A Pilot Study of Hemoglobin A1C Levels in Patients with Type 2 Diabetes after Creation of a Patient Assistance Program Enrollment Committee at a Student-Run Free Clinic

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Abstract

Background: Our student-run free clinic (SRFC) treats uninsured patients with type 2 diabetes (T2D) in a medically underserved region. Mississippi has the second highest diabetes prevalence in the nation. Increasing access for patients with diabetes to affordable medication is challenging. Some studies provide encouraging results for lowering hemoglobin A1C and increasing medication adherence through patient assistance programs (PAP). None have examined a student-run PAP committee's impact on diabetes outcomes. *Objective:* To compare A1C levels for patients with diabetes enrolled in PAPs by our committee with those not enrolled and to describe clinical outcomes. *Methods:* A retrospective review of patients with T2D at our SRFC between 2015 and 2023 was performed. The primary outcome was change in A1C within a 4-9 month follow-up window. Secondary outcomes were emergency department (ED) visits and hospital admissions. *Results:* Twenty-five patients with T2D were enrolled in PAPs, while 77 were not. The PAP group had a higher baseline A1C (10.9% vs. 8.7%). The difference in A1C between groups was not statistically significant (P=0.68), even with adjustment for covariates (P=0.59). ED visit and hospital admission frequency was similar between groups. Neuropathy was the most common diabetic complication. ED visits and hospital admissions for heart attacks occurred only in the non-PAP group. *Conclusion:* While patients enrolled in PAPs showed a greater average reduction in A1C, the difference was not statistically significant. The higher baseline A1C in the PAP group carries greater reduction potential. A prospective study is necessary to better evaluate PAP enrollment outcomes for uninsured patients with diabetes.

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Introduction

Our student-run free clinic (SRFC) is an independent institution serving the uninsured mainly from a metropolitan city and surrounding rural counties in Mississippi that have been classified as medically underserved areas by the Health Resources and Services Administration.[1] This facility is partnered with a nearby tertiary academic medical center for educational opportunities. As of 2022, Mississippi had the second highest diabetes prevalence in the United States at 15.3%, which is 32% higher than that of the nation (11.6%).[2] Our free-clinic patient demographics are unique: 73% of patients are African American and 46% are obese, compared to the overall United States population of nearly 14% African American and 42% obese.[3,4] In 2022, Hohl et al. highlighted the socioeconomic barriers faced by our patients. This study examined the effect of such disparities on health outcomes, especially for African American patients.[3]

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Increasing access for patients with diabetes to adequate and affordable medication is a major concern,[5] as is improving medication adherence. The use of patient assistance programs (PAP) for uninsured patients at SRFCs is a promising innovation to increase access to medication for chronic diseases including type 2 diabetes.[6] After determining a need for greater patient follow-up and a goal for improved medication adherence, a student-run PAP committee was established. This committee of pharmacy and medical students provides longitudinal management, from completing PAP enrollment applications to liaising between patients and manufacturers for medication refills and follow-up service. Not surprisingly, given the high prevalence in the state, diabetes is the most common reason for enrolling patients in PAPs at this free clinic.

Prior studies at SRFCs have focused their efforts on the longitudinal outcomes for diabetes, hypertension, and hyperlipidemia,[7,8,9] while another study performed a cost savings analysis of PAP enrollment in a similar setting.[10] The former studies did not examine enrollment in PAPs[7,8,9] and the latter study primarily focused on cost analysis rather than outcomes.[10] Trompeter et al. compared therapeutic outcomes in PAPs with pharmacist intervention for patients with diabetes, using hemoglobin A1C levels as the outcome variable.[11] A higher proportion of patients in PAPs achieved an A1C less than 7% than in the prescription insurance group,[11] which is an

encouraging sign for PAP enrollment outcomes. Our patient population differs in many ways from other clinics, so the applicability of their findings remains in question. As a preliminary study before conducting a prospective investigation, we examined clinical outcomes in diabetic patients at a SRFC by PAP enrollment status. To our knowledge, this has not been done before.

Methods
Study criteria
Institutional review board approvals were obtained at the nearby academic medical center and the SRFC. A retrospective review of 102 patients with type 2 diabetes (T2D) who received medical treatment between 2015 and 2023 at this SRFC was conducted. Patients 18 years and older were included. Patients were excluded if they did not have at least two documented hemoglobin A1C levels since initiating treatment for T2D at our clinic. Demographic, laboratory, and subsequent encounter and complication data were extracted from our SRFC and nearby academic medical center electronic medical records. Hemoglobin A1C was used as the outcome variable to determine clinical progression.

