Pharmacists' Impact on Improving Outcomes in Patients With Type 2 Diabetes Mellitus

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Purpose

The purpose of this study was to evaluate a diabetes education program that includes a pharmacist as a member of the diabetes management team by assessing the change in hemoglobin A1c (A1C), cholesterol, and blood pressure for patients with type 2 diabetes in outpatient clinics.

Methods

This was a retrospective study in outpatient clinics at Shands Jacksonville Medical Center. The patients were assigned into either the pharmacist group or the nonpharmacist group, according to the presence or the absence of a pharmacist in the clinic. The primary end point was the absolute change in A1C versus baseline. Secondary end points included change in cholesterol and blood pressure and the number of patients to attain American Diabetes Association goals. End points were recorded to correlate within 3 months of the initial visit and final visit with a provider.

Results

Compared to the nonpharmacist group, patients in the pharmacist group had more advanced and uncontrolled diabetes at baseline. The pharmacist group showed a greater percent change in A1C and improvement between the initial and final clinic visits, after adjusting for baseline confounders. Despite the statistically significant improvement in A1C in the pharmacist group, there was

no difference found between the 2 groups for the end points of cholesterol and blood pressure.

Conclusion

Including a pharmacist as a part of the diabetes management team may result in lower A1C in patients with more advanced and uncontrolled type 2 diabetes mellitus versus a health care team without a pharmacist.

Keywords: outcomes, pharmacist

Diabetes mellitus is a complex disease that is associated with a variety of health complications. Patients with diabetes often have comorbidities such as hyperlipidemia and hypertension.[1] In the United States, the number of people with diabetes has increased over the years. In 2010, nearly 25.8 million people in the United States were estimated to have diabetes, and over 1.9 million persons 20 years of age or older were diagnosed.[2] Microvascular and macrovascular complications of poorly controlled diabetes include retinopathy, neuropathy, nephropathy, and cardiovascular disease. Improved glycemic control prevents or delays disease onset and helps mitigate progression of lifelong complications.[3-6] The Diabetes Control Complications Trial and the United Kingdom Prospective Diabetes Studies demonstrated that intensive outpatient glycemic control can improve hemoglobin A1c (A1C) and prevent complications of diabetes.[3-5] These trials support current practice guidelines for diabetes management established by the American Diabetes Association (ADA).[6] Patients who lack insurance, have financial hardships, have transportation difficulties, and/or are not followed by a primary care provider face unique challenges. As a result of such challenges, these patients may lack early detection and proper management and may experience poorer outcomes as well as earlier complications.[7] A multidisciplinary team can assist patients in overcoming such barriers and help improve diabetes management. Patients with early detection and management have a higher quality of life and improved long-term benefits, including the delay or prevention of organ system damage or complications.[6]

A diabetes management team plays a key role in the management of this complex disease state. The multidisciplinary team may include pharmacists, diabetes educators, endocrinologists, dieticians, nurses, exercise physiologists, podiatrists, and ophthalmologists.[8] Diabetes teams work together to ensure patients have regular lab work, as well as help patients achieve target values. In a previous Medicare claim review, 29% of patients did not have the ADA-recommended A1C values measured within 1 year of diagnosis.[9,10] A team approach helps best manage patients with diabetes and can improve outcomes and reduce health care costs. This multidisciplinary team approach becomes increasingly important as medical home models are implemented in diabetes outpatient management programs.

Pharmacists are valuable assets to the multidisciplinary team, as they provide education to the patient about diabetes, medications, nutrition, and exercise. Pharmacists also contribute to the health care team by making medication and laboratory recommendations to help manage comorbidities, and by assisting patients in obtaining and properly using their prescribed medications. The diabetes management team helps patients better understand and become empowered to take control of their diabetes.

Previous studies such as The Asheville Project and the Ten City Challenge have shown improved outcomes with pharmacist involvement in a multidisciplinary team.[11,12] These studies exemplified an expanded role of a community pharmacist in the outpatient management of diabetes through education on diabetes, nutrition, exercise, and medication adjustments. Pharmacists were trained in a diabetes certificate program and practiced with physicians under a collaborative practice model. The pharmacists' role was to follow patients long-term through consultations, clinical assessment, goal setting, monitoring, and drug therapy management. These studies also demonstrated that pharmacists helped improve outcomes of A1C, cholesterol, blood pressure, medication use, and cost; however, it was unknown whether similar impacts were being made in the ambulatory clinics at Shands Jacksonville Medical Center (SJMC).

