

SENIOR HEALTH

## Vitamin E: Heart Disease and Cancer Rates in High-Risk Older Patients

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"The major finding of the HOPE trial, including the initial trial and trial extension, is the lack of benefit for vitamin E in preventing cancer or major cardiovascular events after a prolonged period of treatment and observation. Furthermore, our studies raise concern about an increased risk of heart failure related to vitamin E."<sup>1</sup>

The above quote made headlines around the world. The Heart Outcomes Prevention Evaluation (HOPE) trial was an international one, involving 267 centers and 9,541 patients. It lasted 64 months, between December 1993 and April 1999. None of the patients was younger than 55 years old, and the mean age was 66. The participants were in a group considered high risk for cardiovascular disease. This was defined as having a history of coronary artery disease, peripheral artery disease, stroke, or diabetes mellitus.

Of the study participants, 4,761 took 400 IU of natural vitamin E daily for the duration of the study, and 4,780 took an identical placebo pill. The HOPE study was then extended an additional 49 months, from April 1999 until May 2003. It was called The Ongoing Outcomes study, or HOPE-TOO. One hundred and seventy-four of the original 267 centers continued to participate. In the 174 centers, there were 3,056 vitamin E patients and 3,060 placebo patients left over from the initial HOPE trial; 2,025 in the vitamin E group and 1,969 in the placebo group agreed to continue the intervention. Please note that this study was double blinded: Neither the researchers nor the patients knew who was taking the vitamin E.

Rather than give an opinion, a percentage, or an extrapolation, like doubling the risk, I thought that clinicians would prefer to look at the raw data when encountering patient questions such as, "Is vitamin E going to give me heart disease?" (When I see or hear a report telling me my risk for something is doubled, I am always irritated at receiving spin - because without raw data, doubling one's risk means little. For example, increasing your risk from 1 out of a million to 2 out of a million doubles your risk, as does increasing your risk from 1 out of 4 to 2 out of 4.)

Total Patients	Vitamin E	Placebo
HOPE	4761	4780
HOPE-TOO	2025	1969
-	-	7
Cardiovascular Deat	hs Vitamin	E Placebo
HOPE	482	475
HOPE-TOO	364	361
Total	846	836
Cancer Deaths	Vitamin E	Placebo
HOPE	156	178
HOPE-TOO	128	133
Total	284	311

Deaths From All Causes	Vitamin E	Placebo
HOPE	799	801
HOPE-TOO	620	604
Total	1419	1405

HOPE Cardiovascular Events	Vitamin E	Placebo
Unstable Angina	712	698
Heart Failure	641	578
Myocardial Infarction	724	686
Stroke	270	246
Total Events	2347	2208

HOPE-TOO Cardiovascular Events	Vitamin E	Placebo
Unstable Angina	565	547
Heart Failure	519	443
Myocardial Infarction	580	534
Stroke	208	191
Total Events	1872	1715

HOPE Cancer Incidents	Vitamin E	Placebo
Breast	25	29
Colorectal	69	54
Lung	69	96
Melanoma	15	18
Oral and Pharyngeal	9	18
Prostate	116	119
Total Incidents	303	331

HOPE-TOO Cancer Incidents	Vitamiı	n EPlacebo
Breast	19	26
Colorectal	61	44
Lung	58	74
Melanoma	13	17
Oral and Pharyngeal	8	15
Prostate	91	101
Total Incidents	250	277

## Conclusion

I predict the HOPE/HOPE-TOO study will be used to advance the agendas on both sides of the supplement debate. It does appear that 400 IU of natural vitamin E increases the rate of nonfatal heart disease in high-risk older age populations. It also appears that 400 IU of natural vitamin E decreases some cancers in high-risk older populations.

Knowing the raw data will give you insight as to how biased a given author is when this study is quoted to support an argument. For example, an author with an anti-supplement bias can correctly state that in both the HOPE and HOPE-TOO trials, there were more deaths from heart disease in people who took vitamin E than in people who took placebos. Conversely, the author with the prosupplement bias can say that in both the HOPE and HOPE-TOO trials, there were fewer deaths from cancer in those subjects who took vitamin E. Looking at the overall death rates due to cardiovascular disease, cancer, and deaths from all causes, it appears that 400 IU of vitamin E is neither the toxic substance that some authors will claim it is, nor is it a panacea for health that other authors will state.

## Reference

1. Lonn E, et al. The HOPE and HOPE-TOO trial investigators. Effects of long-term vitamin E supplementation on cardiovascular events and cancer. *JAMA* 2005;293(11):1338-1347.

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