Intensive Diabetes Management: Implications of the DCCT and UKPDS

The Diabetes Educator 2002; 28; 735
DOI: 10.1177/014572170202800514

position STATEMENT

Intensive Diabetes Management: Implications of the DCCT and UKPDS

This is an official position statement of the American Association of Diabetes Educators (AADE). AADE is dedicated to advancing the role of the diabetes educator and improving the quality of diabetes education and care.

AADE Board approval: April 2002

Currently, 17 million people (6.2% of the population) in the United States have diabetes mellitus: approximately 11.1 million are diagnosed and 5.9 million are undiagnosed.[1] When considering age, 8.6% of persons ages 20 years or older and 20.1% of persons ages 65 years or older have diabetes.[1] By 2025, it is estimated that 21.9 million adults will have diabetes.[2] Diabetes is the sixth leading cause of death due to disease in the United States and shortens average life expectancy by up to 15 years. Diabetes also is the primary cause of kidney failure, adult blindness, and amputations in the United States, accounting for 42% of new cases of end-stage renal disease and more than half of nontraumatic amputations of the lower extremities. Sixty percent of people with diabetes have hypertension, and persons with diabetes suffer from heart disease and strokes 2 to 4 times more frequently than those without diabetes. Currently, it is estimated that diabetes costs the United States over $105 billion annually in health-related expenditures, with more than 1 of every 10 healthcare dollars and about 1 of every 4 Medicare dollars spent on the care of people with diabetes.[1]

Large proportions of patients with type 2 diabetes in the United States have unacceptable glycemic control. Data collected in the Third National Health and Nutrition Examination Survey (NHANES III) from 1988 to 1994 revealed that only 44.6% of persons with diabetes had hemoglobin A1C (A1C) values <7%, defined by the American Diabetes Association (ADA) as the treatment goal for persons with diabetes.[3,4] Moreover, 37.1% of persons with diabetes had A1C values >8%, the level at which the ADA recommends more aggressive intervention to improve glycemic control.[3,4] Data collected in the final 3 years of the NHANES III from 1991 to 1994 indicated that the health status and outcomes of people with type 2 diabetes remained far from optimal despite high rates of healthcare access and utilization, screening for complications, and treatment of hyperglycemia, hypertension, and dyslipidemia.[5] This report found that 58% of people with type 2 diabetes had an A1C value >7% and that the overall mean A1C was 7.8%, with a mean A1C of 8.3% for those on insulin, 8.0% for those on oral agents, and 6.7% for those on diet alone.[5] It should be noted that these surveys predated the introduction of biguanides, α-glucosidase inhibitors, and insulin sensitizers in the United States and also predated reports from the Diabetes Control and Complications Trial (DCCT)[6] and the United Kingdom Prospective Diabetes Study (UKPDS).[7]

The DCCT and the UKPDS demonstrated that intensive diabetes management can achieve A1C levels close to the ADA treatment goal of 7%, resulting in significant reductions in diabetes complications in persons with both type 1 and type 2 diabetes.[6-8] The use of a multidisciplinary team, frequent clinic visits with nurses and dietitians, and extensive telephone access to these healthcare practitioners have been cited as key elements in the sustained lowering of A1C levels accomplished by the DCCT.[9] Although these elements are difficult to incorporate into everyday clinical

practice, the potential benefits of doing so on the health status and health outcomes for people with diabetes are enormous.

BACKGROUND

Prior to 1993, data supporting the relationship between glycemic control and the chronic complications associated with diabetes were limited. However, during the past decade, 2 major multicenter, randomized controlled clinical trials were completed, providing scientific evidence to support the hypothesis that improving glycemic control prevents or delays the development of the chronic complications associated with diabetes.

DCCT

The DCCT, conducted from 1983 to 1993, was designed to evaluate the relationship between glycemic control and the development of microvascular complications in persons with type 1 diabetes. The DCCT cohort consisted of 1441 individuals who, at entry, were 13 to 39 years of age (mean=27 years), with duration of diabetes from 1 to 15 years. Participants without complications and duration of diabetes less than 5 years comprised the primary prevention cohort; those with minimal complications comprised the secondary intervention group. The mean duration of follow-up was 6.5 years (range=3 to 9 years).

Intensive treatment in the DCCT included insulin therapy via multiple daily (3 or more) injections or use of continuous subcutaneous insulin infusion; frequent self-monitoring of blood glucose (4 or more tests daily) with active adjustment of insulin, diet, and activity based on blood glucose results; and regular contact with the healthcare team for ongoing diabetes education and management assistance. Participants were seen monthly; the goal of treatment was glycemic control as close to the nondiabetic range as safely possible.[6]

By contrast, individuals randomized to the conventional treatment group continued to receive 1 or 2 insulin injections per day and performed daily self-monitoring of glucose levels; diet and exercise education also was provided. Participants were seen every 3 months; the treatment goal was the absence of symptoms attributable to glucose excursions.

