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Clinical Inertia Contributes to Poor Diabetes Control in a Primary Care Setting

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Purpose

The purpose of this study was to determine whether “clinical inertia”—inadequate intensification of therapy by the provider—could contribute to high A1C levels in patients with type 2 diabetes managed in a primary care site.

Methods

In a prospective observational study, management was compared in the Medical Clinic, a primary care site supervised by general internal medicine faculty, and the Diabetes Clinic, a specialty site supervised by endocrinologists. These municipal hospital clinics serve a common population that is largely African American, poor, and uninsured.

Results

Four hundred thirty-eight African American patients in the Medical Clinic and 2157 in the Diabetes Clinic were similar in average age, diabetes duration, body mass index, and gender, but A1C averaged 8.6% in the Medical Clinic versus 7.7% in the Diabetes Clinic ($P < .0001$). Use of pharmacotherapy was less intensive in the Medical Clinic (less use of insulin), and when patients had elevated glucose levels during clinic visits, therapy was less than half as likely to be advanced in the Medical Clinic compared to the Diabetes Clinic ($P < .0001$). Intensification rates were lower in the Medical Clinic regardless of type of therapy ($P < .0001$), and intensification of therapy was independently associated with improvement in A1C ($P < .001$).

Conclusions

Medical Clinic patients had worse glycemic control, were less likely to be treated with insulin, and were less likely to have their therapy intensified if glucose levels were elevated. To improve diabetes management and glycemic control nationwide, physicians in training and generalists must learn to overcome clinical inertia, to intensify therapy when appropriate, and to use insulin when clinically indicated.

Diabetes care in the United States now confronts major challenges: we are in the middle of a pandemic, with lifetime risk close to 1 in 3 Americans,¹ and our management is failing, with average A1C rising from 7.8% in the Third National Health and Nutrition Examination Survey (NHANES III) in 1988 to 1994 to 8.1% in NHANES 1999 to 2000.² Although effective care can improve diabetes outcomes,³⁻⁵ most Americans with diabetes are managed predominantly in primary care sites, where management often falls short of American Diabetes Association (ADA) national standards. In many practices, measurement of A1C, dilated eye examinations, and foot examinations are infrequent, and associated hypertension is treated less aggressively than recommended⁶⁻⁸; a recent analysis indicated that ADA standards of care were met less frequently in a primary care clinic than in a diabetes clinic.⁹ Thus, although intensive management should be cost-effective,¹⁰ care is often substandard.

Since ADA standards of care can be met in diabetes specialty sites,^{9,11,12} it is important to determine whether deficiencies in outcomes of treatment can be attributed to underlying differences in clinical decision making. Appropriate clinical decision making is essential for the management of disorders such as diabetes, hypertension, and dyslipidemia, since control of these problems depends predominantly on health care provider decisions to intensify therapy or not. Unfortunately, "clinical inertia"—failure of providers to intensify therapy when appropriate¹³—is a common problem in management of diabetes,^{14,15} hypertension,^{16,17} and dyslipidemia.¹⁸

The purpose of this study was to determine whether clinical inertia contributes to high A1C levels in patients

with type 2 diabetes managed in the primary care setting. It was hypothesized that A1C levels would be higher in a primary care site than in a diabetes specialty care site and that high A1C levels in the primary care site would be associated with greater clinical inertia. These hypotheses were tested in a prospective observational study of clinical decision making in the Grady Medical Clinic, a primary care site, and the Grady Diabetes Clinic. Both sites are components of a major academic medical center that serves a common population in a municipal hospital setting, and both sites have availability of health care team resources such as dietitians and health educators.

