A Nurse Practitioner Based Educational Intervention Of The Impact Of Glycemic Control In An Urban Sample Of Type 11 Diabetics Of Hispanic Origin

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A. Background, Purpose, And Rationale

Background Diabetes mellitus is among the most prevalent chronic medical illnesses in the U.S. today. In 1994, roughly 7.7 million persons in the U.S. reported having DM and the age-adjusted prevalence of diagnosed diabetes was estimated to be 29.3 per 1000. A study of the economic impact of NIDDM in 1986 found that 6.8% of total U.S. mortality and a total economic burden of 19.8 billion dollars was attributable to NIDDM. In addition, because of the strong association of NIDDM prevalence with age more cases can be expected as the U.S. population ages.

Amongst minority populations the incidence and prevalence of DM is significantly higher. Several epidemiologic studies have estimated a prevalence of NIDDM in African Americans to be 1.4-2.2 times greater than the prevalence in white persons. Similarly, prevalence of NIDDM in Hispanic persons has been estimated to be two to five times higher than in non-Hispanics. Fewer studies exist addressing the incidence of DM in minority populations but thus far incidence rates in the U.S. have been found to be higher in African Americans and Mexican Americans than in white persons.

Diabetic complications fall into two groups: microvascular and macrovascular complications. Microvascular complications consist of nephropathy leading to ESRD and retinopathy leading to blindness. Macrovascular complications consist of atherosclerosis leading to myocardial infarction, stroke, and peripheral vascular disease. Neuropathy and PVD both contribute to amputations in diabetics. Hence amputations are the end result of a combination of microvascular and macrovascular complications.

African Americans and Hispanics have been found to have a higher prevalence of microvascular complications than white persons. This is better studied with respect to ESRD although existing data also suggests this is true for retinopathy. After adjusting for prevalence of DM African-Americans still have a 2-4 times higher rate of diabetic ESRD. This is not true for Mexican Americans and essentially unstudied in Hispanics of Caribbean background. With respect to macrovascular complications, Blacks and Hispanics with DM have the same risk of cardiovascular disease as their white counterparts. However, the higher prevalence of DM in the minority groups places them at a higher absolute risk of developing CVD attributable to DM. Data comparing prevalence of neuropathy and PVD between minority groups and white diabetics is limited. However, black diabetics have been shown to have a 2-4 times higher amputation rate than Hispanic and white diabetics.

B. Study Rationale and Purpose

The DCCT trial demonstrated that better glycemic control in Type I diabetics was associated with a lower rate of progression of the microvascular complications of DM. This finding has been felt to be applicable to type H diabetics by most experts. This observation underlies the rationale for attempting to achieve optimal glycemic control in type H diabetics.

Various educational interventions in diabetics have been shown to have a significant, positive impact on glycemic control. However, most of these studies failed to include significant minority patients. Those studies which have included significant minorities have lacked significant Hispanic patients.

Barriers to education in Hispanic patients are significant. Lower SES and language present the most significant obstacles to providing educational intervention to this group of patients. Hence, the applicability of educational strategies developed and tested in non-Hispanic groups is not known.

The AIM clinic patient population at CPMC provides an ideal population for addressing this question. The clinic population is predominately Caribbean Hispanic and African American. In 1994, a Diabetes Management Clinic was formed to address the educational needs of diabetics in the AIM clinic population.

The purpose of this study is to assess the impact on glycemic control of a nurse practitioner based educational intervention in this urban, Hispanic population of diabetics.

C. Study Design And Statistical Analysis

The design of the study will be a retrospective cohort study. There will be two arms consisting of an intervention group and a control group. The intervention group will consist of AIM clinic patients with DM (types I and H) who were referred to the Diabetes Management Clinic(DMC) and who made at least one visit to the DMC clinic. The control group will consist of AIM clinic patients with DM(types I and H) who were not referred to the DMC. Whether a patient was assigned a private AIM attending or a resident physician was a matter of chance. However, due to administrative reasons only resident physicians in the AIM clinic could refer patients to the DMC. AIM attending physicians were not allowed to refer patients. Hence, all patients in the intervention group will be referrals from resident physicians and all control patients will be drawn from AIM attending practices but the assignment to either group is random.

