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Evaluating A1C Reduction in Patients with Diabetes Receiving Pharmacy Intervention

Abstract

Introduction: Diabetes affects 34 million Americans and is the 7th leading cause of death in the United States. According to the American Diabetes Association (ADA) the A1c goal for most patients is less than 7%; however, in patients at risk for hypoglycemia or with complications that goal can be increased up to less than 8%. Management of diabetes with diet and exercise is essential, but insufficient for most patients and pharmacologic intervention is necessary to achieve therapeutic goals. Reducing A1c is associated with lower cardiovascular risk and a reduction in diabetes-associated complications. Previous studies have shown that pharmacist management of the type 2 diabetes pharmacologic regimen has produced statistically significant reductions in A1c as compared to no pharmacy involvement.

Purpose: This research project was created to quantify impact on the A1c values of patients diagnosed with uncontrolled type 2 diabetes following a pharmacist intervention. These pharmacist interventions are designed to improve the effectiveness of the pharmacological treatment for their diabetes. The interventions took place within a Clinically Integrated Network (CIN). The Advantage Point-Laurel Highlands CIN consists of both employed and independent primary care physician (PCP) practices who joined together to improve care and reduce costs.

Methods: The project is designed to be a retrospective data analysis. Patients were patients of the CIN who were referred to the pharmacy team due to poor control. The pharmacist interventions included: addition, deletion, substitution, or dose alteration of antihyperglycemic pharmacologic therapy under physician approval; medication counseling on proper administration times and technique; and diet and exercise education. Change in A1c (repeat – initial and final – initial) was assessed within patients who received at least one of the pharmacist interventions listed above. Retrospectively, data was extracted from the electronic medical records of adult patients (age ≥18 years) diagnosed with type 2 diabetes who had both a baseline A1c of ≥ 8% who received pharmacy intervention and at least one subsequent A1c from December 2019 through March 2021.

Results: A total of 171 patients met the criteria described previously. The average starting A1c was 10.0% ± 1.51%, the average subsequent A1c was 8.5% ± 1.3% with an average decrease of 1.5% ($P < 0.001$) over an average of 6 months. The average final A1c was 8.3% ± 1.3%; and, when compared to the starting A1C, the average decrease was 1.7% ($P < 0.001$) over an average of 8 months. Additionally, 47% of patients achieved an A1c of < 8%, 74% of patients achieved an A1C of < 9%, and 63% of patients achieved the A1c target set by their 3rd party payer.

Conclusion: Patients with type 2 diabetes who received a pharmacist intervention within the CIN realized a statistically significant decrease in A1c. However, the lack of a comparator group makes it not feasible to comment on differences in A1c reduction between patients who do and do not receive pharmacist intervention based on these results.

Keywords

Diabetes, Type 2 Diabetes, A1C, Hemoglobin A1C, HbA1c, Pharmacy, Pharmacist, Clinical Pharmacist, Ambulatory Care Pharmacist, Intervention, Outcomes

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Conflict of Interest Statement

There are no actual or potential conflicts of interest to disclose by any of the authors.

Cover Page Footnote

Composition of manuscript and statistical analysis (CE/JS); data collection (CE/KH); project design, project oversight, manuscript review and edit (CE/ST/KH/JS); patient interventions (CE/ST/KH)

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Introduction

Diabetes Mellitus affects 34 million Americans and is the 7th leading cause of death in the United States. With such a significant prevalence, patients with diabetes can account for upwards of one-third of a provider's patient population. Hemoglobin A1c represents the percent of the hemoglobin protein found in red blood cells that have been glycosylated, providing a 3-month estimate of a patient's blood glucose concentration.[1] The goal A1c for patients with type 2 diabetes who are otherwise healthy is <7%. Although less stringent goals are clinically appropriate for more comorbid or elderly patients, <8% is generally accepted, while <9% is a definition of poor control used by some 3rd party payors.

The standard of care for patients with diabetes requires visits with the primary provider or endocrinologist every three months until the A1c is at the predetermined patient-specific goal. In many cases, patients may need more frequent follow up to titrate medications to the target dose for glycemic control, assess for side effects of medications, and ensure affordability of the regimen. Given the significant risk and other chronic disease states associated with diabetes, it behooves the patient and provider to control the patients' blood glucose as quickly as is feasible. However, given limited provider resources and time, it is not always possible to follow up with patients more often than every three months.