The aim of this retrospective study was to evaluate diabetes education in management teams that included a pharmacist compared to those that did not include a pharmacist. This evaluation was done by comparing the change in clinical outcomes (A1C, low-density lipoprotein [LDL], high-density lipoprotein [HDL], triglycerides

[TG], and blood pressure) and the number of patients to achieve ADA standards of care at SJMC clinics. Current practice models include differing recommendations for pharmacist involvement. According to the American Association of Clinical Endocrinologists (AACE) practice guidelines, a pharmacist is not included as a part of the diabetes management team, whereas medical home models include a pharmacist.[13] This study was designed to assess whether pharmacists are having a clinical impact on the diabetes management team and to ultimately see whether they should be included in practice models.

Methods

This study was a retrospective study that was approved by the University of Florida and Shands Institutional Review Board. Clinic visits between January 1, 2006 and December 31, 2010 were evaluated by reviewing electronic medical records. The study population included patients from outpatient diabetes clinics at SJMC.

Shands Jacksonville Medical Center, located in northeastern Florida, has many outpatient clinics that help patients who are underinsured and underserved manage their diabetes. In the combined clinics, over 11,000 patients were seen for diabetes management in 2010. Although other clinics may include a pharmacist, only 2 clinics include the pharmacist as a part of the diabetes management team to directly manage diabetes. In diabetes clinics with a pharmacist, patients are referred to a pharmacist once their diabetes becomes advanced or uncontrolled. Pharmacists in these clinics play an extensive role in the management of diabetes, including patient education on diabetes, nutrition, exercise, and working collaboratively with physicians to make medication adjustments. As a part of the diabetes management team, pharmacists schedule clinic visits with patients to monitor A1C, LDL, HDL, TG, and blood pressure. In clinics without a pharmacist, the diabetes management team may consist of physicians, nurses, and diabetes educators. Most patients seen in both clinic groups are covered by a city contract, which allows patients to have access to clinic visits and medications for little or no cost.

Patient Population

Clinics for the pharmacist group included a pharmacist as a part of the diabetes management team. The role of the pharmacist in the diabetes management team is a collaborative practice model similar to that seen in The Asheville Project and the Ten City Challenge. Pharmacists take an active role in following patients in education settings, one-on-one counseling, monitoring, goal setting, and drug therapy management. The control group, or nonpharmacist group, included patients at off-campus clinics that do not have a pharmacist at the clinic. This separation of clinics was intended to avoid the possibility of patients being included in both groups or having a pharmacist influence therapy management in the control group. Patients were identified by ICD-9 code 250, which includes all types of diabetes diagnoses.

Patients were included if they were ≥ 18 years of age; diagnosed with type 2 diabetes; were seen as patients at UF and Shands Jacksonville ambulatory primary care clinics between January 1, 2006 and December 31, 2010; and had ≥ 2 clinical visits for diabetes within 6 months. Patients were excluded if they had type 1 or gestational diabetes or incomplete medical records, which were defined as a baseline measurement recorded outside 3 months before or after initial appointment or < 2 end points measured (A1C, LDL, HDL, TG, systolic blood pressure [SBP], diastolic blood pressure [DBP]), in correlation with the initial and final visit. Patients taking investigational medications or who were incarcerated or pregnant were also excluded.

Data Collection

After the patients were assigned to a group, medical records were reviewed to collect data on patient demographics. Baseline demographics were determined by the patient's documented health status and laboratory values as recorded in the initial visit clinic note. Complications were included in the analysis if they were reported subjectively or objectively. This criterion included self-reporting, medical diagnosis, or laboratory and physical findings of such complications, all according to documentation in clinic notes. Microvascular or macrovascular complications were defined as retinopathy, nephropathy, neuropathy, or cardiovascular disease (CVD). Cardiovascular disease was defined as coronary artery disease, history of myocardial infarction, or heart valve disease.

Study end points were collected to correlate with initial and final visits in each group. The longest duration between the initial and final visits was used based on

