The Association Between Diabetes Metabolic Control and Drug Adherence in an Indigent Population

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OBJECTIVE — Studies of the association between diabetes metabolic control and adherence to drug therapy have yielded conflicting results. Because low socioeconomic and minority populations have poorer diabetes outcomes and greater barriers to adherence, we examined the relationship between adherence and diabetes metabolic control in a large indigent population.

RESEARCH DESIGN AND METHODS — The study population consisted of patients receiving medical care from a university-based internal medicine clinic serving a low-income population in rural central Virginia. The sample comprised 810 patients with type 2 diabetes who received oral diabetes medications from the clinic pharmacy and had at least one HbA_{1c} determination during the study period. Multiple linear regression was used to examine the association of HbA_{1c} level as well as change in HbA_{1c} level with medication adherence, demographic, and clinical characteristics.

RESULTS — Better metabolic control was independently associated with greater medication adherence, increasing age, white (versus African-American) race, and lower intensity of drug therapy. For each 10% increment in drug adherence, HbA_{1c} decreased by 0.16% ($P < 0.0001$). Controlling for other demographic and clinical variables, the mean HbA_{1c} of African-Americans was 0.29% higher than that of whites ($P = 0.04$). Additionally, the intensity of diabetes drug therapy for African-Americans was lower, as was their measured adherence to it. There was no association between metabolic control and gender, income, encounter frequency, frequency of HbA_{1c} testing, or continuity of care.

CONCLUSIONS — Adherence to medication regimens for type 2 diabetes is strongly associated with metabolic control in an indigent population; African-Americans have lower adherence and worse metabolic control. Greater efforts are clearly needed to facilitate diabetes self-management behaviors of low-income populations and foster culturally sensitive and appropriate care for minority groups.

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Adherence to chronic drug regimens is often suboptimal; lower socioeconomic and minority populations have greater barriers to adherence, which may thwart efforts at improving care and outcomes (1,2). With the ever-expanding arsenal of pharmacotherapy for chronic disease and evidence linking such therapy to better outcomes, awareness of the critical role of adherence to drug therapy has heightened. Because lower socioeconomic and minority groups generally have greater burdens of chronic disease, less vigorous treatment, and poorer disease outcomes (3–7), it is appropriate to focus adherence efforts on such populations.

Diabetes is a chronic condition in which evidence clearly links improved metabolic control via drug therapy to better outcomes (8–10). Because of this linkage, one might expect that greater adherence to medical regimens would be associated with better metabolic control, both due to a direct effect and possibly as a marker of adherence to other diabetes self-management behaviors. Alternatively, it has been hypothesized that the absence of such an association could be due to prescription of inadequate medication regimens by physicians, failure to accurately measure adherence, or lack of relationship between medication taking behavior and other diabetes self-management behaviors (11,12). In fact, the concept of adherence with respect to diabetes has been considered dysfunctional, to the extent that blindly following a physician's orders may not promote the desired goal of patient empowerment and greater self-management (13).

Studies that have empirically evaluated the association between medication adherence and diabetes metabolic control have yielded conflicting results (14–22). However, most have relied on small patient samples and self-report as the measure of drug adherence and/or did not use HbA_{1c} as the metabolic outcome measure. The present study was therefore undertaken to evaluate the association between drug adherence and metabolic control in a large sample of patients with type 2 diabetes using objective adherence and outcome measures. We studied an indigent population because their greater barriers to adherence, higher diabetes prevalence, and higher rate of adverse diabetes outcomes are important public health concerns.

