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Limitations of Observational Evidence

Public health recommendations for nutrition are based on expert review of the totality of scientific evidence. Data from randomized controlled trials (RCTs) provide the strongest evidence for establishing relations between exposures, including dietary exposures, and health outcomes. However, not all diet and health outcome relations can be practically or ethically evaluated using RCTs; therefore, many dietary recommendations are supported by evidence primarily from observational data. Although such evidence is of critical importance, limitations are often underappreciated by nutrition scientists and policymakers. This editorial review highlights the limitations of observational analyses and advocates for greater caution in the translation and communication of dietary recommendations based primarily on observational data, not confirmed through well-designed clinical outcomes trials.

Observational investigations, particularly prospective cohort studies, provide critically important information for identifying diet-disease relations. However, distilling a body of scientific evidence into dietary recommendations that promote health and reduce disease risk is challenging, particularly regarding the evaluation and interpretation of the totality of scientific evidence. As observational studies are inherently limited by lack of randomization of exposure, it is difficult to rule out bias and confounding as possible alternative explanations for diet-disease associations.

Dietary guidance is issued with the intent of improving health and reducing disease risk; recommendations need to reflect the state of the science and be effectively communicated. It is the authors' view that the strongest recommendations should be reserved for areas in which results from observational and RCTs align. Also, recommendations would be strengthened considerably by the completion of more RCTs to evaluate the impact of dietary advice on diet quality and markers for disease risk in healthy individuals, as well as in those with common health conditions that confer increased risk of chronic diseases. A larger number of clinical trials need to be undertaken to test dietary interventions and evaluate the full range of risks and benefits for reducing incidence of adverse disease outcomes.

Source: Maki KC, Slavin JL, Rains TM, Kris-Etherton PM. Limitations of observational evidence: implications for evidence-based dietary recommendations. Adv Nutr 2014;5(1):7-15.

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