Diabetes in Urban African-Americans. XVI. Overcoming Clinical Inertia Improves Glycemic Control in Patients With Type 2 Diabetes

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OBJECTIVE — Diabetes care can be limited by clinical inertia—failure of the provider to intensify therapy when glucose levels are high. Although disease management programs have been proposed as a means to improve diabetes care, there are few studies examining their effectiveness in patient populations that have traditionally been underserved. We examined the impact of our management program in the Grady Diabetes Unit, which provides care primarily to urban African-American patients with type 2 diabetes.

RESEARCH DESIGN AND METHODS — We assessed glycemic outcomes in patients with type 2 diabetes who had an intake evaluation between 1992 and 1996 and who were identified on the basis of compliance with keeping the recommended number of return visits. For 698 patients, we analyzed changes in HbA<sub>1c</sub> values between baseline and follow-up visits at 6 and 12 months, and the proportion of patients achieving a target value of ≤7.0% at 12 months. Since a greater emphasis on therapeutic intensification began in 1995, we also compared HbA<sub>1c</sub> values and clinical management in 1995–1996 with that of 1992–1994.

RESULTS — HbA<sub>1c</sub>, averaged 9.3% on presentation. After 12 months of care, HbA<sub>1c</sub>, values averaged 8.2, 8.4, 8.3, 7.7, and 7.3% for the 1992–1996 cohorts, respectively, and were significantly lower compared with values on presentation (P < 0.0025); the average fall in HbA<sub>1c</sub>, was 1.4%. The percentage of patients achieving a target HbA<sub>1c</sub>, ≤7.0% improved progressively from 1993 to 1996, with 57% of the patients attaining this goal in 1996. Mean HbA<sub>1c</sub>, after 12 months was 7.6% in 1995–1996, significantly improved over the level of 8.4% in 1992–1994 (P < 0.0001). HbA<sub>1c</sub>, levels after 12 months of care were lower in 1995–1996 versus 1992–1994, whether patients were managed with diet alone, oral agents, or insulin (P < 0.02). Improved HbA<sub>1c</sub>, in 1995–1996 versus 1992–1994 was associated with increased use of pharmacologic therapy.

CONCLUSIONS — Structured programs can improve glycemic control in urban African-Americans with diabetes. Self-examination of performance focused on overcoming clinical inertia is essential to progressive upgrading of care.

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Abbreviations: ANOVA, analysis of variance.

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

Recent clinical trials have confirmed that optimizing glycemic control is critical to reducing the risk of onset and progression of the microvascular complications of diabetes (1–4). Therefore, together with ancillary measures that have been shown to favorably alter the course of diabetic complications (5–8), aiming for the best possible control of blood glucose must now be considered a primary goal of disease management.

With evidence that control of blood glucose is essential to improve microvascular outcomes in diabetes, attention must now turn to developing strategies that can improve glycemic control in everyday practice, and particularly among populations at high risk for diabetic complications. The need to design and test methods that lead to improved metabolic control in the general practice setting has become more urgent with the realization that patients often do not receive care that meets national standards (9–12). While diabetes treatment in primary care sites may not meet guidelines for process measures such as ordering HbA<sub>1c</sub>, measurements, management in specialized diabetes units may have shortcomings as well (13,14). We identify such deficiencies in management as “clinical inertia”—failure to perform a needed service or make a change in treatment when the health status of the patient indicates that such action is necessary.

Structured diabetes management programs, which typically incorporate elements of patient education, use of nurse case managers, and treatment algorithms to guide therapeutic decisions, have been shown to lead to reductions in HbA<sub>1c</sub>, and represent a promising method of overcoming clinical inertia (15–17). However, there is little experience with the application of structured diabetes treatment programs in underserved or minority populations, who tend to have poor glycemic control and high rates of diabetic complications (18,19). Moreover, in light of the recent U.K. Prospective Diabetes Study demonstrating deterioration of glycemic control over time,
periodic monitoring of outcomes followed by programmatic changes directed at overcoming clinical inertia may be necessary if reductions in hyperglycemia are to be sustained (4). Therefore, to examine the effectiveness of a diabetes management program in an urban population with type 2 diabetes, and to evaluate the impact of an initiative geared toward emphasizing greater intensification of therapy, we analyzed baseline and follow-up HbA1c levels in patients seen at the Grady Diabetes Unit between 1992 and 1996.