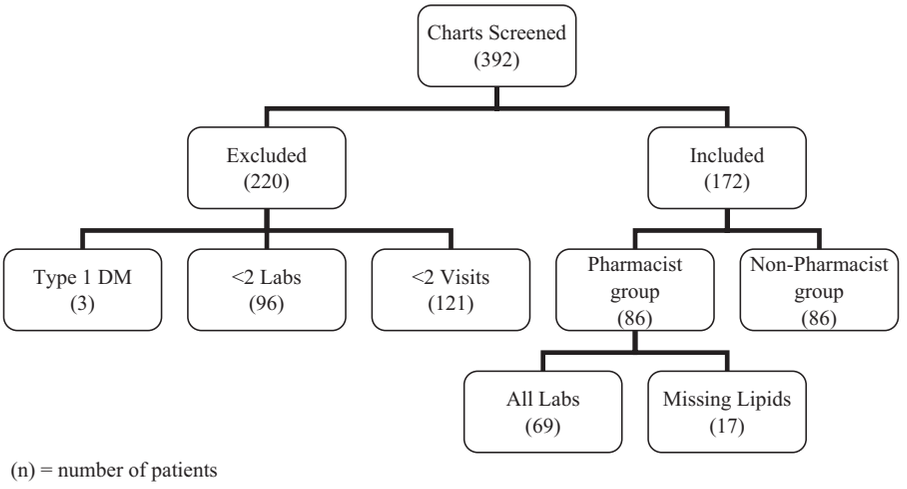

Figure 1. Patient flow chart.

available documented end points that were drawn within 3 months of visits. If an end point was not documented within the 3-month period, the next correlating clinical visit was used as the initial or final visit, respectively, to avoid measurement biases. No laboratory values were recorded between the initial and final visits. Group comparisons were based on the change in the end points between the initial and final visits.

The mean change of the end points and the number of patients to reach goal were evaluated for pharmacist-managed clinics and compared to clinics without a pharmacist-managed diabetes program. The groups were compared to each other, as were achievement of goals established by ADA, defined as A1C < 7%, LDL < 100 mg/dL (in patients without CVD) or < 70 mg/dL (in patients with CVD), HDL > 40 mg/dL (male) or > 50 mg/dL (female), TG < 150 mg/dL, SBP < 130 mmHg, and DBP < 80 mmHg.

Data Analysis

An a priori calculation was conducted to determine a sample size prior to initiating the study. In order to achieve an 80% power to detect a 0.5% difference in A1C, 86 patients were needed in each group, and a 2-sided $\alpha = 0.05$. Analysis of baseline demographics to determine statistically significant differences between the groups was conducted using the Student *t* test (eg, continuous data) and chi-square test for independence (eg, for nominal data). The results were analyzed using linear mixed models for continuous outcomes, whereas logistic regression was used for categorical outcomes, so that statistically significant factors could be identified and odds ratios calculated. The data were analyzed using SAS (version 9.2, SAS, Inc, Cary, NC. 2008).

Results

Eighty-six patients were included in each group for end point analysis of A1C and blood pressure values. However, for cholesterol end point analysis, 69 patients were included in the pharmacist group and 86 for the nonpharmacist group. This difference was caused by a lack of available lab results within the specified time frame for the pharmacist group (Figure 1). The mean age (± standard deviation) in the pharmacist group was 59.5 (± 9.5) years versus 57.9 (± 12.9) years in the nonpharmacist group. The majority of the patients in both groups were obese, African American females with hypertension and hyperlipdemia (Table 1). Statistically significant differences in baseline demographics were found between the 2 groups for the combined average number of complications, defined as retinopathy, neuropathy, nephropathy, or CVD ($P < .001$). The baseline A1C values were 9.68% in the pharmacist group and 7.71% in the nonpharmacist group ($P < .001$). More patients in the nonpharmacist group were at goal A1C than patients in the pharmacist group ($P < .001$). At baseline, the number of patients already receiving insulin therapy was greater in the pharmacist group ($P < .001$).

The number of patients to improve in A1C (eg, lower final value) between the initial and final visits was greater, but not statistically significant, in the pharmacist group compared to the nonpharmacist group, 63 (73.2%)

Table 1.

Baseline Demographics

	Pharmacist		*Nonpharmacist*		*P*
Age, y (SD)	59.5	(9.5)	57.9	(12.9)	.36
Female, n (%)	51	(59.3)	62	(72)	.37
Ethnicity, n (%)					
African American	52	(60.4)	42	(48.8)	
Caucasian	33	(38.3)	38	(44.2)	
Hispanic	1	(1.1)	5	(5.8)	
Other	0		1	(1.1)	
Mean body mass index, kg/m2 (SD)	37.1	(9.5)	35.5	(9.5)	.56
Hyperlipidemia, n (%)	67	(77.9)	62	(72.1)	.85
Hypertension, n (%)	82	(95.3)	75	(87.2)	.59
Mean no. of complications	1.39		0.8		< .001
Retinopathy, n	28		8		< .001
Neuropathy, n	44		19		< .001
Nephropathy, n	20		21		.99
CVD, n	28		21		.31
Tobacco use, n (%)	22	(25.5)	35	(40.7)	.22
A1C, % (SD)	9.68	(2.6)	7.71	(1.6)	< .001
A1C at goal, n (%)	7	(8.1)	34	(39.5)	< .001
Mean no. of oral medications for diabetes	1.01		0.96		.59
Aspirin, n	59		18		< .001
ACE inhibitors, n	63		53		.14
ARB, n	11		12		.99
HMG CoA reductase inhibitors, n	69		49		< .01
No. of patients on insulin, n%	64	(74.4)	31	(36)	< .001

