The Problem With Intensive Therapy

RODNEY LORENZ, MD

The Diabetes Control and Complications Trial (DCCT) established for patients with type 1 diabetes the unequivocal health benefits of a comprehensive treatment program that maintained the blood glucose level near normal (1). The experimental regimen employed in the DCCT was associated with statistically and clinically significant delays in the onset and/or progression of diabetic retinopathy, nephropathy, and neuropathy. A subsequent trial in Japanese subjects with type 2 diabetes showed nearly identical effects of similar therapy on the risk of complications (2). This and other evidence has led to a growing consensus that maintaining the blood glucose level near normal is the most appropriate treatment goal for all people with diabetes whose health and life expectancy are such that they may benefit from the reduced risk of chronic microvascular complications. The health care community is now challenged to provide this new standard of care.

The challenge has many facets (3,4). Most physicians practicing today are not skilled in using the new treatment methods. The U.S. health care system is not structured or financed in ways that facilitate optimal care of patients with diabetes. There are insufficient numbers of educators and nutritionists with the requisite knowledge and skills, and too few settings where team care is available. Some patients decline up-to-date therapy, even when the benefits are known (5). The purpose of this commentary is to highlight two additional problems with intensive therapy.

The first problem is the term itself. It can be argued that the label "intensive therapy" is no longer appropriate and that it may actually inhibit the use of the best treatment available. The term "intensive insulin therapy" was used before and during the DCCT to signify regimens that used three or more daily insulin injections or an insulin pump. Experience taught that the new treatments involve much more than complicated insulin regimens, and the more inclusive terms "intensive therapy" or "intensified management" are frequently used today. The problem is that the words "intensive" and "intensified" are inherently relative; they imply a comparison with something else that is less strenuous, i.e., with "conventional" therapy in pre-1993 terms. The natural tendency is to assume that the other, nonintensive treatment is the norm.

In 1998, however, DCCT-style intensive therapy is the standard of care for otherwise healthy individuals with type 1 diabetes and for many patients with type 2 diabetes. Conventional treatment today includes frequent self-monitoring of blood glucose; an insulin delivery system that simulates normal physiology (in type 1 diabetes); meticulous attention to matching food intake, physical activity, and hypoglycemic drug(s); and a team approach to care—all orchestrated to achieve and maintain specific, near-normal blood glucose targets. It is incorrect to imply that this form of treatment is unusual or special in any way.

The term "intensive therapy" may discourage people with diabetes from attempting this treatment method. Personal experience suggests that when people hear the term "intensive" applied to medical treatments, they assume that something extraordinary is meant, that most people do not need such treatment, and that such treatment is intended only for those who are worse off than themselves in some way. This message is indeed the opposite of what should be conveyed about the modern treatment of type 1 diabetes. We want our patients to believe that DCCT-style treatment is the norm, that anything else is second-rate (it is), and that they should want nothing less. We want our patients to demand DCCT-style treatment, not to avoid it because it sounds somehow undesirable.

The diabetes community should abandon the term "intensive therapy" in referring to what must now be considered conventional therapy for type 1 diabetes. If a new label is essential, "modern diabetes therapy" may be suggested. Any treatment program that is less aggressive than that briefly outlined above should be called "simplified therapy." Any recommendation to use simplified therapy should be justified by an explanation of why something less than the most effective treatment is being recommended. More descriptive or useful labels may be possible; readers are invited to offer their own thoughts.

The second problem relates to intensive therapy of type 2 diabetes. Without a treatment that repairs pathophysiology, optimal therapy is more difficult to define than in type 1 diabetes. Indeed, the treatment required to control blood glucose seems to change over time as the disease evolves. Some authorities speaking on the subject of type 2 diabetes have used the term "intensive therapy" to mean multiple-dose insulin regimens for individuals whose diabetes has evolved to insulin deficiency. To others, intensification of type 2 diabetes management means using multiple drugs (up to four at once) in various combinations to take advantage of their different modes of action.

These may be examples of slamming the barn door after the horse has left, because they seem to ignore the potential improvement from "intensive" behavioral therapy during the early stages of disease, when modest weight loss can be associated with significant metabolic improvement, as well as the potential contributions of meticulous nutrition and lifestyle management to metabolic control in the later stages of disease. "Intensive therapy" of type 2 diabetes should refer to truly aggressive and exhaustive use of available behavioral treatment modalities at diagnosis and thereafter.

From the Diabetes Research and Training Center, Vanderbilt University School of Medicine, Nashville, Tennessee.