Methods

Study Sites

Subjects were recruited from 2 sites, the Medical Clinic and the Diabetes Clinic, within the Grady Health System. Data were collected as part of baseline evaluations for the Improving Primary Care for African-Americans with Diabetes (IPCAAD) study. The IPCAAD study is a randomized, controlled trial to determine whether interventions aimed at provider behavior can improve diabetes control¹⁹ and was approved by the Emory University Institutional Review Board for conduct without informed consent forms. The Medical Clinic is Grady's largest site of primary care, with roughly 60 000 patient visits per year, and is staffed by residents, nurse practitioners, physician assistants, and attending physicians. Approximately 30% of the patients have diabetes, and support for their management is available from pharmacists, nutritionists, health educators, and social workers. About two thirds of the patients are cared for by internal medicine residents who attend the clinic one-half day per week throughout their 3 years of postgraduate training. During each visit, such patients are seen first by a resident (primary provider) who makes initial therapeutic recommendations and then by a faculty member who finalizes the plan for management. The present study focuses on patients of residents supervised by Division of General Medicine faculty from Emory University School of Medicine; the 170 residents had an average age of 28 years and were 63% male, 67% non-Hispanic White, and 10% African American.

The management of patients in the Grady Diabetes Clinic has been described in detail previously.^{14,20,21}

During each visit, patients are seen first by nurses or nurse-practitioners (primary providers) who make initial therapeutic recommendations and then by a Division of Endocrinology faculty endocrinologist who finalizes the plan for management; the 12 nurse-providers had an average age of 40 years and were predominantly female and African American.

Patient Identification

Study subjects were all individuals presenting for follow-up visits to the Medical Clinic or Diabetes Clinic between July 1, 1999, and December 31, 1999; had type 2 diabetes based on typical clinical criteria; had measurement of capillary or plasma glucose during the visit and available to the health care provider during the visit; and had data available on incoming and recommended outgoing medications. If a patient had more than 1 visit or A1C measurement during the time period, only the more recent data were used. In the Medical Clinic, patients were directed to research assistants who determined if they met criteria for type 2 diabetes, obtained baseline demographic information, recorded the time since the last meal, and measured capillary glucose. These data, together with information abstracted from the patient encounter form at the end of the visit, were entered into a registry. In the Diabetes Clinic, plasma glucose was determined on site. To evaluate clinic-specific characteristics, only patients who were not receiving concurrent care in the Medical Clinic and the Diabetes Clinic were considered; to evaluate provider-specific characteristics, all patients seen by each provider in the Medical Clinic or the Diabetes Clinic were considered, whether or not those patients came to the other clinic as well.

Measurements

Capillary glucose was measured with the MediSense Precision PCx Point-of-Care System (Abbott Laboratories, Bedford, Mass); output values correspond to plasma glucose levels.²² Plasma glucose was measured with a Hitachi 717 (Indianapolis, Ind). For patients in both clinics, A1C was measured using National Glycohemoglobin Standardization Program–certified instrumentation from Boehringer Mannheim Corporation (Hitachi 717, Indianapolis, Ind), with a normal range of 3.5% to 6.0%.

Data Analysis

To assess clinical inertia, the extent to which diabetes pharmacotherapy was intensified when glucose levels were high was determined. As an indicator of need for intensification, the level of glucose determined at the time of the visit was used. Such values are proxies for the combination of home glucose monitoring values, A1C levels,²³ and other laboratory determinations, and such an approach has been used in other studies^{14,21,24,25}; at Grady, diabetes management is often guided by such determinations²⁶ and is associated with little problem from severe hypoglycemia.¹² Although glucose monitors and measuring strips are made available to patients at reduced cost and instruction in glucose monitoring is routine in both the Medical Clinic and the Diabetes Clinic, home glucose monitoring data are frequently not available in the Grady setting.²⁴

Patients were stratified according to random glucose levels measured during the visit; glucose was defined as “random” if determinations were less than 5 hours since the previous meal and “fasting” otherwise. To simplify the analysis, 25 mg/dL was added to fasting glucose levels to render them comparable to random glucose levels; it has been found that the relationship between A1C and random glucose levels is almost identical to the relationship between A1C and fasting glucose + 25 mg/dL.²⁶ Intensification of diabetes therapy was considered indicated if the random plasma or capillary glucose exceeded 150 mg/dL; such a level is likely to be associated with A1C >7%.²⁵ Use of therapy was categorized as diet alone, diet plus oral agents (“oral agents”), and diet plus insulin alone or in combination with oral agents (“insulin”).

