

ORIGINAL REPORTS: DIABETES

DIABETES CONTROL THROUGH AN EDUCATIONAL INTERVENTION

Objective: We evaluated the effect of an educational intervention administered to patients or/and physicians on the reduction in HbA_{1c} and achieving diabetic control in a high-risk primarily Black inner-city population.

Methods: The study was designed as a four-arm randomized clinical trial where an educational program on diabetes was offered to physicians only, patients only, and both physicians and their patients, while the fourth arm did not receive any instruction. We built regression models at 24 months of follow-up to assess the likelihood of reaching glycemic goal as well as to measure the absolute reduction in HbA_{1c} controlling for arm assignment, insulin use, race, age, sex, smoking, insulin use, and having achieved blood pressure control.

Results: Between April 2005 and July 2007, there were 823 patients randomized into the study. In multivariate analyses, the intervention group in which only patients received education showed a trend toward achieving a significant mean reduction in HbA_{1c} with 49% ($P=.06$) higher odds of reaching glycemic control and .12 ($P=.06$) greater absolute percentage point drop in HbA_{1c} compared to the no education group.

Conclusion: Although our study reports positive results, it warrants a special emphasis on the behavior of the patient. Study results bring attention to disease management programs such as peer support networks that empower the patients that shift some of the responsibility to them. (*Ethn Dis.* 2014;24[2]:182–188)

Key Words: Patient Education, African Americans, High Risk, Inner-City

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INTRODUCTION

Diabetes, one of the leading causes of death in the United States, represents a significant health care burden that is expected to continue rising.¹ In 2007, the total estimated diabetes cost was \$174 billion, including \$116 billion direct medical cost and \$58 billion indirect cost.² Existing racial disparities exacerbate the clinical and economic burden of diabetes. It is estimated that 18.7% of all non-Hispanic Blacks and 10.2% of all non-Hispanic Whites aged ≥ 20 years are diagnosed or undiagnosed with diabetes in the United States.^{3–6} Such diabetes disparities are especially apparent in Maryland, where Black adults, while considered to be under-diagnosed, have up to twice the prevalence rate of diagnosed diabetes, as compared to Whites.⁷ Moreover, the mortality rate of diabetes is higher in Blacks compared to Whites with a rate of 37.2/100,000 among Blacks vs 17.6/100,000 among Whites.⁸ Exploring various types of interventions to help eliminate health disparities is a national commitment of the *Healthy People 2020* national framework.⁹

While diet, oral medications, and insulin are fundamental components to managing diabetes, they alone are insufficient in helping patients reach acceptable levels of diabetes control. In addition to the use of treatment, an engaging process involving both physicians and patients could be conducive to exchanging medical information to effect a behavior change in patients and optimize their clinical outcomes.^{10,11} At the very core of this exchange is the idea of empowering patients with proper

information about diabetes, the treatment of diabetes, and their role in their own care.¹²

The education of patients can be a very effective approach in managing diabetes.^{13,14} For instance, poor patient knowledge resulting in improper use of an oral medication and insulin simultaneously can carry serious consequences including hypoglycemia, hyperglycemia, and possibly death.^{15–17} While some prior interventions focused on physician training have indicated no significant improvement in controlling adverse effects,¹⁸ others aimed at patient education have reported significant improvement in blood glucose control.^{19–22} Additionally, other studies have looked at programs where physician training and patient education were implemented simultaneously, and have seen that those combined interventions resulted in significant improvements in hypertension,¹¹ diabetes knowledge,²³ as well as glycemic control.²⁴

Patient- and clinician-level factors have been identified as barriers to diabetes management, but further research is needed to elucidate their separate contribution as well as interplay in influencing diabetic health outcomes.^{16,25,26} The aim of our study was to assess the impact of an intensive educational intervention to physicians or/and their patients on glycemic control in a high risk Black inner-city population with diabetes.

METHODS

We conducted this study within the scope of the Baltimore Cardiovascular

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Partnership, a community-university collaboration generally aimed at improving communication between research institutions and surrounding communities in Baltimore. The high burden of cardiovascular disease and diabetes and their recalcitrant nature in Black communities in Baltimore, who have about 50% higher mortality rates due to diabetes than national averages,²⁷ highlight the need to study ethnicity-related health disparities in this population.²⁸ The Partnership was made possible by a grant from the National, Heart, Lung, and Blood Institute (U01 HL79151). The study was approved by the Institutional Review Board of Bon Secours Baltimore Health Systems (BSHS). Written informed consent was obtained from all participating subjects.

