THEORETICAL PERSPECTIVES TO INCREASE CLINICAL EFFECTIVENESS OF LIFESTYLE MODIFICATION STRATEGIES IN DIABETES

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INTRODUCTION

The prevalence of diabetes in the United States has more than doubled in the past 20 years, affecting more than 18 million people. Thirty million people have been diagnosed, but an estimated additional 5 million people are unaware that they have this disease. Minorities are disproportionately affected by diabetes. Since 1980 the age-adjusted prevalence of diagnosed diabetes has been found to be higher among African Americans than Caucasians, increasing by 66%, with the highest rates found in African-American women. Diabetes causes significant morbidity and mortality. It is the sixth leading cause of death when listed as the underlying cause of death, but the true rates are likely to be underreported, as less than 40% of all persons with diabetes have the disease listed anywhere on a death certificate. The economic impact of this disorder is staggering, costing the United States $132 billion dollars in 2002. Without preventive interventions these clinical and economic outcomes will only get worse, as the prevalence of diabetes is anticipated to increase by 50% within the next 10 years. The majority of new cases are expected to be type 2 diabetes, which accounts for 90% to 95% of all diagnosed cases. Even more alarming is the staggering increase in the prevalence of type 2 diabetes in children. Previously, less than 2% of all children with diabetes suffered from type 2 diabetes; now it is estimated that as many as 45% of the cases of childhood diabetes are due to type 2 diabetes. The increasing rates of type 2 diabetes in both children and adults is strongly associated with the increasing prevalence of obesity. Given the fact that 1.7 billion people, or 1 out of every 4 persons around the world are overweight or obese, we are in the midst of a global epidemic of obesity, and at the start of a global epidemic of diabetes.

Lifestyle interventions play an important role in attacking this double epidemic. The purpose of this paper is to briefly discuss the state of the science regarding the efficacy of lifestyle interventions in the prevention and treatment of diabetes, and then discuss theoretical concepts that may assist healthcare providers in increasing the clinical effectiveness of these interventions.

EFFICACY OF LIFESTYLE INTERVENTION TO PREVENT TYPE 2 DIABETES

Research has shown that changing dietary intake and increasing physical activity can prevent or at least delay the onset of type 2 diabetes in a variety of cultures, racial, and ethnic groups, and in both genders. Three prospective, randomized clinical trials have shown the efficacy of these interventions. Targeting high-risk persons, those with impaired glucose tolerance, the Chinese Da Quing study reported that a program of combined diet and exercise resulted in a 42% decreased incidence in diabetes at 6 years. Diet alone resulted in a 31% reduction in risk, while exercise alone resulted in a 46% reduction in risk. Dietary interventions involved consumption of more vegetables, controlled alcohol intake, and reduced intake of simple sugars. Participants with body mass index (BMI) ≥25 kg/m² also were encouraged to reduce calorie intake to promote weight reduction of 1 to 2 pounds per month until a BMI of 23 kg/m² was achieved. Patients were asked to increase...
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their physical activity by one unit of activity per day, with a unit value ranging from 30 minutes of slow walking to five minutes of strenuous exercise such as jumping rope or swimming. The interventions included individual counseling by physicians combined with small group counseling sessions. Participants in the control group received generic brochures with standard information about healthy diets and increased physical activity but no individual or group counseling.

Similar results were reported in the Finnish Diabetes Prevention Study where combined dietary and physical activity interventions were associated with a 58% reduction in risk of developing diabetes at 3 years. In the Finnish study, control patients also received generic information on diet and exercise, but no individualized tailored information. Participants in the intervention group received detailed individual dietary instruction from a nutritionist designed to assist in weight reduction of ≥5% of baseline weight, and to reduce dietary fat while increasing fiber intake. The exercise component encouraged participants to engage in 30 minutes of moderate exercise per day. The exercise interventions also were individually tailored to participant preference and included aerobic activities to improve cardiorespiratory fitness as well as resistance training to improve strength and functional capacity.

