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Clinical impact of a pharmacist managed diabetes mellitus drug therapy management service

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ABSTRACT

Three hundred sixteen patients aged 18 years or older, with a diagnosis of diabetes mellitus (89% with type 2), who were referred to a clinical pharmacy service. Data were collected for glycosylated hemoglobin At_e (A1C), blood pressure, and low-density lipoprotein cholesterol (LDL), high-density lipoprotein cholesterol (HDL), and triglyceride concentrations. Data also were collected regarding patient adherence with American Diabetes Association guidelines for preventive care, including annual eye and foot examinations, influenza shots, and daily aspirin use at both baseline and follow-up. Mean $\pm$ SD A1C reduction was 1.4% $\pm$ 1.94% (p<0.001); the percentage of patients whose A1C was at goal level at baseline (< 7%) increased from 14.8% to 43.2% (p<0.001). Mean $\pm$ SD LDL level reduction was 14 ± 41.1 mg/dl (p=0.002), mean $\pm$ SD triglyceride level reduction 42 ± 97.6 mg/di (p<0.001). The percentage of patients who reached goal for LDL level (< 100 mg /dl), HDL level (> 40 mg/dl), and blood pressure (< 130/80 mm Hg) did not increase significantly from baseline, whereas those who reached the triglyceride level goal (< 150 mg/dl) increased from 36% to 55% (p<0.005). Frequency of annual dilated retinal examinations and monofilament foot examinations increased by 29% (p<0.05) and 12.5% (p<0.05), respectively. Daily aspirin use increased from 35% to 59% (p<0.05). Significant clinical improvement occurred in patients referred to the pharmacist in a diabetes drug therapy management program.

Keywords: Disease management, Diabetes mellitus, Clinical pharmacy, Drug therapy management.

INTRODUCTION

The number of patients diagnosed with mellitus in the United States is reaching epidemic proportions. This growing rate is probably due to increases in obesity and sedentary lifestyles as well as the aging of our population. Diabetes is characterized by many long-term complications, including cardio- vascular disease, retinopathy, neuropathy, and nephropathy. These complications confer significant morbidity and mortality along with a staggering economic impact on patients, the managed care system, and society as a whole [1].

Pharmacist-managed diabetes drug therapy management service

Cardiovascular disease is the leading cause of among patients with diabetes, and diabetes is the leading cause of blindness and end-stage rental disease in the United States.' Total direct and indirect costs associated with diabetes are an estimated $132 billion/year. The decreased quality

of life for patients requiring dialysis and amputations is immeasurable [2].

Several landmark clinical trials have established a correlation between improved glycemic control and reduced occurrence of micro vascular complications with diabetes. [2-6] Other studies have suggested reduced occurrence in macro vascular complications as well." Clinical evidence has also demonstrated significant reduction in complications with stricter control of comorbid conditions such as hypertension and dyslipidemia [3] Specifically, reduction of low-density lipoprotein cholesterol (LDL) concentration has been one of the most significant modifiable risk factors in reducing the frequency of cardiovascular complications in patients with diabetes. [4]

American Diabetes Association (ADA) clinical practice recommendations include evidence-based preventive strategies for reducing the frequency of all of the long-term complications of diabetes. [5] In addition to glycemic control, strategies include control of comorbid disease states such as hypertension and dyslipidemia. First-line therapy for hypertension consists of angiotensin - converting enzyme inhibitors or angiotensin receptor blockers, and 3-hydroxy-3- methyl glutaryl coenzyme A reductase inhibitors for dyslipidemia. Additional ADA recommendations are for adequate immunizations, annual dilated retinal examinations, annual monofilament foot examinations, and daily aspirin use.

Successful treatment of diabetes requires attention to glycemic control and to the various long-term strategies for preventing complications. In today's managed care environment, this scenario often presents time constraints during patient visits with primary care physicians. Historically, glycemic control and adherence to ADA guidelines have been suboptimal in the primary care setting. [6] Various disease management models have been explored in an attempt to improve overall patient care in a cost-effective manner. An interdisciplinary approach to management of diabetes has been the most successful. [7] Various models use ancillary providers, such as nurses, dieticians, and pharmacists, to function as educators and drug therapy managers. This allows more contact time with patients outside of the physician's office.