Study Design

The study was designed as a four-arm randomized clinical trial, where the educational programs were offered to physicians only, patients only, or both physicians and their patients. In the fourth arm, neither physicians nor patients received any education. This was a hypothesis-testing, prospective study, with an experimental two-by-two factorial design. Patients were not made aware of whether or not their physicians were receiving the educational intervention, and vice-versa. (Figure 1)

Participant Enrollment

We enrolled ten BSHS primary care physicians and patients of these physicians. The intervention cohort consisted of five physicians that attended twelve 90-min interactive lectures over two years and their patients, half of whom received education and half did not receive education. The control group consisted of five physicians who did not receive intensive training and their patients, half of whom received education and half did not receive education. (Figure 1). We maintained internal validity as factors that influence practice style were consistent across, as well as within, these two groups. Those included the criteria to be met by a physician to join practice and stay on staff, credentials, the level of education, as well as exposure to new practice guidelines.

Patients who consented were recruited from all sites. Within each clinic, patients were randomized to the education or to the control group, retaining their physician of record. Patients were enrolled on a rolling basis, over a period of 2.5 years, starting on April 1, 2005. Inclusion criteria included uncontrolled diabetes ($HbA_{1c} \geq 7$), and the absence of medical conditions or treatments that would preclude standard diabetes drug therapies.

Study Intervention

The physician education intervention consisted of an in-depth series of 90-minute interactive lecture sessions presented every two months by members of the study clinical and research team. The curriculum was implemented over 2 years, starting with the first patient enrollment. Topics covered cardiovascular health disparities, pathophysiology of diabetes, pharmacologic and non-pharmacologic management, managing co-morbidities, and research methods. Individual case consultations were also offered.

The patient education intervention consisted of up to 30 minutes of personal counseling by the study nurse, at each patient visit, at six-month

intervals. The topics included weight reduction, the Dietary Approach to Stop Hypertension eating plan, sodium and alcohol reduction, physical activity, as well as adherence to visits and to medications. The counseling sessions were interactive and customized to the patient. We educated the patients on the importance of adhering to medications and adopting lifestyle modification including proper diet, exercise and smoking prevention. We also emphasized the importance of self-monitoring, and regularly checking for symptoms of complications by performing self-foot exams in order to identify early signs of ulcers.

Statistical Analysis

We collected data on patients, to include the following: whether they were in the intervention or the control group, age, sex, race/ethnicity, as well as clinical data; smoking status, diabetes, weight, and diagnosed comorbidities. A descriptive analysis was performed to compare the characteristics of participants in the study arms. Logistic regression analysis and time-to-event analyses were used to examine the effect of the interventions on the likelihood of reaching HbA_{1c} control. Ordinary least square analyses were conducted to assess the association between the interventions and absolute changes in HbA_{1c} .

Outcome Measures

The primary outcome was the percentage of patients whose HbA_{1c} had reached a level $<7.0\%$, which is the definition of glycemic control for this study. Secondary outcomes included time to reach goal as well as absolute and relative changes in HbA_{1c} . We followed the patients' changes in HbA_{1c} at six-month intervals.

Sample Size and Power Analysis

The study was powered for the primary outcome of the proportion of patients who brought their HbA_{1c} to goal. A total of 600 patients balanced over the four study arms would have