Intensification of diabetes therapy during a patient visit was defined as an increase in the dosage or number of hypoglycemic agents that the patient was taking. Frequency of intensification was expressed as the percentage of poorly controlled patients who had therapy intensified. Intensification of diabetes therapy was examined both clinicwide and as a measure of management by the individual providers who saw each patient for the greatest number of visits within the study period.

It was hypothesized that (1) compared to the Diabetes Clinic, the Medical Clinic would be characterized by (a) higher A1C levels and (b) more clinical inertia (less frequent intensification of therapy in patients with high glucose levels). This hypothesis was tested by analysis of

variance, Student's *t* test, or χ^2 tests, as appropriate to compare the 2 clinics. It was also hypothesized that (2) across both clinics, providers with less clinical inertia (who intensified therapy more often) would have patients with lower A1C levels. This hypothesis was tested by using multivariate linear regression analysis to measure the relationship between the frequency of intensification by individual providers and the patterns of absolute A1C levels and change in A1C levels in their patients. Data are expressed as mean \pm SEM.

Results

Patients in the Medical Clinic ($n = 438$) and the Diabetes Clinic ($n = 2157$) who attended only these sites ("separate") were not significantly different in average age (63 vs 59 years), ethnicity (97% vs 93% African American), gender (76% vs 68% female), or diabetes duration (12 vs 10 years), although body mass index (BMI) was slightly higher in the Medical Clinic (34 vs 33 kg/m², $P < .01$). However, the average A1C was 8.6% in Medical Clinic patients compared to 7.7% in Diabetes Clinic patients ($P < .0001$). Use of diet alone and oral agents alone was somewhat higher in the Medical Clinic, but use of insulin was significantly less frequent in the Medical Clinic compared to the Diabetes Clinic (40% vs 55%, $P < .0001$). However, as shown in Figure 1, A1C levels in Medical Clinic patients were higher than those in Diabetes Clinic patients using each form of therapy: 7.3% versus 6.8% for patients managed with diet alone, 8.4% versus 7.2% for those using oral agents, and 9.3% versus 8.2% for those using insulin, all $P < .05$.

Provider behavior when glucose levels were elevated during the visit was then examined, considering all patient visits to either site. When random glucose levels exceeded 150 mg/dL, therapy was much less likely to be advanced in the Medical Clinic as compared to the Diabetes Clinic (overall frequency of intensification 32% vs 65%, $P < .0001$), even though average A1C levels were higher in the Medical Clinic. As shown in Figure 2, intensification rates were lower in the Medical Clinic than in the Diabetes Clinic, regardless of the therapy patients were using: 36% versus 54% for patients managed with diet alone, 31% versus 49% for patients using oral agents, and 28% versus 75% for patients using insulin (all $P < .02$). As shown in Figure 3, the frequency of intensification of therapy was also uniformly lower

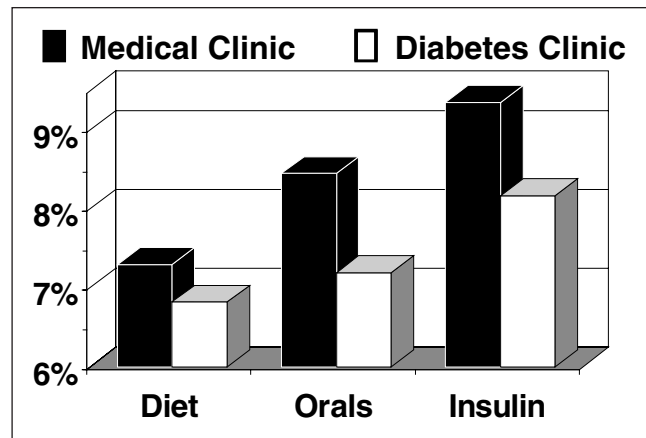


Figure 1. Average A1C in Medical Clinic and Diabetes Clinic patients with type 2 diabetes managed with diet alone, oral agents alone, or insulin (with or without oral agents).