Within the United States, results from the Diabetes Prevention Program revealed that lifestyle changes involving 7% weight loss and 150 minutes of physical activity per week resulted in a 58% reduction in risk of developing diabetes at 3 years. The results were similar in both genders and in all racial and ethnic groups. Another arm of that study revealed that treatment with metformin (850 mg twice daily) resulted in a 31% reduction of risk. Participants in the control group, as well as those in the metformin group, received written information regarding standard lifestyle interventions and one annual 20- to 30-minute individual session emphasizing the importance of lifestyle interventions. Generic goals were established suggesting that patients follow the Food Guide Pyramid, reduce weight, and increase physical activity. Participants in the lifestyle intervention group received a 16-lesson curriculum on diet, exercise, and behavior modification designed to assist them to achieve a goal of 7% weight loss with a low-carbohydrate, low-fat diet, and to engage in moderate intensity physical activity (eg, brisk walking) for at least 150 minutes per week. A case manager administered the intervention on a one-on-one basis, with the program designed to be flexible and culturally sensitive so that it could be tailored to the individual’s needs.

Combined, these 3 studies show the efficacy of the individualized lifestyle intervention in reducing the incidence of type 2 diabetes in different racial and ethnic groups around the world. Similar beneficial results were found for lifestyle interventions in the treatment of persons already diagnosed with diabetes.

Efficiency of Lifestyle Interventions in Treatment of Type 2 Diabetes

The obese patient with diabetes is one of the most difficult patients for primary care providers to treat. The 2 conditions present a double-edged, conflicting problem. Obesity is exponentially related to BMI so obese patients are more likely to become diabetic, and the most effective treatments for type 2 diabetes (ie, insulin and sulphonylureas) are commonly associated with weight gain, compounding the problems for already obese patients. Reducing obesity however has been shown to have significant positive benefits for both the physical and mental health in obese patients with diabetes.

A meta-analysis of 89 studies examining weight loss in patients with type 2 diabetes revealed that dietary, behavioral, and exercise interventions all produced significant reductions in BMI and improved glycemic control. The dietary interventions produced the greatest improvements, including weight loss averaging 20 pounds, a 2.7% reduction in HbA1c, improved fasting blood sugar levels, and improved 2-hour postprandial blood sugar levels. Only bariatric surgery produced a larger effect size than dietary interventions on these outcome measures. Weight loss programs that assist patients with diabetes to reduce their weight by 7% have been found to reduce fasting blood sugar by approximately 3 mmol/L within 6 months and several studies have shown that a weight loss of 10% can result in clinically significant reductions in HbA1c, comparable to the improvements noted with the addition of a second anti-diabetic agent.

In addition to improved glycemic control, weight loss also is associated with decreases in hypertension, hypertriglyceridemia, and hypercholesterolemia. Surprisingly, there are very few studies that have examined the effect of the commonly prescribed American Diabetic Association (ADA) diets for weight loss. Those that have reported ADA dietary results revealed moderate effect for weight loss, but large effect for glycemic control. Very low-calorie diets have been found to produce the quickest weight loss, but these results are not sustained at one year given the difficulty for the patient in maintaining such a restrictive diet over the long term. There is evidence that a combined low-calorie diet supplemented with sibutramine provides significantly greater weight loss and improved HbA1c. While dietary interventions produce weight loss, they do not improve cardiorespiratory fitness. Exercise improves cardiorespiratory fitness, but by itself, produces only modest weight loss. However, exercise has been found to significantly improve glycemic control in patients with dia-
betes even without significant changes in BMI. Thus, there is evidence that obesity and sedentary lifestyle are independently related to glycemic control. A meta-analysis examining the effect of exercise on glycemic control evaluated 14 studies, 12 involving aerobic exercise and 2 using resistance training. The results revealed a mean post-intervention HbA1c of 7.65% in the exercise groups compared to 8.31% in the control groups. The weighted mean difference of −0.66% is statistically significant. In studies that combined exercise and diet, the reduction in HbA1c (−0.76%) was not significantly different than that obtained by exercise alone. It is important to note that the reduction noted in HbA1c from lifestyle interventions is similar in magnitude to the difference found between conventional and intensive glucose-lowering therapies. Exercise has been found to have a “domino” effect in that people who increase physical activity are also more likely to eat healthier diets, and smoke and drink less. However, for long-term weight loss and overall improved glycemic control, a combination of diet and physical activity is most effective than either intervention alone.