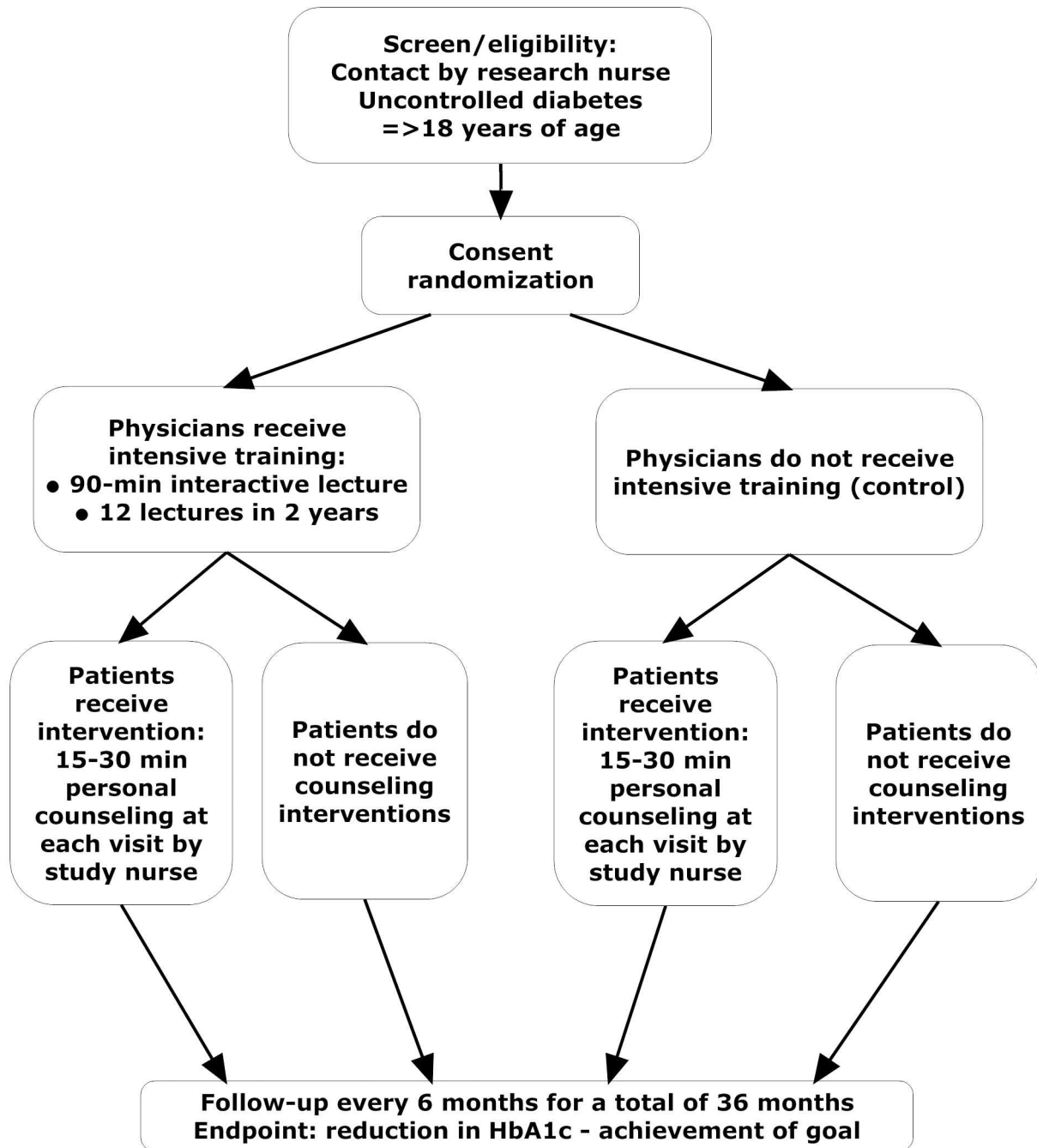


Fig 1. Study design and sampling scheme

been sufficient to detect a 10 percentage point change in the proportion of patients at goal attributable to either the patient or physician intervention (with power of 80% and one-tailed significance level of .05). Our total enrollment was actually 830 patients, thus affording us a power of over 80%.

A Microsoft Access relational database was built for the data repository, to provide sufficient functionality for security, patient confidentiality, and data integrity; HIPAA compliant data, without patient names, was exported to SAS (version 8; SAS Institute, Cary, NC) for analysis.