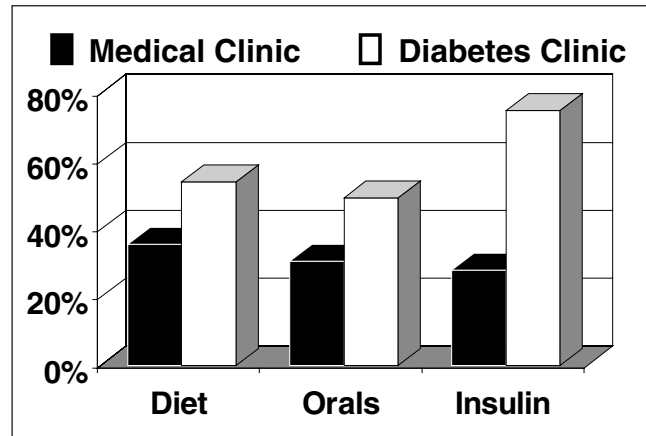


Figure 2. Frequency of intensification of therapy by providers (residents in the Grady Medical Clinic, nurses in the Diabetes Clinic) when patients had casual glucose levels exceeding 150 mg/dL at the index visit. There were 261 patients managed with diet alone, 824 patients using oral agents, and 1427 patients using insulin alone or in combination with oral agents.

in the Medical Clinic than in the Diabetes Clinic when patients were stratified according to their glucose levels: 24% versus 47% when glucose was 151 to 200 mg/dL, 32% versus 74% for glucose 201 to 250 mg/dL, 37% versus 84% for glucose 251 to 300 mg/dL, and 52% versus 91% for glucose >300 mg/dL (all $P < .0001$).

To examine the impact of individual provider behavior on A1C levels, we calculated for each provider the average frequency of intensification when any patients seen by her or him had glucose levels >150 mg/dL; the average intensification frequency was $33\% \pm 2.6\%$ in the Medical Clinic but $65\% \pm 7\%$ in the Diabetes Clinic,

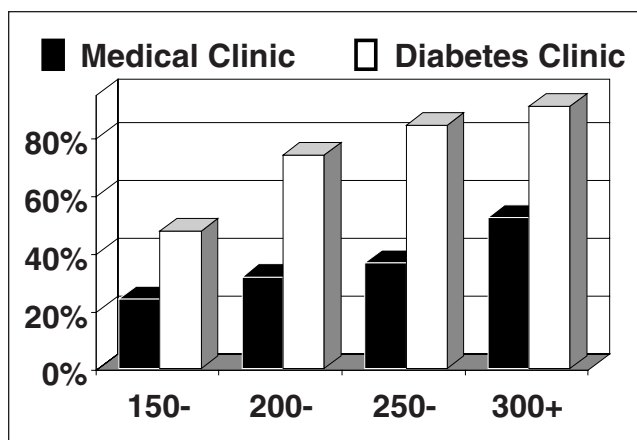


Figure 3. Frequency of intensification of therapy by providers (residents in the Grady Medical Clinic, nurses in the Diabetes Clinic) when patients had different ranges of casual glucose levels at the index visit.

$P < .0003$. Multiple linear regression analysis was then used to determine whether individual providers who intensified more often tended to have patients with lower A1C levels, considering only those patients who were followed principally by that provider and who received diabetes management only in that clinic. For the 306 Medical Clinic patients and 2035 Diabetes Clinic patients who had at least 1 A1C measurement and all other information available within the 6-month study period, Table 1 shows that older age and higher BMI were associated with lower A1C levels, while use of any pharmacologic therapy was associated with higher A1C levels. After adjusting for age, BMI, gender, race, duration of diabetes, and use of oral agents or insulin, the tendency of individual providers to intensify therapy more often was independently associated with lower A1C levels in his or her patients ($P < .0001$). On average, a 10% higher frequency of intensification was associated with a 0.15% lower level of A1C; the ~30% higher absolute frequency of intensification in the Diabetes Clinic could account for A1C levels being approximately 0.45% lower in the Diabetes Clinic.