RESEARCH DESIGN AND METHODS

Setting and treatment paradigm

The patients seen in the Grady Diabetes Unit are predominantly African-American, with high rates of retinopathy, nephropathy, and poverty and poor functional health literacy (20–22). The Diabetes Unit treatment program has included components that are now recognized as important elements of chronic disease management models (23), and a preliminary analysis of the effectiveness of the program has been reported previously (20).

An intensive 6-month diabetes educational program is offered to all patients presenting for treatment. After the intake visit, patients are requested to return at 1, 2, and 4 weeks, and then again at 2, 4, and 6 months (i.e., six return visits within 6 months). A follow-up visit at ~1 year is also requested, and generally at least one additional visit between 6 and 12 months. HbA1c measurements are typically obtained at the initial and 2-, 4-, 6-, and 12-month visits.

The Unit is staffed by nurse case managers, dietitians, podiatrists, and endocrinologists. Patients are first evaluated by the nurse managers, and then by endocrinologists, who make final modifications in therapy if needed. With each visit, self-management principles are reinforced, and medications are adjusted according to a stepped-care algorithm. The algorithm in use between 1992 and 1996 emphasized lifestyle changes during the first 2 months of therapy, with pharmacologic agents tapered or discontinued in those who were not ketosis prone or did not have symptomatic hyperglycemia. If glycemic targets (HbA1c ≤7.0%) were not being met within the first 2 months, pharmacologic agents were to be reinstated or advanced. Because metformin was not available at Grady during that period, sulfonylureas were usually instituted first, followed by the addition of bedtime insulin and then a switch to multiple daily injections of insulin (14,20). Intensification was based on either the fasting or random glucose that was generally available at the time of the visit; the utility of this information as a basis for advancing therapy has been reported previously (24).

With the exception of the increased emphasis on intensification of therapy, the management and educational program did not change between 1992 and 1996. Recognizing the potential importance of clinical inertia, beginning in 1995, we initiated a quality improvement program that placed an increased emphasis on intensification of therapy. During this process of self-evaluation, we determined the proportion of patients in whom therapy was intensified and evaluated perceived provider barriers to advancing treatment (14,25).

Diabetes registry

A computerized registry of patients seen at the Diabetes Unit, first established in April 1991, has allowed us to track outcomes. Data include patient demographics (age, sex, ethnicity), BMI (in kilograms per square meter), dates of initial and follow-up visits, disease characteristics (duration of diagnosed diabetes, diabetes classification), type of therapy, and laboratory values.

Selection of patients for analysis

Patients were selected for analysis from our registry according to the following criteria: 1) diagnosis of type 2 diabetes; 2) initial visits to the Diabetes Unit between 1 January 1992 and 31 December 1996; and 3) return for scheduled follow-up visits at 2, 4, 6, and 12 months. Patients were classified as having type 2 diabetes on their intake visit based on classical clinical features (26). By limiting the data set to those who kept follow-up visits at 2, 4, 6, and 12 months, we selected patients who not only had HbA1c values available, but who also kept the required number of return visits. Therefore, available data permitted evaluation of five cohorts, defined by the year of initial visit (1992–1996).

Data analysis

Average HbA1c values were calculated for the intake and 6- and 12-month follow-up visits. A 6- or 12-month visit was considered to have occurred if the patient returned at 26 ± 5 or 52 ± 10 weeks, respectively, after the initial visit. We also assessed the percentage of patients achieving an HbA1c level ≤7.0% by the 12-month visit. Between-year differences in HbA1c and other variables were tested using analysis of variance (ANOVA), and within-year differences using ANOVA with repeated measures (StatView; SAS Institute, Cary, NC). Because in 1995 we began to monitor provider adherence with treatment protocols, measure the proportion of patients in whom therapy was intensified, and assess provider barriers to advancing therapy (14,25), average HbA1c values from 1995 and 1996 were compared with those from 1992–1994. Finally, to further understand the basis for improvements in HbA1c, and to evaluate whether an increased emphasis on intensification was translated into changes in treatment, we examined patterns of therapy and doses of oral agents and insulin used at follow-up visits. Changes in dietary therapy were assessed using χ² for trend (27).

