Unproven Therapies

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Every Sunday morning, I have the opportunity to hear several "infomercials" on the radio. There used to be a single 1-hour program focusing on the virtues of a specific brand of food supplements, vitamins, and minerals. These days, I can listen for 3 hours on several different stations to hear about a much broader array of products that will supposedly help me lose weight, improve my libido, lower my cholesterol or blood pressure, decrease the size of my prostate gland, improve the function of my liver, or achieve numerous other health-related goals.

Perhaps this shouldn't be surprising. In Germany, some form of alternative or complementary medicine is used by 65% of the population.[1] Nine years ago, it was reported in the United States that 34% of one large survey used some form of unconventional therapy, and about a third of these people saw providers for these therapies.[2] Extrapolated, this would include 425 million visits at a cost of $13.7 billion for these alternative therapies in the United States. Based on my experiences with my patients and the Sunday morning infomercials, I suspect this number has grown substantially during the past decade.

It is important to define alternative medicine. One definition simply states that it is any therapy that has not been scientifically tested, defined as having "rigorous evidence of safety and efficacy, as required by the Food and Drug Administration (FDA) for the approval of drugs."[3] The National Institutes of Health funds research into alternative

therapies through its Office of Dietary Supplements and its Center for Complementary and Alternative Medicine. The latter divides alternative medicine into five domains: biological therapies, manipulative and body-based therapies, alternate systems of healing, mind-body medicine, and energy medicine.[4]

I often find it difficult to discuss this topic with patients because one first needs to clearly understand the differences among several important concepts related to the scientific method. The importance of controlled, double-blinded, randomized trials with appropriate placebos, for example, is a concept everyone considering alternative therapies needs to appreciate.

Anecdotes and testimonials (particularly popular on the Sunday infomercials) are commonly used to convince individuals with chronic medical conditions that they require some form of alternative therapy. All too often, these anecdotes and testimonials are followed by an "opportunity" to purchase the alternative therapy in question, sometimes for large sums of money. Many of these seems-too-good-to-be-true therapies are quite expensive, and credulous consumers who are not educated about scientific method and are often desperate for help are more than willing to pay up. In 1990, consumers paid $13.7 billion, with $10.3 billion out of pocket.[2]

The most recent revision of the American Diabetes Association's position statement on unproven therapies[5] was published last year. It concluded by noting that new and innovative, but unproven, diagnostic and therapeutic measures may acceptably be provided for patients in two circumstances: *1*) as part of an investigative trial; and *2*) with appropriate supervision under provisions of compassionate use.

An important point that is not well appreciated is that not all alternative therapies are safe.[6] For example, there is evidence that some lay books on complementary medicine offer advice to patients with diabetes that, if followed, could be dangerous or even life-threatening.[7] Surprisingly, it was also recently reported that in a group of patients with coronary artery disease and low HDL cholesterol, the consumption of additional antioxidants (vitamins E and C, beta-carotene, and selenium), a therapy that seems so harmless, resulted in a *reduction* in the HDL cholesterol rise seen with combination simvastatin and niacin.[8] This is a classic example of a situation in which epidemiological evidence suggests that an increased intake of antioxidants will lower the risk of atherosclerosis,[9,10] and yet clinical trial data do not support the population-based observation.[11]

In perhaps no other area of medicine are unproven therapies more prevalent than in the realm of weight reduction. There are numerous misconceptions among both providers and patients about carbohydrates, insulin resistance, ketosis, and fat burning as mechanisms of action for weight loss. As noted in a recent American Heart Association Science Advisory,[12] there are no scientific studies to support high-protein, low-carbohydrate diets in overall efficacy and safety.[12] Although some may find it surprising, these diets are associated with a higher intake of total fat, saturated fat, and cholesterol. The statement notes that individuals who follow these diets are at risk for compromised vitamin and mineral intake, and for patients with diabetes there are further concerns for potential cardiac and renal abnormalities.[12]

High-protein diets are discussed almost daily in my patient population. It is important for all providers to be aware of both the data on and the national policies regarding such diets for their obese patients.

Another topic I hear about often from my patients is the use of magnets for the treatment of neuropathic pain. A review of the literature does not support the efficacy of magnet therapy for pain syndromes.[13,14] Still, it is important to keep an open mind about this and other alternative therapies because future studies may alter our current state of understanding. For now, however, I cannot recommend magnet therapy, and I consider it still unproven. Parenthetically, it is interesting that the greatest believers in this therapy also happen to sell it, usually out of their homes.

My suggestion for providers whose patients inquire about unproven therapies is to take the time to explain the scientific method of testing medical therapies. Hypotheses are often generated from single or perhaps epidemiological observations. Concepts such as randomization, control groups, and bias should be mentioned. Every week, the public receives information through the media about the results of important landmark studies. And yet, I am not convinced that our patients understand even the basics of scientific study methods. The difference between randomized, controlled trials on one hand, and testimonials on the other, is an extremely important one that I discuss with my patients frequently.

In an ideal world, everyone would understand the fundamental concepts of the scientific method and would choose their medical therapies accordingly. Until they do, I am changing radio stations on Sunday mornings to one that only plays music, and I'm hoping my patients will do the same.

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