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Vitamin D in the Treatment of Breast Cancer

By Maria Cayelli

Dr. Cayelli is Family Medicine Specialist, Anderson, SC; she reports no financial relationships relevant to this field of study.

An estimated 182,460 new cases of invasive breast cancer, and approximately 40,930 breast cancer deaths (40,480 women, 450 men), are expected to occur among women in the United States during 2008.[1] While breast cancer in men is rare, breast cancer is the most frequently diagnosed cancer in women, ranking second among cancer death in women.[1] In light of this, many factors have been studied in relation to altering breast cancer risk.[2] Breast cancer is a multifactorial disease. While the cause of breast cancer is not completely understood, the major risk factors are being a woman, family history, increasing age, age of menarche, age of menopause, age of first live birth, use of oral contraceptive pill, and hormone replacement.[3] Prevention may be based on a healthy lifestyle including diet and exercise.[1]

Normal body cells grow, divide, and die in an orderly fashion, replacing worn out or injured cells.[1] Cancer cells have damaged DNA that makes it evolve abnormally.[1] Vitamins, which are nutrients that must be ingested through diet, may play a role in the possible prevention of breast cancer.[4] Decreased intake of certain vitamins have been implicated in an increased risk of chronic diseases.[4] Calcium and vitamin D have anticarcinogenic properties that have been studied related to breast cancer.[5]

Calcium

Calcium is a vital mineral with several important functions in bone and muscle health.[6] In adults, 99% of calcium is found in bones and teeth, while the rest is in the blood and extra cellular fluid.[6] Blood levels of calcium is helped regulated by vitamin D 1,25 dihydroxyvitamin D via a feed back loop.[2] Calcium anticarcinogenic properties include regulating cell proliferation and differentiation.[2]

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Calcium Source

Supplements and dairy products are the main calcium source for humans.[2] Other foods high in calcium include sardines, salmon, kale, Chinese cabbage, broccoli, and calcium fortified foods.[6]

Clinical Effect of Calcium

Abbas et al found a moderate risk reduction for premenopausal breast cancer associated with higher dietary calcium intake but was not statistically significant.[7] In a prospective cohort study of 7,847 women, Almquist et al found an insignificant inverse relationship between serum calcium levels and premenopausal breast cancer risk.[8] High calcium levels were positively related to increased breast cancer risk in overweight peri/postmenopause women.[8] McCullough et al found a moderate risk reduction breast cancer with high calcium intake and low fat dairy products in postmenopausal women.[5] In addition, McCullough et al found intake of calcium was inversely related to estrogen receptor (ER) positive tumors but not ER negative tumors.[5]

Vitamin D

Vitamin D is a fat soluble vitamin metabolically inter related to calcium.[2,4] Vitamin D status depends on sun exposure, leading to its skin synthesis as well as dietary intake.[8] With adequate mounts of sun exposure, vitamin D3 (cholecalciferol) is produced in the skin from 7-dehydrocholesterol.[4] Vitamin D3 is then metabolized into 25-hydroxyvitamin D in the liver.[4] In the kidney, 25-hydroxyvitamin D is converted into 1,25-dihydroxyvitamin D.[4] This vitamin D active metabolite inhibits cellular proliferation of breast cancer cells mainly through binding to a nuclear vitamin D receptor (VDR) and induce differentiation of malignant breast cells.[2,4,7] 25-hydroxyvitamin D may also circulate to breast tissue and be locally converted to 1,25 dihydroxyvitamin D, which then exerts its anticarcinogenic actions.[2]

Vitamin D Source

Although diet plays a role, the main source of vitamin D in humans is sun exposure.[9] A daily ten-minute unprotected sun exposure of hands and face may be sufficient to maintain adequate levels of vitamin D.[10] In the United States, the dietary source of vitamin D are vitamin D fortified dairy products, orange juice, fish, eggs, and supplements.[2] Vitamin D3, which is more efficient in raising the levels of the active metabolites, comes from animal sources, and vitamin D2 is synthetically made from plants.[2,4]

