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Invited Commentary

Clinical Effectiveness of Lifestyle Management Programs: Importance of the Class Effect Paradox

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Opinion Statement

It is well appreciated in pharmacotherapy that all drugs belonging to the same class of agents are not necessarily equally safe or effective. Because of this so-called "class effect paradox," pharmaceutical companies must do extensive research to prove the safety and efficacy of a new drug before introducing it into the market, even if it belongs to a well-established class of medications. Like pharmaceutical agents, lifestyle management interventions can be organized into classes. This commentary examines the rationale for, and importance of, considering the class effect paradox when balancing the need for new and innovative lifestyle management programs with the need for evidence-based interventions with proven outcomes. In view of the fact that all lifestyle management programs within a specific broad intervention class do not necessarily result in clinical benefit, it is recommended that any new approach should not be widely implemented until it has been shown to be effective as evidenced by results of clinical studies published in peer-reviewed journals.

Introduction

The class effect concept is well known in pharmacotherapy. The use of drugs perceived as being similar in their clinical effects and, therefore, interchangeable, is very frequent in clinical practice. A few of numerous examples include the use of beta-blockers in hypertension, angiotensin-converting enzyme inhibitors in heart failure, and statins in hyperlipidemia.

It is now also well appreciated that all drugs belonging to the same class of agents are not necessarily equally safe or effective, and that data from studies with one specific drug cannot necessarily be extrapolated to another drug in the same class without evidence to prove parity. For example, statins are a well-established class of medications to lower choles-

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terol levels, but clearly, all statins are not equally safe or effective. Because of this so-called "class effect paradox," pharmaceutical companies must do extensive research to prove the safety and efficacy of a new statin drug before introducing it into the market, even though as a class, statins are generally known to be acceptably safe and effective.

Like pharmaceutical agents, lifestyle management interventions can be organized into classes. A lifestyle management intervention may address a single major behavior (e.g., physical activity only, nutrition only, stress management only, or tobacco cessation only), or multiple behaviors in an integrated fashion. At one of the broadest levels, common classes of lifestyle management interventions targeting a single major behavior include physical activity/exercise training programs, nutrition programs, weight management programs, stress management programs, and tobacco cessation programs. As a class, lifestyle management interventions targeting multiple behaviors in an integrated fashion are often referred to as multi-component programs. This commentary examines the rationale for, and importance of, considering the class effect paradox when balancing the need for new and innovative lifestyle management programs with the need for evidence-based interventions with proven outcomes.

Need for innovative lifestyle management programs

A considerable body of evidence shows that regular physical activity, correct nutrition, tobacco cessation, and a few other lifestyle practices can help mitigate the progression of many non-communicable chronic diseases [1]. Despite this overwhelming scientific evidence, potentially preventable lifestyle-related chronic diseases remain the leading causes of death, disability, and avoidable health care costs in Westernized society, and they are increasing dramatically in many developing nations [2, 3].

With the exception of cigarette smoking cessation, there is evidence that minimal, if any, improvement in key lifestyle practices related to the prevention of cardiovascular disease (CVD) and other chronic diseases occurred during the last two decades in the United States (US) [2]. Moreover, from a CVD perspective, data from the National Health and Nutrition Examination Surveys (2003–2008) demonstrated that fewer than 1 % of adult Americans exhibit ideal cardiovascular health based on seven American Heart Association-defined cardiovascular health behaviors and factors (namely, diet, physical activity, smoking, blood pressure, total cholesterol, body mass index, and fasting blood glucose) [4].

Clearly, there is an urgent need for innovative solutions aimed at effectively helping individuals make and adhere to meaningful lifestyle changes. In response to this urgent need, in recent years a variety of new approaches to lifestyle intervention have been implemented in both clinical and non-clinical settings (such as the workplace). These approaches span a wide spectrum, ranging from physician-supervised/nurse-case managed interventions to interactive telephonic and web-based programs.

