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Big Bucks, No Bang: PHS II Shows No Benefits of Vitamins for Preventing CVD

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LOS ANGELES — The largest, randomized, double-blind trial to date has confirmed what smaller studies have suggested and what many physicians have long believed: a daily multivitamin does not reduce the risk of CVD [1].

Dr Howard D Sesso (Brigham and Women's Hospital, Boston, MA) presented the results of the **Physicians' Health Study (PHS) II** here today at the **American Heart Association 2012 Scientific Sessions**; the study was simultaneously published in the *Journal of the American Medical Association*.

"Individuals who believe they are deriving benefits from supplements may be less likely to engage in other preventive health behaviors, and chronic use of daily supplements poses a financial burden, with annual vitamin-supplement sales in the billions of US dollars," Sesso and colleagues write. "These [PHS II] data do not support multivitamin use to prevent CVD, demonstrating the importance of long-term clinical trials of commonly used nutritional supplements."

A vitamin a day

PHS II launched in 1997, with a total of 14 641 US male physicians, age 50 or older at the outset, randomized to different vitamin arms or placebo. The other three arms of the study--looking at beta-carotene, vitamin E, or vitamin C--have all been previously reported.

The fourth arm of PHS II was randomization to a daily multivitamin or placebo, looking at the impact on both cancer and CVD. Of men enrolled in PHS II, 5% had a history of MI or stroke.

Over a median follow-up of 11.2 years, 1732 CV events occurred, but the rate of events was no higher among men taking placebo than those taking a daily multivitamin. Rates of major CV events were 11 and 10.8 per 1000 person-years in the multivitamin and placebo groups, respectively.

Looking at components of the primary end point individually and a range of secondary end points, Sesso and colleagues found no statistically significant differences in rates of MI, all stroke, hemorrhagic stroke, ischemic stroke, congestive heart failure, angina, coronary revascularization, CVD mortality, or overall mortality. An additional analysis, which excluded the first few years of follow-up (to allow for a cumulative effect of exposure), did not alter the results. No major differences in adverse effects were seen between groups.

Of note, however, was that a daily multivitamin did appear to have a modest, statistically significant impact in reducing the risk of total cancers, although not prostate, colorectal, or other site-specific cancers. These results were published last month in the *Journal of the American Medical Association* [2].

A well-nourished population

PHS II investigators acknowledge that multivitamin supplementation may play a role in populations with nutritional deficiencies, and their study results do not extend to such groups. PHS II participants were, on the whole, "quite healthy," Sesso told a morning press conference. Most exercised regularly, ate reasonably well, and didn't smoke. As a whole, the group "likely represent, on average, a well-nourished population who already have adequate or optimum intake levels of nutrients, for which supplementation may offer no benefits," they write.

In an accompanying editorial, **Dr Eva Lonn** (McMaster University, Hamilton, ON) notes that over one-third of the US population takes some kind of daily multivitamin, swelling sales of dietary supplements to almost \$24 billion in 2008 [3]. Regulations governing their approval and marketing, however, are less strict than for drugs. "This has allowed for claims of benefit in preventing or curing an amazingly diverse and ever-increasing variety of illnesses ranging from CVD to cancer, arthritis, infections, macular degeneration, Alzheimer's disease, wrinkles, hair loss, decreased libido, and low sexual prowess.

"As a result," she argues, "many people with heart disease or risk factors continue

to lead unhealthy lives yet take daily vitamins and supplements in the hope of mitigating future problems.

"This distraction from effective CVD prevention is the main hazard of using vitamins and other unproven supplements. The message needs to remain simple and focused: CVD is largely preventable, and this can be achieved by eating healthy foods, exercising regularly, avoiding tobacco products, and, for those with high risk-factor levels or previous CVD events, taking proven, safe, and effective medications."

Vitamin-users unstudied, generally

To **heart wire**, several experts acknowledged that it has not, in fact, been studied and proven that people who take vitamins are less likely to adhere to medication or other health habits. Indeed, said Sesso, that's one reason why the PHS II is so unusual--it shed some light on an otherwise understudied, but common, behavior.

But as to whether vitamin-taking truly supplants "healthier" habits is unclear.

"These are personal anecdotal experiences in the office," Antman said, based on years of seeing patients who confess they regularly take their vitamins, but not always their prescription drugs. "When patients tell us, 'Gee, I'm taking so many pills,' first on the list in my review as to whether or not they need to be taking them are vitamins. What I've heard today will just give me a lot more ammunition in that regard, from a cardiovascular perspective."

Dr Dariush Mozaffarian (Brigham and Women's Hospital and Harvard Medical School, Boston, MA) points out that it's not just pills that people are potentially substituting with vitamins, but also physical activity and eating better.

"If someone has a great lifestyle and a great diet, exercises, and doesn't smoke, that's a rare person in the US. But if they do and they want to take a multivitamin as well, that's great, all the power to them."

In fact, he points out, there are two groups of people who tend to take vitamins: the uber-healthy and the ill. Indeed, many people go out and stock up on vitamins and supplements after being diagnosed with CVD or diabetes, he notes.

"Ninety percent of Americans have poor lifestyles or suboptimal lifestyles; only about 10% have optimal lifestyles in every way," Mozaffarian told **heart wire** . "So most people taking vitamin supplements don't have optimal lifestyles. . . . It's an open question whether that person would have a better or worse lifestyle if they weren't spending money or time on vitamin supplements."

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