Clinical Pharmacy Specialists Help Achieve an LDL-Cholesterol Performance Goal in Veterans With Diabetes

Justin M. Metzger, PharmD; and Kelley J. Oehlke, PharmD

A retrospective study revealed success rates of veterans with diabetes in achieving LDL-C goals after clinical pharmacy specialists' intervention.

According to the American Diabetes Association (ADA), an estimated 25.8 million Americans have type 2 diabetes mellitus (DM), which accounts for 8.3% of the U.S. population.[1] The prevalence of type 2 DM in the VA population is substantially higher than in the general population. Five million veterans (20%) have type 2 DM. In 2006, the Veterans Integrated System Network 23 (VISN 23), which consists of VA medical centers in the upper Midwest, initiated a chronic disease management program that focused on improving the care of veterans in a registry of patients with type 2 DM, including guidelines for management of their cholesterol.

Adults with type 2 DM have heart disease death rates about 2 to 4 times higher than adults without type 2 DM.[2] Dyslipidemia, including elevated levels of low-density lipoprotein-cholesterol (LDL-C), is a major risk factor associated with adverse cardiovascular events. Numerous clinical trials that sought to lower LDL-C decreased cardiovascular events and mortality. Improved control of LDL-C may reduce cardiovascular complications by 20% to 50% in patients with diabetes.[3] The National Cholesterol Education Program Adult Treatment Panel III guidelines goal for serum levels of LDL-C among patients with DM is < 100 mg/dL. The VA's Office of Quality and Performance has promulgated this guideline recommendation as a national performance measure. The measures serve collectively to effectively, safely, timely, efficiently, and equitably improve the health care provided to veterans.[4] The VA performance measure for LDL-C in type 2 DM is a goal of < 100 mg/dL.

Clinical pharmacy specialist-managed clinics are one strategy to help attain patient-specific disease goals. The consult-based clinics manage a variety of diseases, including but not limited to dyslipidemia, in patients with type 2 DM. The assessment of dyslipidemia, in patients with type 2 DM includes a laboratory assessment, in-depth medication and lifestyle histories, counseling on therapeutic lifestyle changes, which includes diet and exercise, medication adjustments if warranted, and appropriate follow-up. In addition to assisting patients with meeting their lipid goals, the clinical pharmacy specialists assist primary care providers (PCPs) with medication management and clinical access. We were interested in determining whether or not our local clinic was helping the PCPs achieve the LDL-C performance measure.

METHODS

Study Design

This retrospective, matched study using concurrent controls evaluated the impact of the clinical pharmacy specialist in assisting PCPs with achieving an LDL-C performance measure in patients with type 2 DM. This study was reviewed and approved by the local investigational review board and the VA Research and Development Committee.

The primary endpoint was the percentage of patients achieving or maintaining their LDL-C at a value meeting the VA performance measure. Data were extracted from the VA's electronic medical record, including patients' age, sex (all were males), body mass index (BMI), baseline, and a follow-up LDL-C. Follow-up LDL-C values were collected on the control group at least 6 months following patients' first clinic visit in

Dr. Metzger is the clinical pharmacy supervisor and **Dr. Oehlke** is a clinical pharmacy specialist, both at the Sioux Falls VAMC in South Dakota. Dr. Oehlke is also an adjunct associate professor at South Dakota State University College of Pharmacy in Sioux Falls.

the study time frame. In the pharmacist's clinic, LDL-C values were recorded about 6 months following the first encounter with the clinical pharmacy specialist.