A possible solution to this time constraint is the use of clinical pharmacists, who have proven their value across a multitude of settings by alleviating provider burden and assisting patients in achieving ideal health outcomes. Pharmacist integration in chronic disease state management is an effective means to unburden day to day workload of physicians.[2] Furthermore, pharmacists are particularly effective in facilitating A1c reduction within the population of patients with type 2 diabetes.[3,4] A particular 2016 VA study, Sullivan et al., assessed A1c reduction after pharmacist intervention and saw an average absolute A1c decrease of 2.8% in patients with type 2 diabetes.[4]

The Advantage Point Laurel Highlands Clinically Integrated Network (CIN) comprises primary care physicians either independent or employed by Conemaugh Physician Group. The network of physicians is located throughout the west-central region of Pennsylvania. The CIN was designed to promote good patient outcomes and reduce unnecessary costs for patients and third-party payors. The CIN is particularly instrumental in a rural area where resources are relatively limited. In addition, ambulatory care pharmacists are utilized within the CIN for chronic disease state interventions, including interventions on patients with type 2 diabetes.

Purpose

The study's primary objective was to quantify any impact on the A1c values of patients diagnosed with type 2 diabetes within the CIN, whose initial A1c was greater than or equal to 8%, after pharmacist intervention. The hypothesis for this objective was that patients receiving pharmacist intervention within the CIN would have a statistically significant decrease in A1c.

The study's secondary objectives included assessing the percentage of patients achieving a final A1C of <9%, <8%, and the prespecified A1c target set by the 3rd party payer.

Methods

Ethics Statement

Institutional Review Board (IRB) approval was not necessary for this data collection within the CIN due to ongoing quality assurance analysis of A1c values. Pharmacy intervention with patients who have type 2 diabetes was an ongoing process before this study. This study provided an avenue to quantify the impact of pharmacy intervention on patients' A1c that was already being performed. Patient consent was not obtained due to the retrospective nature of the study.

Patient Selection

The study included patients attributed to primary care physicians in the CIN by three insurers: Highmark ®, UPMC ®, or Medicare Fee for Service who received a pharmacy intervention within December 2019 to March 2021. Included patients had to be 18 years of age or older, be diagnosed with type 2 diabetes, have an initial A1c of ≥8%, have a repeat A1c, and finally, have at least one documented pharmacist intervention. There were no exclusion criteria other than failure to meet the inclusion criteria. The patient population intervened upon included a mixture of patients who were referrals and those identified through various reports in EPIC or from the 3rd party payor.

Intervention

The study was conducted within the CIN from December 2019 to March 2021. Patient interventions occurred in person in an office within the CIN or via telephone. Throughout the 1.5 years of the study, 11 pharmacists provided interventions to patients included in this study. Those interventions could have included any combination of diet and exercise counseling, medication education,

medication discontinuation, new medications, dose adjustment, and follow-up. Interventions were documented in the electronic medical record. In addition, a standardized documentation process was implemented in November of 2020, which provided a more definitive way of describing the types of interventions that occurred.

Data Collection

Data analysis was conducted retrospectively through a combination of data reports for the A1c values and chart review of the electronic health record by the primary investigator. Measures were extracted via chart review included gender, race, age, body mass index (BMI), previous diagnosis of hypertension, previous formal diabetic education, and amount and type of pharmacist intervention(s).

Statistical Analysis

The investigators reviewed only de-identified patient data. The institutional statistician determined appropriate statistical tests. The research team performed the statistical tests. The primary outcome was assessed using a repeated-measures analysis of variance (ANOVA) with alpha set at 0.05; Bonferroni correction was applied where applicable to adjust for multiple testing.

Results

Baseline Characteristics

A collection of 171 patients (out of 421) were included in the final analysis of A1c reduction. Two hundred fifty patients were excluded due to a lack of pharmacist intervention. These patients were initially going to be a comparison group. However, of the population of patients that did not receive pharmacist intervention, only 12 had repeat A1c values within our study period, which was not enough to attempt to make a comparison. No patients included in the study were lost to follow-up due to the inclusion criteria of a repeat A1c.

