The Hispanic Diabetes Management Program: Impact of community pharmacists on clinical outcomes

Ola O. Oyetayo, Clyde James, Anita Martinez, Kim Roberson, and Robert L. Talbert

Abstract

Objective: To assess the impact of community pharmacists on clinical outcomes in Hispanic patients with type 2 diabetes.

Methods: 126 patients were enrolled in this longitudinal pre/post cohort study that took place in nine community and four workplace pharmacies in San Antonio, TX. Pharmacists provided education, point-of-care testing for glycemic and metabolic parameters, clinical assessment, goal setting, and drug therapy management with physicians. Study outcomes were changes in glycosylated hemoglobin (A1C) and accompanying metabolic parameters (blood pressure, lipid parameters, and body mass index) during a 1-year time frame.

Results: In the overall cohort, A1C was not reduced significantly from baseline to 12 months (7.8% vs. 7.6%, $P = 0.516$). However, statistically significant reductions occurred for fasting plasma glucose, triglycerides, and diastolic blood pressure. None of the other parameters was affected significantly. In the subgroup of patients not at target values at baseline, significant reductions occurred for A1C (9.2% vs. 8.6%, $P = 0.001$), systolic blood pressure (147 vs. 143 mm Hg, $P = 0.031$), diastolic blood pressure (91 vs. 87 mm Hg, $P < 0.001$), triglycerides (259 vs. 219 mg/dL, $P < 0.001$), LDL cholesterol (139 vs. 123 mg/dL, $P < 0.001$), and total cholesterol (237 vs. 222 mg/dL, $P = 0.008$).

Conclusion: Interventions performed by community pharmacists are effective in improving clinical outcomes in a Hispanic cohort with diabetes. Pharmacists' efforts were most successful in patients not at target glycemic and metabolic levels.

Keywords: Diabetes, Hispanic patients, health outcomes, medication therapy management, community pharmacists.

J Am Pharm Assoc. 2011;51:623–626.
doi: 10.1331/JAPhA.2011.09229

Diabetes is a growing epidemic among the Hispanic community in the United States. The Centers for Disease Control and Prevention (CDC) estimated that in 2007, about 2.2 million Hispanic Americans were living with diabetes.[1] This represented an increase of 26% from 2004 to 2007. Mainous et al.[2] further projected that by 2031, 20% of the adult Hispanic population in the United States will have diabetes.

The National Health and Nutrition Examination Survey (conducted from 1999 to 2006) showed that rates of glycemic control were significantly lower in Hispanics compared with non-Hispanic whites.[3] Pooled 8-year glycemic control, which was defined as glycosylated hemoglobin (A1C) less than 7%, in U.S.-born Hispanics, was 38% compared with 42% and 58% in blacks and non-Hispanic whites, respectively. Mean A1C was 7.7% in Hispanics and blacks compared with 7% in non-Hispanic whites.[3] Diabetes complications also occur more frequently in Hispanics than non-Hispanic whites, with

Received December 2, 2009, and in revised form October 7, 2010. Accepted for publication October 18, 2010.

Ola O. Oyetayo, PharmD, MSc, BCPS, was Pharmacotherapy Resident, College of Pharmacy, University of Texas at Austin, and University of Texas Health Science Center at San Antonio, at the time this study was conducted; he is currently Assistant Professor of Pharmacy Practice, Irma L. Rangel College of Pharmacy, Texas A&M Health Science Center, Kingsville, TX. **Clyde "C.J." James, BSPharm,** is National Account Director, AstraZeneca, San Antonio, TX. **Anita Martinez, BSPharm, CDE,** is Manager, Healthy Outcomes, Benefits, H-E-B Grocery Company, San Antonio, TX. **Kim Roberson, BSPharm,** is Senior Director, Professional Affairs, Texas Pharmacy Association, Austin. **Robert L. Talbert, PharmD, BCPS, FAHA, FCCP,** is Professor of Pharmacy, College of Pharmacy, University of Texas at Austin, and Professor of Medicine, University of Texas Health Science Center at San Antonio.

Correspondence: Ola O. Oyetayo, PharmD, Irma L. Rangel College of Pharmacy, Texas A&M Health Science Center, TAMU II Bldg., Room 303C, 2401 South 31st St., Temple, TX 76508. Fax: 254-724-1731. E-mail: oyetayo@pharmacy.tamhsc.edu

Disclosure: Mr. James is an employee of AstraZeneca and holds stocks options in AstraZeneca. The other authors declare no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, employment, gifts, stock holdings, or honoraria.