UKPDS

The UKPDS, conducted from 1977 to 1997, was designed to assess the relationship between glycemic control and the development of macrovascular and microvascular complications in persons with type 2 diabetes. In addition, specific treatment options were evaluated for their potential to influence the risk of complication development. The UKPDS cohort included 3867 individuals with newly diagnosed type 2 diabetes; the median age was 54 years. The mean duration of follow-up was 10 years.

Participants in the UKPDS were randomly assigned to conventional or intensive treatment. Conventional treatment focused on diet intervention; the goal of treatment was the absence of hyperglycemic symptoms. Intensive treatment included sulfonylureas, biguanide, or insulin; the treatment goal was normoglycemia. Patients in both treatment groups were seen every 3 to 4 months.[7]

The intensive and conventional treatment groups in the DCCT as well as the UKPDS achieved statistically significant differences in glycemic control as measured by A1C. In the DCCT, the intensive treatment group achieved a mean A1C of 7.2% compared with 9.1% in the conventional treatment group. Intensive treatment resulted in an approximate reduction of 60% in the risk of microvascular complications.[6] In addition, for every 10% reduction in A1C there was a 43% reduction in retinopathy progression.[10]

In the UKPDS, the mean A1C values were 7.0% and 7.9% in the intensive and conventional treatment groups, respectively.[7] Intensive treatment, utilizing sulfonylureas, biguanide, or insulin reduced the risk of microvascular complications by 25%.[7] In addition, for every 1 point decrease in the A1C level (eg, from 8% to 7%), the risk of microvascular complications was reduced by 35%, diabetes-related deaths were reduced 25%, and all-cause mortality was reduced 7%.[11] Risk reduction for macrovascular complications was seen in the intensive treatment groups of both the DCCT and UKPDS. Although this reduction was not statistically significant, over larger populations or with longer follow-up the risk reduction for macrovascular complications could very well reach statistical significance.

Increased risk for severe hypoglycemia was seen in the intensive treatment groups of both the DCCT and UKPDS,[6,7] indicating that efforts to improve glycemic control must be balanced with patient safety. In addition, treatment

interventions and patient education efforts must be tailored to minimize risk.

DISCUSSION

The DCCT and UKPDS demonstrated conclusively that improvement in glycemic control decreases the risk for major adverse outcomes in both type 1 and type 2 diabetes. This reduction in risk is proportional to the degree of change in glycemic control, with no minimum threshold. Because the mortality and morbidity associated with diabetes are so profound, even small improvements in glycemic control have the potential to enhance the quality and quantity of life for persons with diabetes.

If intensive treatment is to be safe and enduring, it must be carefully tailored to the individual person with diabetes. An individual's capacity to improve glycemic control is jointly determined by biology, personality, cognitive capacity, and life circumstances, and is further influenced by the personality and cognitive capacity of family members and significant others who are involved in the person's care. All of these domains need to be addressed initially and throughout the treatment process. Thus, it is essential to conduct ongoing assessments of every patient's ability and willingness to participate in personal care.

A major challenge for both patient and healthcare provider is the sheer effort and inconvenience involved in improving control. Human beings are not easily motivated when the drawbacks are immediate and the benefits delayed.[12] A second challenge is integrating, to the fullest extent possible, treatment models provided by the DCCT and UKPDS into daily clinical practice. It clearly will take the best efforts of both healthcare professionals and patients to achieve or approach the recommended standard for glycemic control. Diabetes educators play a pivotal role in this endeavor.

RECOMMENDATIONS

The results of the DCCT and the UKPDS provide data to support the relationship between glycemic control and the chronic complications in type 1 and type 2 diabetes. In light of these unequivocal results, the AADE advocates that all persons with diabetes strive for *optimal glycemic control*, defined as glycemia as close to the nondiabetic range as safely possible. In addition, the following specific recommendations further clarify AADE's position regarding the management of diabetes:

1. Diabetes educators and all healthcare professionals providing care to people with diabetes are encouraged to remain current in diabetes management methods and issues. Emerging technology and treatment options, as well as information on how to integrate new technologies and/or knowledge into daily practice, will foster the implementation of more intense and/or diverse treatment options.

2. Diabetes educators are ideally suited to act as patient advocates. Diabetes educators play a pivotal role in assisting patients in understanding their treatment regimen, facilitating access to needed supplies and services, advocating for referral to other providers as needed, and educating decision makers.

3. All persons with diabetes should be encouraged to be actively involved in their healthcare management. Access to education that encourages guided self-management efforts is necessary to promote informed independence in self-care. Patients will benefit from a treatment approach that recognizes them as a valuable member of their personal healthcare team.