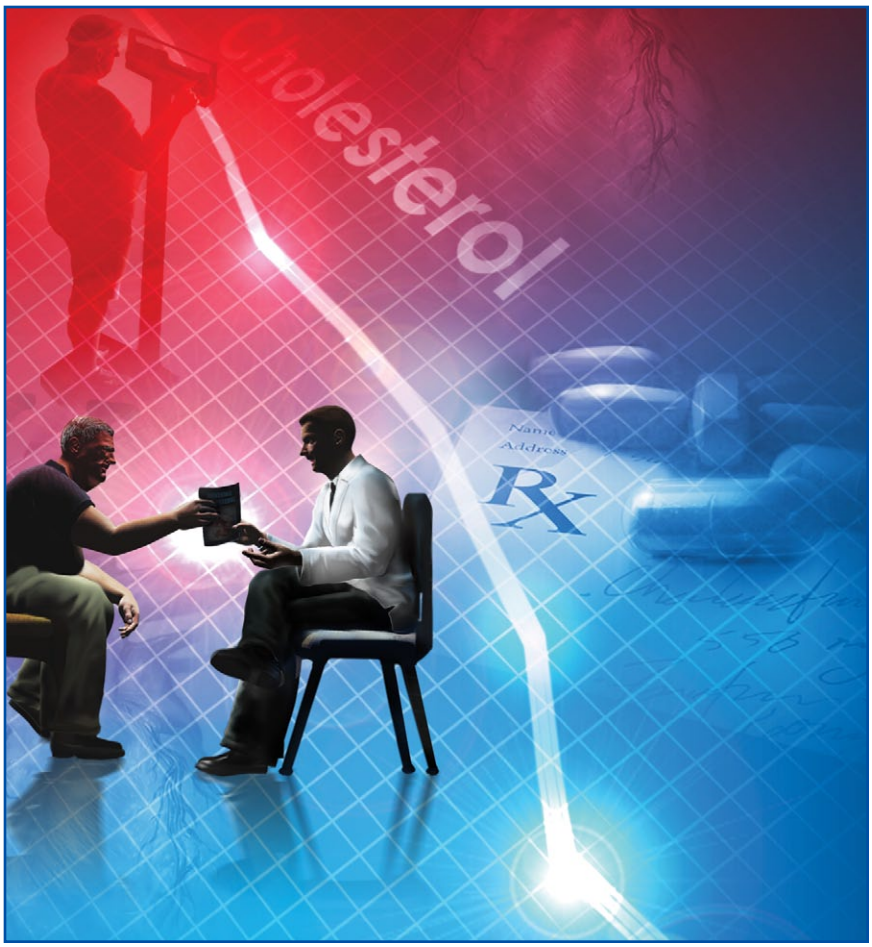
Study Groups

Clinical pharmacists provided consultations to patients with type 2 DM who were referred by 2 PCPs who routinely requested assistance from the clinical pharmacy specialists. Patients were required to have a follow-up LDL-C that was at least 6 months from the encounter date with the clinical pharmacy specialist. Seventy-one patients met these criteria.

The VISN 23 Chronic Disease Registry was used to obtain a concurrent control group of patients with diabetes from 2 other PCPs who did not routinely request assistance for lipid management. Patients were excluded from the control group if they had been seen by a clinical pharmacy specialist for lipid management during the study time period and/or if they did not have a follow-up LDL-C.

There were a sufficient number of eligible controls to select as many as 2 patients that were good matches for most patients in the intervention group (n = 71). However, there was not a good match for 1 patient in the intervention group that had a baseline LDL-C of 195 mg/dL who was excluded from further analyses. There was only 1 good match for 8 other patients in the control group whose baseline LDL-C levels ranged from 149 mg/dL to 173 mg/dL. Thus, 70 subjects in the intervention group were compared with 132 matched controls.

During the evaluation, all PCPs were encouraged to treat their patients with type 2 DM for reaching an LDL-C level < 100 mg/dL through various mechanisms, such as presentations at primary care meetings,



which included provider specific LDL-C performance measure achievement. Both groups being compared were subject to the ongoing chronic disease management initiatives.

STATISTICAL ANALYSIS

Group characteristics are described using means and standard deviations of continuous variables or percentages for categorical variables. Paired *t* tests were used to analyze changes within groups. Logistic regression clustered according to matched patients was used to estimate the effect of the pharmacists' intervention on the odds that patients achieved and maintained the LDL-C goal. Robust standard errors were estimated to account for the potential lack of independence between observations due to the matching and clustering of patients within physicians and pharmacists. To control for any differences between groups, baseline LDL-C, age, and BMI were included as covariates. Sex was omitted because all were male.

RESULTS

Baseline characteristics are displayed in Table 1. Most patients in each group were near the LDL-C goal at baseline, and approximately one-third were already at goal.

At baseline, 46 of the 70 clinical pharmacy intervention group patients were not meeting the performance measure goal. As summarized in Table 2, of the 46 patients, 29 (41%) in the clinical pharmacy specialist–

managed group achieved the goal during follow-up. The mean decrease in their LDL-C levels was 37 mg/dL to a mean level of 83 mg/dL. Of the 24 patients that were at baseline goal, 20 maintained their LDL-C below goal at an average level of 78 mg/dL. The 4 patients that were meeting the performance measure at baseline, but no longer met it at follow-up, were defined as lost goal (Table 2). Overall, there was a significant 36% increase in the percentage of patients at goal (34% to 70%; $P < .001$) at the follow-up visit in the clinical pharmacist intervention group. On average, the LDL-C decreased by 15 mg/dL from 137 mg/dL to 122 mg/dL in the group of 17 patients (24%) where the goal was not attained.

At baseline in the concurrent control group (n = 132), 83 patients were not meeting the goal. Of the 83 patients, 41 achieved the goal during follow-up. The mean decrease in their LDL-C levels was 43 mg/dL to an average level of 77 mg/dL. Of the 49 patients that were at baseline goal, 33 maintained an LDL-C goal at a mean level of 77 mg/dL. Sixteen patients were considered lost goal. There was a significant 19% increase in the percentage of controls at goal (37% to 56%; $P < .001$). On average, the LDL-C decreased by only 7 mg/dL from 127 mg/dL to 120 mg/dL in the group of 42 patients (32%) where the goal was not attained.

Overall, 70% vs 56% of patients were at goal at the follow-up visit in the intervention and control groups, respectively. Controlling for baseline LDL-C, age, and BMI via logistic regression, referral to the clinical pharmacy specialist was associated with an increase in the odds of achieving the goal LDL-C and meeting the VA performance measure (odds ratio = 1.86, 95% confidence interval 1.04-3.31; $P = .03$).