Acknowledgments: To the Texas Pharmacy Association and AstraZeneca (the founding partners of the project); to H-E-B, Dermatological Pharmaceuticals of Texas, Humana, Outcomes Pharmaceutical Health Care, and Walgreens (the community-based coalition partners); to Bexar County Pharmacy and Bexar County Medical Associations, Senator Leticia VanDePutte, and Father David Garcia for support with development of the project; to Chris Frei, PharmD, for reviewing statistical methods; and to the patients who elected to participate in the study.

Funding: AstraZeneca.

Previous presentation: Alcalde XXIII Southwest Leadership Conference, Austin, TX, April 16–17, 2009.

Published concurrently in ***Pharmacy Today*** and the ***Journal of the American Pharmacists Association***.

Hispanics having higher rates of microvascular complications.[1] Similarly, they have lower rates of blood pressure and cholesterol control, which are key targets to reduce macrovascular complications.

Given the growing prevalence and lagging control of diabetes in Hispanics, a need exists for developing better approaches to improve diabetes care in the Hispanic population. Pharmacists are readily available and have been shown to improve outcomes for a variety of medical conditions, including hypertension, asthma, and diabetes.[4–7] To our knowledge, this is the first study to focus on the impact of pharmacists in Hispanic patients with diabetes.

Objective

We sought to assess the impact of community pharmacists on clinical outcomes in Hispanic patients with diabetes.

Methods

The Texas Hispanic Diabetes Management Program is a community pharmacist–led, patient-centered medication therapy management (MTM) program that was developed to improve diabetes care in Hispanic patients living in San Antonio, TX. The study was considered exempt from review by the University of Texas Health Science Center Institutional Review Board. Study participants were required to provide consent before enrolling.

AstraZeneca, in partnership with the Texas Pharmacy Association, established the Texas Hispanic Healthcare Coalition with employers and health care providers. Coalition participants included H-E-B (a Texas-based food and pharmacy company), Humana, Walgreens, and Dermatological Pharmaceuticals of Texas (DPT; a San Antonio–based pharmaceutical manufacturer). AstraZeneca provided funding for the project through Outcomes Pharmaceutical Health Care (Outcomes) and the Texas Pharmacy Association. Outcomes served as the third-party administrator for the project. The Texas Pharmacy Association received an unrestricted grant from AstraZeneca for educational tracks, tools, and resources to educate pharmacists and to support the development of a pharmacy network. The pharmacy network included pharmacists from H-E-B and Walgreens who elected to receive additional training in diabetes management. A total of 22 pharmacists received the training and were included in the pharmacy network; however, services were provided by 14 pharmacists only. The pharmacists attended a live 4-hour education session provided by an endocrinologist and a pharmacist with expertise in diabetes management. Compensation for services rendered by the pharmacists was provided through Outcomes.

The pharmacists used a Web-based system provided by Outcomes. The Outcomes system captured all necessary documentation for patient enrollment and progress through the protocol. Interacting with the system, pharmacists were able to create an MTM profile that included a master medication list and medication action plan. Pharmacists also were able to generate fax-ready prescriber communications from the Outcomes system in order to communicate drug therapy recommendations to appropriate prescribers. Consistency of documentation streamlined reporting processes for pharmacists and program administrators. The study protocol appears in Appendix 1 (electronic version of this article, available online at www.japha.org).

Employees of participating organizations (H-E-B, Walgreens, Humana, and DPT) were eligible to enroll if they had been diagnosed with type 2 diabetes and were of Hispanic descent. The criterion for Hispanic descent was met if at least one grandparent was of Hispanic descent. No other inclusion or exclusion criteria were applied. Participants were free to choose from any of the H-E-B or Walgreens pharmacies participating in the study as their primary site.

The pharmacist–patient interaction took place during a 12-month period. Initial enrollment began in 2004, and the final set of patients was enrolled in 2007. Participants had face-to-face meetings with pharmacists every 3 months for diabetes counseling and education that centered on increasing glycemic control by improving medication adherence, diet, and exercise. Participating pharmacies were not required to have private consultation areas. Other interventions included point-of-care testing for blood pressure, A1C, lipid parameters, and weight. Pharmacists also were encouraged to make drug therapy recommendations to patients' diabetes care providers.

Outcomes definition

Clinical outcomes data were collected at 3-month intervals for participants enrolled in the program. Data were collected on A1C, fasting plasma glucose, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, total cholesterol, triglycerides, body mass index (BMI), and weight.