This study examined the impact of a phar-macist-managed diabetes drug therapy management service on clinical outcomes relevant to diabetes in a multispecialty physician group practice within a managed care environment.

METHODS

The clinical pharmacist–coordinated diabetes drug therapy management service was implemented in October 2001. Specific goals are to improve clinical outcomes for patients with diabetes, decrease microvascular and macro-vascular complications, and ultimately decrease managed care costs associated with these morbidities. The program involves an interdisciplinary team with two registered nurses, one registered dietician, and one clinical pharmacist. All team members are certified diabetes educators. Within the program, nurses provide general diabetes education, monofilament foot examinations, and glucometer training. Dieticians provide individualized dietary instruction and classes on weight loss and carbohydrate counting. The pharmacist provides general education as well as drug therapy management services. Patients are referred to the program by their primary care physician for various indications, such as newly diagnosed diabetes, poor glycemic control, poor adherence, or a combination of these. Patients are given the option to visit with a nurse and dietician. All patients are seen by the clinical pharmacist.

Clinical pharmacist interventions involve patient education; laboratory monitoring; referrals for podiatry, optometry, and diet counseling; and drug therapy management through drug initiation, dosage adjustment, or drug discontinuation. Collaborative practice agreements are held between the clinical pharmacist and numerous primary care physicians in the practice. Each visit is individualized based on patient-specific needs; appointments last 15-45 minutes. Once enrolled in the program, patients are followed by the clinical pharmacist frequently and indefinitely. Follow-up is conducted through a combination of telephone appointments and office visits.

A total of 316 patients were referred to the clinical pharmacist in the newly developed diabetes management program. The laboratory and progress note sections of each patient's medical record were retrospectively reviewed. Data were collected by an independent data entry specialist with no interest in the outcome. Accuracy of the data collected was

verified through random chart audit by a second independent data entry specialist.

Data were collected for hemoglobin A1c (A1C), lipid levels, blood pressure values, and compliance with ADA guidelines for preventive care (annual foot and eye examinations, daily aspirin use). Baseline values for laboratory data were recorded as the most recent value within the 6 months preceding each patient's initial visit. Baseline data regarding blood pressure and preventive care were taken from the progress note for the first visit with the clinical pharmacist. Follow-up data consisted of the most recently documented information for the patient's last visit to the clinical pharmacy service.

Baseline and follow-up data were compared to determine the magnitude of change. Continuous variables, such as values for laboratory tests and blood pressure, were statistically analyzed for significance using the paired Student t test. Adherence with ADA preventive care guidelines was statistically analyzed using the McNemar test. The population size allowed for a 90% power to detect a statistically significant change in A1C of 0.5% or greater. The a priori (a) level of significance was set at 0.05. This analysis consisted of a review of previously existing documents as part of quality assurance efforts. All patient identifiers were removed before presentation; thus,

the evaluation received institutional review board exemption.
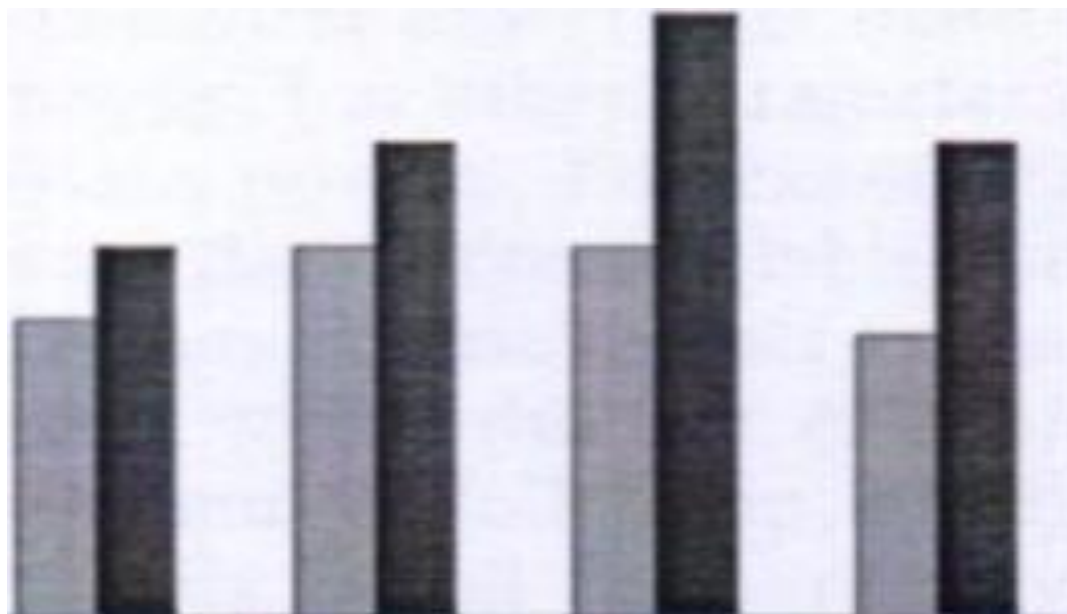
RESULTS