**Lifestyle Recommendations for Obese Patients with Diabetes**

Based on the results of numerous research studies, there is clear evidence that lifestyle interventions of diet modification and physical activity prevent the onset of diabetes, as well as producing improved glycemic control and additional health benefits (eg, reduced lipid levels) in persons already diagnosed with diabetes. The research also provides guidelines to assist clinicians in working with obese patients with diabetes. The guidelines include increasing physical activity such that patients engage in a moderate intensity activity program for 30 minutes most days of the week (150 minutes/week). Dietary modifications for obese persons with diabetes include weight loss of 7% to 10% of initial body weight. The dietary interventions should focus on a diet that reduces saturated fats while decreasing calorie intake by 500 to 1000 kcal a day to achieve a weight loss of 1 to 2 pounds per month for 6 months. The targeted goal of 10% weight loss is often difficult for any obese person to achieve, and is especially difficult for obese patients with diabetes who have greater difficulty attaining weight loss than persons without diabetes. As a result, many patients may need assistance with anti-obesity drugs to achieve this weight goal. The National Heart, Lung and Blood Institute guidelines for the treatment of obesity recommend the addition of pharmacologic agents for all patients with BMI ≥30, and at BMI ≥27 for patients with diseases such as diabetes. However, the NHLBI strongly states that weight loss drugs should never be used without concomitant lifestyle modification interventions. In patients with diabetes who have severe obesity, BMI ≥35 kg/m², bariatric surgery may be required to achieve weight control.

**Effectiveness of Primary Care Lifestyle Interventions**

While randomized clinical trials have demonstrated the efficacy of lifestyle interventions for improving diabetic outcomes, this research has not been easily translated into clinical practice. There is little research done that specifically addresses implementation of such guidelines in practice settings. Research done to evaluate effectiveness of lifestyle counseling by primary care providers (PCP) in the clinical setting is limited in numbers and scientific rigor. Studies evaluated by the United States Preventive Services Task Force (USPSTF) revealed that there is insufficient evidence “to recommend for or against behavioral counseling in primary care settings to promote physical activity or promote healthy diet in a general population.” However, the USPSTF recommends intensive behavioral counseling for adult patients with diet-related chronic diseases. The intensive counseling can be delivered by primary care physicians or by referral to other specialists. The USPSTF found that 2 approaches appear most promising: 1) medium-intensity face-to-face counseling in 2 to 3 individual or small group sessions delivered by a specially trained primary care physician, nurse practitioner, or nutritionist; and 2) lower intensity interventions that involve 5 minutes or less of PCP intervention supplemented with patient self-help materials, telephone counseling, or other interactive health communications. Examples of additional interactive communication include the use of email and internet counseling.

Evaluation of the research related to primary care counseling to promote physical activity revealed that PCPs who did counseling usually did not perform the initial activity assessment, which may have limited their effectiveness. Studies found that written prescriptions for specific exercise behaviors were more effective than verbal advice alone, and that referral to community programs that provide ongoing social support increased physical activity levels as did frequent telephone follow up by the PCP along with personalized messages matched to the participants readiness to change activity behavior.

There are numerous barriers to translating research findings into clinical practice. Barriers within the macroenvironment, the healthcare delivery system, the provider, and the patient all combine to make implementation of lifestyle modification difficult to attain. This paper will focus on factors within the patient/provider dyad, interactional variables, that influence the success or
failure of clinician-initiated lifestyle interventions. Emphasis will be on 4 key theoretical concepts that can significantly improve the outcomes of clinically based interventions. The concepts are perceptual congruence, mutual goal setting, readiness for change, and tailored interventions.

Perceptual Congruence

King’s Theory of Goal Attainment is based on the premise that health care is a process of human interaction where patients and providers perceive each other and the health situation and, through communication set goals, explore options, and agree on the means to achieve the goals. Through this process, goal attainment will occur. From King’s perspective, the first step in achieving goal attainment begins with perceptual congruence, an important concept that is often overlooked in health communication. Providers work within a normed, mental model framed by goals that are based on empirical evidence as previously described (eg, 150 minutes of exercise a week). Patients bring to the encounter their own mental models that explain the etiology and natural history of their disease, as well as ideas relating to appropriate treatment. Patients’ mental models frequently are very different from the normed models and problems occur at the very start of interaction.