Multiple linear regression analysis was also used to determine how much the A1C tended to fall in response to a single episode of intensification of therapy. A subset of 575 Diabetes Clinic patients was examined who had measurement of A1C at both 1 clinic visit and at a subsequent visit at least 60 days later. Compared to the full set of patients (above), they were also predominantly African American (94%) but were somewhat older (aver-

Table 1

Multivariate Linear Regression HbA1C as Outcome of Interest (n = 2341)

Variable	Coefficient	P Value
Age	-0.038	<.001
Duration	0.010	.067
Body mass index	-0.012	.027
Therapy with insulin	1.229	<.0001
Therapy with oral agents	0.394	.0025
Intensification, %	-0.015	<.0001

Multivariate linear regression analysis of A1C levels of patients in the Grady Medical Clinic and Diabetes Clinic as influenced independently by demographic and provider-related factors. Coefficients shown reflect analysis with respect to differences in 1 year of age, 1 year of known duration of diabetes, 1 kg/m² of body mass index, therapy with insulin or oral agents (yes = 1, no = 0 for each), and 10% greater frequency of provider tendency to intensify diabetes therapy when patients present with elevated glucose levels. Data are adjusted for differences in gender and racial/ethnic background as well (African American or not).

age 62 years), more likely to be female (70%), heavier (BMI 32.9), and had a longer duration of diabetes (11.5 years); their return visit averaged 99 days after their index visit. As shown in Table 2, A1C levels tended to fall over this period in older patients and to rise in patients with longer duration of diabetes, but the magnitude of these effects was modest. In contrast, a single episode of intensification of therapy was associated with an average 0.7% reduction in A1C levels.

Discussion

The findings show that in a large municipal hospital that is part of a major academic medical center, diabetes patients in a primary care clinic are similar to diabetes patients in a specialty clinic in demographics such as age, gender, duration of diabetes, and obesity, but the patients in the primary care clinic have higher glucose levels. Average A1C levels were 0.9% higher in Medical Clinic patients than in Diabetes Clinic patients, which puts the Medical Clinic patients at increased risk of development and progression of microvascular and macrovascular complications.^{3,5} The difference in glycemic control was associated with less frequent use of insulin in the primary care clinic and less frequent intensification of therapy when glucose levels were high.

Providers who tended to intensify therapy more often tended to have patients with lower A1C levels, and a single episode of intensification of therapy was independently associated with an average 0.7% improvement in A1C. The results in combination indicate that high glucose levels in patients with diabetes managed in primary care sites may be due in large part to inadequate use of pharmacologic therapy by their health care providers.

The high A1C levels in the Medical Clinic patients are consistent with a study of 600 patients in an Atlanta neighborhood health center in 1999, which found an average A1C of 8.5%,²⁴ with the median A1C of approximately 8.6% in patients in a large health maintenance organization (HMO) in Florida,²⁷ and with the average A1C of 8.4% in 735 insulin-treated patients in a large staff-model HMO in the northwestern United States.²⁸ Thus, although A1C levels in Medical Clinic patients are somewhat higher than average values in US adults found in the NHANES 1999-2000 (8.1%,²⁹ possibly reflecting the prevalence of poverty and low literacy in the Grady patient population^{20,30}) glucose control in the Medical Clinic is typical of that for many patients with type 2 diabetes.

Although assessment of diabetes management in any setting must recognize the importance of patient factors such as age, years of education, occupation, and literacy,^{31,32} as well as adherence to scheduled visits³¹ and prescribed medications,³³ the findings suggest that poor glucose control may also reflect a lack of intensification of pharmacologic therapy by providers. The failure of health care providers to intensify therapy when indicated is designated as clinical inertia,¹³ and the authors believe that clinical inertia is often the limiting factor in attaining standard-of-care goals. In support of this hypothesis, a quality improvement intervention aimed at overcoming clinical inertia in the Diabetes Clinic led to more frequent intensification of therapy, with improvement in A1C levels.²¹ Moreover, in the present study, the tendency of providers to intensify therapy more often was independently associated with lower A1C levels in their patients (Table 1), and intensification of therapy was independently associated with improvement in A1C levels at subsequent visits (Table 2). The hypothesis is also being tested through a randomized, controlled trial in the IPCAAD study.