Address correspondence and reprint requests to Rodney Lorenz, MD, 1211 21st Ave. S., No. 315, Nashville, TN 37212. E-mail: rod.lorenz@mcmail.vanderbilt.edu.

Received for publication 20 April 1998 and accepted in revised form 10 July 1998.

R.L. serves on a scientific advisory committee for Diabetes Treatment Centers of America; he also receives consulting fees from and holds stock in the company.

Abbreviations: DCCT, Diabetes Control and Complications Trial.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Some investigators argue that diet and exercise are ineffective (6), largely because the weight lost is usually regained. Perhaps because of general discouragement with weight management, these forms of therapy are often given lip service in clinical practice, and even in research settings are used only for a short time. It is lip service when a physician advises a patient to "lose weight" and hands over a printed brochure outlining a low-calorie diet. It is lip service when a managed care organization allows only one visit with a nutritionist at the time of diagnosis of diabetes. Recent data confirm how close to reality these examples are. Of randomly selected patients with type 2 diabetes in Michigan, 36% had never seen a dietitian, and 51% had seen one only once or twice. Thirty-nine percent had never been given advice about exercise (7). Even a traditional 12-week group weight-loss program is a modest investment compared with modern therapy for type 1 diabetes. "Intensive therapy" using multiple daily injections in the DCCT costs about $4,000 per year. Why should an individual with recently diagnosed type 2 diabetes be limited to one $50 visit with a dietitian as the only nutrition management offered? Should we be rushing to develop multiple-drug regimens for patients who have never been assisted to change eating behaviors and lifestyle? Why should weight-loss programs end after a few weeks or months?

Eastman et al. (8) have estimated that therapy for type 2 diabetes is cost-effective when total costs are no more than about $3,000 per year. More of these resources should be directed to truly aggressive weight-management and fitness programs that begin at diagnosis and continue for the patient's lifetime. More research resources should be directed to the development of new behavioral treatments, because those available now are not effective enough. It is time for innovative thinking about behavioral treatments, incentives, and the design of systems for delivering behavioral treatments over years instead of weeks, and for integrating behavioral treatments with medical management. The DCCT suggested, among other things, that people with diabetes could accomplish and maintain major changes in behavior. The DCCT success was likely partly related to the continuous application of behavior management principles (9). Aggressive behavioral management of type 2 diabetes should not be abandoned until it has been tried.

Finally, it may be useful to replace the term "intensive therapy" in reference to type 2 diabetes with another term. An appropriate goal might be to select labels that emphasize the central role of behavioral treatment modalities, applied aggressively for life, and sometimes supplemented by drugs.

References

1. The Diabetes Control and Complications Trial Research Group: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*329:977–986, 1993
2. Ohkubo Y, Kishikawa H, Araki E, Miyata T, Isami S, Motoyoshi S, Kojima Y, Furuyoshi N, Shichiri M: Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract*28:103–117, 1995
3. Fisher, EB, Heins JM, Hiss RG, Lorenz RA, Marrero DG, McNabb WL, Wylie-Rosett J (Eds.): *Metabolic Control Matters: Nation - wide Translation of the Diabetes Control and Complications Trial: Analysis and Recommen - dations* Washington, DC, U.S. Govt. Printing Office, 1994 (NIH publ. no. 94-3773)
4. Vinicor F: Barriers to the translation of the Diabetes Control and Complications Trial. *Diabetes Rev*2:371–383, 1994
5. Tercyak KP, Johnson SB, Kirkpatrick KA, Silverstein JH: Offering a randomized trial of intensive therapy for IDDM to adolescents: reasons for refusal, patient characteristics, and recruiter effects. *Diabetes Care* 21:213–215, 1998
6. Samaras K, Campbell LV, Chisholm DJ: Can the effectiveness of physical activity programs be improved? (Letter) *Diabetes Care* 21:195, 1998
7. Hiss RG (Ed.): *Diabetes in Communities .II* Ann Arbor, MI, Michigan Diabetes Research and Training Center, University of Michigan, 1992
8. Eastman RC, Javitt JC, Herman WH, Dasbach EJ, Copley-Merriman C, Maier W, Dond F, Manninen D, Zbrozek AS, Kotsanos J, Garfield SA, Harris M: Model of complications of NIDDM. II. Analysis of the health benefits and cost-effectiveness of treating NIDDM with the goal of normoglycemia. *Diabetes Care*20:735–744, 1997
9. Lorenz RA, Bubb J, Davis D, Jacobson A, Jannasch K, Kramer J, Lipps J, Schlundt D: Changing behavior: practical lessons from the DCCT. *Diabetes Care*19:648–653, 1996