Clinical Effect of Vitamin D

According to the National Health and Nutrition Examination Survey Epidemiologic Follow-up Study, there was no statistically significant association between dietary and supplemental vitamin D intake and breast cancer.[11] Overall, Bertone et al also found insignificant inverse association between plasma levels of 25(OH)D and breast cancer risk.[12] However, Bertone et al concluded that postmenopausal women, and older women (> 60-years-old) with higher levels of vitamin D, may be at lower risk for breast cancer.[12]

On the basis that vitamin D3 status is predominately correlated to sun exposure, Robsahm et al studied the effect of solar-induced vitamin D levels on the prognosis of breast, colon, and prostate cancer. Robsahm et al found that the highest endogenous cutaneous synthesis of vitamin D was associated with the lowest risk for cancer death. In addition, the highest survival rate was with those who were diagnosed during the fall.[10]

Garland et al assessed the association between the serum levels of 25(OH)D and breast cancer risk through a pooled analysis of two studies involving 1,760 individuals.[13] They found at levels of 52 ng/mL (corresponding to an intake of 4000 IU a day), there was a 50% lower risk of breast cancer.[13] Lowe et al had similar results, reporting a significant association of low vitamin D levels with breast cancer risk in the

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Table 1

Selected food sources of vitamin D

Food	IUs per serving*	Percent DV**
Cod liver oil, 1 tablespoon	1,360	340
Salmon, cooked, 3.5 ounces	360	90
Mackerel, cooked, 3.5 ounces	345	90
Tuna fish, canned in oil, 3 ounces	200	50
Sardines, canned in oil, drained, 1.75 ounces	250	70
Milk, nonfat, reduced fat, and whole, vitamin D-fortified, 1 cup	98	25
Margarine, fortified, 1 tablespoon	60	15
Ready-to-eat cereal, fortified with 10% of the DV for vitamin D, 0.75-1 cup (more heavily fortified cereals might provide more of the DV)	40	10
Egg, 1 whole (vitamin D is found in yolk)	20	6
Liver, beef, cooked, 3.5 ounces	15	4
Cheese, Swiss, 1 ounce	12	4

***IUs** = International Units

****DV** = Daily Value. DVs were developed by the US Food and Drug Administration to help consumers compare the nutrient contents of products within the context of a total diet. The DV for vitamin D is 400 IU for adults and children age 5 and older. Food labels, however, are not required to list vitamin D content unless a food has been fortified with this nutrient. Foods providing 20% or more of the DV are considered to be high sources of a nutrient.

Source: http://ods.od.nih.gov/factsheets/vitamind.asp

United Kingdom Caucasian population.[14] Colston et al found that lower serum levels (less than 50 nM) of vitamin D was associated with five times the risk for breast cancer than those with over 150 nM.[3]

In trying to find the link between vitamin D and breast cancer, studies have looked at the VDR and its link to certain types of cancer.[14] Lowe et al and Colston et al found that polymorphisms in the VDR may increase risk of breast cancer.[3,14] In addition, both studies found a greater risk of breast cancer with the combination of lower vitamin D levels and VDR polymorphism.[3,14]

High intake of dietary vitamin D was associated with a significantly decreased risk of developing breast cancer in premenopausal women.[7,15,16] Up to age 69 in women, Knight et al found an inverse association between vitamin D intake and breast cancer.[15]

In postmenopausal women, Robien et al found a lower incidence of breast cancer with vitamin D intake of greater than 800 IU a day than with less than 400 IU a day.[17] Shin et al found, among premenopausal women with more than 500 IU a day of vitamin D intake, a lower risk for breast cancer.[16] They also found significantly lower incidence of in situ breast cancer with higher total vitamin D intake.[17]

Adverse Effect

Vitamin D is generally well tolerated, but toxicity can occur causing nausea, vomiting, poor appetite, weakness and weight loss.[6] Excess intake of vitamin D can lead to hypercalcemia. Hypercalcemia may lead to impaired kidney function and decreased absorption of other vitamins and minerals.[6]

Conclusion

The results of epidemiologic studies of vitamin D and calcium intake and breast cancer risk are inconsistent. Vitamin D and calcium are metabolically interrelated, and may have anticarcinogenic properties. Limited research shows an inverse relationship between vitamin D and the risk of breast cancer in premenopausal women. In postmenopausal women, vitamin D and calcium may play a role in decreasing the risk of breast cancer.