Abbreviations: A1C, hemoglobin A1c; ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; CVD, cardiovascular disease; SD, standard deviation.

patients and 40 (46.5%) in each group, respectively (P = .11; Table 4). For the primary end point, the mean difference in A1C in each group was -1.49% versus 0% (P = .04; Table 2). This mean difference in A1C was statistically significant after the confounders of (1) comorbidities, (2) insulin, and (3) patient initially already at goal for A1C were adjusted for through regression analysis.

For secondary end points, the mean difference in LDL, HDL, TG, and blood pressure were not found to be statistically significantly different between the 2 groups (Table 2). Secondary end points for achieving ADA goals were not statistically significantly different for any of the outcome measurements (Table 3).

The average number of hospitalizations per patient was 0.15 for the pharmacist group and 0.41 for the nonpharmacist group (P = .02). On average, the patients in the pharmacist group had fewer clinic visits with a provider than those in the nonpharmacist group, 10.7 versus 12.4, respectively (P = .27); however, this was not a statistically significant difference. The pharmacist group had a lower mean number of days between the initial and final visits (P < .001). Patients in the pharmacist group had a higher mean number of medication changes or adjustments of 2.45 versus 1.38 in the nonpharmacist group (P < .001). Sixteen adverse drug reactions were identified in the pharmacist group compared to 10 in the nonpharmacist group (P = .05; Table 4). The most common adverse drug reaction in each group was hypoglycemia.

Discussion

The results of this study show that having a pharmacist participate in the diabetes management team is associated

Table 2.

Mean Laboratory Values

	Pharmacist group			Nonpharmacist group			
	Initial	**Final**	**Change**	**Initial**	**Final**	**Change**	***P***
A1C (%)	9.68	8.19	-1.49	7.71	7.71	0	.04
LDL (mg/dL)	96.2	83.2	-13	110.3	99.4	-10.9	.21
HDL (mg/dL)	44.1	44.7	+0.6	47.4	48	+0.6	.99
TG (mg/dL)	198.9	152.7	-46.2	162.3	154.8	-7.5	.80
SBP (mmHg)	133.1	132.8	-0.3	140.5	141.3	+0.8	.14
DBP (mmHg)	74.9	75.5	+0.6	81.3	82.8	+1.5	.08

Abbreviations: A1C, hemoglobin A1c; DBP, diastolic blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure; TG, triglycerides.

Table 3.

Group Results for Patients at ADA Goals

	Pharmacist group			Nonpharmacist group			
	Initial, n (%)	**Final, n (%)**	**Change, %**	**Initial, n (%)**	**Final, n (%)**	**Change, %**	***P***
A1C	7 (8.1)	18 (20.9)	+12.8	34 (39.5)	35 (40.6)	+1.1	.25
LDL, mg/dL	30 (43.4)	46 (66.6)	+23.2	33 (38.4)	44 (51.2)	+12.8	.80
HDL, mg/dL	24 (34.7)	23 (33.3)	-1.4	33 (38.4)	39 (45.3)	+6.9	.77
TG, mg/dL	33 (47.8)	43 (62.3)	+14.5	54 (62.8)	57 (66.2)	+3.4	.49
SBP, mmHg	32 (37.2)	39 (45.3)	+8.1	29 (33.7)	24 (27.9)	-5.8	.39
DBP, mmHg	49 (56.9)	52 (60.4)	+3.5	44 (51.2)	35 (40.6)	-10.6	.56

Abbreviations: A1C, hemoglobin A1c; DBP, diastolic blood pressure HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure; TG, triglycerides.

with improved outcomes in patients with type 2 diabetes, particularly in lowering A1C. In this study, compared to the nonpharmacist group, the pharmacist group had patients with more advanced and less controlled diabetes, which was apparent with patients in the pharmacist group because they had higher baseline A1C and more diabetes-related complications compared to the nonpharmacist group. This difference between groups is not surprising, since patients are referred for pharmacy follow-up only if their diabetes has become uncontrolled or complications have occurred. At SJMC, patients followed by pharmacists are released back to the care of the primary care physician once the patient's diabetes becomes controlled and ADA goals are obtained. This procedure is consistent with the results in this study, which show that patients in the nonpharmacist group had longer duration of follow-up and a higher mean number of visits compared to the pharmacist group.