RESEARCH DESIGN AND METHODS

— The study was conducted at the University of Virginia (UVA) Health System's principal internal medicine primary care practice site. This site serves 13,138 patients, making 37,500 visits per year, and is staffed by 90 resident and faculty physicians. UVA is the largest provider of primary care to indi-

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Abbreviations: UVA, University of Virginia.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—*Study population description*

	N (%)	Mean (SD)
Race		
African-American	346 (41.7)	
Caucasian	483 (58.3)	
Sex		
Male	327 (39.5)	
Female	502 (60.5)	
Age (years)		58.7 (11.5)
Income		
<Federal poverty	503 (60.7)	
100–110% poverty	61 (7.4)	
110–133% poverty	98 (11.8)	
133–167% poverty	71 (8.6)	
167–200% poverty	28 (3.4)	
>200% poverty	68 (8.2)	
HbA_{1c} level (most recent)		8.1% (2.0)
HbA_{1c} decrease		0.52% (2.16)
No. HbA_{1c} levels (20 months)		3.5 (1.6)
No. clinic visits per year		6.6 (5.1)
No. oral agents per patient		
1	403 (48.6)	
2	363 (43.8)	
3	63 (7.6)	
Concomitant insulin	252 (30.4)	
Oral agent adherence		79.7% (21)
Adherence to nondiabetes drugs		71.8% (17)
Visits to single provider (continuity)		73.5% (23)

gent patients in central Virginia and is the only institution within a 45-mile radius that is obliged to care for all patients regardless of ability to pay. Greater than 60% of the patients qualify for discounted care at UVA, using state family income guidelines. UVA uses a sliding fee scale based on income (as verified by federal income tax returns). With respect to prescription drug costs, the patient copayment ranges from 1 to 100% of the UVA drug acquisition cost. Although the patient population served is racially and socioeconomically diverse, 92% of the patients in the current study received a 50–99% subsidy of their prescription drug costs. Considering the high level of subsidy provided, lack of insurance drug coverage, and low income levels, it is unlikely that they had alternative sources of pharmaceuticals. Analysis did not reveal a difference in refill rates between patients with higher and lower income/copayment levels.

The study population was limited to patients taking at least one oral agent (sulfonylureas, metformin, α-glucosidase inhibitors, and thiazolidinediones) for type 2 diabetes. Although we controlled for insulin use, we were unable to determine drug adherence for insulin through use of an administrative data set because dosage instructions may change frequently and may not be well documented. There were 844 patients identified on one or more oral agents for diabetes during the study period of January 2000 through March 2001. The study population was further limited to the 829 patients that identified themselves as either African-American or Caucasian in their UVA registration data.

Adherence to prescribed drug therapy was calculated using prescription-refill data from the UVA pharmacy serving this patient population. The sum of the number of days of therapy dispensed on all but the last prescription in this period was used as the numerator of the adherence statistic. Using dates of the first and last prescriptions during this period as the boundaries, the number of days in the treatment interval served as the denominator. This method for calculation of proportional adherence is similar to that of previous adherence studies using prescription refill data (23–26). A sample chart audit of 96 prescriptions indicated that the pharmacy database drug dosage and progress note dosage were in agreement 88.5% of the time and that only 3% of medications had been filled by outside pharmacies.

The association of diabetes metabolic control with patient demographic, clinical, and adherence characteristics was modeled using bivariable and multivariable statistical methods. Metabolic control, the dependent variable, was defined as the most recent HbA_{1c} level during the study period (the results were similar using the mean HbA_{1c} level). Improvement in metabolic control was defined as the difference between the first and last HbA_{1c} levels during a 20-month time frame concluding at the end of the study period. Adherence was modeled as the mean adherence for all diabetes drugs taken by each patient. The association of HbA_{1c} with patient sociodemographic variables (age, gender, race, income level) and prescription drug or disease characteristics (number of diabetes medications taken, mean adherence, number of clinic visits, proportion of visits to a single physician, number of HbA_{1c} levels obtained during the study period) was evaluated by simple and multivariable linear regression. Improvement in metabolic control (change in HbA_{1c}) was similarly modeled; the initial HbA_{1c} level added as an independent variable. Associations were considered statistically significant at a two-tailed α of 0.05. Of the 829 eligible study patients, 810 (98%) had at least one HbA_{1c} level and were included in the metabolic control model; 726 (88%) had at least two levels during the study period and were evaluated for improvement in metabolic control.

