoint instead of a timeline to obtain a sufficient sample size.
5. Changing recruiting techniques for obtaining a larger sample size.
6. Obtaining funding for serum vitamin D levels of patients in the study as an objective measurement of vitamin D for comparison to BMD results.

Implications for Practice

Practitioners need to assess vitamin D intake independent of calcium intake in their patients, particularly women. Women undergoing BMD screening for the first time would benefit from vitamin D education to learn what foods and supplements they can incorporate into their lifestyle to enhance bone health as they age. Education is needed

during this phase of a woman's life because women may not realize the importance that vitamin D has on bone health.

Women undergoing repeat BMD testing due to abnormal screenings would benefit from vitamin D education also. Mocanu et al. (2009) demonstrated in 92% of the participants in their study that women had statistically significant Z scores for mean BMD at the lumbar spine level when vitamin D supplementation brought their serum vitamin D levels to 29.6 ng/ml. Overall Z scores for hip BMD at 12 months increased 23.4% from initial baseline measurements. This research provides evidence of bone responsiveness in adults lacking adequate vitamin D and is important to consider when optimizing treatment of patients with abnormal BMD scores.

Osteoporosis is a clinical indication for prescribing biphosphonate therapy. Healthcare providers should consider optimizing vitamin D levels before prescribing biphosphonates. They should also assure adequate vitamin D levels prior to initiating alendronate therapy for women with osteoporosis. Muneaki et al. (2009) found that a vitamin D level of 25 ng/ml. was the minimum level required for alendronate therapy to have an optimal response in improving lumbar spine bone mineral density. Every effort should be made by practitioners to provide their patients with optimal drug therapy, particularly when statistics show that one of every two women over 50 years old will have an osteoporosis related fracture in their remaining lifetime.

Many different brands of vitamin D exist in retail stores in the U.S. Health care providers and nurses should educate their patients on label reading since many over-the-

counter supplements of calcium with vitamin D contain less than 800-1,000 IU as recommended by the NOF.

Other risk factors for osteoporosis need clarifying and healthcare providers need to do a thorough review of medical history and the medication record on each individual. Individuals who have risk factors, diseases that contribute to osteoporosis or medications that interfere with bone metabolism, should be screened for bone disease and educated on their risk factors so they may reduce their risk as much as possible by practicing good calcium, vitamin D and nutritional habits along with lifestyle modification in areas such as exercise, weight lifting, smoking and alcohol consumption.

Elderly patients, particularly institutionalized patients, need to have adequate sun exposure to absorb enough vitamin D, and proper vitamin D nutrition and supplementation. Staff caring for elder patients in the community and in extended care facilities need to be educated on the benefit of vitamin D in all forms for fracture reduction and decreasing the incidence of falls.

In order to decrease risk of fracture and maximize their quality of life, women need bone health assessment. Teaching patients and exploring barriers to change diet and lifestyle is an ongoing process as evidenced by Segal, et al. (2009). They found that patients with surgical hip fracture correction had a 55.7% drop out rate from taking supplementation following surgical correction.

Incorporating the HBM model into practice can provide a systematic framework to assist practitioners in increasing awareness of the susceptibility of bone disease and addressing changes that could have a positive effect on function and quality of living later

in life. Educating women in regard to normal bone metabolism and risk for fracture may cue them to take action in lifestyle modification necessary to enhance bone health. Education is key and ongoing throughout the spectrum of bone maturity for women, but acting on the needs is even more important.

APPENDIX A

Vitamin D Questionnaire

VITAMIN D QUESTIONNAIRE
PLEASE DO NOT ASK FOR ASSISTANCE FILLING OUT THIS FORM
PLEASE FILL OUT THIS FORM AND PLACE IN THE PROVIDED ENVELOPE.
WHEN ALL FORMS COMPLETED, DROP IN THE DECORATED BOX ON THE TABLE.

TYPE of VITAMIN D SOURCES:	HOW	OFTEN							
	Never	1-3 times a Month	1per week	2-4 per week	5-6 per week	1 per day	2-3 daily	4-5 daily	6+ daily
8 oz of milk, soy milk, or lactose free milk Include amount you cook with also									
4 oz. yogurt: **Indicate Brand** _____									
Margarine, 1 Tablespoon **Indicate Brand** _____									
8 oz. Orange juice fortified with Vitamin D									
Salmon, 3.5 oz Pink, canned									
Mackerel, Atlantic 3 oz.									
Tuna fish in canned oil, 3 oz.									
Shrimp 3 oz.									
Sardines, Atlantic canned in oil, 1.75 oz.									
Sardines, Pacific, canned in tomato sauce 2 oz.									
Herring 3 oz.									

Herring, pickled 3 oz.									
TYPE OF VITAMIN D SOURCES	Never	1-3 Times a Month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 daily	4-5 daily	6+ daily
Halibut 3 oz.									
Beef liver 3.5 oz Catfish 3 oz.									
Oyster 3 oz.									
Shitake mushrooms Dried, 4									
Cod liver oil, 1 teaspoon									
Cheese,1 slice **Indicate types:** _____ _____ _____									
Egg, yolk included									
Tofu **Indicate brand:**									
Pudding Made with milk ½ cup									
Cereal, fortified ¾ cup									
Butter, salted 1 Tablespoon **Indicate brand:** _____									
Butter, unsalted 1 Tablespoon **Indicate brand:** _____									

M. Miller 2009

APPENDIX B

Demographic/Health Questionnaire

Demographic and General Health Information
Please fill in the answers and place in envelope. Seal envelope and place in box.

