Race and Medication Adherence in Medicaid Enrollees with Type-2 Diabetes

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Objective: The association of medication adherence with race has been inadequately studied previously in type-2 diabetes patients. The study objective was to determine the association between race and medication adherence among type-2 diabetes patients.

Methods: This was a retrospective cohort study, which compared medication adherence among different races of Medicaid insured patients with type-2 diabetes newly starting oral antidiabetic medication. A total of 1,527 African-American patients newly starting antidiabetic medication between July 2001 and June 2002 were compared with 1,128 white patients and 514 patients of other race. Medication adherence was measured as medication possession ratio using prescription refill patterns. Multivariate regression analyses were used to determine the difference in adherence rates adjusting for other covariates.

Results: Medication adherence rate was significantly higher for whites [0.59 (0.31)] as compared to African Americans [0.54 (0.31), ($p<0.05$)]. In multivariate analyses, the adherence rate of African-American patients was found to be significantly lower by 12% as compared to whites after adjusting for other covariates. Metformin users were associated with a 62% decrease in adherence rate as compared with the sulfonylureas group ($p<0.05$).

Conclusion: The antidiabetic medication adherence was associated with race. Future research should investigate patient-related factors affecting medication adherence in type-2 diabetes patients.

Key words: medication adherence ■ type-2 diabetes ■ race/ethnicity ■ Medicaid

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INTRODUCTION

Diabetes is one of the leading causes of morbidity and mortality in the United States.[1] Currently, around 18 million people are ailing with diabetes and an estimated 13 million of them are diagnosed[2], while, worldwide, the number of diabetics is expected to double by 2010.[3] Diabetes poses an enormous economic burden accounting for $91.8 billion in direct costs in 2002.[4] Poor glycemic control is often a cause of diabetic complications in type-2 diabetes patients. Aggressive glycemic control reduces long-term microvascular and macrovascular complications in diabetic patients and has been associated with significantly lower medical expenditures[5,6,11] and considerable cost savings.[7-11]

African Americans, Latinos and native Americans experience a 50–100% higher burden of illness and mortality as a result of diabetes than white Americans.[12] African-American patients with diabetes have worse glycemic control than other groups;[13-15] however, evidence is mixed on the source of this apparent disparity. Few studies have examined treatment and adherence patterns among disadvantaged groups. A recent study found that black patients in a Medicaid managed care plan were less likely to be prescribed thiazolidinediones (TZDs) than white patients;[16] however; effects of this difference on outcomes such as adherence or glucose control were not examined.

Medication adherence is one of the important factors in achieving glycemic control. It has a well-established relationship with treatment outcomes[12] and is associated with decreased utilization of medical resources.[17] A systematic review of literature showed that diabetes patients as a group have poor compliance rates with treatment, including both oral hypoglycemic agents and insulin.[18] It was found that adherence to oral hypoglycemic therapy ranged from 36–93% in patients remaining on treatment for 6–24 months, while insulin adherence among type-2 diabetes patients was 62–64%. Adherence to diabetes medications improves glycemic control,[19,20] while poor adherence is a major barrier to gaining the benefits of appropriate drug therapy of type-2 diabetes.[21]

Medication adherence is a multidimensional phe-

nomenon that is affected by patient-related, therapy-related, condition-related and socioeconomic factors. Patient-related factors include patient knowledge, attitudes, beliefs, perceptions of severity of disease and expectations from a treatment, while therapy-related factors include factors such as frequency of dosing and complexity of regimen. Patient adherence to treatment regimen could differ depending on the influence of the above factors on patients.[22]

The impact that these factors have on patients could depend on other demographic characteristics of the patients such as race. The patient-related factors could also differ among racial groups. According to the Centers for Disease Control and Prevention (CDC), patient awareness of the seriousness of diseases such as diabetes was associated with a greater likelihood of adherence for several of the health-promoting behaviors related to these diseases.[23] Another national study showed an association between health literacy and cultural factors, including the influence of family, beliefs about diabetes, access and utilization of healthcare, and diabetes self-management practices among Hispanics.[24] Due to such differences between races and the preponderance of diabetes in minority racial populations, it is therefore important to study differences in adherence rates between different races. The objective of this study was to determine the association between race and medication adherence among type-2 diabetes patients newly starting oral antidiabetic medication.