Table 1. Baseline characteristics

	Clinical pharmacy intervention group	Control group
Number of patients	70	132
Mean age (years)	64 ± 7	64 ± 7
Male (%)	100	100
Mean BMI (kg/m^2)	32 ± 5	34 ± 6
Mean baseline LDL-C (mg/dL)	111 ± 28	108 ± 25
% of patients with baseline LDL-C < 100 mg/dL	34	37

Data are summarized as the mean ± 1 standard deviation.

Table 2. Assessment of LDL-cholesterol at follow-up

	Clinical pharmacy intervention group (n = 70)	Control group (n = 132)
At goal (< 100 mg/dL)	70%	56%
Achieved goal	41%	31%
Maintained goal	29%	25%
Lost goal	6%	12%
Never at goal	24%	32%

DISCUSSION

The analysis suggests that the clinical pharmacy specialists working in a primary care clinic helped patients with type 2 DM achieve the recommended LDL-C. Results of other published trials have demonstrated that having a clinical pharmacy specialist involved in the management of dyslipidemia has a proven significant benefit.[5-8] Similar results to ours were observed in a retrospective analysis of an intervention by the clinical pharmacy specialists at 2 other VA medical centers, where the percentage of patients who met their baseline LDL-C goal increased from 37% to 65%.[9] Our results were attained in patients with type 2 DM and in the context of a networkwide initiative to improve the care of patients. Clinical pharmacy specialists may be underused in ours and other practices despite an increased amount of evidence supporting their involvement in medication management of common chronic diseases.

LIMITATIONS

The findings are limited by the retrospective nature of the analysis, the small sample, and a 100% male population at a single VA medical center. Referral of patients who had met the < 100 mg/dL LDL-C goal most likely was due to the presence of other cardiovascular risk factors that would make the optimal LDL-C goal < 70 mg/dL. Nevertheless, matching the patients according to their baseline LDL-C levels should have made the groups comparable. Potential confounders such as the presence and severity of comorbidities, concurrent medications, and socioeconomic status were not ascertained and could

have contributed to the observed differences. All patients in both groups did have type 2 DM and would be expected to be similar in their common comorbidities, although this conjecture was not examined. Perhaps the most important determinant of achieving the recommended LDL-C level, the baseline level, was taken into consideration as were the patient's age and body mass.

CONCLUSION

Given the VA performance measurement system to assess and improve the health care delivery system, an opportunity existed to review the impact of clinical pharmacy specialists on achievement of a performance measure. By providing education, medication management, and consistent follow-up, the clinical pharmacy specialist was able to help the VA medical center achieve its LDL-C performance goals for managing dyslipidemia in patients with type 2 DM. This analysis demonstrates that a health care organization can improve performance by involving clinical pharmacy specialists.

Author Disclosures

The authors report no actual or potential conflicts of interest with regard to this article.

Disclaimer

The opinions expressed herein are those of the authors and do not necessarily reflect those of Federal Practitioner, *Quadrant HealthCom Inc., the U.S. Government, or any of its agencies. This article may discuss unlabeled or investigational use of certain drugs. Please review complete prescribing information for specific drugs or drug combinations—including indications, contraindications, warnings, and adverse effects—before administering pharmacologic therapy to patients.*

REFERENCES

1. American Diabetes Association. All about diabetes. http://www.diabetes.org/diabetes-basics/diabetes-statistics/?utm_source=WWW&utm_medium=DropDownDB&utm_content=Statistics&utm_campaign=CON. Accessed October 20, 2011.
2. American Diabetes Association. Complications of diabetes in the United States. http://www.diabetes.org/diabetes-basics/diabetes-statistics/. Accessed October 20, 2011.
3. Centers for Disease Control and Prevention. National Diabetes Fact Sheet 2007. http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf. Accessed October 24, 2011.
4. The Health Care System for Veterans: An Interim Report. December 2007. http://www.cbo.gov/ftpdocs/88xx/doc8892/MainText.3.1.shtml. Accessed October 20, 2011.
5. Straka RJ, Taheri R, Cooper SL, Smith JC. Achieving cholesterol target in a managed care organization (ACTION) trial. *Pharmacotherapy.* 2005;25(3):360-371.
6. Till LT Jr, Voris JC, Bourne Horst J. Assessment of clinical pharmacist management of lipid-lowering therapy in a primary care setting. *J Manag Care Pharm.* 2003;9(3):269-273.
7. Geber J, Parra D, Becky NP, Korman L. Optimizing drug therapy in patients with cardiovascular disease: The impact of pharmacist-managed pharmacotherapy clinics in a primary care setting. *Pharmacotherapy.* 2002;22(6):738-747.
8. Bozovich M, Rubino CM, Edmunds J. Effect of a clinical pharmacist-managed lipid clinic on achieving national cholesterol education program low-density lipoprotein goals. *Pharmacotherapy.* 2000;20(11):1375-1383.
9. Mazzolini TA, Irons BK, Schell EC, Seifert CF. Lipid levels and use of lipid-lowering drugs for patients in pharmacist-managed lipid clinics versus usual care in 2 VA medical centers. *J Manag Care Pharm.* 2005;11(9):763-771.