When it comes to working with patients with diabetes, providers bring additional perspectives beyond the normed model to the encounter. Studies have shown that PCPs perceive diabetes to be more difficult to treat than other chronic disease such as hypertension, arthritis, or hyperlipidemia. Providers often experience frustration in working with patients with diabetes, especially obese patients. The frustration stems from: the lack of system resources to provide the comprehensive care required; the amount of time individual clients require to make even modest changes; the sense of inevitability that, despite their best efforts, complications will occur with patients having uncertain-to-poor prognosis; and the lack of control they have over the lifestyle changes that are an essential component of diabetes care. These factors can contribute to a feeling of decreased self-efficacy, with many providers finding it professionally unrewarding to work with such difficult patients. Despite their frustration, providers perceive diabetes as requiring a sense of urgency to get the patients to glycemic control, and they bring this urgency into the exam room when they meet with patients. Thus, at the beginning of the encounter, providers start with a perception of a patient as being overweight, not in good control, needing to implement a complex system of behavioral and pharmacologic interventions, and the possibility of a long, difficult road ahead.

Patients may have an entirely different perception. First, many patients may not perceive themselves to have a weight problem. A recent Associated Press poll found that 60% of adults who qualify as overweight based on a BMI ≥25 kg/m², perceive themselves to be at a “healthy” weight. In another study, only 44% of parents thought that their children’s weight was a problem, despite the fact that 69% of the children met criteria to be considered obese, or severely obese. In addition to perceptions about what constitutes a healthy weight, patients with diabetes often do not have the same sense of urgency about glycemic control as the providers. Healthcare providers define health based on evidence of clinical disease, whereas patients often define health based on their ability to carry out their daily roles and functions. Since some patients with type 2 diabetes usually lack dramatic symptoms and are able to function with minimal restrictions, especially in the early stages of the disease, many patients underestimate the severity of the condition and question the need for aggressive changes in their life. In addition, many patients have a mental model that suggests that disease, and especially obesity, is not much under their control. They attribute their weight to genetics, slow metabolism, and for women, to menopause. For many obese patients, the problem is further compounded if they have attempted to lose weight before and have been unsuccessful.

When providers and patients bring these different perceptions to a health visit, it is impossible to reach a mutual goal, unless there is clear communication and discussion of these issues. Attaining perceptual congruence is the first, but often overlooked, step in working to achieve lifestyle goals.

Mutual Goal Setting

The second important theoretical concept is the one of mutual goal setting. Research with King’s theory has shown that for health behavior change to occur, goals must be mutually established. Too often, providers simply tell patients the normative goals to be achieved, such as 150 minutes of exercise a week, without ascertaining the patient’s perception, understanding, or acceptance of such a goal. In addition the normative goals often are unrealistic for the patient’s current status. Setting normative, rather than realistic, individualized goals is ultimately self-defeating and frustrating to both the patient and provider. If success is measured only by attainment of these long-term goals, then providers miss opportunities to provide encouragement and support for short-term progress. Yet, such positive feedback is an effective method for enhancing patient self-efficacy and self-esteem, both of which are critical to long-term behavioral change. Mutual goal setting is an extension of perceptual congruence; it is a time where patients and providers together determine what a patient is willing and able to change in relation to their health status.