METHODS

Design

This was a retrospective cohort study of Medicaid-insured patients with type-2 diabetes newly starting oral antidiabetic medication. Medication adherence was compared among the different races: African Americans, whites and others. This study was conducted using patient data from the North Carolina Medicaid program, which provides coverage to all enrollees who maintain eligibility, including coverage of prescription medications. For this study, the North Carolina Medicaid program database was queried from July 1, 2000 to June 30, 2003. A cohort of type-2 diabetes patients aged ≥18 years were identified using at ≥1 ICD-9 code (International Classification of Diseases, Ninth Revision (ICD-9), Clinical Modification) for type-2 diabetes (250.xx) and one NDC code (National Drug Code) for antidiabetic medication, who maintained continuous eligibility for the entire 36-month study period. This was done to ensure that patients starting a new antidiabetic medication in the middle fiscal year (i.e., July 1, 2001 to June,

Figure 1. Steps involved in creation of the analytical data set for the study

Step 1: Paid or adjusted claims were selected for services between July 1, 2000 and June 30, 2003 with any type-2 diabetes diagnosis of 25000 or 25002. Recipients 65 years of age, Aid Category Codes "QB"(QB=qualified Medicare beneficiary) and crossovers O=professional, W=outpatient, and X=inpatient were excluded. This step produced an unduplicated list of 59,150 recipients.

Step 2: The Medicaid IDs for the 59,150 recipients were loaded into a table and were joined with drug claims in the data warehouse with service dates between July 1, 2000 and June 30, 2003. Only drug claims that had NDC codes from a list containing ThioTZDs (TZD) and other diabetes drugs were selected. Of the 59,150 recipients, 36,656 recipients had ≥1 drug claim that matched up with the NDC list. The data set produced in step 2 consisted of 709,780 drug claims for 36,656 recipients.

Step 3: Taking the data set produced in step 2, TZD drugs (from the list you provided) were split out from other diabetes drugs. There were 34,029 recipients who had ≥1 drug in the other diabetes drug list. There were 15,357 recipients who had received a TZD. Of the 36,656, 12,730 had received TZDs as well as other diabetes-related drugs, 21,299 received other diabetes-related drugs but no TZDs, and 2,627 received TZDs but no other diabetes-related drugs.

Step 4: 36,656 recipients were uploaded to the data warehouse to be used for further matching.

Step 5: An eligibility count across the three-year period was produced for the 36,656 recipients.

Step 6: Two sets were created. One set contained 17,685 recipients who were eligible the entire 36 months. Another set contained 18,970 recipients who were eligible under 36 months. No eligibility information was obtained for one individual.

Step 7: All of the paid and adjusted claim details were pulled for the 17,685 recipients who had eligibility the entire 36 months. Six months of data were pulled at a time.

Following this step, procedures were used to narrow down the cohort, which are described in the paper.

30, 2002) had complete follow-up on healthcare service utilization for one year before and one year after they start the therapy. This inclusion criterion was important in determining the confounder-adjusted impact of each therapy.[25] Recipients aged ≥65 years, Aid Category Codes "QB" (QB=qualified Medicare beneficiary) and crossovers were excluded due to a potential lack of complete data. Patients with type-2 diabetes who were exclusively on insulin were excluded from the analysis, because this group represents the most severe type-2 diabetics and cannot be compared with patients on oral therapy only. This procedure is described in Figure 1.

This procedure resulted in a sample of approximately 17,600 eligible enrollees. From the resulting size based on the above inclusion criteria, further intention was to identify new starts to the therapy. The start year was defined to be between July 2001 and June 2002.

The database was programmed to identify new starts of TZDs, sulfonylureas and metformin during the study period between July 1, 2001 to June, 30, 2002. We identified such "new starts" by ensuring that there were no claims for either of these medications in the 12 months before the prescription fill appeared for the first time in the patients' claims records. Through this procedure, 1,774 patients starting TZDs, 1,179 patients starting sulfonylureas and 216 patients starting metformin during this period were identified. The distribution of patients on different therapies was similar to those obtained in other studies of antidiabetic medication adherence in diverse populations.[26,27] After applying the above procedure, subjects who were on monotherapy were obtained. These patients belonged to only one of the three groups. Therefore, patients on combination therapy or patients taking ≥1 antidiabetic medication were not included in the study.