Statistical analysis

Descriptive statistics were generated using JMP 7 software (SAS, Cary, NC) to summarize baseline demographics and laboratory parameters. Data were analyzed using intention-to-treat analysis. Statistical analysis was performed using paired *t* test for normally distributed data and Wilcoxon signed-rank test for non–normally distributed and ordinal data. The McNemar's chi-squared test was performed for nominal data. To account for missing data at visits or patients lost to follow-up, the last-observation-carried-forward (LOCF) method was used for data analysis. The last available values were substituted for missing values in patients lost to follow-up or with incomplete data at prespecified visits. An a priori significance level of $P < 0.05$ was used throughout the study. For analyses involving target values, the following values were defined as optimal using the American Diabetes Association (ADA) Standards of Medical Care in Diabetes guidelines: A1C less than 7%, LDL cholesterol less than 100 mg/dL, total cholesterol less than 200 mg/dL, triglycerides less than 150 mg/dL, SBP less than 130 mm Hg, DBP less than 80 mm Hg, BMI less than 25 kg/m^2, and HDL cholesterol greater than 40 mg/dL for men and greater than 50 mg/dL for women.[8]

Results

A total of 126 patients were enrolled in the study, which ran from March 2004 to September 2007. The participants were evenly divided by gender. Available baseline information was not complete for each laboratory parameter measured. Compliance with study visit requirements decreased progressively at each follow-up. For example, A1C values were available for 122 patients at baseline, 89 patients at 3 months, 62 patients at 6 months, 51 patients at 9 months, and 44 patients at 12 months. Baseline demographics are summarized in Table 1. On average, 3.7 pharmacist contacts per patient occurred, including scheduled and unscheduled visits.

Clinical outcomes

Table 1 summarizes the changes in metabolic parameters using the LOCF method at the prespecified time points. A1C was not reduced significantly in the overall cohort from baseline to 12 months (7.8% vs. 7.6%, $P = 0.516$). Overall, the number of patients with A1C values less than 7% did not change from baseline to 12 months (43% vs. 42 %, $P = 1.000$).

A number of patients enrolled in the program had values at baseline that were consistent with ADA-defined target values. We therefore conducted a subgroup analysis on patients not at target at baseline with the assumption that this cohort of patients would be more likely to have significant reductions in metabolic parameters. In this group, mean A1C values decreased significantly from baseline at all time points. Table 2 summarizes the changes in metabolic parameters at 12 months in patients who were not at target values at baseline.

Discussion

The current results demonstrate the impact that community pharmacists can have in helping to improve clinical outcomes in Hispanic patients with diabetes. The results serve as an extension of the results seen in the Asheville Project to Hispanic patients. The Asheville Project demonstrated sustained improvements in glycemic and cholesterol control during a 5-year period in a predominantly white population (85% white and 15% black) using a community pharmacist–led diabetes management program. In our study, similar to the Asheville Project, improvements in lipid parameters were achieved; however, the benefits of pharmacist interventions on A1C were only apparent in patients not at target levels. This finding is consistent with the Asheville Project, in which patients with higher baseline A1C values were most likely to show improvement.[9]

Table 1. Metabolic parameters at baseline and 3, 6, 9, and 12 months for overall patient cohort

	n	Baseline	3 months (mean)	6 months (mean)	9 months (mean)	12 months (mean)	Mean difference (baseline vs. 12 months)	*P* (baseline vs. 12 months)
A1C (%)	122	7.8	7.7	7.8	7.8	7.6	–0.2	0.516
FPG (mg/dL)	124	163	155	154	150	149	–14	0.019
DBP (mm Hg)	124	87	86	85	84	85	–3	0.0003
SBP (mm Hg)	124	133	133	133	133	133	0	0.452
LDL cholesterol (mg/dL)	118	109	106	103	104	105	–4	0.083
HDL cholesterol (mg/dL)	121	40	40	41	40	40	0	0.595
Total cholesterol (mg/dL)	103	182	182	178	180	182	0	0.701
Triglycerides (mg/dL)	125	191	187	179	179	176	–15	0.003
BMI (kg/m^2)	121	33.9	34.2	34.1	34.1	34.3	0.4	0.206

Abbreviations used: A1C, glycosylated hemoglobin; BMI, body mass index; DBP, diastolic blood pressure; FPG, fasting plasma glucose; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure.

Table 2. Metabolic parameters at baseline and 3, 6, 9, and 12 months for patients not at goal values

	n	Baseline	3 months (mean)	6 months (mean)	9 months (mean)	12 months (mean)	Mean difference (baseline vs. 12 months)	*P* (baseline vs. 12 months)
A1C (%)	70	9.2	8.9	8.8	8.8	8.6	–0.6	0.006
DBP (mm Hg)	96	91	89	87	87	87	–4	<0.001
SBP (mm Hg)	66	147	144	143	144	143	–4	0.031
LDL cholesterol (mg/dL)	60	139	128	121	124	123	–-16	<0.001
HDL cholesterol (mg/dL)								
Men	40	32	32	31	31	31	–1	0.725
Women	46	38	39	41	41	41	3	0.025
Total cholesterol (mg/dL)	32	237	228	221	221	222	–15	0.008
Triglycerides (mg/dL)	69	259	238	223	221	219	–40	<0.001
BMI (kg/m^2)	113	35	35	35	35	35	0	0.238

Abbreviations used: A1C, glycosylated hemoglobin; BMI, body mass index; DBP, diastolic blood pressure; FPG, fasting plasma glucose; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure.