The comparability of both groups at baseline will be achieved via 1:2 matching on intervention subject characteristics. Control subjects will be matched on demographic variables, extent of diabetic end organ complications, and the average of two glycohemoglobins(one on the baseline visit and one within 6 months of the baseline visit). The data will analyzed by study investigators who will not be blinded to the assignment of individual subjects.

Twenty percent of patients in the intervention group are estimated to be under adequate glycemic control at baseline. If matching is successful approximately 20% of patients in the control group will also be under adequate control at baseline. The main outcome variable will be the difference in proportion of patients under adequate glycemic control in the intervention vs. control group at study's end. Using a chi square analysis, for an effect size of .6-.7 and a power of .80, 44 subjects are needed in both the intervention and control group. Overmatching on control subjects will allow for in increment in power above .80

D. Study Procedures

a. Control Group

The control group will undergo standard of care procedures for diabetics in the AIM clinic. Glycohemoglobin levels are routinely drawn at the AIM attending's discretion as part of this standard of care. In addition, repeatedly elevated glycohemoglobin values would likely prompt some attempt on the AIM attending's part to attempt to improve glycemic control via either patient education, dietary counseling (or referral for counseling), a change in diabetic medication regimen, or more frequent follow up.. However, the control group will not undergo any additional procedures solely related to the study. That is the possible additional. procedures mentioned above would still be considered standard of care.

The time window for control group baseline visits will occur between 3/93-10/97. The starting date is 1 year before the DMC began operating. As described below, this would allow control subjects up to I year to have an initial glycohemoglobin level drawn prior to their baseline visit which will be the day of the second glycohemoglobin draw. This would allow for control baseline visits to begin roughly around the opening date of the DMC in 3/94. The ending date for this time window will be 10/97. This date would allow for at least 6 months of follow-up for control patients having a baseline visit in 10/97. The exact baseline visit date will determined by the day a second glycohemoglobin level is drawn within the above described time window. In addition, the initial and second glycohemoglobin will need to have been drawn within 3-12 months of one another.

b. Intervention Group

The intervention group will be exposed to standard of care and at least one counseling session with a nurse practitioner trained in diabetes education and clinical management. In addition, the patient will have the opportunity to participate in two modules of diabetes education on successive evenings within a week of the initial counseling visit. Control group patients will also have the opportunity to follow-up with the nurse practitioner and have diabetic regimens adjusted at here discretion for a period of time to be determined by the nurse practitioner. Control group patients will also undergo phlebotomy for glycosylated hemoglobin and at the discretion of the nurse practitioner. The frequency and duration of clinical visits will be determined by nurse practitioner.

The time window for intervention group baseline visits will be between 3/94-10/97. Baseline visits will be defined as the first visit to the DMC.

E. Study Drugs

N/A

F. Medical Devices

N/A

G. Study Questionnaires

N/A

H. Study Subjects

Inclusion criteria for all patients will be as follows:

1) diagnosis of DM type I or type H as verified by PMD;
2) PMD is either a resident or attending in the AIM Clinic practice at CPMC
3) Age >18.

Exclusion criteria for all patients will be a lack of two glycohemoglobin levels within the defined time frame as described in the study procedures section.

I. Recruitment Of Subjects

N/A

J. Confidentiality Of Study Data

All patients included in the study will data coded using a unique identifier for each patient consisting of 3 digits and the first two letters of their last name. Hence, all data will remain confidential. The data will be stored in a secure location accessible only to the study investigators.

K. Potential Conflict Of Interest

N/A

L. Location Of The Study

N/A. Study consists of chart review.

M. Potential Risks

Given the design of the study there are no risks to subjects related to the study itself.

N. Potential Benefits

Given the design of the study there are no potential benefits to participants related to the study itself.

O. Alternative Therapies

N/A

P. Compensation To Subjects

N/A

Q. Costs To Subjects

N/A

R. Minors As Research Subjects

N/A

S. Radiation Or Radioactive Substances

N/A

T. References

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