Measurements and Outcomes

The primary objective was to study the association between race and medication adherence adjusting for other covariates. The information for patients' race was obtained from North Carolina Medicaid database. The race is self-reported by patients during the time of enrollment in Medicaid program. The race of the patients represented three categories: whites, African Americans and other race. Those who reported as being neither African-American nor white were collapsed into a single race category: "other." Prescription-refill patterns were used to derive measures of adherence under the assumption that a prescription filled was a prescrip-

Table 1. Descriptive characteristics of the study population (comparison of African Americans versus whites versus other race)

Variable	African Americans (n=1,527) Mean (SD§) [Range]	Whites (n=1,128) Mean (SD§) [Range]	Others (n=514) Mean (SD§) [Range]
Baseline Characteristics			
Age of the patient (years)	47.66 (11.1) [18–65]*	49 (11.2) [18–65]*	51.4 (9.55) [18–65]*
Male gender (%)	23.5*	32.2*	18.6*
Metformin (%)	6.8	7.5	5.3
Sulfonylureas (%)	36.5	37.8	38.3
Thiazolidinedione (%)	56.7	54.7	56.4
Any prescription in year 1 (%)	96.9	98	97.5
Presence of an event requiring ED visit or hospitalization in year 1 (%)	57.4	57.1	58.6
Total number of prescription fills for all conditions for year 1	49.1 (38.9) [0–251]*	66.2 (45.14) [0–305]*	57.74 (44.8) [0–231]*
Number of comorbidities	2.02 (1.81) [0–9]†‡	2.42 (1.9) [0–11]†	2.43 (1.96) [0–9]‡
Total number of medications in year 2	18.67 (10.42) [1–79]*	23.5 (12.5) [2–83]*	21.81 (12.21) [1–109]*
Total healthcare costs in year 1 ($)	8063.4 (13339) [0–139264]	8791.8 (12866) [0–104896]	8398 (12429) [0–95270]
Total healthcare costs in year 2 ($)	9588.3 (13853) [0–131291]	10182 (15776) [0–191567]	11061 (18038) [27–212258]
Study Outcome			
Adherence rate to new medication (year 2)	0.54 (0.31)† [0–1]	0.59(0.31)† [0–1]	0.56 (0.32) [0–1]

* Indicates differences between all three groups are significant at ≤0.05 level; †, ‡ indicates difference between two groups are significant at ≤0.05 level; § Standard deviations presented, where applicable in parentheses; Note: Medication possession ratio is expressed as adherence rate. Adherence rate of 0.54 for African-American group is same as adherence rate of 54%.

tion taken. Pharmacy records have been demonstrated to have acceptable predictive validity as measures of cumulative exposure and gaps in medication supply.[28] These data were thus used to describe medication adherence in the study populations.

Adherence

An index of antidiabetic medication utilization for the postnew medication start date year was computed for each patient based on the Med-Total approach by Steiner et al.[29] The medication possession ratio (MPR) was calculated as the days of antidiabetic prescription supply dispensed divided by the number of days between these prescription refills. The observation period began with the first date of dispensing within each year and ended as the dispensing date of the last prescription. The number of days a person was in a hospital was subtracted from the denominator because any drug taken during this time was provided by the hospital and was captured in the pharmacy records. While calculating the MPR for antidiabetic medications, we avoided double counting any concomitant antidiabetic medications patients were taking. The MPR can also be referred to as the adherence rate to a therapy.

Measurement of Covariates

The covariates entered in the regression analysis included demographic characteristics such as age; gender; and clinical confounders such as propensity for healthcare utilization in previous year, type of therapy, total number of medications consumed by the patients in the year adherence was measured (year 2) and number of comorbidities. The above covariates were included because previous literature has shown these variables to be associated with medication adherence.[22,26] The information for demographic characteristics was extracted from the database. The propensity for high healthcare utilization was based on total annual healthcare costs in year 1. Those above the 75th percentile of the annual healthcare costs in year 1 were considered to have propensity for high healthcare utilization in year 1, whereas those in <75th percentile were categorized into the low healthcare utilization group. We felt that classification based on their healthcare utilization in year 1 would be a better risk stratifier to adjust for degree of severity. The study examined total annual healthcare costs associated with total healthcare utilization, as opposed to examining diabetes-related utilization and charges. This was done to avoid problems inherent in attributing all billings for healthcare service utilization to a specific condition due to miscoding of diagnosis.[25] Patients were followed up for complete healthcare service utilization [hospitalizations, emergency department (ED) visit, outpatient physician visits, utilization of antidiabetic medication] and costs one year before and one year after start of the new oral antidiabetic therapy. Reimbursements made by Medicaid were used to compute total healthcare costs based on ICD-9 codes (primary and secondary diagnosis) and NDC codes. The total number of medications consumed by the patients was calculated by identifying medications using NDC codes. Similarly, comorbidities were identified by ICD-9 codes, and number of comorbidities was obtained.