4. Multidisciplinary team management and education are recommended. Patients will benefit from access to healthcare providers with targeted expertise in the management of diabetes. Communication between team members must be ongoing to assure instruction that is consistent in content and emphasis. The frequency of contact and mode of communication between the patient and healthcare team should be individualized and incorporate family members and/or significant others as appropriate.

5. Treatment goals must incorporate patients' medical needs as well as their willingness and/or ability to participate in their health care. Not all patients will be willing or able to do what is recommended to optimize their healthcare behaviors at a given time. Ongoing assessment of patient readiness is essential to assure adequate integration of treatment goals and methods into daily life. Treatment goals may need to be modified during periods of stress and for children, the elderly, and those individuals with certain medical conditions such as history of severe hypoglycemia or coronary artery disease.

6. Treatment goals and strategies must take demographic factors into account. Consideration should be given to the patient's age, educational and cultural background, emotional and intellectual capabilities and readiness, adequacy of a support system, and resources to cover the financial and daily burdens associated with treatment.

7. Daily treatment strategies should be matched to the person's lifestyle preferences. An ongoing dialogue between the patient and healthcare team is needed to identify values or lifestyle preferences that may influence acceptability and safety of the prescribed treatment plan. Thoughtful consideration of individual preferences will maximize the patient's active involvement in the decision-making process.

8. Daily blood glucose monitoring is recommended for all persons with diabetes. The frequency and timing of testing must be individualized, with consideration given to patient safety, the prescribed medication regimen, glycemic control goals, patient willingness to test, and resources available to cover the requisite medical supplies.

9. Patient education strategies should promote knowledgeable independence in self-care activities. Patients should be knowledgeable about all components of their diabetes treatment regimen, understand how and when the medication(s) work, and receive the required education to allow for reasoned adjustments in their daily care regimens. The extent of understanding and ability to actively adjust the daily diabetes regimen will vary across patients and time and thus will require ongoing, individualized assessment.

SUMMARY

Diabetes self-management education is an essential component of diabetes treatment. Diabetes educators play a vital role in recognizing and addressing potential barriers to self-care, facilitating appropriate selection of treatment strategies and tools, and fostering the integration of diabetes care practices into daily life. It is incumbent upon diabetes educators to ensure that diabetes self-management education is appropriately tailored and delivered to ensure safe implementation of intensive diabetes management.

DEVELOPMENT OF THIS DOCUMENT

This position statement was developed by a multidisciplinary task force of the American Association of Diabetes Educators. The following members were selected for their expertise, professional discipline, and geographical location to ensure a broad representation of perspectives and practices.

Task Force

Gayle M. Lorenzi, RN, CDE
Linda M. Delahanty, MS, RD
John R. Kramer, PhD
Neil H. White, MD, CDE

REFERENCES

1. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion. National Diabetes Fact Sheet. March 27, 2002.

2. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995-2025: prevalence, numerical estimates, and projections. Diabetes Care. 1998;21: 1414-1431.

3. Harris MI, Eastman RC, Cowie CC, Flegal KM, Eberhardt MS. Racial and ethnic differences in glycemic control of adults with type 2 diabetes. Diabetes Care. 1999;22:403-408.

4. American Diabetes Association. Standards of medical care for patients with diabetes mellitus. Diabetes Care. 2001; 24(suppl 1):S33-S43.

5. Harris MI. Health care and health status and outcomes for patients with type 2 diabetes. Diabetes Care. 2000;23:754-758.

6. 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. 1993;329:977-986.

7. United Kingdom Prospective Diabetes Study Group. Intensive blood glucose control with sulfonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352:837-853.

8. United Kingdom Prospective Diabetes Study Group. Intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). Lancet. 1998;352: 854-865.

9. Diabetes Control and Complications Trial Research Group. Resource utilization and costs of care in the Diabetes Control and Complications Trial. Diabetes Care. 1995;18: 1468-1478.

10. Diabetes Control and Complications Trial Research Group. The relationship of glycemic exposure (HbA1c) to the risk of development and progression of retinopathy in the Diabetes Control and Complications Trial. Diabetes. 1995: 44:968-983.

11. American Diabetes Association. Implications of the United Kingdom Prospective Diabetes Study. Diabetes Care. 1998:21: 2180-2184.

12. Kramer JR, Jacobson AM, Ryan CM, Murphy WD, and the DCCT Research Group. Psychological aspects of the Diabetes Control and Complications Trial. In: Bradley C, Home P, Christie M, eds. The Technology of Diabetes Care: Converging Medical and Psychosocial Perspectives. Harwood Academic Publishers; 1991:122-139.