Is this your first bone mineral density test? Yes No

Height_____Weight_____Age_____

Level of Education _____years

Race:

White _____ Black/African-American_____ American Indian_____

Hispanic/Latino _____ Asian_____ Alaska Native _____

Native Hawaiian or Pacific Islander _____ Other_____

Have you ever had a broken bone (fracture)? Yes No

If yes, what was broken? _____

Do you exercise or walk for exercise? Yes No

Indicate _____minutes _____times per week.

Do you lift weights? Yes No

Indicate _____times per week.

Do you smoke? Yes No

If you have smoked in your lifetime how many packs?_____ how many years?_____

Do you drink?: Beer Yes No _____ounces per week

Wine Yes No _____ounces per week

Liquor Yes No _____ounces per week

Do you use sunscreen? Yes No

In summer months, my arms, hands and face are exposed to lightly sunburn:

_____times a week for _____minutes

_____times a month for _____minutes

_____Never

I take a multivitamin supplement: Yes No

_____times per week

Brand: _____

I take a vitamin D supplement: Yes No

_____times per week

Amount of Vitamin D_____IU.

PLEASE LIST ALL MEDICATIONS, OVER THE COUNTER MEDICATIONS, OVER THE COUNTER SUPPLEMENTS AND HERBS YOU TAKE:

_____

_____

_____

_____

_____

_____

_____

_____

Thank you for participating in the study.

APPENDIX C

Written Consent

Informed Consent

Place one copy of this consent in envelope and keep one copy for yourself.

I am Mary Miller, a graduate nurse practitioner student at the University of Wisconsin, Oshkosh, College of Nursing. I am writing a paper on vitamin D intake and osteoporosis. I am surveying women who come in for their first bone mineral density test to compare vitamin D intake habits to their bone mineral density scores.

There are two questionnaires to fill out, one on vitamin D food intake and one on general health information. Each questionnaire will take 5-10 minutes to complete. Your participation in this research project is voluntary. If you do not want to participate, you may stop at any time.

I also would like to review your medical record to obtain your bone mineral density test scores, a list of medications from your health history and a history of your medical diagnoses.

Information you provide in this study will be kept confidential. All data will be given a code number instead of using your name or other information that could identify you. The results of this study may be published. Names will not be identified. All information will be shredded or deleted from computers after completion of the study. Only Mary Miller, BSN and Dr. Roxana Huebscher, PhD. (chairperson) will have access to the information.

Permission for this study was given by the Institutional Review Board of the University of Wisconsin-Oshkosh and the Institutional Review Board of Affinity Health Systems. If you have questions or complaints about the study, you may contact the chairperson at the Institutional Review Board of UW-Oshkosh at (920)-424-3215.
If you have any questions about your rights as a research subject at Affinity Health System, please contact Affinity Health System's Institutional Review Board chairperson: Dr. Robin Price, Affinity Medical Group- Family Practice, W6981 Park View Drive, Greenville, WI. 54942, (920)-882-2450.

Should you have questions regarding this study contact:

Mary Miller, BSN, RN
PO Box 74
Butte Des Morts, WI 54927
or the Graduate Program at 920-424-2106

I, _____, understand the written information provided to me for the purposes of this study and I am willing to participate in this research project. Signature _____Date_____.

I give permission to have my medical record reviewed for medications, bone density scores and medical diagnoses.

Signature_____Date of Birth_____.

APPENDIX D

UW Oshkosh IRB Approval Letters

THE UNIVERSITY OF WISCONSIN
OSHKOSH

October 16, 2009

Ms. Mary Jo Miller
UWOSH
CON

Dear Ms. Miller:

On behalf of the UW Oshkosh Institutional Review Board for Protection of Human Participants (IRB), I am pleased to inform you that your application has been approved for the following research: Comparison of Vitamin D Practice Habits in Women Undergoing Initial Bone Densitometry.

Your research has been categorized as NON-EXEMPT, which means it is subject to compliance with federal regulations and University policy regarding the use of human participants as described in the IRB application material. Your protocol is approved for a period of 12 months from the date of this letter. A new application must be submitted to continue this research beyond the period of approval. In addition, you must retain all records relating to this research for at least three years after the project's completion .

Please note that it is the principal investigator's responsibility to promptly report to the IRB Committee any changes in the research project, whether these changes occur prior to undertaking, or during the research. In addition, if harm or discomfort to anyone becomes apparent during the research, the principal investigator must contact the IRB Committee Chairperson. Harm or discomfort includes, but is not limited to, adverse reactions to psychology experiments, biologics, radioisotopes, labeled drugs, or to medical or other devices used. Please contact me if you have any questions (PH# 920/424-7172 or e-mail: rauscher@uwosh.edu).

Sincerely,

Dr. Frances Rauscher CM

Dr. Frances Rauscher
IRB Chair

cc: Roxana Huebscher
1664

INSTITUTIONAL REVIEW BOARD
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THE UNIVERSITY OF WISCONSIN
OSHKOSH

November 3, 2009

Mary Jo Miller
5150 Lakewind Dr.
Butte Des Morts, WI 54927

Dear Ms. Miller:

Based on the additional materials that you provided, your request for a modification has been approved for the study "Comparison of Vitamin D Practice Habits in Women Undergoing Initial Bone Densitometry."

Sincerely,

Dr. Frances Rauscher

Dr. Frances Rauscher
IRB Chair

Cc: Roxana Huebscher

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