Readiness to Change

Readiness to change is another important theoretical concept that is close-
ly related to perceptual congruence and mutual goal setting. Readiness is a concept included in the Transtheoretical Model of Behavior Change (TTM). This model posits that health behavioral change is a process that occurs as people move through a sequence of 6 stages. These stages include: pre-contemplation (not thinking about making a change); contemplation (thinking about change in the next 6 months); preparation (taking active steps to change); action (having maintained behavioral change for a period of 6 months); maintenance (having maintained behavioral change beyond 6 months); and termination (when there is no further temptation to return to unhealthy behavior and the person has 100% self-efficacy). Basic research, including work with 20,000 HMO members regarding 15 different health behaviors (including diet and exercise) has provided evidence that the vast majority of subjects (80%) are in the pre-action stages, not really ready to make change. This data indicates that the majority of patients are not ready to make the lifestyle modifications necessary to achieve the normed goals that providers bring to an encounter. Thus, providers who spend time giving action-oriented instructions (eg, how to incorporate more activity into daily life) are not making the most of their counseling time. However, without some planned interventions, individuals will remain in the early stages of change. Additional research has shown that patients can be helped to move through the 6 stages of change if counseling is done to influence the individual’s decisional balance. Decisional balance reflects the person’s beliefs and relative weighting of the pros (benefits) and cons (costs and barriers) to change. Specifically, research has shown that to get people to move from pre-contemplation to contemplation the benefits of changing must increase, while moving from contemplation to action requires that the costs of change must decrease. Targeting a patient’s decisional balance begins with communication to obtain perceptual congruence about the nature, scope, and seriousness of the problem, along with an idea of the goals the client is realistically willing to work toward.

Tailored Interventions

Once communication has provided the information described above, it is then important for providers to tailor lifestyle interventions to meet individual needs. The diabetes prevention studies described previously used generic lifestyle intervention information in the control groups, and found it to be ineffective. The success of the clinical trials is highly related to the ability of healthcare providers to provide information that is needed for each patient. Interventions tailored to the patient’s stage of change should work to: 1) increase the benefits of change to move people from pre-contemplation to contemplation; 2) decrease the barriers to change in order to move contemplators to action; 3) provide action-oriented interventions for persons in the preparation stage when there is evidence that their benefits of changing are higher then their barriers; and 4) enhance self-efficacy skills among those in the action and maintenance stages. This type of tailored intervention has been shown to be efficacious in diabetes control. The Diabetes Stages of Change (DISC) Study was a randomized clinical trial based on the TTM where patients received stage-matched interventions in the way of a self-help manual, newsletters, and individual telephone counseling to improve their readiness to change 3 specific behaviors: healthy eating, blood glucose monitoring, and smoking cessation. More than 1,000 patients with diabetes in one of the 3 pre-action stages were recruited. Results revealed that the tailored intervention assisted 30.5% of patients to move to an action stage for glucose monitoring; 32.5% to move to action stage for healthy eating, and 24.3% to move to action for smoking cessation. Each of these changes was a significant improvement over the treatment-as-usual control group. The tailored intervention also resulted in significantly greater reduction in HbA1c for patients who moved to the action stage for healthy eating and glucose monitoring. The results of this study provide evidence that tailoring interventions can assist even those patients who are initially not ready to make behavioral change.

CONCLUSION

Managing diabetes requires a complex regimen of both lifestyle and pharmacologic interventions. The regimen is further complicated in the case of the obese patient with diabetes. Lifestyle interventions have been shown to provide significant clinical benefit including decreased insulin resistance, increased insulin sensitivity, improved fasting and postprandial blood glucose levels, and decreased HbA1c. Attaining these goals has occurred in randomized clinical trials but the results in general clinical practice have not been as encouraging. Part of this discrepancy may be that people who agree to participate in clinical trials are at an action stage of change, at a point in time where they are “ready” to adopt lifestyle modification. In general practice however, the vast majority of patients are likely to be in pre-action stages and are not well served by the traditional action-oriented interventions commonly used by providers. Providers may be more effective in their counseling efforts if they would take the time to assess their patients for perceptual congruence, and then work toward setting mutual goals that match the patients’ readiness for change. Initially, it may be important for clinicians to spend time not on action instructions but on changing decisional balance by helping patients value the benefits of lifestyle change while decreasing the barriers to such a change. Recognizing that normed goals are long-term goals.
which are often difficult to attain and maintain, it is important for providers and patients to celebrate the short-term goals achieved along the way. Achieving short-term goals may increase the sense of self-efficacy and decrease the sense of frustration for both patients and providers, paving the way for more rewarding interactions and improving the possibility of long-term lifestyle modification.

REFERENCES