Patient categorization
Patients were grouped by PAP enrollment. The PAP group included patients enrolled by our dedicated PAP committee for T2D medications while being treated at our SRFC. The individual PAP enrollment date for these patients served as their initiation for treatment of T2D in this study; as such, all A1C levels and collected data are post-enrollment. The non-PAP group included all other patients not enrolled in a PAP for T2D. Diabetic patients enrolled in PAPs receiving medications for other conditions were included in the non-PAP group; these patients received their diabetes medications from traditional dispensaries, including our in-house pharmacy.

Supplemental characteristics
Subsequent encounter and complication data were extracted from the EMR of the nearby tertiary referral hospital. Additional A1C data were also obtained from the EMR of the nearby tertiary referral hospital for the appropriate patient-specific timeframes of treatment. We refer our patients for immediate and emergent treatment to this academic medical center.

Outcomes
Our primary outcome was change in A1C level at specific time points, comparing PAP and non-PAP groups. We sought to collect baseline, 6-month, 12-month, and most recent follow-up A1C levels and diabetic complications for each patient but were unable to standardize the non-baseline collection timepoints. Standardization of follow-up and A1C testing remained difficult due to poor follow-up and varying ordering practices by weekly-changing student-led medical teams. A 6-month follow-up window was used to compare baseline and follow-up A1C levels. Follow-up laboratory values collected

within 4 to 9 months after treatment initiation for each individual patient were included in this 6-month follow-up period. If a patient had multiple A1C levels during that time, then the lowest value was used for analysis. This 6-month follow-up window serves to provide standardization for our group comparison. Secondary outcomes were prescription rates of diabetes medications, as well as numbers of emergency department visits and hospital admissions at any point after T2D treatment initiation at our SRFC.

Statistical analyses
Descriptive statistics are displayed as medians with interquartile ranges or frequencies with percentages. The A1C levels of PAP and non-PAP groups were compared using analysis of covariance, with adjustment for the covariates age, body mass index (BMI), gender, and race. Stata software (version 18.0, StataCorp) was used for data analysis. Statistical significance was defined as $P < 0.05$.

Results
A total of 102 patients were included, with 25 in the PAP group and 77 in the non-PAP group. African American patients comprised 68% of the PAP group and 74% of the non-PAP group. Median age, body mass index (BMI), and gender distribution were similar in each group (Table 1).

Medications prescribed
The generic metformin was prescribed for 86 (84.3%) patients overall. Lantus (N=11, 44%) and Basaglar (N=8, 32%) were the most frequently prescribed brands in the PAP group; in the non-PAP group, Lantus (N=20, 26.0%) and Basaglar (N=10, 13.0%) were similarly the most frequently prescribed brands from traditional dispensaries. Lantus and Basaglar are brand names for insulin glargine, a long-acting basal insulin.

A1C measurements
Fifteen patients in the PAP group and 46 patients in the non-PAP group had both a baseline A1C and at least one follow-up A1C collected within 4 to 9 months after beginning diabetes treatment (Table 2). Only five patients (all non-PAP) had more than one A1C recorded within this window. The PAP group had a higher baseline A1C (10.9%) than the non-PAP group (8.7%) as seen in Figure 1. The difference in A1C between PAP and non-PAP groups was not statistically significant (P=0.68). Adjustment for the covariates age, BMI, gender, and race made little change (P=0.59).

Diabetic complications and subsequent encounters
Neuropathy was the most frequently encountered diabetic complication at both treatment initiation and follow-up for both groups (respectively, PAP: N=8, 8; non-PAP: N=18, 22) as seen in Figure 2. At treatment initiation, vision change (N=4) and nephropathy (N=4) were the next most common complications in the PAP group, while at follow-up, vision change (N=6) and skin wounds (N=5) were next most frequent.

For the non-PAP group, vision change was the next most common complication both at treatment initiation (N=14) and follow-up (N=17), followed by skin wounds at follow-up (N=6). Overall there were small differences in the number of ED visits and hospital admissions between the two groups (Table 3). In the non-PAP group, there were two ED visits and one hospital admission for heart attacks, but none in the PAP group for heart attacks. One patient from each group was admitted for stroke, while three ED visits occurred for stroke in the non-PAP group.

Discussion

Patients with T2D and enrolled in a PAP have been shown to reach their A1C goals at a higher rate.[11] Trompeter et al. examined pharmacist guidance alongside PAP enrollment, so the question remains as to whether PAP utilization itself or the addition of a pharmacist for guidance contributed to the improved A1C outcomes.[11] While the current analysis did not yield statistically significant differences between PAP and non-PAP groups, qualitative analysis of the current data in our SRFC demonstrates that the A1C of the PAP group proportionally decreased to a greater degree. One thing to consider is the patients in the PAP group presented with markedly higher A1C level during their first recorded visit, which inherently lends to the greater potential for reduction in A1C. Because we did not record data concerning the individual goals of each patient, the current data may not fully represent the progress of each patient relative to the goals set by their physician.