Of the population included in the analysis, 52% were males, and the average age was 60 (Table 1). Additionally, 98% of the population were Caucasian, with 2% African American (Table 1). Other characteristics included: average BMI at initial A1c, underlying hypertension, initial A1c of 8% or greater, and previous formal diabetic education (Table 1).

Table 1: Baseline Characteristics (n=171)

Variable	n (%)
Gender, male	89 (52)
Race	
Caucasian	168 (98)
African American	3 (2)
Average age, years	60 [33 to 95]
Average BMI at initial A1C (kg/m^2)	35.2
Underlying hypertension	156 (91)
Initial A1C of 9% or greater	127 (74)
Previous formal diabetic education	32 (19)

Abbreviations: A1C, glycosylated hemoglobin A1C; BMI, body mass index

Primary Endpoint

The average initial A1c was found to be 10.0 ± 1.5% with a subsequent average A1c of 8.5 ± 1.30% (*P*-value <0.001) and an average final A1c of 8.3 ± 1.30% (*P*-value <0.001) post pharmacist intervention. There was an average of 6 months between initial and subsequent A1c measurements and eight months between initial and final A1c measurements (Table 2). It should be noted that without a comparison group, it is challenging to isolate pharmacist intervention as the primary factor for the A1c reduction.

Table 2 Primary Outcome

Variable	n	Average Initial	Average Subsequent	*P*-value	Average Decrease	Average time between measurements (months)
A1C (%)	171	10.0 ± 1.5	8.5 ± 1.30	<0.001	1.5	6
			Average Final	*P*-value	Average Decrease	Average time between measurements (months)
			8.3 ± 1.30	<0.001	1.7	8

Abbreviations: A1C, glycosylated hemoglobin A1C

Secondary Endpoints

The team of pharmacists performed 486 interventions, with an average of 2.8 interventions per patient (Table 3). Interventions included the following: 48% included dose adjustments, 69% included new medications, 11% included

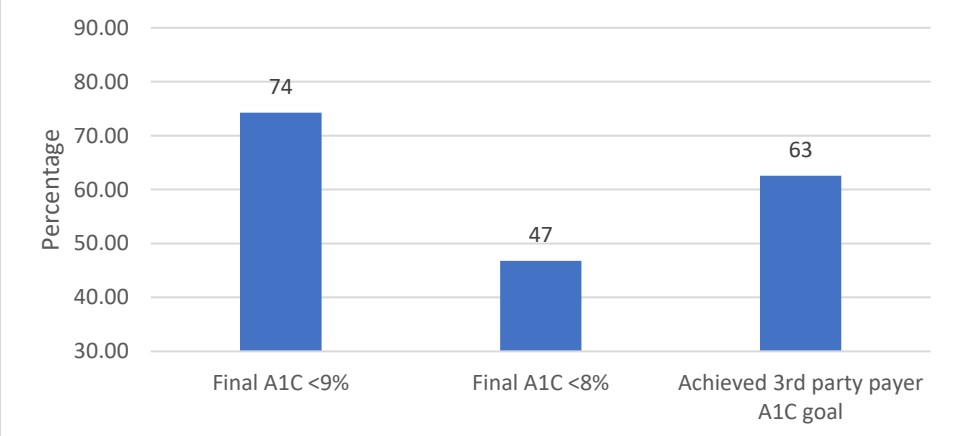
medication discontinuation, 89% had medication education, 81% included diet and exercise counseling, and 64% had follow-up (Table 3).

Table 3: Interventions (n=486)

Variable	n (%)
Total in-person interventions	42 (8.6)
Total telephone interventions	444 (91.4)
Average interventions per patient	2.8
Patients who received:	
Dose adjustment	82 (48.0)
New medication	69 (40.4)
Follow up	109 (63.7)
Medication discontinuation	18 (10.5)
Medication education	152 (88.9)
Diet and exercise counseling	139 (81.3)

Out of 171 patients, 74% achieved a final A1c of less than 9%, 47% achieved a final A1c of less than 8%, and 63% achieved the prespecified 3rd party payer goal [less than 8% in most cases but less than 9% in some] (Figure 1). The study was not powered to assess the statistical significance of secondary outcomes.