The results for change in A1C for this study are similar to findings in other published literature for pharmacist-followed patients, although the study designs differed. In The Asheville Project, A1C and lipid levels improved at each measurement in more than 50% of patients.[11] In the Diabetes Ten City Challenge, mean A1C levels decreased from 7.5% to 7.1% ($P = .002$), mean LDL cholesterol decreased from 98 to 94 mg/dL ($P < .001$), and mean SBP decreased from 133 to 130 mmHg ($P < .001$).[12]

Table 4.

Mean Group Results

	Pharmacist group, n (SD)		Nonpharmacist group, n (SD)		*P*
No. that improved in A1C	63		40		.11
No. of provider visits	10.7	(8.7)	12.4	(10.1)	.27
Time between initial and final visits, d	260	(236.2)	534.4	(473.8)	< .001
Hospitalizations	0.15	(0.5)	0.41	(0.95)	.02
Medication changes	2.45		1.38		< .001
No. of ADRs identified	16	(0.42)	10	(0.36)	.05

Abbreviations: A1C, hemoglobin A1c; ADRs, adverse drug reactions; SD, standard deviation.

Another study of interest by Rothman et al showed a mean percent change in A1C of -1.9% after 6 months of pharmacist intervention.[7] In that study, the baseline A1C was 10.8%, which is similar to that in this study, but the study lacked a control group. In 2006, Morello et al examined outcomes in A1C, cholesterol, and blood pressure in a retrospective analysis comparing baseline values to final values after 1 year.[8] That study showed a -1.3% change in A1C, -16 mg/dL in LDL, and 1 mg/dL in HDL for males and -3 mg/dL for females. Other results included a change of -65 mg/dL for TG, -4 mmHg SBP, and -2 mmHg DBP, although the study lacked a control group. Taveira et al compared a pharmacist-led group versus usual care using a prospective study design.[14] That study showed a statistical significance between the 2 groups and a difference in A1C of -0.9% (± 1.6) in the pharmacist group versus 0% (± 1.5) in the usual care group.

In this study, the difference in mean number of hospitalizations between the 2 groups should be interpreted with caution. Documentation for such hospitalizations was available only at SJMC. It is undetermined whether or not patients were admitted to other hospitals. The total number of hospitalizations was recorded, including those not directly attributed to diabetes.

Limitations

Limitations of this study include the nature of the retrospective design itself, which led to a lack of documentation for medications, diagnoses, and complications. Other inherent limitations to retrospective studies include their nonblinded nature and a lack of control of confounding factors between groups, as seen in this study. However, retrospective studies can show a weak cause and effect relationship that would direct investigators to conduct large-scale, progressive trials.

In this study, the sample size obtained achieved power for A1C, but it did not meet power requirements for secondary end points. It is possible that the reason no difference was found for the secondary end points was that this study was not powered to detect a difference for cholesterol and blood pressure outcomes. The patient population was not well matched between the groups and was a convenience sample of all the patients that had been referred to the pharmacist clinics from January 2006 to December 2010. Another limitation of the study was the lack of recorded end points between the initial and final clinical visits, although medication adjustments, changes, and adverse effects were noted between visits.

Strengths

This study has many strengths and supports other available literature. Compared to other studies, this study has a relatively large sample size. This study also included a comparison group and evaluated multiple outcomes related to diabetes. Other strengths include that outcomes were well-defined and reproducible and statistically adjusted for identified confounders. Finally, the data were also reviewed to show validity.

As outpatient diabetes management is progressing toward medical home models, this study supports the initiatives to implement pharmacists into diabetes management

teams. Although the AACE practice guidelines currently do not include pharmacists as a part of diabetes management recommendations,[13] medical homes use a team approach to take advantage of the expertise of many medical professionals to address the needs of the patient in order to control the progression of this complex disease, and pharmacists have been shown to have an important role.

Conclusion

This study showed that inclusion of a pharmacist in the diabetes management team was associated with significantly lower A1C compared to that in the nonpharmacist group. Although no difference was found in cholesterol, blood pressure, or helping patients to achieve ADA goals in this study, other studies have shown a clear benefit. Pharmacists continue to play an important role in diabetes education and can have extensive involvement on a diabetes management team, which therefore provides an added benefit for the patient.

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