The Impact of Glucose Management by a Diabetes Center on the Quality of Life of Patients with Non-Insulin Dependent Diabetes

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Lay Abstract

Medicine traditionally uses outcomes such as improved mortality, increased life expectancy, or cure in the treatment and management of various diseases. Recently there has been a growing interest in the measurement of quality of life as an important outcome in health care, especially as the number of patients with chronic conditions continues to increase. In chronic disease, there is no hope for cure; at the same time, patients are asked to take on an ever-increasing burden of medications and lifestyle changes to manage their disease. This may actually detract from the quality of life, which is often the patient's most important goal.

In diabetics, studies have shown that intensive treatment regimens aimed at tight control of blood glucose slow the progression of complications of diabetes such as blindness, neuropathy, and kidney failure. The potential downside of intensive treatment programs is patients may not necessarily experience a better quality of life because their blood glucose is well-controlled, and may in fact experience a lower quality of life because of the extra effort and many restrictions imposed by an intensive diabetes program.

The primary purpose of this study is to examine the impact that an intensive glucose control program has on the quality of life of diabetics. The patients will be adults enrolled from the Naomi Berrie Diabetes Center at Columbia Presbyterian Medical Center. In addition to the standard care given at the diabetes center, questionnaires will be administered at the beginning and at the end of the study.

A. Study rationale and purpose

The results of the Diabetes Control and Complications Trial (DCCT) solidified physicians' conviction that tight glucose control is of paramount importance in the care of diabetics. However, physicians run the risk of making rigorous glucose control the only outcome of interest in diabetes, without regard for the impact this has on quality of life.

Many instruments have been developed that attempt to measure the health-related quality of life in different patient populations. A very popular questionnaire is the Medical Outcomes Study Short Form 36 (SF-36) which has been tested and validated in many populations, including patients with hypertension, diabetes, congestive heart failure, myocardial infarction, arthritis, COPD, gastrointestinal disorders, and angina. This instrument has proved useful in comparing different patient populations both to each other and to the general population.

Although global measurements of quality of life allow comparison between diseases, they may be less useful within a specific population. For this reason, many instruments have been developed to address the specific concerns of each set of patients. In diabetes, studies have supported the increased sensitivity of diabetes-specific instruments as compared to general instruments such as the SF-36. Instruments that have been validated in the literature include the Diabetes Impact Measurement Scales (DIMS), the Diabetes Quality of Life scale (DQOL), and the Diabetes Care Profile (DCP).

A number of cross-sectional studies have looked at the correlation between the level of glycemic control and the quality of life. The results of these studies have been mixed. Studies using general instruments such as the SF-36 have generally found no positive or negative correlation between glycosylated hemoglobin and quality of life. Studies that have used diabetes specific instruments have tended to find improved quality of life with improved glycemic control.

Very few longitudinal studies have been done. One study using the DQOL was done during the DCCT, which showed that there was no measurable increase or decrease in the quality of life of intensively treated individuals when compared to normally treated individuals. Another longitudinal study used the SF-36 in a population of VA patients with non-insulin-dependent diabetes and followed them over 1 year. This study found no relationship between glycosylated hemoglobin and quality of life either at baseline or after 1 year of slightly more intensive diabetes management.

Many factors have been thought to contribute to the relationship between diabetes and quality of life in addition to the long-term complications of the disease itself. Symptoms of hyperglycemia may detract from the quality of life. In addition, a poor understanding of diabetes in individuals who are not followed by diabetes specialists may further contribute to poor quality of life. However, the impact of complex medication and diet regimens, the need to frequently inject insulin, episodes of hypoglycemia, side effects from medication, and the need for close monitoring may detract from quality of life as well. The hypothesis being tested in this study is that patients managed by a diabetes center will achieve a better quality of life than patients who are managed by primary care physicians.