Statistical Analyses

Descriptive analyses (frequencies and percentages) of baseline characteristics and univariate (one-way analysis of variance and Chi-squared) analyses were conducted to compare demographic characteristics and outcome variables between the three cohorts.

Multiple log-linear regression analysis was performed on the second-year data to compare the differences in medication adherence between different races adjusting for other study variables such as demographic and clinical confounders. The dependent variable in the regression analyses was the MPR. The distribution of MPR was noted to be skewed (as determined by the Shapiro-Wilk test)[30], which could introduce statistical estimation problems such as heteroscedasticity into the model and, therefore, the natural logarithm of MPR was used as the dependent variable for this analysis.

The model that was utilized in multiple regression analysis can be specified as follows:

- Outcome [ln(MPR)] = f (race indicator, treatment group indicator, demographic and clinical confounders, race x treatment interaction)

Table 2. Comparison of adherence rates between different races across different therapies

	African-American Race	White Race	Other Race	
	Medication Possession Ratio Mean (Standard Deviation)	Medication Possession Ratio Mean (Standard Deviation)	Medication Possession Ratio Mean (Standard Deviation)	Medication Possession Ratio Mean (Standard Deviation)
Metformins	0.22 (0.18)	0.24 (0.183)	0.19 (0.16)	0.22 (0.18)
Sulfonylureas	0.55 (0.31)	0.6 (0.32)	0.56 (0.32)	0.57 (0.35)
Thiazolidinediones	0.58 (0.31)	0.63 (0.32)	0.59 (0.32)	0.6 (0.31)

- Race indicator: African-American race, other race
- Treatment group indicator: Metformin, TZD
- Demographic confounders: age, gender
- Clinical confounder: high healthcare costs in year 1, total number of medications in year 2, number of comorbidities
- Interactions: Metformin x African-American race interaction, Metformin x other race interaction, TZD x African-American race interaction, TZD x other race interaction

The parameter estimates obtained from regressing log-transformed MPR on covariates were back-transformed using antilogarithms of the parameter estimates.[31] Adherence was measured in year 2 only, because patients started the medication of interest at the beginning of year 2, and year 1 data was used for risk adjustment. All analyses were conducted using STATA software (StataCorp LP, Texas).[32]

RESULTS

Table 1 presents the descriptive characteristics of three groups representing three races: African-American, white and other. The mean age was significant among three groups. The mean age of African Americans was significantly lower as compared to whites and other race ($p<0.05$). Percentage of males was significantly higher in whites as compared to African Americans and other race ($p<0.05$) .There were no significant differences in healthcare costs in year 1 between three groups. Total number of prescription refills and total number of medications consumed in year 2 were significantly higher for whites as compared to the other two groups ($p<0.05$). Whites as well as other race had significantly higher number of comorbidities as compared to African Americans (both $p<0.05$). Medication adherence rate was significantly higher for whites [0.59 (0.31)] as compared to African Americans [0.54 (0.31), ($p<0.05$)].

Table 2 presents the results of comparison of adherence rates between races and therapies. Adherence rates were lowest for metformin and highest for TZDs irrespective of the race. Whites had higher adherence rate for all the therapies as compared to other two races. Blacks had lower adherence rates for sulfonylureas and TZDs as compared to other races.

Table 3 illustrates the results of regression analysis for comparison across different races adjusting for other covariates using adherence rate as a dependent variable. The regression analysis included data from year 2 only. Multiple regression analysis showed significant association between race and adherence. The adherence rate of African-American patients was significantly lower by 12% as compared to whites after adjusting for other variables. ($p<0.05$) The secondary finding was that Metformin users were associated with a 62% decrease in adherence rate as compared with the sulfonylureas group ($p<0.05$) and 63% decrease in adherence rate as compared with TZDs).

DISCUSSION

Nonwhite persons with diabetes have a proportionately higher burden of diabetes in the population and its complications[12] and, thus, it is important to identify potential gaps in adherence to diabetes medicines and to develop self-management strategies to overcome barriers faced by

Table 3. Comparison of adherence rate between different races using multiple regression analysis