Limitations of the study include the possibility that Medical Clinic patients have comorbid problems that

Table 2

Multiple Linear Regression Analysis of Change in A1C in Grady Diabetes Clinic Patients as Influenced Independently by Demographic and Provider-Related Factors

Variable	Coefficient	P Value
Age	-0.013	.019
Duration	0.014	.040
Body mass index	0.007	.377
Initial glucose	-0.001	.535
Intensification, yes/no	-0.677	<.0001

Multiple linear regression: change in A1C (n = 575), return visit average 99 days later. Coefficients shown reflect analysis with respect to differences in 1 year of age, 1 year of known duration of diabetes, 1 kg/m² of body mass index, 1 mg/dL in plasma glucose measured during the index visit, and whether diabetes therapy was intensified (yes = 1, no = 0).

either complicate the management of hyperglycemia or take up so much time during office visits that diabetes-related issues cannot be addressed properly. However, it has been found that the presence of comorbidities does not limit metabolic control in either Diabetes Clinic patients³⁴ or a neighborhood health center.³⁵ Intensification in the Medical Clinic might have been limited by problems with hypoglycemia, but such difficulties should be infrequent.¹² Providers in the Medical Clinic may have been fatigued, distracted by other medical problems, and/or inexperienced in diabetes management, but it seems likely that differences in attention, focus, and experience would have been captured under the assessment of clinical inertia in the present study.

The differences in frequency of intensification between the Medical Clinic and Diabetes Clinic do not fully account for the differences in A1C levels in the 2 sites, indicating that there must also be contributions from factors that could not be measured. For example, it seems likely that A1C levels would be influenced by amount as well as frequency of intensification of therapy.³⁶ The patient education program in the Diabetes Clinic involves the entire health care team much more routinely than that in the Medical Clinic, but a recent study showed that a focus on patient education alone without emphasis on use of pharmacotherapy may produce only modest improvements in A1C levels.³⁷ It is also possible that Diabetes Clinic patients had been fol-

lowed longer and/or benefited from that site's diabetes skills, but it seems likely that such skills would be manifest as less clinical inertia, as shown in the present study.

The possibility cannot be ruled out that elevated A1C levels in Medical Clinic patients are due in part to differences in patient adherence or clinic structure. Diabetes Clinic patients might be more highly motivated, but their socioeconomic status^{20,38} and clinical demographics were comparable. Moreover, while the Diabetes Clinic structure emphasizes adherence, only 39% of Diabetes Clinic patients reported home glucose monitoring results during the study period—relatively low adherence—and the Diabetes Clinic structure did not lead to low A1C levels until implementation of an intervention aimed at overcoming clinical inertia.²¹ Thus, it seems unlikely that differences in A1C levels are due largely to unmeasured differences in patient adherence or clinic structure.

Finally, the basis for higher clinical inertia in the Medical Clinic is not known. Diabetes Clinic providers are likely to be better informed about different glucose-lowering medications, but the options at Grady were limited (only sulfonylureas, metformin, and insulin) and the same at both sites. Rapid A1C determinations are routine in the Diabetes Clinic, but such availability has only modest impact on A1C levels in either primary care or specialty sites.^{24,39} It is possible that the need to deal with other disorders during Medical Clinic visits limits the opportunity to focus on diabetes; although diabetes should receive attention during every visit, it has been found that an average of only 5 minutes is spent on diabetes care during Medical Clinic visits.⁴⁰ It is also possible that Medical Clinic patients refuse to have their therapy intensified, but it seems unlikely that patient refusal explains failure to intensify therapy in patients who are already using insulin (Figure 2). The authors believe that clinical inertia in the Medical Clinic reflects limited exposure to education that emphasizes treating to target and the need to act each time that intensification of therapy is clinically indicated; the actions of the provider to intensify therapy can have a major impact on glycemic control.²¹

The findings show that patients with diabetes in a primary care site have higher glucose levels than comparable patients in a diabetes specialty site and that the major difference in management appears to involve failure of the providers to intensify pharmacotherapy in patients

with inadequate glycemic control—clinical inertia. Analyses of provider behavior must be conducted in other health care systems to ascertain whether results in other settings are similar to the results presented here, but it is clear that such clinical inertia is a common problem and limits successful management of hypertension and dyslipidemia as well as diabetes. It will be of particular importance to determine whether appropriate education and interventions aimed at supporting provider behavior can improve management of chronic disorders such as diabetes in the primary care setting.

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