RESULTS

Patient characteristics

Between January 1992 and December 1996, 4,461 new patient visits to the Diabetes Unit were recorded in the registry. Of these, 3,912 (88%) were individuals classified as having type 2 diabetes. Some 698 individuals met the additional selection criteria of having visits at 2, 4, 6, and 12 months after their initial presentation to the Unit. These 698 patients had a mean age of 57 years, a duration of diagnosed diabetes of 5.3 years, an HbA1c of 9.3%, and a BMI of 32.0 kg/m² (Table 1); 66% percent of the patients were female, and the majority were African-American. An average of 6.5 visits occurred during the first 6 months of follow-up, indicating that the selection criteria that were applied likely identified those who completed the self-management training components of the program; patients had an average of 8.6 return visits for the full 12-month period. The characteristics of this subset of 698 patients were not statistically different from those of the 3,214 patients who did not meet the criteria because of return visit behavior; the only exception was that the mean age (52 years) of those who did not meet this selection criterion was statistically lower (P < 0.0001) than that of the 698 who did (Table 1). No statistical differences (ANOVA) were present for mean age, BMI, duration of diagnosed diabetes, or sex/ethnic makeup from year to year.
Overcoming clinical inertia in type 2 diabetes

Table 1—Patient characteristics at the time of first visit to the Grady Diabetes Unit, according to return visit behavior, 1992–1996

<table>
<thead>
<tr>
<th>Type 2 diabetic patients meeting return visit criteria</th>
<th>Type 2 diabetic patients not meeting return visit criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>698</td>
</tr>
<tr>
<td>Age (years)</td>
<td>57.3 ± 0.4</td>
</tr>
<tr>
<td>Duration of diabetes (years)</td>
<td>5.3 ± 0.3</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>9.3 ± 0.1</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>32.0 ± 0.3</td>
</tr>
<tr>
<td>Female (%)</td>
<td>66</td>
</tr>
<tr>
<td>Ethnicity (%)</td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>88.4</td>
</tr>
<tr>
<td>Caucasian</td>
<td>8.7</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1.0</td>
</tr>
<tr>
<td>Other</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Data are means ± SEM unless indicated otherwise. *P < 0.0001 compared with those meeting selection criteria.

Changes in average HbA1c
Mean HbA1c values for all cohorts combined were 9.3% at intake, 7.8% at 6 months, and 8.1% at 12 months. The mean reduction in HbA1c at 12 months was 1.4%. Significant decreases from baseline were seen at 6 and 12 months (Fig. 1A) for each year (P = 0.0025), and average 12-month HbA1c values differed significantly across the five cohorts (P = 0.0002). Subsequent to our greater emphasis on intensifying therapy that began in 1995, average 12-month HbA1c values were lower in 1995 (7.7%) and 1996 (7.3%) than in the previous 3 years. A separate analysis comparing combined values for 1995–1996 with those in 1992–1994 (Fig. 1B) showed that HbA1c levels were significantly lower in 1995–1996 compared with 1992–1994 at both 6 months (7.6 vs. 8.0%, P = 0.018) and 12 months (7.6 vs. 8.4%, P < 0.0001). Since no significant differences at initial presentation were detected for age, sex, duration of diagnosed disease, or HbA1c between patients seen during 1992–1994 versus those in 1995–1996, the improved HbA1c values during the latter 2 years likely reflect more vigorous attempts to control glucose levels.

Proportion achieving HbA1c ≤7.0%
For all 698 patients who had first visits to the Diabetes Unit between 1992 and 1996, 19% had HbA1c ≤7.0% on presentation, and 37% overall achieved an HbA1c at or below the target value by the 12-month follow-up visit. Beginning in 1993, the percentage of patients achieving this target value rose with each subsequent year, so that for those with first visits during 1996, 57% had reached an HbA1c of ≤7.0% at 12 months (Fig. 2). Although cohorts presenting in 1992–1994 and 1995–1996 were similar with respect to the percentage of patients presenting with an HbA1c ≤7.0%, 46% of those seen during 1995–1996 had achieved a 12-month HbA1c of ≤7.0%, versus 31% of those with first visits in 1992–1994 (Fig. 2).

Changes in BMI
There was a small but significant increase in BMI by 12 months, from 31.9 to 32.2 kg/m² (P = 0.0025) for all cohorts combined. The increase in BMI was comparable (P = 0.31) in 1992–1994 and 1995–1996 (12-month BMI 31.9 vs. 32.9 kg/m²).