Implications of class effect paradox: workplace wellness programs

Approximately half of US employers with at least 50 employees now offer workplace wellness initiatives [5]. Such initiatives typically include interventions to promote healthy lifestyles. The current unprecedented interest in workplace lifestyle management programs in the US stems partly from the recognition that over 60 % of Americans obtain their health insurance cov-

erage through employment-based plans and the fact that most employees spend the majority of their time at work.

In order to meet the increased demand for workplace wellness programs, there has been a recent explosion in commercially available lifestyle management programs. While it is commonly believed that all workplace lifestyle management programs that address the same behaviors (that is, lifestyle management programs in the same intervention class) can be expected to result in similar clinical benefits and are therefore interchangeable, research has disproven this belief.

For example, in a recent clinical trial, 133 university employees with CVD risk factors completed a health risk assessment after which they were randomly assigned for 1 year to either an intensive multi-component lifestyle intervention group or a less-intensive multi-component lifestyle intervention group [6]. Participants in the less-intensive group were provided a summary report of their assessment results, had a consultation with a nurse to review their risk factors, and were encouraged to use a variety of free health promotion facilities and services offered by the university, including a fitness center and wide range of group classes and workshops on exercise, nutrition, stress management, cholesterol control, blood pressure control, smoking cessation, and weight management. In addition to being encouraged to use the same health promotion facilities and services, participants in the intensive intervention group received longitudinal, one-on-one, behaviorally-oriented lifestyle health coaching with a focus on nutrition, physical activity, weight management, stress management, and/or smoking cessation. The main outcome measure was the difference between groups in the change in Framingham 10-year coronary heart disease risk scores from baseline to 1 year. There was no statistically significant baseline difference between groups in the Framingham risk score and there were no significant differences between groups for changes in medications during the study. However, in the intensive intervention group the mean Framingham risk score decreased by 22.6 % (relative risk reduction), whereas in the less-intensive intervention group the mean score rose by 4.3 % (p=0.017 for the difference between groups).

These data serve to highlight an important concept that is inadequately appreciated in the field of workplace wellness and lifestyle intervention in general; namely, that not just any kind of lifestyle management program done in any way at all will produce high levels of clinical benefit. Lifestyle management programs must be appropriately designed and executed in order to significantly impact clinical variables. Thus, as is the case with certain classes of medications, the class effect paradox is of considerable importance from a lifestyle intervention perspective, in that all lifestyle management programs belonging to the same broad class of interventions are not necessarily equally effective. Just as pharmaceutical manufacturers are expected to document the clinical effectiveness of new medications in an established class of drugs, it would seem extremely important for providers of new lifestyle management programs to conduct research documenting the clinical effectiveness of their programs before implementing them on a wide-scale basis.

Implications of class effect paradox: clinical settings

Although patients perceive their doctors as one of the most reliable sources of information on lifestyle management, data on counseling practices indicate that

providers typically pay very limited attention to lifestyle intervention in daily clinical practice [7]. Evidence further suggests that even when doctors do provide counseling, one of the most common approaches to lifestyle intervention in daily clinical practice involves simply telling patients to do more physical activity, eat healthier, quit smoking, etc., and providing handouts. While it is critically important for doctors to set the agenda for behavior change by emphasizing the importance of lifestyle intervention to their patients, available research indicates that the aforementioned low-intensity approach to counseling is unlikely to be of much benefit to most patients.

Like workplace settings, the class effect paradox also has important implications for lifestyle management interventions delivered in clinical settings. Consistent with workplace-related findings, a recent US Preventive Services Task Force-related systematic literature review focusing on the effectiveness of primary care-relevant trials of physical activity and/or dietary counseling to prevent CVD concluded that the most important factor for differences in effect sizes among studies was intervention intensity—the strongest evidence for improvement of physiologic outcomes was for higher-intensity counseling interventions [7, 8]. Indeed, low-intensity dietary counseling did not produce significant behavioral changes, and no consistent behavioral benefit was found for low-intensity counseling to increase physical activity. Low-intensity interventions involved 30 minutes or less of contact with providers. Thus, simply providing patients with educational handouts and very brief counseling does not equate to effective lifestyle and behavioral intervention.