RESULTS — The study population demographics as well as means and variability of the analysis variables are summarized in Table 1. The mean age was 59 years, 42% were African-American, and 61% were women. A total of 61% of subjects had family income below the federal poverty line and 92% had family income less than twice the poverty level. Slightly more than half of subjects were taking two or more oral diabetic agents and 30% were also using insulin. The patients averaged more than six primary care visits (for all problems) per year and had a mean of 3.5 HbA_{1c} measurements recorded during the past 20 months (in-

Table 2—*Bivariable associations with diabetes metabolic control*

Independent variable	Dependent variable: most recent HbA_{1c} level			Dependent variable: change in HbA_{1c} level*		
	Parameter estimate	*P* value	R^2	Parameter estimate	*P* value	R^2
Race (white = 0)	0.29	0.04	0.5%	0.25	0.05	0.3%
Sex (male = 0)	−0.17	0.24	NA	−0.04	0.74	NA
Age	−0.026	<0.0001	2.3%	−0.01	0.04	0.4%
Income/copay	0.06	0.11	NA	−0.008	0.83	NA
Adherence (0–100%)	−0.019	<0.0001	4.0%	−0.013	<0.0001	1.7%
No. oral agents	0.79	<0.0001	6.1%	0.55	<0.0001	2.6%
Insulin use (0 or 1)	0.56	0.0003	1.6%	0.38	0.007	0.7%
No. HbA_{1c} levels	−0.004	0.93	NA	0.03	0.55	NA
No. encounters	−0.008	0.45	NA	0.006	0.50	NA
Continuity index	−0.09	0.78	NA	0.55	0.13	NA

*The initial HbA_{1c} level was controlled for in this model. A negative parameter estimate indicates HbA_{1c} improved with increment in independent variable.

cluding the 15-month period for which medication adherence was measured). The mean HbA_{1c} level was 8.1%; the average decrease was 0.5% over the study period.

The bivariable associations between HbA_{1c} level and the analysis variables are shown in Table 2. Metabolic control was associated with race, age, adherence, and intensity of drug therapy. For each 10% increment in adherence to oral diabetes agents, HbA_{1c} was 0.19% lower ($P < 0.0001$). The change in HbA_{1c} over time was also strongly associated with adherence: for each 10% adherence increment, there was a 0.13% greater decrease in HbA_{1c} ($P < 0.0001$). HbA_{1c} was 0.26% lower per decade increase in age ($P < 0.0001$) and tended to decrease more over time among older patients ($P = 0.04$). More intensive therapy (vis-à-vis number of oral agents and insulin use) was strongly associated with higher HbA_{1c} levels. The mean HbA_{1c} decreased over time by 0.25% more for whites than for African-Americans ($P = 0.05$), with the most recent HbA_{1c} being 0.29% higher among African-Americans ($P = 0.04$). No association was found between metabolic control or change in control over time and income/copayment level, gender, frequency of HbA_{1c} testing, frequency of visits, or proportion of visits to a single provider (continuity index).

In the multivariable analyses (Table 3), the independent association of diabetes medication adherence with metabolic control and its change over time was undiminished by controlling for the other demographic and clinical factors. The most recent HbA_{1c} was 0.16% lower for each 10% increment in adherence ($P < 0.0001$); the absolute change over time was 0.13% greater for each 10% increment in medication adherence ($P < 0.0001$). The intensity of drug therapy (both oral agents and insulin) also maintained very strong inverse associations with metabolic control and its change over time. The strength and magnitude of the association between race and HbA_{1c} was also unchanged in the multivariable models. The HbA_{1c} of African-Americans was still an average of 0.29% higher than that of whites ($P = 0.04$) and improved less over time. The strength of the association between age and HbA_{1c} level diminished after adjustment and there was no longer an association between age and HbA_{1c} change over time. The model without interaction terms accounted for 16% of the variance in metabolic control, although race explained <1%.