Therapeutic management
HbA1c levels after 12 months of follow-up care were improved in 1995–1996 compared with 1992–1994, whether patients were being managed with diet alone, oral agents, or insulin (Fig. 3). In 1995–1996, patients managed with diet alone had an average HbA1c of 6.3%, those on oral agents had a value of 7.6%, and those on insulin had an HbA1c of 8.3%—each significantly improved compared with patients in 1992–1994 (each P < 0.02).

To better understand the basis for the improved HbA1c outcomes in 1995–1996 relative to 1992–1994, we analyzed the treatment strategies used during the two time periods (Fig. 4). At presentation in 1992–1994, 25% of patients were on diet alone, 34% were on oral agents, 2% were using oral agents and insulin in combination, and 38% were using insulin alone. With our stepped-care program, diet was emphasized initially, and in 1992–1994, the proportion of patients managed with diet alone increased to 49% at 2 months. If metabolic control was unsatisfactory after 2 months, therapy was intensified, and in 1992–1994, the proportion of patients managed with diet alone decreased to 43% at 4 months, 38% at 6 months, and 32% at 12 months (P < 0.005, χ² for trend 2–12 months). Thus, attempts to deintensify therapy led to substantial use of diet alone at 2 months, followed by progressive increase in use of pharmacologic therapy thereafter. Although the process of attempted deintensification followed by
intensification of therapy was generally similar in 1995–1996, fewer patients were managed with diet alone (35% at 2 months, decreasing to 31% at 4 months, 29% at 6 months, and 29% at 12 months), and there was less change from 2 to 12 months \((P < 0.10, \chi^2\) for trend). The apparent pattern of earlier use of pharmacologic therapy in 1995–1996 may have contributed to improved follow-up \(\text{HbA}_1c\) levels during this period.

We also evaluated dosage of sulfonylureas and insulin prescribed at 12 months. For both oral agents and insulin, there was a significant trend for increased dosage over the 5 years of study \((P < 0.03, \text{not shown})\). Thus, although differences in average dosage were small \((e.g., 14\ mg\ of\ sulfonylureas\ in\ 1995–1996\ vs.\ 11\ mg\ in\ 1992–1994)\), use of higher doses of therapeutic agents may also have contributed to improved follow-up \(\text{HbA}_1c\) levels during this period.

**Overcoming clinical inertia**

Recognizing the potential importance of clinical inertia, we began in 1995 to assess provider attitudes regarding intensification and to measure the proportion of patients in whom therapy was advanced \((14,25)\); an emphasis on overcoming clinical inertia may have contributed to improved \(\text{HbA}_1c\) levels after 12 months of follow-up care. Our approach is shown schematically in Fig. 5. We stressed to providers that patients should remain in a treatment category (or have therapy stepped down) only if their control is good. With such a strategy, the residual patients in each treatment category should be responders, while the nonresponders in each group are stepped to the next treatment category, where they may be expected to be more responsive.

Figure 6 shows the relationship between 12-month \(\text{HbA}_1c\) levels (this study) and intensification of therapy in patients with fasting plasma glucose \(>140\ mg/dl\) (all type 2 patients in our registry). Rates of intensification of 30–55% in 1992–1994 were associated with average 12-month \(\text{HbA}_1c\) levels ranging from 8.2 to 8.5%. However, rates of intensification of 60–65% in 1995 and 1996 were associated with improved 12-month \(\text{HbA}_1c\) levels of 7.7 and 7.3%, respectively \((25)\).

**CONCLUSIONS** — Structured diabetes management programs have been shown to be effective in lowering \(\text{HbA}_1c\) levels. However, there is little knowledge of the effectiveness of such programs in underserved or minority populations, which tend to have poor glycemic control and high rates of diabetic complications \((15–19)\). Therefore, we conducted a 5-year retrospective analysis of the impact of a disease management program on \(\text{HbA}_1c\) levels in patients who presented to the Grady Diabetes Unit in 1992–1996 and kept scheduled return appointments. The analysis reported here demonstrates that a structured diabetes program, combined with an emphasis on overcoming clinical inertia, can improve glycemic control in an urban underserved population.