Additionally, the financial benefits of PAPs in the medically underserved patient population of our SRFC cannot be overlooked. An internal audit for all PAP medications at our SRFC examined the 12-month cost savings for patients. The total cost savings is estimated to be $313,776, equivalent to $6,972 per patient. Many of the brand-name medications with the highest annual cost savings due to PAP enrollment are primarily used by diabetic patients, such as Lantus, Basaglar, Apidra, Trijardy, and Xigduo. A similar study from a SRFC in Texas examined total cost savings through PAP enrollment by monetizing cost of brand name medications prescribed through PAPs using GoodRx values. There, Chow et al. found that from February 2019 through February 2020, patients enrolled in PAPs for exclusively diabetes medications saved $114,110 of their total $222,563 saved among all patients enrolled in PAPs.[10] In Mississippi, where almost 20% of residents report an income below the federal poverty line,[12] PAP programs may offer favorable clinical outcomes at no cost to the patient.

There are limitations to our study. First, the small sample size of both groups limits the study power. It has proved difficult to improve patient return rates at our institution. Hohl et al. found during a similar timeframe that over half of all patients visited our clinic once without any follow-up, whereas only one quarter of patients returned greater than three times.[3] We did not record information concerning rates of clinical follow-up and similar variables relating to continuity of care. However, patients with diabetes enrolled in a PAP have previously been found to show improved self-monitoring behaviors and lower rates of missed follow-up appointments,[13] which supports their continued enrollment by our PAP committee.

Ideally, comparison between PAP and non-PAP groups would control for all potentially confounding medical conditions or medications to most accurately characterize the effects of PAP enrollment. In addition to the statistically insignificant differences in demographic variables, as shown in Table 1, the PAP and non-PAP groups were determined to be similar concerning many other relevant clinical variables. Second, confounding variables such as adherence to medication regimen and differences in dosage were not recorded, although PAP patients have been previously found to have higher rates of medication adherence.[14] Future studies should evaluate information concerning primary care follow-up rates, level of education and knowledge about diabetes, and effects of continued pharmaceutical management in SRFCs, issues previously found to confound the favorable effects of PAPs in small samples.[15]

Conclusion

While patients in the PAP group showed, on average, a greater percentage reduction in A1C within the 4-9 month follow-up window, this was not statistically significant. PAP enrollment began for patients with a median higher A1C which innately carries greater reduction potential. ED visits and hospital admissions did not differ greatly between groups. A prospective study is necessary to better evaluate outcomes for patients with diabetes enrolled in PAPs.

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Link to streaming media: none

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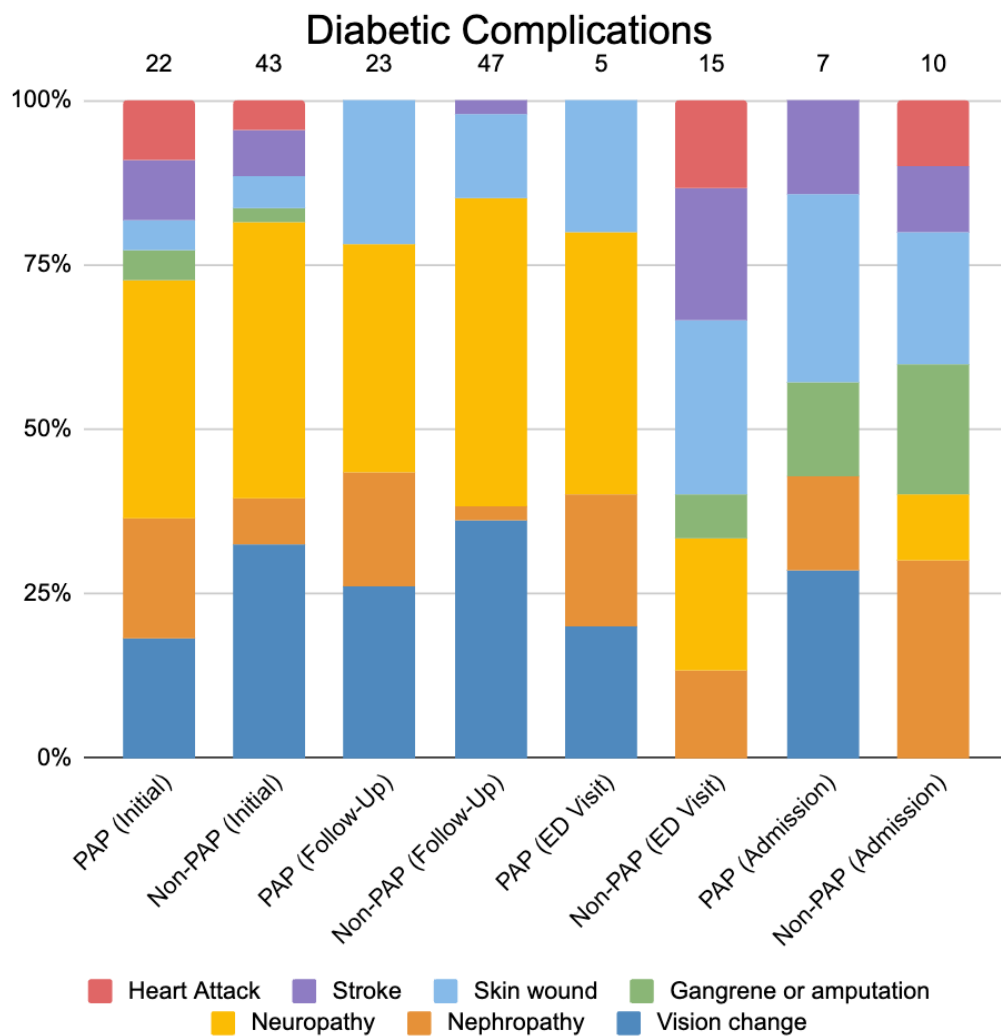|	PAP (N=25)	Non-PAP (N=77)
Age	53 (45-60)	52 (46-59)
Male	15 (60%)	39 (51%)
Female	10 (40%)	38 (49%)
African American	17 (68%)	57 (74%)
Caucasian	6 (24%)	17 (22%)
Hispanic	2 (8%)	3 (4%)
BMI (kg/m^2)	33 (28-36)	34 (30-40)