RESULTS

Between April 2005 and July 2007, there were 823 patients randomized into the study. At baseline, patient characteristics were uniformly distributed across groups and did not differ significantly. Most of the patients in the

Table 1. Baseline characteristics (N=823)

| Characteristic | n (%) |
|--|-------------|
| Race/Ethnicity | |
| White | 56 (6.79) |
| Black | 749 (91.01) |
| Other | 17 (2.06) |
| Male | 295 (35.84) |
| Age, mean (SD) | 64 (13.82) |
| HbA _{1c} , mean (SD) | 8.03 (2.13) |
| HbA _{1c} control ^a | 293 (35.52) |
| SBP, mean (SD) | 137 (20.20) |
| DBP, mean (SD) | 77 (11.57) |
| BP control ^b | 432 (52.36) |
| Insulin user | 204 (24.72) |
| Smoker | 157 (19.03) |

^a Control defined as HbA1c value <7.

^b BP measurement <130/80.

study were Black (91%) and female (64%). The average age of the population was 64 years of age. Only slightly more than one-third of the population had HbA_{1c} controlled to <7% and about one fourth were insulin users (Table 1). Starting off with a somewhat higher HbA_{1c} at baseline, the intervention cohort, in which physicians received diabetes education, achieved consistently lower levels of HbA_{1c} than the control (Figure 2).

We examined and present the results from the adjusted models for the impact of education on glycemic changes at 24 months, as this time point marked the largest gap between the intervention groups and the control group. Furthermore, while the study ran for a total of

36 months, the study was subject to a great degree of selective attrition after the 24th month. Those intervention patients who had reached their optimal HbA_{1c} reduction were withdrawing from the study, thus possibly leading to the cross of the two curves at the end of follow up in Figure 2. We found that the patient-education-only group showed 49% ($P=.06$) higher odds of reaching glycemic control compared to the group in which neither physicians nor patients received education (Table 2). In secondary analyses, the group in which patients received education exhibited a trend toward achieving a significant mean reduction in HbA_{1c} with .12 ($P=.06$) greater percentage point drop than the group without

education intervention (Table 3). When we took into consideration the time to achieving glucose control, in time-to-event analysis we found that patient education again had a significant impact on reaching that control goal but with a smaller effect size of HR=1.06 ($P=.06$) (Table 4). Across analyses, insulin users had a significantly higher likelihood of achieving glycemic control than non-insulin users.

DISCUSSION

Our study aimed at examining the comparative effectiveness of four different interventions that can readily be implemented in every day practice models: physician training and patient education, physician training only, patient education only, and no education. We found that the mean HbA_{1c} of patients with education was lower than patients without education after two years of observation. Also, we found that patient education was effective at maintaining appropriate glycemic control in the long-term regardless of the availability of physician training. The other three groups did not differ significantly in the mean HbA_{1c}. Our results are in line with previous research interventions incorporating physician training or/and patient education, which have been found to lower blood glucose.^{18-22,24} It should, however, be noted that in our study additional physician training seemed to be ineffective in lowering HbA_{1c} in the long-term, regardless of whether the patient received education. Our finding is consistent with negative results from previously published educational interventions targeting physicians treating diabetes.^{29,30} While somewhat unexpected, in our study this could be explained by the observation that family members are regarded as the most trusted health information source in Black families, although health professionals are the most common source of

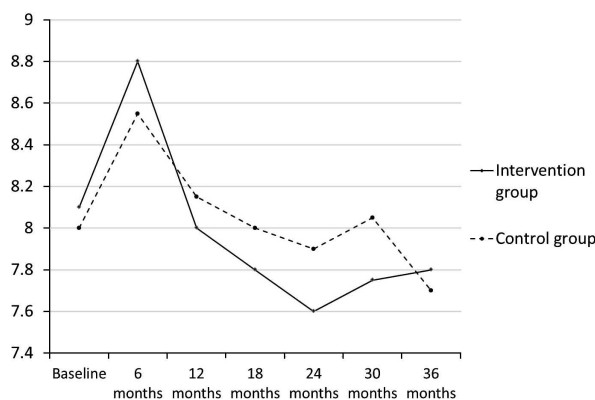


Fig 2. Mean HbA_{1c} (%) trend of intervention and control patients over time

Table 2. Impact of education on odds of achieving glycemic control HbA_{1c}<7.0% at 24 months from baseline (N=823)

| | OR | P |
|-----------------------------|-------------------|--------|
| Reference: no education | | |
| Physician/patient education | .99 | .95 |
| Patient education | 1.49 ^b | .06 |
| Physician education | .99 | .81 |
| Insulin user | 1.33 ^a | <.0001 |
| BP control | .98 | .53 |
| Male | 1.04 | .27 |
| Age | .997 ^b | .08 |
| Black race | .99 | .85 |
| Smoking | 1.01 | .80 |

^a Statistically significant at .05 level.