Recommendation

Adult women older than 50-years-old are recommended to ingest a total of 1200 mg calcium (dietary and supplemental). The current adult upper limit of vitamin D3 is 2000 IU/day.[6] ❖

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Cognitive/Non-cognitive Function in Elderly Patients

ABSTRACT & COMMENTARY

By Donal P. O'Mathuna, PhD

Dr. O'Mathuna is a lecturer in Health Care Ethics, School of Nursing, Dublin City University, Ireland; he reports no financial relationships relevant to this field of study.

Source: Riemersma-van der Lek RF, et al. Effect of bright light and melatonin on cognitive and noncognitive function in elderly residents of group care facilities: a randomized controlled trial. *JAMA*. 2008;299:2642-2655.

Cognitive decline, mood, behavioral and sleep disturbances, and limitations of activities of daily living commonly burden elderly patients with dementia and their caregivers. Circadian rhythm disturbances have been associated with these symptoms.

Objective: To determine whether the progression of cognitive and non-cognitive symptoms may be ameliorated by individual or combined long-term application of the two major synchronizers of the circadian timing system: bright light and melatonin.

Design, Setting, and Participants: A long-term, double-blind, placebo-controlled, 2x2 factorial, randomized trial performed from 1999 to 2004 with 189 residents of 12 group care facilities in the Netherlands; mean (SD) age, 85.8 (5.5) years; 90% were female and 87% had dementia.

Interventions: Random assignment by facility to long-term daily treatment with whole-day bright

(±1000 lux) or dim (±300 lux) light and by participant to evening melatonin (2.5 mg) or placebo for a mean (SD) of 15 (12) months (maximum period of 3.5 years).

Main Outcome Measures: Standardized scales for cognitive and non-cognitive symptoms, limitations of activities of daily living, and adverse effects assessed every six months.

Results: Light attenuated cognitive deterioration by a mean of 0.9 points (95% confidence interval [CI], 0.04-1.71) on the Mini-Mental State Examination or a relative 5%. Light also ameliorated depressive symptoms by 1.5 points (95% CI, 0.24-2.70) on the Cornell Scale for Depression in Dementia or a relative 19%, and attenuated the increase in functional limitations over time by 1.8 points per year (95% CI, 0.61-2.92) on the nurse-informant activities of daily living scale or a relative 53% difference. Melatonin shortened sleep onset latency by 8.2 minutes (95% CI, 1.08-15.38) or 19% and increased sleep duration by 27 minutes (95% CI, 9-46) or 6%. However, melatonin adversely affected scores on the Philadelphia Geriatric Centre Affect Rating Scale, both for positive affect (-0.5 points; 95% CI, -0.10 to -1.00) and negative affect (0.8 points; 95% CI, 0.20-1.44). Melatonin also increased withdrawn behavior by 1.02 points (95% CI, 0.18-1.86) on the Multi Observational Scale for Elderly Subjects scale, although this effect was not seen if given in combination with light. Combined treatment also attenuated aggressive behavior by 3.9 points (95% CI, 0.88-6.92) on the Cohen-Mansfield Agitation Index or 9%, increased sleep efficiency by 3.5% (95% CI, 0.8%-6.1%), and improved nocturnal restlessness by 1.00 minute per hour each year (95% CI, 0.26-1.78) or 9% (treatment X time effect).

Conclusions: Light has a modest benefit in improving some cognitive and non-cognitive symptoms of dementia. To counteract the adverse effect of melatonin on mood, it is recommended only in combination with light.

