Maintenance of Goal Blood Pressure, Cholesterol, and A1C Levels in Veterans With Type 2 Diabetes After Discharge From a Pharmacist-Managed Ambulatory Care Clinic

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ABSTRACT

Objective. This study evaluated the ability of patients with type 2 diabetes to maintain systolic blood pressure (SBP), LDL cholesterol, and A1C at goal levels after being discharged from a pharmacist-managed ambulatory care clinic. The goals of this study were to *1*) document the length of time to failure of maintenance of each goal and *2*) characterize risk factors that may be associated with a shorter time to failure.

Methods. Researchers reviewed the medical records of veterans with diabetes who were discharged from the clinical pharmacy ambulatory care clinic between 1 July 2007 and 30 June 2009 after attaining their goal SBP, LDL cholesterol, or A1C. The time to goal failure, medical history, laboratory data, medications, demographic information, and clinic appointment attendance were documented.

Results. A total of 69 patients who were discharged from the clinic after meeting their SBP, LDL cholesterol, or A1C goal subsequently failed to maintain that goal. The mean time to failure was 9.4 months (SD 8.75 months) for SBP, 25.8 months (27.45 months) for LDL cholesterol, and 20.4 months (15.1 months) for A1C. Multiple risk factors were associated with a shorter time to failure of maintenance of SBP and A1C goals.

Conclusion. Veterans with type 2 diabetes in this study demonstrated durable maintenance of their goal LDL cholesterol and A1C levels after being discharged from a pharmacist-managed ambulatory care clinic. However, maintenance of SBP goals did not demonstrate the same durability. Patients who meet their SBP goal may benefit from receiving continued disease state management services from a pharmacist-managed ambulatory care clinic instead of being discharged to receive their usual care.

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The American Diabetes Association (ADA) has developed well-established goals for blood pressure, LDL cholesterol, and A1C levels for people with type 2 diabetes(1). These goals are promoted to reduce micro- and macrovascular complications of diabetes and other associated cardiovascular risk factors. Achieving and maintaining these goals can be difficult for patients. However, appropriate interventions and specialized care initiatives, such as independent clinical pharmacist–led disease state management clinics or team-based care that includes a clinical pharmacist, have yielded improvements in success rates (2–5).

There are also summative data regarding the impact of pharmacist care in terms of patient outcomes. A 2011 Cochrane review (6) examining the effect of outpatient pharmacists' nondispensing role on patient and health professional outcomes supported the involvement

of pharmacists in improving patient outcomes. However, this review included only randomized, controlled trials and could not draw conclusions regarding how pharmacist care compares to usual care. A 2012 systematic review (7) comparing pharmacist care to standard care with regard to the attainment of lipid goals found that patients in contact with a pharmacist, either in collaboration with a physician or practicing independently, were twice as likely to reach their target lipid goals and achieved a mean difference from baseline in LDL cholesterol 10.7 mg/dL greater than those receiving standard care. Another 2011 systematic review (8) examined the impact of pharmacist care and found statistically and clinically significant improvements in cardiovascular disease (CVD) risk factors such as blood pressure, LDL cholesterol, and smoking status.

Research has shown that goal attainment with standard care is not adequate. Patients with type 2 diabetes receiving standard care in a managed care setting were shown to have less than ideal attainment rates for A1C (37%), LDL cholesterol (23%), and blood pressure (41%) goals (9). Cross-sectional data from the National Health and Nutrition Examination Surveys have also been examined to evaluate the number of people meeting A1C, LDL cholesterol, and blood pressure goals and evaluate the role of factors such as age, sex, race, education level, diabetes medications, time since diagnosis of diabetes, and history of CVD. From 2007 to 2010, a study of almost 5,000 patients with diabetes revealed that only 52.5% of patients met the goal A1C of <7.0%, 56.2% met the goal LDL cholesterol level of <100 mg/dL, 51.1% met goal blood pressure level of <130/80 mmHg, and 18.8% met all three goals (10).