^b Statistically significant at .10 level.

information.³¹ A possible contrast between physician’s advice and the informational influence of the patient’s family support might have led to mixed effects in those patients whose physicians were in the intervention cohort.

The main limitation of the study is that it falls in the domain of education interventions yielding mixed results in achieving glycemic control in diabetes patients. The evaluation of such educational interventions is difficult because they are not administered in a vacuum but interact with factors such as patient lifestyles, the food environment,³² patients’ adherence and health beliefs, financial resources, co-morbidities, social support as well as clinicians’ attitudes.¹⁶ Therefore, it is not clear whether the impact of such interventions, or lack thereof, is due to one of its

specific program components or an interplay between them. Another limitation is that this sample is from an urban city and findings may not be applicable to rural areas or areas with mostly non-Black population.

During 2005–2008, 53.5% of adults with diagnosed diabetes met the American Diabetes Association (ADA) goal of HbA_{1c} control (<7%) and 51.8% of them met the goal of blood pressure control.³³ These health metrics are short of meeting the *Healthy People 2020* goals of 58.9% in glycemic control and 57.0% in blood pressure control.³⁴ In order to fulfill the goal, new models of health care should be examined and employed. Based on evidence that only studies with regular patient reinforcement and longer follow-up are likely to improve blood

We found that the mean HbA_{1c} of patients with education was lower than patients without education after two years of observation.

sugar control,^{35,36} non-professional peer support programs have been suggested as an innovative approach in reducing HbA_{1c} as such models provide ongoing support for diabetes self-management.^{37–39} This is not surprising as in group interventions patients create a support environment for behavior change.⁴⁰ While our study had a relatively long follow-up of 3 years, the education sessions in it were administered without regular reinforcement. Given published literature suggesting that Black diabetic patients could rely more heavily on peer social networks to manage their disease than those who were White,⁴¹ future research should assess how to employ patients’ natural social support network of friends and relatives as a motivational support pillar for behavior change.^{42,43} Some health plans have already successfully incorporated such new health delivery models for patient activation in their practice.⁴⁴

CONCLUSION

As one of the most prevalent chronic diseases in the United States, diabetes requires long-term, continual health care to control blood glucose and to reduce the risk of long-term complications. Our study warrants a special emphasis on the behavior of the patient and brings special attention to disease management programs that empower Black patients and focus on personal responsibility. Although our study reports positive results, it poses new questions as to what type of intervention is both effective in lowering

Table 3. Impact of education on change in HbA_{1c} (%) at 24 months from baseline (N=823)

| | HbA _{1c} Change from Baseline (%) | P |
|-----------------------------|--|-----|
| Reference: no education | | |
| Physician/patient education | .06 | .90 |
| Patient education | -.12 ^a | .06 |
| Physician education | -.42 | .24 |
| Insulin user | .30 | .19 |
| BP control | -.08 | .72 |
| Male | .09 | .68 |
| Age | -.004 | .72 |
| Black race | .56 | .13 |
| Smoking | -.23 | .49 |

^a Statistically significant at .10 level.

Table 4. Time to event analysis of physician and patient education on time to glycemic control at 24 months from baseline (N=823)

| | Hazard Ratio | P |
|-----------------------------|-------------------|--------|
| Reference: no education | | |
| Physician/patient education | .98 | .96 |
| Patient education | 1.06 ^b | .06 |
| Physician education | 1.35 | .2 |
| Insulin user | 2.50 ^a | <.0001 |
| BP control | .67 | .01 |
| Male | 1.23 | .2 |
| Age | .99 | .23 |
| Black race | 1.11 | .7 |
| Smoking | .68 ^b | .09 |

^a Statistically significant at .05 level.

^b Statistically significant at .10 level.

blood glucose and translatable to a new model of healthcare delivery, such as Accountable Care Organizations.⁴⁵

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