Patients enrolled in the program are primarily Caucasians with private insurance and a diagnosis of type 2 diabetes. Baseline characteristics of the patients are provided in Table 1; percentages of patients reaching ADA goals at baseline and follow-up are provided in Figure 1.

Hemoglobin A_{1c}

Of the 316 patients whose records were reviewed, 26 (8.2%) were referred to the diabetes management program with no baseline A1C measurement; however, all 26 had undergone A1C testing within 1 week of their initial visit. Both baseline and follow-up A1C levels were obtained for 155 (49%) patients. In this group, overall mean ± SD reduction in A1C was 1.4% ± 1.94% (p<0.001); mean ± SD follow-up

A1C was 7.49% ± 1.51%. The percentage of patients who reached the ADA goal of less than 7% increased significantly from baseline to follow-up (p<0.001; Figure 1). Mean ± SD time between baseline and follow-up Al C measurements was 144 ± 82 days.

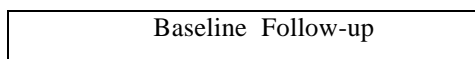| AIC	1.131. Wei	BP	Annual	Amu&	Daly
<7% 040.001) (n4155)	100 mg/dl (NS) (n486)	< 13W80 mm Mg (NS)	*eye* examination (p<0.05)	foot eeeexamination (P4.05)	ASA use (p<0.05) "[1]=36)
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Baseline Follow-up

Figure 1. Attainment of ADA goals in the 316 patients at baseline and follow-up. ADA = American Diabetes Association; A1C = hemoglobin Ai,: LDL = low-density lipoprotein cholesterol; BP = blood pressure; ASA = aspirin.

PHARMACIST-MANAHEMENT DIABETES DRUG THERAPY MANAGEMENT SERVICE

Lipid Levels

From the 316 study patients, 55 (17.4%) did not have a baseline lipid panel on referral to the diabetes management program. Subsequently, all 55 underwent a complete risk factor assessment, including fasting lipid panel. At least two complete lipid panel measurements were obtained in the specified time from baseline through follow-up for 86 (27.2%) patients. Overall mean ± SD reduction in LDL for this group was 14 ± 41.1 mg/d I (p=0.002); mean ± SD follow-up LDL level was 119 ± 37.4 mg/dl. The percentage of patients reaching the National Cholesterol Education Program Adult Treatment Panel IlI (NCEP ATP III) guideline26 LDL level goal of less than 100 mg/dl increased, although significantly. Overall mean ± SD reduction in triglyceride levels was 42 ± 97.6 mg/dl (p<0.001). The percentage of patients whose triglyceride levels met the NCEP ATP 111 goal of less than 150 mg/d I increased from 36% at baseline to 55% at follow-up (p<0.005). Mean ± SD follow-up triglyceride level was 150 ± 69.8 mg/dl; high-density lipoprotein cholesterol did not change significantly from baseline to follow-up. Mean ± SD time between baseline and follow-up lipid profiles was 127 ± 67 days.

Blood Pressure

Fifty-two (16.5%) of the 316 patients had documented and retrievable blood pressure readings at both baseline and follow-up. Overall mean ± SD reduction in systolic blood pressure for enrolled patients was 2.8 ± 13.1 mm Hg (p=0.131);

mean ± SD follow-up systolic blood pressure was 133 ± 13.6 mm Hg. The percentage of patients at the ADA goal systolic blood pressure of less than 130 mm Hg increased from 37% at baseline to 46% at follow-up (p=0.267). Mean ± SD change in diastolic blood pressure was -2.4 ± 8.9 mm Hg (p=0.058); mean ± SD follow-up diastolic blood pressure was 74 ± 7.8 mm Hg. The percentage of patients at the ADA goal diastolic blood pressure of less than 80 mm Hg increased from 67% at baseline to 71% at follow-up (p=0.774). The percentage of patients reaching the overall ADA goal for blood pressure (130/80 mm Hg) is provided in Figure 1.