With regard to people with diabetes in particular, a large evidence base exists supporting improvement in A1C and CVD outcomes with pharmacist care (11–15). These retrospective studies have shown reductions in A1C ranging from 1.4 to 3.4 percentage points and an improvement of ~30% in the number of patients reaching an A1C <7%. These same studies found that LDL cholesterol levels improved between 14 and 16 mg/dL, and there was an increase of ~26% in the number of patients reaching an LDL cholesterol level <100 mg/dL. Blood pressure goals were twice as likely to be achieved with pharmacist care, as well.

Clinicians who care for patients with diabetes recognize the difference between meeting a clinical goal and maintaining it, and the challenges of achieving each. Research has identified some risk factors that play a role in patients' ability to initially meet goals and has also established that this effort can be aided by focused care from specialized disease management clinics. However, very little evidence exists regarding whether attained goals are maintained over time and what risk factors, if any, may influence goal maintenance.

A recent prospective study (16) followed 421 patients with coronary artery disease (CAD) who had met their LDL cholesterol goal and were then evenly randomized to be maintained within a pharmacist-managed clinic or discharged to receive usual care. Patients who were discharged with usual care were also sent a laboratory reminder letter 1 year after discharge. After a mean follow-up of 1.7 years, there was no difference in how well the two groups maintained their goal LDL cholesterol level. However, only ~10% of the participants in this study had diabetes.

A retrospective study (17) investigating patients with diabetes who received care through a Department of Veterans Affairs (VA) clinic examined how long patients maintained clinical goals after being discharged from a pharmacist-managed cardiovascular risk reduction clinic to receive usual care. To date, this is the only known research that has specifically examined risk factors influencing the maintenance of clinical goals in patients with diabetes. The mean time to failure of goal maintenance was slightly more than 21 months for LDL cholesterol and A1C, and slightly more than 6 months for SBP. The investigators concluded that there was a significant correlation (hazard ratio [HR] 1.02) between the time to failure of SBP goal maintenance after discharge and the magnitude of elevation in SBP when first enrolled in the clinic. The study focused on SBP only because it is the most clinically relevant blood pressure measurement to predict cardiovascular events in elderly patients. Investigators in this study also identified being on insulin (HR 3.08) as a risk factor for time to failure of LDL cholesterol goal maintenance, and BMI (HR 1.08) as a risk factor for time to failure of A1C goal maintenance. The findings of this study have not been substantiated by any other research to date.

As previously noted, pharmacist-managed clinics have played a major role in improving the achievement rate of therapeutic goals for people with diabetes (2–5,11–15). The VA St. Louis Health Care System in St. Louis, Mo., offers clinical pharmacy ambulatory care services similar to those described by Pirraglia et al. (17) in the aforementioned study of goal maintenance after participation in a VA pharmacy clinic for patients with diabetes. Patients are referred, usually by their primary care provider (PCP), in an effort to aid in disease state management. Most patients managed through the clinic have some combination of hypertension, hyperlipidemia, and type 2 diabetes. Typically, once patients achieve the therapeutic goals for the disease state for which they were referred, they are discharged from the clinic for usual-care follow-up with the PCP. To be discharged from the clinic, patients must meet their therapeutic goals for two consecutive measures at two separate clinic visits.

Very little research has been done to examine how well these goals are maintained after patients are discharged from a specialty clinic and what risk factors may influence the rate of failure.

Additional investigation of this subject may provide greater insight into which patients may benefit from continuing care from a specialty clinic, as opposed to being discharged to receive usual care after attaining their clinical goals. The purpose of this study was to examine and compare clinical goal maintenance rates of patients discharged from the pharmacist-managed ambulatory care clinics of the VA St. Louis Health Care System and to validate the findings of the studies described above.