Trial Registration: controlled-trials.com/isrctn Identifier: ISRCTN93133646

■ COMMENTARY

As the population ages, the number of people in residential homes is increasing. More women than men become residents in these homes for a variety of reasons, something reflected in the gender make-up of this study: 90% of the participants were female. This limits the generalizability of the findings, however. When age-related dementia develops, cognitive decline is often accompanied by sleep and mood disturbances. These affect quality of life, functional abilities, and the burden on those caring for residents.

When sleep is disturbed, the body's circadian pacemaker can become desynchronized. This system is highly sensitive to both environmental light and the hormone melatonin. The body's production of melatonin cycles during the day, influenced by light and darkness. Production also changes with age. Jet lag develops as a result of desynchronization of the circadian rhythms, which has led to much interest in supplemental melatonin to relieve the symptoms of jet lag. While earlier studies were encouraging, more recent studies have not found benefit for jet lag.[1] At the same time, use of melatonin to treat various sleep disorders has been receiving much attention.[2] The study by Riemersma-van der Lek et al is the first to examine the long-term efficacy of both bright light and melatonin on cognitive and non-cognitive functions associated with sleep disturbances.

The study recruited participants from 12 facilities in the Netherlands where residents have their own apartments but spend much of their time in common living areas supervised by caregivers. The majority of participants (87%) had dementia. The homes were randomly assigned to deliver bright light or normal light. For the bright light group, sufficient fluorescent lights were installed in the common living areas to deliver approximately 1000 lux. Similar fixtures, but with fewer lights, were installed in the homes in the placebo light group. The participants were randomized a second time to receive either melatonin (2.5 mg 1 hour before bedtime) or placebo tablets. The participants were then monitored for up to 3.5 years, with assessments conducted six weeks after enrollment and every six months subsequently.

A total of 13 different outcome measurements were made: four mood scales, four functional status scales, one functional limitations scale, and three estimates of sleep quality. While a large number of measures has advantages, it can also increase the chances of finding spurious positive results. It can lead to situations, as with this study, where some results are positive and others negative, making straight-forward recommendations difficult.

However, the results of this study did show several significant benefits from bright light. Based on these findings, the use of whole-day bright light in residential homes for the elderly can be recommended. However, the benefits were very modest and,

while statistically significant, it would be difficult to determine their clinical significance. For example, baseline sleep efficiency ranged between 70% and 76%. Combined treatment with bright light and melatonin led to an average improvement of 3.5%. This remains short of the 85% efficiency that is often used as a cut-off for overcoming sleep disturbances. In addition, the cost of installing and running the additional lights was not calculated.

The findings for melatonin were not as clear-cut. While positive changes were found for some sleep parameters, other outcomes were negatively affected (see the summary above for details). Those receiving both melatonin and bright light had more beneficial changes. The strength of the changes increased over time. This may offer insight into some of the variability found in previous melatonin studies, as they may not have been conducted over a sufficiently long period to allow changes to develop. Of concern is the finding that those receiving melatonin showed more withdrawn behaviors and mood deterioration. The researchers suspected that this may have been due to the long-term administration of a dose of 2.5 mg. Melatonin has been associated with day-time sleepiness. The researchers recommended a lower dose for older people. In general, melatonin was tolerated well. No serious adverse events were reported by the physicians caring for the participants. The daughter of one participant suspected the study treatments led to her mother's increased restlessness and falls. She was withdrawn from the study and found to have been in the double placebo group.

Overall, the study found some limited benefits for whole-day bright light in residential homes. It also demonstrated the feasibility of conducting a rigorous clinical trial of combination complementary therapies.[3] ❖

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4. offer guidance to patients based on latest science and clinical studies regarding alternative and complementary therapies.