At inception, no incentives were offered for participation in the program. A decision was made to offer incentives (i.e., waived copays on diabetes medications) because of low enrollment. The coalition partners were approached; however, only H-E-B instituted such an incentive program. For participants who were H-E-B employees, they received zero copays on generics and $5 copays on branded diabetes medications (antidiabetic, antilipemic, and antihypertensive agents). The introduction of reduced copays helped improve enrollment, from 3 patients in the previous quarter to 24 patients in the next quarter.

The results of the program contribute to the growing evidence supporting the ability of pharmacists to improve care in patients with diabetes. Although definite outcomes, such as reduction in micro- and macrovascular complications, were not available, expecting such reductions in diabetes complications with improved glycemic control and risk factor control is reasonable.

Limitations

An important limitation of our study was the lack of a prespecified control group. Although significant reductions were noted in several clinical parameters, quantifying the degree to which the reductions seen in our study compared with patients who were receiving usual care was not possible. Further, patients choosing to enroll in the study may have introduced a self-selection bias and altered their lifestyle because of enrollment.

The economic impact of the modest changes seen in our study is unknown. We were unable to collect sufficient cost-related data to determine the cost effectiveness of the program. However, in similar studies, significant reduction in costs occurred when pharmacist-managed MTM services were provided.[4,10]

Community pharmacists who participated in the program did not have collaborative agreements or prescriptive authority to make medication-related therapy changes. Recommendations for changes in patients' regimens were conveyed to the diabetes care provider, who had the final authority on whether to accept the recommendations. In a systematic review of the effects of pharmacist interventions in adults with diabetes that was published in 2008, programs that used direct medical management by pharmacists reported greater improvements compared with those that used a design such as the one reported here.[11]

The study had a high drop-out rate. By the sixth month of the intervention, more than 50% of patients had dropped out, and at the final follow-up, more than 60% had dropped out. The drop-out rate reduced the sample size available for analysis, which we corrected for using the LOCF method. However, the LOCF method has its own limitations such as underestimation of the treatment effect. Underestimation of treatment effect is often greater in studies such as the current one, in which there was no control group.

Conclusion

In this community pharmacist–managed MTM program for diabetes, reductions were observed in glycemic and metabolic parameters. The improvements were most apparent in patients who were not at goal values at baseline.

References

1. Centers for Disease Control and Prevention. National diabetes fact sheet: 2007. Accessed at http://apps.nccd.cdc.gov/ddtstrs, June 21, 2010.
2. Mainous AG, Baker R, Koopman RJ, et al. Impact of the population at risk of diabetes on projections of diabetes burden in the United States: an epidemic on the way. Diabetologia. 2007;50:934–40.
3. McWilliams JM, Meara E, Zaslavsky AM, Ayanian JZ. Differences in control of cardiovascular disease and diabetes by race, ethnicity, and education: U.S. trends from 1999 to 2006 and effects of Medicare coverage. Ann Intern Med. 2009;150:505–15.
4. Bunting BA, Smith BH, Sutherland SE. The Asheville Project: clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. J Am Pharm Assoc. 2008;48:23–31.
5. Bunting BA, Cranor CW. The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. J Am Pharm Assoc. 2006;46:133–47.
6. Fera T, Bluml BM, Ellis WM. Diabetes Ten City Challenge: final economic and clinical results. J Am Pharm Assoc. 2009;49:383–91.
7. Planas LG, Crosby KM, Mitchell KD, Farmer KC. Evaluation of a hypertension medication therapy management program in patients with diabetes. J Am Pharm Assoc. 2009;49:164–70.
8. American Diabetes Association. Standards of medical care in Diabetes: 2009. Diabetes Care. 2009;32(suppl 1):S13–61.
9. Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc. 2003;43:173–84.
10. Monte SV, Slazak EM, Albanese NP, et al. Clinical and economic impact of a diabetes clinical pharmacy service program in a university and primary care–based collaboration model. J Am Pharm Assoc. 2009;49:200–8.
11. Wubben DP, Vivian EM. Effects of pharmacist outpatient interventions on adults with diabetes mellitus: a systematic review. Pharmacotherapy. 2008;28:421–36.