Methods

This was a single-center, retrospective, observational cohort analysis. The primary outcome was length of time to failure of maintenance of a SBP goal of <130 mmHg, an LDL cholesterol goal of <100 mg/dL, or an A1C goal of <7% in patients with type 2 diabetes after being discharged from a pharmacist-managed ambulatory care clinic to receive usual care. The secondary goal of the study was to determine if any factors present at clinic discharge were associated with a shorter time to failure of goal maintenance.

To identify potential risk factors, we collected information on significant demographic and clinical characteristics, including patients' age, sex, copayment exemption status (i.e., whether a patient was responsible for a copayment on any medication), smoking status, medical comorbidities, and pertinent physical exam findings (i.e., height, weight, BMI, and blood pressure), and laboratory values (i.e., SBP, serum creatinine, LDL cholesterol, total cholesterol, A1C, and microalbumin/creatinine ratio). Comorbid conditions recorded including chronic kidney disease (CKD), CAD, myocardial infarction, coronary artery bypass graft (CABG), percutaneous coronary intervention, cerebrovascular accident/transient ischemic attack, heart failure, chronic obstructive pulmonary disease, peripheral artery disease, and abdominal aortic aneurysm. Information was also recorded regarding patients' number of prescription medications, insulin use, duration of enrollment in the pharmacy clinic before discharge, and number of visits to the PCP during their clinic enrollment.

The pharmacy-based clinics within the VA St. Louis Health Care System manage patients mostly through a formal electronic consultation from other health care providers within the system. Through this process, most patients are referred to this service for aid in the management of hypertension, hyperlipidemia, diabetes, or a combination thereof. However, patients are also referred for complex medication reconciliation reviews and management of other chronic disease states such as heart failure, chronic obstructive pulmonary disorder, and thyroid disease. Within the VA system, clinic pharmacists have a written scope of practice that includes the ability to order, change, and discontinue noncontrolled medications and to order relevant laboratory tests.

Study patients were identified through a medical informatics database query on the basis of having had an encounter in one of the pharmacy-based clinics between 1 July 2007 and 30 June 2009. During this time frame, patients were managed by pharmacists in six face-to-face clinics and two telephone clinics. Quantifying the precise number of pharmacists involved in these clinics is difficult because some clinic responsibilities were handled by several rotating pharmacist faculty members. Approximately 1,800 patients were seen in the clinics during the study time period and were reviewed for study inclusion.

The records of patients with type 2 diabetes who met initial screening criteria were analyzed to determine whether they met study inclusion criteria. The study included all patients aged 18–89 years who had two consecutive measurements of either SBP, LDL cholesterol, or A1C at goal by discharge and had a documented history of type 2 diabetes, an A1C value ≥6.5% during clinic enrollment, or were on any diabetes medication (including insulin, biguanides, secretagogues, thiazolidinediones, GLP-1 receptor agonists, DPP-4 inhibitors, amylin analogs, and α-glucosidase inhibitors).

Patients were excluded if they did not have a follow-up LDL cholesterol or A1C measurement within 1.25 years after discharge or if they had no follow-up SBP measurement within 0.5 years after discharge. For LDL cholesterol, clinical practice guidelines recommend annual lipid panel tests. A follow-up time of 1.25 years was selected to ensure that patients were maintained within goal while allowing a time buffer for patients who might have had to reschedule their clinic appointment, were late in scheduling an annual follow-up appointment, or for whom a provider forgot to order laboratory testing. Although the follow-up criteria could have been shortened for A1C, investigators felt that having a repeat A1C test within 1.25 years of discharge was an adequate time period to ensure reasonable follow-up while again allowing for scheduling or other logistical difficulties. Because SBP is more variable, investigators narrowed the follow-up interval to within 0.5 years to ensure that patients were being followed up in a reasonable amount of time to maintain blood pressure control while balancing the fact that patients might not return to the clinic in a short time span if they were otherwise healthy and having no acute problems.