Predictor Variable	Medication Possession Ratio (Natural Log) Estimated Coefficient (Standard Error)	Transformed Parameter Estimates (e^{β} -1) x 100%	95% Confidence Interval of Estimated Coefficient
Age (years)	0.029 (0.01)*	2.9%	[0.009–0.048]
Age squared	-0.0001 (0.0001)	-0.01%	[-0.0003–0.00004]
Male gender	0.044 (0.034)	4.4%	[-0.023–0.113]
TZD	0.03 (0.053)	3%	[-0.073–0.134]
Metformin	-0.955 (0.1)*	-62%*	[-1.15– -0.759]
African Americans	-0.123 (0.054)*	-12%*	[-0.23– -0.02]
Other race	-0.121 (0.073)	-11%	[-0.26–0.021]
High healthcare costs in year 1 (>$10,000)	Dropped	–	–
Number of medications in year 2	-0.003 (0.001)*	-0.3%	[-0.006– -0.0002]
Number of comorbidities	-0.052 (0.009)*	-5.6%	[-0.07– -0.033]
Metformin–black race interaction	0.102 (0.1359)	10%	[-0.162–0.366]
Metformin–other race interaction	-0.21 (0.199)	21%	[-0.602–0.18]
TZD–black race interaction	0.043 (0.07)	4.3%	[-0.093–0.18]
TZD–other race interaction	0.028 (0.094)	2.8%	[-0.156–0.213]
Constant	-1.54 (0.224)*	-79%	[-1.98– -1.1]

Reference group: female gender, white race, sulfonylureas, <$10,000 costs in year 1; Adjusted R^2=0.1128; * Indicates significance at the 0.05 level for a t test examining whether ß=0; Regression is for year-2 data only

these groups, such as treatment affordability and insufficient patient education, which may affect adherence. This study examined the issue of differences in adherence to different therapies by self-reported race category (white, black and other races). We conceptualized that there could be variation in medication prescription utilization and adherence among different races, as people with different ethnicity have varying beliefs and attitudes about the disease and the treatment. Notably, few studies have looked at race effects on both diabetes medication prescription utilization and adherence.

In multiple regression analyses, a significant association was found between race and medication adherence. The results suggest that within a low income and disadvantaged population, there are potential race disparities in healthcare utilization or outcomes such as medication adherence. Future research should focus on investigating the reasons for such differences. In addition, factors such as patients' beliefs and attitudes, other factors such as socioeconomic status, type of insurance, and access could lend some explanation for the difference. The results also extend a previous research[26] by showing that superior adherence to TZDs is general to both white and black patients at high risk for complications due partly to their poverty status.

As there was a significant association between adherence and medication therapy, additional research is needed to understand the difference in the adherence to various antidiabetic medications and if this difference exists across different races. Other determinants of adherence to antidiabetic medications could involve therapy-related factors such as complexity of the regimen, dosing and desire for immediate effects.[33,34] Further, it is important to know if the difference in adherence arises due to the fact that those consuming TZDs were more likely high-risk patients and could be more adherent to prevent complications of the disease. Unfortunately, we did not have access to laboratory values, such as Hba1c levels of these patients, a measure of severity.

This study, however, should be considered an initial exploration of these issues, and caution should be exercised in interpreting these findings due to a number of study limitations. First, the observational study design does not permit causal inferences to be directly attributed to these results. In spite of confounder adjustment, the study results may be subject to some issues of treatment group selection, although we controlled for type of therapy in multivariate analysis. Also, the measure of adherence was dependent on pharmacy records. Even though this method has been shown to be reliable, it cannot guard against instances of undetected adherence such as the case when hospitalized patients get a generous supply of medication at time of discharge, and no record of the medication exists in the patient's pharmacy data. It was also not possible to measure the direct consequences of nonadherence (e.g., hyperosmolar coma) nor associated utilization-based outcomes. Our measures of adherence, while accounting for many patient medication-taking patterns, still do not completely account for the impact of product switching and combining. Information that could be obtained by creating many study variables was limited from the use of an administrative claims database. As a result, confounder adjustment was limited in two ways: 1) many behavioral predictor variables such as smoking/alcohol status and clinical outcomes such as HbA1c levels were unavailable, and 2) proxy variables were used (healthcare costs >75th percentile (i.e. ,$10,000/year) for stratifying high baseline risk of the patient), since actual medical records documenting disease severity could not be obtained.

Lastly, we studied medication adherence in a precisely defined group. We excluded the elderly, noncontinuously eligible, those on combination therapies and those that were institutionalized. Due to such exclusions, this study may not be generalizable to a large insured population. Although the study has some limitations, it should be considered an initial exploration of association between race and medication adherence. Further studies could be more rigorously designed to obtain more information on factors related to both race as well a medication adherence.

In conclusion, this study showed that there was a significant association between adherence to antidiabetic medication and race. Future research should focus on investigating patient-related factors that affect the adherence to medications in type-2 diabetes patients.

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