Figure 1: Percentage of Patients Achieving Goals



Exploratory Outcomes

In terms of patients who received at least one in-person pharmacist intervention, an average A1c decrease of 1.76% was observed, while those who received no in-person interventions saw a total reduction of 1.74% (Figure 2). Patients with a

starting A1c of 9% or more saw an average decrease in A1C of 2.1% (Figure 2). Notable A1c reduction in terms of interventions included: 1.9% with those receiving dose adjustments, 1.7% with those receiving medication education, and 1.8% with those receiving diet and exercise counseling (Figure 3). Finally, an inverse trend was seen when looking at A1c reduction concerning the number of interventions within the study period. Patients who received 1 to 3 interventions saw an average decrease of 1.8%, 4 to 7 interventions an average reduction of 1.7%, and greater than seven interventions an average decrease of 1.6% (Figure 4). Figure 5 shows the visual trend over time of continued decrease in the A1c value until an average of 8 months. Of note, each of these patient populations had an initial A1C of 10.0%. The study was not powered to assess the statistical significance of exploratory outcomes.

Figure 2: Exploratory A1C Reductions

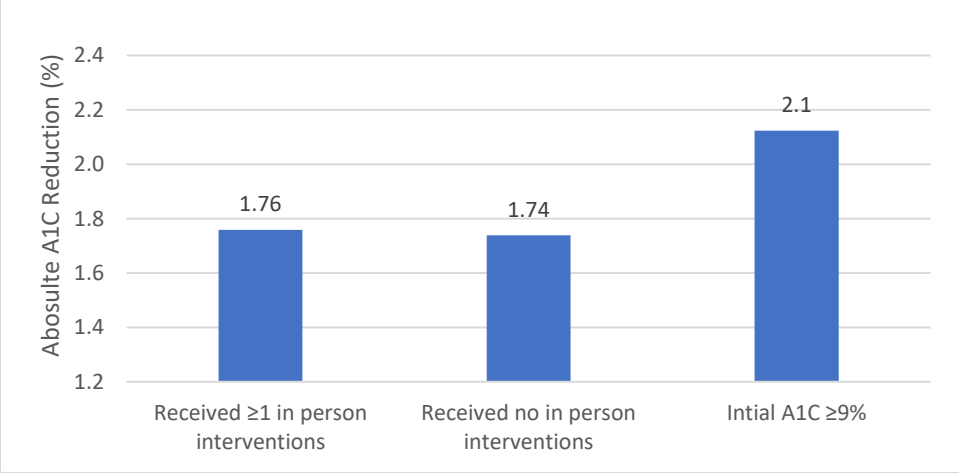


Figure 3: A1C Reduction Based on Intervention

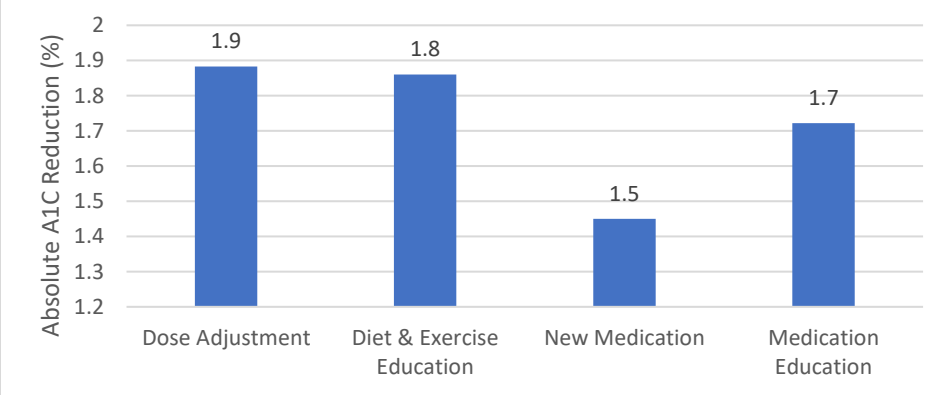
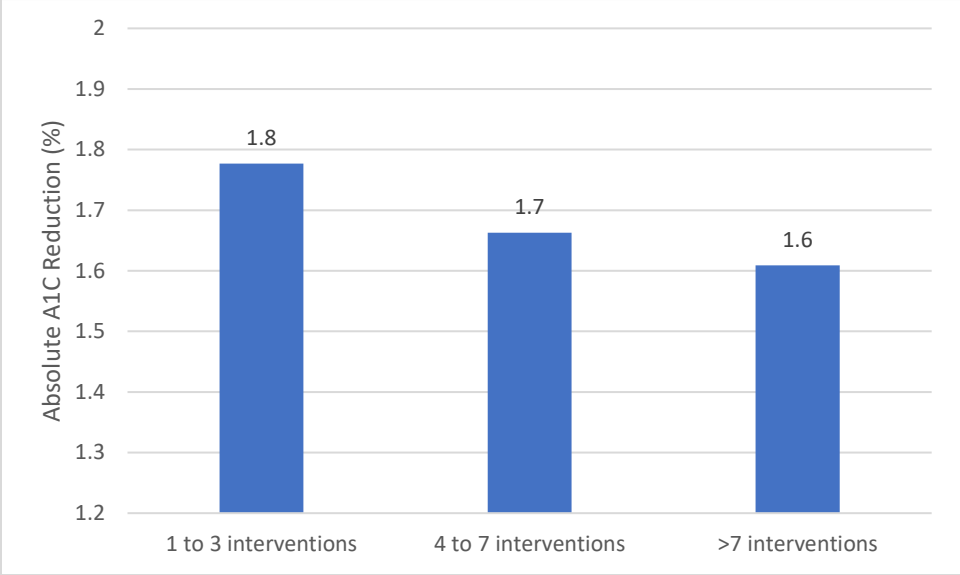