For these 698 patients who adhered to the recommended schedule of return visits, a significant reduction in \(\text{HbA}_1c\) occurred in each year analyzed. When all cohorts were combined, an average reduction in \(\text{HbA}_1c\) of 1.4% was detected by 1 year of follow-up care. Moreover, almost 40% of all 698 patients achieved a target \(\text{HbA}_1c\) of \(\leq 7.0\%\) by 12 months. Beginning in 1993, the percentage of patients who were successfully treated to target increased, and nearly 60% of those who had initial visits in 1996 had an \(\text{HbA}_1c\) \(\leq 7.0\%\) after 12 months of care.
Improvements in 12-month HbA₁c levels in individuals with initial visits in 1995–1996 could not be attributed to baseline patient demographics (age, sex, ethnic composition), broad disease characteristics (duration of diagnosis and diabetes classification), or baseline HbA₁c levels, since significant differences were not present between the two time periods. Accordingly, it seems likely that the significantly lower HbA₁c achieved at 12 months in 1995–1996 reflects more consistent application of disease management protocols. Supporting this hypothesis are the findings of improved HbA₁c values in each treatment category, earlier use and higher doses of pharmacologic agents, and increased provider adherence as measured by intensification of therapy in 1995 and 1996.

Because metformin was not available at Grady until 1997, the improvements in glucose control were accomplished with the use of lifestyle modification, sulfonylureas, and insulin. Patients who were being managed with nonpharmacologic approaches had lower HbA₁c levels than patients managed with oral agents or insulin after 12 months of follow-up care, consistent with what has been reported by others (19). Since the proportion of patients on dietary therapy alone increased at 12 months, management paradigms should include provisions for dual application of stepped care, i.e., a step down as well as a step up of therapy.

While this analysis cannot distinguish which aspect of our program had the greatest impact on HbA₁c, an important component was the use of a staged treatment algorithm. Because protocols are established in different patient care settings, it will be important for providers to appreciate both the process and potential impact of effective stepped care. If stepped care is applied successfully, only those patients who have responded well should be maintained in a given treatment category. Those without a satisfactory outcome should be moved either to a higher dose of pharmacologic agent or to a different class of agent (e.g., sulfonylurea to insulin), where further improvements in HbA₁c might occur.

Our findings should be considered in the context of the broad problem of provider nonadherence to protocols and guidelines. Recent reports document that providers often fail to institute effective pharmacotherapy for patients with hyperlipidemia (28) or hypertension (29), and prior analysis of our own care indicates that providers may often fail to advance therapy appropriately even in a specialized diabetes unit (14,25). Because of provider concerns about factors such as patient noncompliance and risk of hypoglycemia, it should be expected that therapy will not be intensified in all patients with elevated glucose levels. However, we have reported previously that a programmatic emphasis on barriers to intensification can facilitate better provider adherence (25). If diabetes care is to be improved, it is likely that staged management protocols must be complemented by changes in the health care system (23), such as partnering primary care physicians with those more experienced in diabetes management (23,30). Regardless of the approach that is undertaken, periodic self-evaluation of program effectiveness will be necessary to ensure that improvement is sustained.

Although we are encouraged by our progress, our study has limitations and should be viewed as only a preliminary assessment of the success of our program. An analysis of HbA₁c levels beyond 1 year has not yet been undertaken in this subset of patients, so whether the management paradigms result in sustained glycemic control beyond 12 months needs to be established. Such an analysis will be particularly...
important in light of the recent U.K. Prospective Diabetes Study findings that glycemic control tends to deteriorate over time (4). The impact of our program on other metabolic parameters, such as lipids and blood pressure, and on the prevention of complications, also needs to be evaluated.

The selection of patients for analysis was based on documentation that they kept the recommended number of appointments, resulting in a subset that was substantial (698 patients), but still small relative to the entire set of patients with type 2 diabetes contained in our registry. A preliminary analysis of HbA1c values in type 2 diabetic patients who did keep a 12-month follow-up appointment indicates that missing return visits during the first 6 months of our program is associated with higher HbA1c values at 1 year (31). While those who met our selection criteria were slightly older than those who did not, no other differences in demographic features were found. Nonetheless, our analysis may be biased toward those who were the most compliant with treatment in 1992–1996.

Grady patients are typical of inner-city populations, where obesity and poverty are high and literacy is low. The main strengths of this report are the demonstration that national standards of glycemic control can be attained in disadvantaged urban patients at high risk for diabetic complications and the finding that a focus on overcoming clinical inertia may be critical to improving care. Diabetes management protocols that include an emphasis on overcoming clinical inertia may be necessary if glucose control is to be sustained over time in populations with a high burden of disease. We believe that further testing of these paradigms in such groups should be a high priority for future studies.

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References