The Naomi Berrie Diabetes Center is one resource that physicians at CPMC have to assist them in managing diabetics. The Center attempts to achieve glucose control to the level suggested by the DCCT study. This study proposes to examine in a prospective trial the impact of these interventions on quality of life in a group of non-insulin dependent diabetics over a period of 1 year.

B. Study design and statistical analysis

Study subjects will be chosen from the patients referred to the Naomi Berrie Diabetes Center from the AIM clinic. All patients will receive the initial first visit assessment at the diabetes center. Patients will be randomly assigned to one of two arms. Patients will then be randomly assigned to one of two groups. The first group will be sent back to their primary care physician with the recommendations of the center. The second group will continue to be followed at the diabetes center and receive the standard care offered there.

The number of subjects enrolled in each arm will be 200. The SF-36 consists of twenty questions that measure six areas of quality of life: physical function, role function, social function, mental health, health perceptions, and bodily pain. Each of these areas are scaled from 1 to 100. The DQOL consists of 46 questions measuring four areas of diabetes-related quality of life: satisfaction, impact, social/vocational worry, diabetes-related worry, each scaled from 1 to 100. Enrolling this number of subjects in each arm will allow for the detection of a change in score of 2.83.

Statistical analysis will include measurement of the change in quality of life score over one year for each individual in the Berrie Center group as compared to the AIM clinic group. The change in score will be compared between the two groups using the t-test.

C. Study Procedures

The initial visit to the diabetes center includes a one hour visit with an endocrine fellow or attending, a one hour visit with a nutritionist, a one hour teaching session about glucose monitoring, and blood work which includes a hemoglobin A1C level. Patients who return to their primary physician will be sent back with a set of recommendations regarding glucose management. Continuing care will be at the discretion of the primary physician. Patients who continue to follow at the Berrie Center will receive the standard care offered at the center.

All patients will be administered the DQOL and the SF-36 questionnaires at the beginning and the end of the study.

D. Study Drugs

The use of insulin, oral agents, or both will be at the discretion of the primary care physician and the Berrie Center.

E. Medical Devices

None.

F. Study Questionnaires

Please see included copies of the SF-36 and the DQOL.

G. Study Subjects

a. Inclusion criteria

- Age greater than 30
- Age of diagnosis of diabetes greater than 30.
- Currently using either insulin or an oral agent for the treatment of diabetes.
- Referred to the Naomi Berrie Diabetes Center from the AIM clinic.

b. Exclusion criteria

- Active psychosis or dementia.
- Diagnosis of stage IV malignancy.
- Class IV congestive heart failure.
- Oxygen-dependent lung disease.
- Requiring dialysis.
- Cirrhosis with history of encephalopathy or variceal bleeding.

H. Recruitment of Subjects

Subjects will be recruited from those patients referred to the Berrie Diabetes Center from the AIM clinic. Both the patient and the primary care physician will agree to entering the study prior to enrollment.

I. Confidentiality of Study Data

All data will be collected on questionnaires with uniquely coded ID numbers.

J. Potential Conflict of Interest

None.

K. Location of the Study

All research will be conducted at the Naomi Berrie Diabetes Center and at the AIM clinic at CPMC.

L. Potential Risks

A small time commitment will be required to fill out the questionnaires.

M. Potential Benefits

The subjects may or may not have the benefit of an increased understanding of their diabetes and how it affects them. Potential benefits also include a better understanding of the impact of diabetes management on quality of life.

N. Alternative therapies

The alternative to the study is to receive the care offered at the diabetes center without the necessity of filling out surveys at the beginning and the end of 1 year. It will be made clear to the patients that their decision to participate in the study will have no effect on the quality of their care.

O. Compensation to Subjects

Participating subjects will receive $25 for completing the initial survey and $25 for completing the final survey.

P. Costs to Subjects

None.

Q. Minors as Research Subjects

Minors will not be participating in the study.

R. Radiation or Radioactive Substances

No radioactive substances will be used in the study.

S. References

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