Interactions between race, number of oral agents, insulin use, and adherence were assessed in both multivariable models. There was a significant interaction between race and number of oral agents ($P = 0.04$) in the metabolic control model, accounting for 1.7% of the variance in HbA_{1c} (model R^2 improved to 17%). As shown in Table 4, the HbA_{1c} level of African-Americans was progressively greater than that of whites with increasing intensity of oral therapy. The association of insulin use and adherence with metabolic control did not vary between African-American and white patients. No other interactions were statistically significant in either model.

Adherence to nondiabetes medications was highly correlated with adherence to diabetes medications in the study population ($r = 0.51$, $P < 0.0001$). However, when added to the multiple regression models, adherence to nondiabetes medications was not independently associated with HbA_{1c} or change in HbA_{1c} level.

Although adjusting for medication adherence did not alter the association between race and metabolic control, African-American patients in this study population had substantially lower calculated adherence levels to diabetes medications than white patients (mean adherence 76.5 vs. 82%, $P = 0.0002$). Despite having poorer metabolic control on

Table 3—*Multivariable associations with diabetes metabolic control*

Independent variable	Dependent variable: most recent HbA_{1c}			Dependent variable: change in HbA_{1c}*		
	Parameter estimate	*P* value	Partial R^2	Parameter estimate	*P* value	Partial R^2
Race (white = 0)	0.29	0.04	0.5%	0.28	0.04	0.4%
Sex (male = 0)	−0.21	0.13	NA	−0.12	0.36	NA
Age (years)	−0.014	0.02	0.7%	−0.005	0.38	NA
Income/copay	Multiple	0.12	NA	Multiple	0.57	NA
Adherence (0–100%)	−0.016	<0.0001	2.7%	0.013	<0.0001	1.5%
No. oral agents	0.89	<0.0001	7.5%	0.63	<0.0001	3.6%
Insulin use (0 or 1)	0.75	<0.0001	2.6%	0.50	0.001	1.1%
No. HbA_{1c} levels	−0.09	0.06	NA	−0.05	0.33	NA
No. encounters	−0.006	0.61	NA	0.004	0.68	NA
Continuity index	−0.10	0.74	NA	0.28	0.35	NA

*The initial HbA_{1c} level was controlled for in this model.

Table 4—*HbA_{1c} level as a function of race and number of oral agents*

Number of oral agents	African-American: mean HbA_{1c} (*n*)	White: mean HbA_{1c} (*n*)
One	7.79% (181)	7.76% (222)
Two	8.81% (150)	8.35% (213)
Three	10.78% (15)	9.37% (48)

average, African-Americans tended to take fewer oral diabetes drugs than white patients (mean number 1.52 vs. 1.64, $P = 0.006$); odds of taking two or more oral agents were 1.3 times higher for whites, and odds of taking three agents were 2.4 times higher ($P = 0.006$). The odds of taking a thiazolidinedione was 1.5 times higher for whites ($P = 0.04$). The proportion of African-Americans and whites taking insulin was similar (29.8 vs. 30.8%, $P = 0.74$). The number of physician encounters and the number of HbA_{1c} tests did not differ between African-American and white patients, nor did continuity of care, as defined by the proportion of visits to a single primary care physician.

CONCLUSIONS — In summary, type 2 diabetes metabolic control and its improvement over time were strongly associated with adherence to diabetes medication in a large relatively indigent clinic population in central Virginia. Other predictors of metabolic control included age, number of oral diabetes medications, insulin use, and race. Controlling for these and other factors by multivariable analysis did not diminish the adherence association.

The strong association between adherence to diabetes drug therapy and metabolic control stands in contrast to several previously published reports. A prospective study by Wooldridge (17) of 189 patients with diabetes, two-thirds with type 2 diabetes, demonstrated improved metabolic control after intensive individual education but no association of HbA_{1c} with self-reported adherence to therapy. Glasgow et al. (15) also found no association between self-reported insulin adherence and HbA_{1c} among 93 individuals with type 1 diabetes. Reports from the Medical Outcomes Study by Hays et al. (18) and Kravitz et al. (16) also demonstrated no association between self-reported adherence and HbA_{1c} levels, except among insulin-requiring patients and a subset with myocardial infarction. However, the reliance of these and other studies (19) on self-reported adherence calls into question the validity of their negative findings (20,21).