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CME Questions

23. What percent of calcium is found in the bones and teeth of adults?

a, 15%
b. 50%
c. 75%
d. 99%

24. The primary source of vitamin D is sun exposure.

a, True
b. False

25. The National Health and Nutrition Examination Survey Epidemiologic Follow-up Study found there was not a statistically significant association between dietary and supplemental vitamin D intake and breast cancer.

a, True
b. False

Answers: 23. (d); 24. (a); 25. (a)

News Briefs

NCCAM encourages patients to talk to providers about CAM

The National Center for Complementary and Alternative Medicine (NCCAM), part of the National Institutes of Health (NIH), has launched Time to Talk, an educational campaign to encourage patients — particularly those age 50 or older — to openly discuss the use of complementary and alternative medicine (CAM) with their health care providers.

According to a national consumer survey conducted by NCCAM and AARP and published in January of 2007, almost two-thirds of people age 50 or older are using some form of CAM, but less than one-third of these CAM users talk about it with their providers. The NCCAM/AARP survey revealed some reasons why this doctor-patient dialogue about CAM does not occur. The most common reasons survey respondents cited were:

- The physician never asked
- The patients did not know they should discuss CAM
- There was not enough time during the office visit

More than one-half of respondents who had talked about CAM with their physician said they (not their physician) initiated the CAM discussion. The telephone survey was administered to a nationally representative group of 1,559 people age 50 or older.

The Time to Talk campaign is aimed at addressing the need for this dialogue to help ensure safe, coordinated care among all conventional and CAM therapies. Talking not only allows integrated care, it also minimizes risks of interactions with a patient's conventional treatments, NCCAM says in a statement. When patients tell their providers

about their CAM use, they can more effectively manage their health. When providers ask their patients about CAM use, they can ensure that they are fully informed and can help patients make wise health care decisions.

To begin the dialogue, NCCAM suggests that providers include a question about CAM use on medical history forms. Medical providers also can initiate the conversation and ask patients to bring a list of all therapies they use, including prescription, over-the-counter, herbal therapies, and other CAM practices.

Free tools and resources for the NCCAM's Time to Talk campaign, such as wallet cards, posters, and tip sheets, are available on the NCCAM Web site. They can also be ordered from NCCAM's information Clearinghouse at (888) 644-6226. For more information on Time to Talk, or to read the full NCCAM/AARP report on CAM use communication, visit www.nccam.nih.gov/timetotalk.

FDA sends Warning Letter to firms offering cancer "cures"

The US Food and Drug Administration has sent Warning Letters to 23 US companies and two foreign individuals that it says have been marketing a wide range of products fraudulently claiming to prevent and cure cancer. North American consumers should not use or purchase these products, which include tablets, teas, tonics, black salves, and creams, and are sold under various names on the Internet, according to the FDA.

The names of the companies and individuals warned, the complete list of cancer "cure" products, and their manufacturers — along with a consumer article on health scams — can be found at http://www.fda.gov/cder/news/fakecancercures.htm. The products contain ingredients such as bloodroot, shark cartilage, coral calcium, cesium, ellagic acid, Cat's Claw, an herbal tea called Essiac, and mushroom varieties such as *Agaricus blazeii*, Shitake, Maitake, and Reishi.

The FDA maintains that because these products claim to cure, treat, mitigate, or prevent disease, and these products have not been shown to be safe and effective for their labeled conditions of use, they are unapproved new drugs marketed in violation of the Federal Food, Drug, and Cosmetic Act. Examples of fraudulent claims for these products include:

- "Treats all forms of cancer."
- "Causes cancer cells to commit suicide!"
- "80% more effective than the world's number one cancer drug."
- "Skin cancers disappear."
- "Target cancer cells while leaving healthy cells alone."
- "Shrinks malignant tumors."
- "Avoid painful surgery, radiotherapy, chemotherapy, or other conventional treatments"

Parties that fail to properly resolve violations cited in Warning Letters are subject to enforcement action up to, and including, seizure of illegal products, injunction, and possible criminal prosecution.

Consumers and health care professionals should notify the FDA of any complaints or problems associated with these products. These reports may be made to MedWatch, the FDA's voluntary reporting program, by calling (800) FDA-1088, or electronically at www.fda.gov/medwatch/report.htm. ❖

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