Figure 4: A1C Reduction with Respect to Number of Interventions



Discussion

The primary outcome of this study did show statistical significance with average A1c decreases of 1.5% (initial) and 1.7% (final). Almost half of the patients (47%) achieved an A1c of less than 8%, which is significant improved control versus the baseline. Nearly three-quarters (74%) of the study population achieved an A1c of less than 9%, which is a major advance in the care of a population uncontrolled at the start of the intervention, especially over a limited timeframe of the average of 8 months of the intervention. Most patients (63%) achieved their 3rd party payer's prespecified A1c target.

One area of concern during this study period was whether patients who did not receive in-person interventions would not realize equivalent A1c reductions compared with those who did receive in-person interventions. Analysis revealed that one or more in-person interventions resulted in an average A1c decrease of 1.76%, and no in-person interventions resulted in an average reduction of 1.74%. Although the analysis was not powered to provide statistical significance, it does not appear that there was a clinically significant difference between the two cohorts. It should be noted that there was ten times the number of telephone interventions compared to in-person interventions. It is likely that the skew toward telephone interventions was at least partially attributable to the COVID 19 pandemic and patient hesitation to visit their primary care office.

There were some noted differences in A1c reduction associated with different types of interventions received. Notably, medication dose adjustment was associated with the most significant decrease at 1.9%, with medication discontinuation resulting in the lowest reduction of 1.5%. Patients receiving medication education and diet and exercise counseling trended toward the overall mean at 1.7% and 1.8%, respectively.

The final area of interest in exploratory outcomes was the number of interventions received, and A1c reduction realized. An inverse trend was seen between the number of interventions and A1c reduction. At first, it would seem counter-intuitive that more interventions do not result in a more significant A1c reduction. However, it is postulated that patients who require more interventions are less likely to comply with medication regimens or do not entirely understand their diet and exercise requirements initially. This study was not designed to measure medication compliance or health literacy, and future studies targeting these areas are of interest. Other areas for future study with this intervention include comparator groups, long-term follow-up (beyond the eight months of this study), and assessment of outcomes with an upcoming collaborative practice agreement (CPA) within the CIN as previous studies have shown statistically significant differences between patients receiving standard of care and those receiving pharmacist intervention under a CPA.[3]

Limitations

Limitations of the study included the following: the lack of a comparison (placebo) group, small sample size, little racial diversity within the study sample, multiple pharmacists performing interventions (11 in total), and a lack of standardization of documentation until the last five months of the study period. One additional limitation, the inability to assess medication regimens in data analysis, stemmed from medication lists that were only up to date from the time in which there were evaluated and assessing what medications the patient was on when the first pharmacy intervention did not produce reliable information.

Conclusion

Patients with type 2 diabetes who received a pharmacist intervention within the CIN realized a statistically significant decrease in A1c. However, the lack of a comparator group makes it not feasible to comment on differences in A1c reduction between patients who do and do not receive pharmacist intervention based on these results.

Declaration of Conflicting Interests

There are no actual or potential conflicts of interest to disclose by any of the authors.

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