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**The Miracle of Vitamin D: Sound Science, or Hype?**

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Imagine a treatment that could build bones, strengthen the immune system and lower the risks of illnesses like diabetes, heart and kidney disease, high blood pressure and cancer.

Some research suggests that such a wonder treatment already exists. It’s vitamin D, a nutrient that the body makes from sunlight and that is also found in fish and fortified milk.

Yet despite the health potential of vitamin D, as many as half of all adults and children are said to have less than optimum levels and as many as 10 percent of children are highly deficient, according to a 2008 report in [The American Journal of Clinical Nutrition](http://www.ajcn.org/cgi/content/abstract/88/6/1519).

As a result, doctors are increasingly testing their patients’ vitamin D levels and prescribing daily supplements to raise them. According to the lab company Quest Diagnostics, orders for vitamin D tests surged more than 50 percent in the fourth quarter of 2009, up from the same quarter a year earlier. And in 2008, consumers bought $235 million worth of vitamin D supplements, up from $40 million in 2001, according to [Nutrition Business Journal.](http://www.nutritionbusinessjournal.com)

But don’t start gobbling down vitamin D supplements just yet. The excitement about their health potential is still far ahead of the science.

Although numerous studies have been promising, there are scant data from randomized clinical trials. Little is known about what the ideal level of vitamin D really is, whether raising it can improve health, and what potential side effects are caused by high doses.

And since most of the data on vitamin D comes from observational research, it may be that high doses of the nutrient don’t really make people healthier, but that healthy people simply do the sorts of things that happen to raise vitamin D.

“Correlation does not necessarily mean a cause-and-effect relationship,” said Dr. JoAnn E. Manson, a Harvard professor who is chief of preventive medicine at Brigham and Women’s Hospital in Boston.

“People may have high vitamin D levels because they exercise a lot and are getting ultraviolet-light exposure from exercising outdoors,” Dr. Manson said. “Or they may have high vitamin D because they are health-conscious and take supplements. But they also have a healthy diet, don’t smoke and do a lot of the other things that keep you healthy.”

Dr. Manson is leading a major study over the next five years that should provide answers to these questions and more. The nationwide clinical trial is recruiting 20,000 older adults, including men 60 and older and women 65 and older, to study whether high doses of vitamin D and omega-3 fatty acids from fish-oil supplements will lower risk for heart disease and cancer. (Learn about taking part in the study at [www.vitalstudy.org](http://www.vitalstudy.org).)

Dr. Manson said fish-oil supplements were included in the study because they are another promising treatment that suffers from a dearth of clinical trial evidence. In addition, both vitamin D and fish oil are known to have an anti-inflammatory effect, but each works through a different pathway in the body, so there may be an added health benefit in combining them.

Study participants will be divided into four groups. One will take both vitamin D and fish oil pills. Two will take either a vitamin D or a fish-oil supplement and a placebo. The fourth will take two placebo pills.

Vitamin D is found throughout the body and acts as a signaling mechanism to turn cells on and off. Right now, the recommended dose from food and supplements is [about 400 international units a day](http://dietary-supplements.info.nih.gov/factsheets/vitamind.asp) for most people, but most experts agree that is probably too low. The Institute of Medicine is reviewing guidelines for vitamin D and is expected to raise the recommended daily dose.

Study participants will take 2,000 I.U.’s of vitamin D3, believed to be the form most easily used by the body. The study will use one-gram supplements of omega-3 fish oil, about 5 to 10 times the average daily intake.

The vitamin D dose is far higher than what has been used in other studies. The well-known [Women’s Health Initiative study](http://content.nejm.org/cgi/content/short/354/7/669), for instance, tracked women taking 400 units of vitamin D and 1,000 milligrams of calcium. The study found no overall benefit from the supplements, although women who consistently took their pills had a lower risk of hip fracture. Even so, many experts think 400 units is far too low for any additional health benefits.

[Another study, of 1,200 women](http://www.ajcn.org/cgi/content/abstract/85/6/1586), looked at the effects of 1,500 milligrams of calcium and 1,000 units of vitamin D. Women who took both supplements showed a lower risk for breast cancer over the next four years, but the numbers of actual cases — seven breast cancers in the placebo group and four in the supplement group — were too small to draw meaningful conclusions.

Although consumers may be tempted to rush out and start taking 2,000 I.U.’s of vitamin D a day, doctors warn against it. Several recent studies of nutrients, including vitamins E and B, selenium and beta carotene, have proved disappointing — even suggesting that high doses do more harm than good, increasing risk for heart problems, diabetes and cancer, depending on the supplement.

Despite the promise of vitamin D in observational studies, research into other supplements shows it’s difficult to document a benefit in otherwise healthy people, and virtually impossible to predict potential harms, notes Dr. Eric A. Klein, chairman of the Glickman Urological and Kidney Institute at the Cleveland Clinic. Dr. Klein recently worked as national coordinator for [Select, a study of vitamin E and selenium for prostate cancer](http://jama.ama-assn.org/cgi/content/full/2008.864). The study seemed promising, but in the end it showed no benefit from the supplements and a potentially higher risk for diabetes in selenium users.

“My sentiment is that the lesson we have learned form large trials with other vitamin supplements, including Select, is that there is no proven health or preventative benefit for dietary supplements in nutritionally replete populations, which accounts for most of the people who enter this sort of clinical trial,” Dr. Klein said. “It makes more sense to me to study dietary supplements or vitamins in populations who are deficient.”

People most at risk for vitamin D deficiency are older, have diabetes or kidney disease, stay indoors or have darker skin. African-American teenagers are at particularly high risk, possibly because in addition to their dark skin, they are less likely at that age to drink milk or play outside.

The scientific community continues to debate the optimum level of vitamin D. In general, people are considered to be deficient if they have blood levels below 15 or 20 nanograms per milliliter. But many doctors now believe vitamin D levels should be above 30. The ideal level isn’t known, nor is it known at what point a person is getting too much vitamin D, which can lead to kidney stones, calcification in blood vessels and other problems.

People’s vitamin D levels are influenced by whether they have light or dark skin, where they live, how much time they spend outdoors and by fish and milk consumption. To raise vitamin D without supplements, a person could increase sun exposure for 10 to 15 minutes a day. Eating more fish can help — a 3.5-ounce serving of wild fresh salmon has 600 to 1,000 I.U.’s of vitamin D — but it would take a quart of milk a day to get the recommended dose of vitamin D.

“What we know is that there are a lot of people who are vitamin D deficient based on estimates from national surveys,” said Dr. Michal L. Melamed, assistant professor of medicine at Albert Einstein College of Medicine in the Bronx. “But we don’t know what happens when the curve shifts to the other end. There probably is a risk to having too much vitamin D in the system.”

From David Bee [davidbee2003@att.net] to AP Stat List Serve:

In today's [Feb 2nd] NYTimes, the number one forwarded article is "Vitamin D, Miracle Drug: Is It Science, or Just Talk?", which appeared in the Tuesday Science Times section; it was written by Tara Parker-Pope and is part of her Well blog.

So what? Well, the article describes much of the terminology taught about in APStat. For example, very simply, we find the following: "randomized clinical trials"; "observational research"; 'Correlation does not necessarily mean a cause-and-effect relationship'. A randomized-comparative-experiment design is also outlined (with four treatment groups: Vitamin D and fish-oil pills; Vitamin D and placebo; fish-oil and placebo; two placebo pills).

A good article for APStat teachers, students, and, judging from its e-mailed ranking, a good many others.