Table 1. Patient demographics by group. BMI was documented at the time of T2D treatment initiation. Within group median (interquartile range) or number (%).

	Baseline A1C	Best A1C	A1C Change (%)
PAP (N=15)	10.94	9.55	-1.39 (-12.71)
Non-PAP (N=46)	8.70	8.16	-0.54 (-6.21)

Table 2. Comparison of change in A1C level between PAP and non-PAP patients, unadjusted P=0.68. Baseline A1C was collected at the initiation of treatment for T2D at our clinic. Best A1C represents the lowest A1C in a 4-9 month follow-up period. A1C in percent.
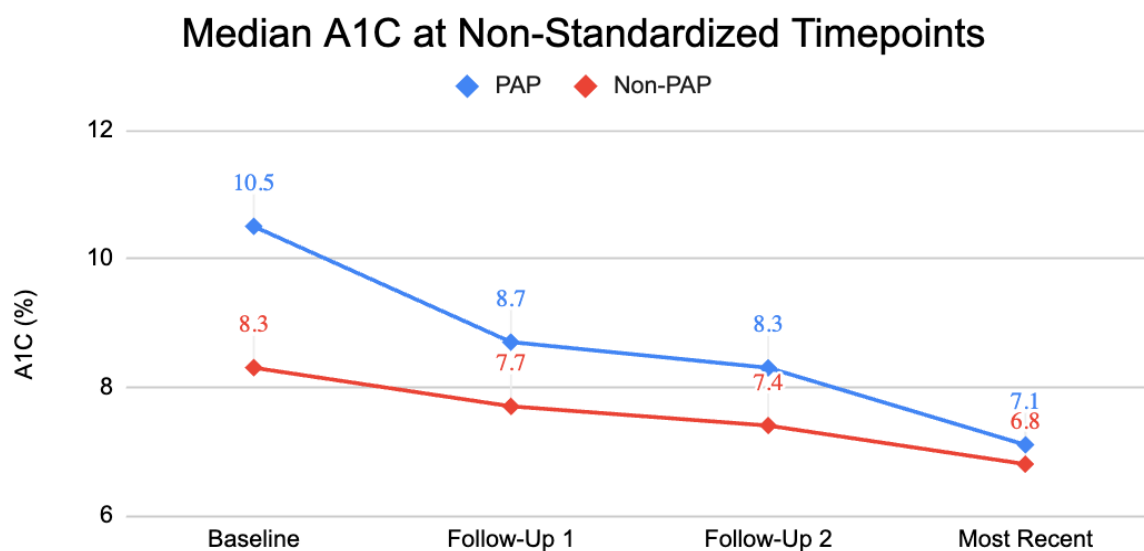
Figure 1. Median A1C level at four different timepoints. Each timepoint varied between patients. All patients had a baseline and first follow-up A1C, but only some patients had additional follow-up A1C levels.

Figure 2. Diabetic complications as a percent of total complications by group and encounter type. The total number of complications for each group and encounter type is given at the top of each column.

	PAP (N=25)	Non-PAP (N=77)
ED Visits	13 (52%)	51 (66%)
Hospital Admissions	13 (52%)	42 (55%)

Table 3. Total encounters (including complications not specific to diabetes). Each patient may have had one or multiple encounters. All encounters took place at the nearby academic medical center after treatment initiation for T2D at our clinic.