

Efficacy and safety of dietary supplement use in the primary prevention of chronic disease in the general non-pregnant United States adult population

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The use of dietary supplements has grown rapidly over the past several decades, and are now used by more than half of the adult population in the United States (US).¹ In 1994, the Dietary Supplements Health and Education Act (DSHEA) significantly changed the Food and Drug Administration's (FDA) role in regulating supplement labeling. According to the DSHEA dietary supplements may contain products taken by mouth including vitamins, minerals, herbs or other botanicals, amino acids, other dietary substances, or combinations or extracts of any of these 'dietary ingredients.' The DSHEA reaffirmed that dietary supplements are to be regulated as foods and not as drugs. Annual sales of supplements to Americans are now reported at about \$23 billion, a substantial share of which is spent on vitamins and minerals.

The purpose of this review is to present the discussion from available research to internists and other clinicians to help guide their decisions behind the efficacy and safety of dietary supplement use in primary prevention of chronic disease in the general non-pregnant adult population.

Profile of a dietary supplement user

In general dietary supplements are used by individuals who practise healthier lifestyles. Its use is higher among women and the children of women who use supplements; in elderly persons; among people with more education, higher income, healthier diets, and lower body mass indices; and among residents of the western US.² Individuals with chronic illnesses, or those who are seeking to prevent recurrence of a serious disease (for example, cancer) also tend to be more frequent supplement users.³ Many dietary supplement users perceive their health as better.

Why use dietary supplements?

The growth in supplement use has accelerated rapidly with marketing spurred by claims that chronic conditions could be prevented or treated by supplement use. The commonly used over-the-counter multivitamin and mineral supplements contain at least 10 vitamins and 10 minerals. On a daily basis consumers receive advertising and promotional material of unproven claims made about dietary supplements or other products and the medical wonders they can achieve. Some of

the promotional material makes a consumer feel guilty if he or she is not using one. Many users feel so strongly about the potential health benefits of some of these products that they reported that they would continue to take them even if they were shown to be ineffective in scientifically conducted clinical studies.⁴ More than half of American adults take dietary supplements in the belief that they will make them feel better, give them greater energy, improve their health, and prevent and treat disease.

Is there clinical evidence for use of dietary supplements?

Most studies do not provide strong evidence for beneficial health-related effects of supplements taken singly, in pairs, or in combinations of 3 or more.⁵ In some studies, or subgroups of the study populations, there is encouraging evidence of health benefits such as increased bone mineral density and decreased fractures in postmenopausal women who use calcium and vitamin D supplements.

Huang et al⁵ performed a systematic review to synthesize the published literature on the efficacy of multivitamin and mineral supplements and certain commonly used single vitamin or mineral supplements in the primary prevention of cancer and chronic disease in the general adult population. The authors concluded that the strength of evidence for the efficacy of multivitamin/mineral supplementation in the general adult US population was very low for primary prevention of cancer, cardiovascular disease, and hypertension; and low for cataract and age-related macular degeneration.

The National Institutes of Health (NIH) consensus panel statement² on 'multivitamin/mineral supplements and chronic disease prevention' did not find any strong evidence for beneficial health-related effects of supplements taken singly, in pairs, or in combinations of 3 or more. The panel concluded that the present evidence is insufficient to recommend either for or against the use of dietary supplements by the American public to prevent chronic disease. It also concluded that the current level of public assurance of the safety and quality of dietary supplements is inadequate, given the fact that manufacturers of these products are not required to report adverse events and the FDA has no regulatory authority to

require labeling changes or to help inform the public of these issues and concerns.

A recent study published in *Archives of Internal Medicine*⁶ raised some disturbing concerns. In this large prospective study, 38,772 older women in the Iowa Women's Health Study were followed up for a mean time of 19.0 years. The authors found that most of the supplements studied were not associated with a reduced total mortality rate in older women. In contrast, they found that several commonly used dietary vitamin and mineral supplements, including multivitamins, vitamins B6, and folic acid, as well as the minerals iron, magnesium, zinc, and copper, were associated with a higher risk of total mortality. Of particular concern, supplemental iron was strongly and dose dependently associated with increased total mortality risk. The association was consistent across shorter intervals, strengthened with multiple use reports and with increasing age at reported use. Supplemental calcium was consistently inversely related to total mortality rate; however, no clear dose-response relationship was observed. The strengths of this study include the large sample size and longitudinal design. In addition, the use of dietary supplements was queried three times: at baseline in 1986, in 1997, and in 2004. The use of repeated measures enabled evaluation of the consistency of the findings and decreased the risk that the exposure was misclassified.

Summary

The use of dietary supplements has grown rapidly over the past several decades even though clinical deficiency of vitamins or minerals, other than iron, is now uncommon in the US.² Fortification of foods has led to the remediation of vitamin and mineral deficits. The cumulative effects of supplementation and fortification have also raised safety concerns about exceeding upper levels besides interactions of dietary supplements with the prescriptions drugs taken by a consumer. There is no evidence-based data about what the optimal compositions and dose of a multivitamin and mineral supplement should be. Though dietary supplements are perceived to be safe, that should not be sufficient reason for using them without a valid medical need. Providers should take into consideration their efficacy and cost-effectiveness. There are also no outcomes data or data about quality adjusted life years gained by using dietary supplements taken singly, in pairs, or in combinations. The current data available on the efficacy and safety of dietary supplements is conflicting. Clinicians considering the use of dietary supplements should be aware of their risks, consider the likelihood of the adverse effects, interaction with prescription medications, safety, efficacy, costs, and possibility of unintended effects of dietary supplements.

Conclusion

The conclusion from the available data (new and old) is that consumption of dietary supplements for prolonged periods appears not to be safe and is not cost-effective in primary prevention of chronic disease in the general non-pregnant adult US population. Practitioners should evaluate each case individually and take a decision based on available evidence-based data when considering dietary supplements in this population. Given the potential for widespread use of dietary supplements, there is a need for robust study methods in the future.

Competing Interests

Consultant, Pfizer Vaccines Primary Care Practice Advisory Board. Specialist Editor, DynaMed. Member Performance Measures Committee, American College of Physicians (non-paid).

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