Other small studies using more objective adherence measures have demonstrated associations with diabetes metabolic control. Diehl et al. (22) used pill counts to assess adherence in 77 patients with diabetes and found a trend toward higher fasting blood glucose levels in those taking <80% of prescribed dosages. Chousa et al. (23) similarly found adherence assessed by pill count to be associated with metabolic control measured by HbA_{1c} among 107 patients with type 2 diabetes. Using self-reported adherence plus the pharmacy records of 65 patients with type 2 diabetes, Peterson et al. (24) also demonstrated an association between adherence and a composite measure of metabolic control, which included HbA_{1c}.

Our study confirms the findings of these earlier reports in a much larger sample of patients. There are several possible explanations for the demonstrated association. Clearly, more intensive pharmacologic management of type 2 diabetes and adherence to such therapy should generally lead to lower HbA_{1c} levels. The widespread use in the study population of newer drug therapies and combinations not available in previously published analyses of adherence and metabolic control would be expected to enhance such an association. In this light, our finding that a 30% absolute increase in adherence was, on average, associated with a roughly 0.5% absolute improvement in HbA_{1c} level seems quite plausible. Alternative or contributory explanations for the association between drug adherence and metabolic control are also possible. Higher adherence to drug therapy may be a marker for better diabetes self-management practices with respect to diet, exercise, and monitoring. Because these other factors were not measured in our study, they may have confounded the demonstrated association of adherence and HbA_{1c}. It is also possible that many potential barriers to adherence (educational, social, cultural, financial, medical, psychiatric, and other), also unmeasured in this study, may contribute to poor metabolic control independent of their impact on adherence. The strong correlation demonstrated between adherence to diabetes and nondiabetes medications is consistent with these alternative explanations. However, the lack of an independent association between nondiabetes medication adherence and metabolic control suggests that the demonstrated association of adherence to diabetes medication with HbA_{1c} level is not entirely due to nonspecific underlying patient adherence characteristics.

It has been recognized that an open and compassionate physician communication style can facilitate improved patient adherence and outcome (25–27), whereas prevailing judgmental styles may impede it (28). Therefore, unmeasured physician factors may have contributed to or confounded the association between medication adherence and metabolic control demonstrated in this study. Because the physician is a logical locus of intervention to improve patient adherence, this area may be worthy of further research.

An additional caveat that must be applied to the demonstrated association is that the use of prescription refill–based data to estimate drug adherence is clearly imperfect. However, it does have the advantage of being an unobtrusive and objective source of adherence estimates and has been validated as a reasonably accurate measure in the absence of alternative patient sources of medication (29–32). The patients with very low income in the present report were only able to receive heavily subsidized medications from a single source. Nevertheless, intercurrent hospitalizations or alternative sources may have falsely lowered apparent adherence, and medication sharing, hoarding, or wasting could have made adherence appear higher than actual. Furthermore, information on adherence to dosing schedules is not available through pharmacy data.

Our finding of an association between increasing age and better metabolic control is consistent with previous reports. Using National Health and Nutrition Examination Survey (NHANES) III data, Shorr et al. (33) demonstrated a significant inverse association between age and HbA_{1c} among those on oral hypoglycemic agents. Nichols et al. (34) found a similar association among 1,333 patients with type 2 diabetes from a managed care population. Previous studies have also shown significant associations between age and

adherence to diabetes regimens (33,35). Our study suggests that the association between age and HbA_{1c} may be largely mediated by adherence, because the strength of the association greatly diminished after controlling for drug adherence.

The association of number of oral medications and insulin use with worsened metabolic control was expected, based on the literature as well as customary clinical practice. Because oral hypoglycemics and insulin are generally added as a result of worsening metabolic control, it is logical that a strong association would exist between required intensity of therapy and HbA_{1c} level. Such an association has been demonstrated previously for oral agents and insulin in general (34,36,37). We found no mention of gradations based on number of oral agents as shown in our study, likely due to the relatively recent availability of multiple drug classes.