From a secondary prevention perspective, a 2011 presidential advisory from the American Heart Association recommended that cardiac rehabilitation/secondary prevention programs be reengineered to include a wide array of service options that meet the needs of individual patients, including lifestyle health coaching interventions delivered via the telephone, Internet, and other means of communication [9]. In keeping with the class effect paradox, the advisory further recommended that any new approach should not be widely implemented until it has been shown to be effective, as evidenced by results of clinical studies published in peer-reviewed journals, and that third-party payers should cover the costs of evidence-based alternative models of delivery that have been shown to be effective in peer-reviewed published clinical trials.

Most recently, the Look AHEAD (Action for Health in Diabetes) research group randomly assigned 5,145 overweight or obese patients with type 2 diabetes to participate in an intensive multi-component lifestyle intervention that promoted weight loss through decreased caloric intake and increased physical activity (intervention group), or to receive diabetes support and education (control group) [10]. Weight loss was greater in the intervention group than in the control group throughout the study (8.6 % vs. 0.7 % at 1 year; 6.0 % vs. 3.5 % at study end), but the magnitude of the beneficial effect of the intervention waned after the initial few years. Likewise, the intensive lifestyle intervention produced greater reductions in glycated hemoglobin and greater improvements in cardiorespiratory fitness and all CVD risk factors (except for low-density-lipoprotein cholesterol levels), but the magnitude of the beneficial effect of the intervention on these variables also diminished as the study progressed. At a median follow-up of almost 10 years, there was no significant difference between the two groups in CVD morbidity and mortality. However, the intervention did appear to have had different effects in different subgroups

of study participants, in that the CVD event rate was nonsignificantly lower in the intervention group than in the control group among patients with no history of CVD at baseline, but was nonsignificantly higher in the intervention group than in the control group among those with CVD at baseline. In addition to highlighting the importance of including event-related outcomes data when assessing the clinical effectiveness of therapeutic interventions whenever feasible, the study also serves to emphasize the need for ongoing lifestyle intervention aimed at maintaining benefits achieved during short-term intervention [11]. From a class effect paradox perspective, the data further suggest that, as is the case with drug therapy, a specific lifestyle intervention may possibly have different clinical effects in different patient populations.

Conclusions and recommendations

Lifestyle management programs undoubtedly constitute an essential component of the armamentarium of interventions that can be used in the global war against CVD and other non-communicable chronic diseases. However, it is important to consider the class effect paradox when balancing the need for new and innovative lifestyle management programs with the need for evidence-based interventions with proven outcomes.

Because all lifestyle management programs within a specific broad intervention class do not necessarily result in clinical benefit, two key recommendations are as follows: 1) It is recommended that just as drugs are assigned to different classes based on multiple characteristics (e.g., similar chemical structure, similar mechanism of action, and similar pharmacological effects), the categorization of lifestyle management interventions into classes should be as highly refined as possible on the basis of multiple programmatic characteristics, rather than simply on the behaviors they are designed to target; and 2) While the first recommendation is important to keep in mind when selecting a specific lifestyle management program for use in clinical and non-clinical settings, it is unlikely to completely negate the class effect paradox, given the vast multitude of possible programmatic characteristics and other variables (such as the specific target patient population). Therefore, in accordance with the principles of evidence-based practice, it is also recommended that emphasis be placed on the use of lifestyle management programs that have specifically been proven effective in peer-reviewed published clinical trials. It is especially important to take the above recommendations into consideration when developing and implementing lifestyle-related measures of quality of medical care for the purpose of quality improvement and accountability.

Compliance with ethics guidelines

Conflict of Interest

Dr. Neil F. Gordon has received consultancies from Wellness Corporate Solutions, LLC and PrevCan, Inc., and serves as a board member for PrevCan, Inc. Dr. Gordon is employed by and holds stock/stock options with Intervent International, LLC. Dr. Gordon holds stock/stock options with PrevCan, Inc.

Human and Animal Rights and Informed Consent
This article does not contain any studies with human or animal subjects performed by any of the authors.

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