Preventive Care

A complete preventive care assessment was performed at both baseline and follow-up for 96 (30.4%) of the 316 study patients. This group demonstrated an increase in patients who annually underwent a dilated retinal examination (29% increase, p<0.05) and a monofilament foot examination (12.5% increase, p<0.05). At follow-up, 58% of these patients had received an annual eye examination and 75% a monofilament foot examination. The frequency of influenza vaccination increased from 36% at baseline to 47% at follow-up; the number of patients who took aspirin daily also increased (Figure 1). Mean ± SD time between baseline and follow-up visits was 138 ± 64 days.

DISCUSSION

Consistent clinical improvement was observed in all patients with both baseline and follow-up data. The most notable improvements were reduction of A1C and improved adherence to preventive care measures, such as annual eye and foot examinations and daily aspirin use. Evidence supports decreased frequency of micro vascular complications, lower managed care costs, and a sustained A1C reduction of 1% or greater. Therefore, one may postulate that this clinical

pharmacy diabetes drug therapy management service ultimately will result in decreased occurrence of complications and reduced managed care costs associated with diabetes. This is only a hypothesis; current data support clinical improvement only over a short period. Because these data represent the first evaluation of this program and cover a relatively short time frame, quality assurance evaluations will continue to increase in breadth and eventually will include an economic analysis.

Although the overall number of patients referred to the clinical service was adequate for a thorough evaluation, the number with complete data, with at least two values for each parameter, was much smaller. The 90% power was maintained for the A1C analysis, but other parameters were less likely to obtain power. For example, complete blood pressure data were available for very few patients. This may be due in part to the clinical service protocol, which did not call for blood pressure measurement at follow-up for all patients. More specifically, blood pressure may not have been measured in patients with no documented blood pressure reading above 130/80 mm Hg over the previous 6 months, or in those seen for a concentrated follow-up on diabetes or lipid drug therapy adjustments. This finding prompted an evaluation of the protocol, which now calls for blood pressure measurement in all patients at every visit.

Recently updated guidelines for cholesterol management recommend considering an LDL goal of less than 70 mg/dl for patients at very high risk of cardiovascular disease. [28] Many of the patients in this evaluation could be considered at men- high risk based on the presence of diabetes and additional cardiovascular risk factors. Subsequent evaluations of this population should include an analysis of those attaining an LDL goal of less than 70 mg/dl.

Mean ± SD time between baseline and follow-up laboratory values and office visits ranged from 120-150 days in the evaluation. This is an important consideration since the most common laboratory follow-up interval is 3 months. For most patients in the analysis, less than 6 months elapsed between baseline and follow-up data. Therefore, these patients may have had only one follow-up visit or value obtained before the analysis. Considering this information, the somewhat modest

clinical improvements observed may be better understood.

Between the implementation of the clinical pharmacy service and the retrospective review, the number of physician referrals to the program increased linearly. Therefore, more patient referrals occurred later in the data collection period as physicians became more aware of and more comfortable with the service. This is yet another possible explanation for the relatively short time between baseline and follow-up values, since many of the patients were referred less than 6 months before the retrospective review took place.

This service provides care through an interdisciplinary team, as in previously published reports. [21, 22, 24, 25] A large percentage of patients in this evaluation were seen by a registered dietician and a registered nurse in addition to the clinical pharmacist. Although interdisciplinary team care is ideal, it introduces the potential confounding influence of other providers, and makes it impossible to attribute clinical improvements solely to the drug therapy management service provided by the clinical pharmacist.

These preliminary data were compelling to the administrators of the medical group and managed care organization within which the clinical service's housed. Since the presentation of these results, additional clinical pharmacy personnel have been approved to assist with the diabetes drug therapy management service and implementation of a dyslipidemia drug therapy management service.

CONCLUSION

Patients enrolled in a clinical pharmacist diabetes drug therapy management service demonstrated significant clinical improvement. Clinical improvement has decreased the frequency of chronic complications as well as overall managed care costs associated with diabetes mellitus.

Acknowledgments

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