The study finding of an association between race, metabolic control, and adherence also deserves further comment. It is well established that African-Americans have a higher prevalence of diabetes (38,39), poorer metabolic control (34,36,40,41), and worse outcomes (42,43) than white Americans. This disparity has not previously been explained by between-group differences in insurance coverage (44), physician visits (42,45), or prescribed drug therapy (42,45,46). Although studies have shown that lower socioeconomic status and minority patients self-monitor blood glucose less often (42,47,48), little is known regarding the linkage between adherence to drug therapy and metabolic control in these groups. Because overall drug adherence may be lower among African-Americans (49,50), our study examined the hypothesis that variation in diabetes medication adherence might explain the racial association with metabolic control and disease outcomes.

Although our study confirmed a significant association between race, adherence, and metabolic control in this rural indigent population, we did not find that measured adherence disparities solely mediated the inferior metabolic control in African-American patients. The 0.3% racial difference in HbA_{1c} levels found by bivariable analysis persisted after controlling for multiple other variables, including adherence. Despite similar rates of physician visits and HbA_{1c} testing, African-Americans were also found to have progressively higher HbA_{1c} levels than white patients as treatment intensified. Because proportionately fewer African-Americans were being treated with multiple drug regimens for diabetes, it seems that the HbA_{1c} threshold used to intensify their therapy may have been higher. Our findings are consistent with previous reports that have shown similar rates of insulin therapy overall but significantly fewer intensive multiple-dose regimens among African-Americans versus white patients with diabetes (42,45).

There are several potential explanations for these findings as well as cautions that must be applied to their interpretation. It is possible that the racial disparity was due to a confounding variable that was not accounted for in the model. Neither educational nor occupational status was available to the investigators, and although income was included in the model, there may have been racial differences within the income strata used. Unmeasured confounding factors such as comorbidity, blood glucose self-monitoring, or patient reluctance to intensify therapy might also explain the observed associations. These and other factors may have contributed to the differences noted in metabolic control, drug treatment, and adherence between African-American and white patients in the study population. In addition, the effect of concordance of physician-patient ethnicity on these disparities could not be evaluated due to the small number of African-American physicians at the study site. Others have shown that cultural and communication barriers, among other issues, associated with nonconcordant physician-patient ethnicity may lead to less participatory decision making, greater mistrust, and poorer outcomes (51–54).

It must also be noted that the racial difference in metabolic control may have been due to a type 1 error. However, this is made less likely by the consistency of the findings from the different study models and the fact that the results are similar to that of other reports. Nonetheless, it must be emphasized that race explained only a very small amount of the variability in metabolic control in our models (~1%). Additionally, due to the fact that this was a single low-income patient population receiving highly subsidized care at one academic institution, the study results do not indicate that the same associations would be found in other settings. Although not necessarily generalizable, these results add to the pattern found elsewhere and suggest that racial disparities in diabetes metabolic control may be attributable, in part, to less intensive and delayed drug therapy among African-Americans, as well as lower adherence levels. Even if such findings are due to unmeasured intervening or confounding effects, they reinforce the call for greater attention to the healthcare needs of minority and otherwise underserved populations that are known to have poor diabetes outcomes.

In conclusion, medication adherence does seem to be associated with diabetes metabolic control in an indigent care setting. We believe that this further underlines the need in these populations to facilitate diabetes self-management behaviors in general. The association of race with diabetes metabolic control in the U.S. is also likely intertwined with issues of adherence behavior as well as differing intensity of diabetes therapy between African-Americans and whites, as demonstrated in our study. Clearly, efforts to foster culturally sensitive and appropriate care are especially critical in minority populations. As articulated by Anderson and Funnell (13), the goal should be to help educate, motivate, and empower patients to improve their self-care skills and take control of their disease rather than simply foster adherence to prescribed medications.

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