Patients' data were collected for a maximum of 3 years after their clinic discharge date. For LDL cholesterol and A1C, time to goal maintenance failure was defined as the time to the first laboratory measurement that was above the given goal. Because

TABLE 1. Study Population (*n* = 69) Characteristics at Discharge (Unless Otherwise Specified)

Characteristic	Value (mean ± SD or *n* [%] unless otherwise noted)
Age at enrollment (years)	64.5 ± 9.7
Male sex	67 (97.1)
Body weight (lb)	225 ± 45.1
BMI (kg/m^2)	32.41 ± 6.0
SBP (mmHg)	126 ± 14.5
Current smoker	11 (15.9)
Copay exempt	36 (52.2)
Chronic kidney disease	6 (8.7)
Coronary artery disease	2 (2.9)
Myocardial infarction	2 (2.9)
Coronary artery bypass grafting	5 (7.2)
Percutaneous intervention	4 (5.8)
Cerebrovascular accident/ transient ischemic attack	3 (4.3)
Heart failure	6 (8.7)
Chronic obstructive pulmonary disease	7 (10.1)
Peripheral artery disease	3 (4.3)
Abdominal aortic aneurysm	1 (1.4)
Serum creatinine (mg/dL)	1.18 ± 0.3
LDL cholesterol (mg/dL)	82.5 ± 27.4
Total cholesterol (mg/dL)	145.4 ± 33.1
A1C (%)	median 6.9 (interquartile range 1.7)
Microalbumin to creatinine ratio (µg/mg)	66.9 ± 116.2
Concurrent medications	13 ± 6
Insulin use	27 (39.1)
Duration of clinic enrollment (months)	6.4 ± 6.0
Clinical pharmacy visits during enrollment	4.2 ± 2.8
PCP visits during clinic enrollment	1.8 ± 1.6

TABLE 2. Clinical Characteristics of Study Population (*n* = 69) at Baseline and Clinic Discharge

Characteristic	Baseline	Discharge	Change (%)
SBP (mmHg; mean SD)	138.5 ± 14.8	126 ± 14.5	–9
LDL cholesterol (mg/DL; mean SD)	95.4 ± 27.5	82.5 ± 27.4	–13
A1C (%; median [interquartile range])	6.9 (1.5)	6.9 (1.7)	none
Total cholesterol (mg/dL; mean SD)	170.6 ± 50.6	145.4 ± 33.1	–15
Current tobacco users (*n*)	12	11	–8.6

of the greater variability in SBP, time to maintenance failure for that goal was defined as the first of three consecutive above-goal readings or documentation of a hypertensive urgency/emergency after clinic discharge.

For data analysis, the primary outcome was analyzed by Kaplan-Meier survival analysis to evaluate the time to maintenance failure for each goal. All covariate data from risk factors were analyzed by Cox proportional hazards to detect significant associations with time to goal maintenance failure. Finally, a step-wise Cox proportional hazard model-building procedure was conducted using forward selection (entering covariates with the smallest *P* values first and only those statistically significant on individual analysis). $P < 0.05$ was deemed statistically significant.

This study was approved by the institutional review boards of both the VA St. Louis Health Care System and the St. Louis College of Pharmacy.

Results

Sixty-nine patients who were discharged from the clinic after achieving goals but then failed to maintain at least one of the three goals also met the other study criteria. Patient characteristics are summarized in Table 1. Subjects were predominantly elderly, obese men. The mean duration of clinic enrollment was 6.4 months, and patients had approximately two PCP visits (mean 1.8) while enrolled in a clinic. Forty-two patients failed to maintain SBP goals, 35 failed to maintain LDL cholesterol goals, and 22 failed to maintain A1C goals after clinic discharge. Of these patients, 26 failed multiple goals; therefore, these populations are not mutually exclusive and were included in the analyses for each applicable goal.

Subjects' clinical characteristics are shown in Table 2. With the exception of A1C, patients discharged from a pharmacy-based clinic displayed all-around improvements in their target

TABLE 3. Clinical Characteristics of Individual Goal Maintenance Failure Groups at Baseline and Discharge

Characteristics	Baseline	Discharge	Absolute Reduction
SBP (mmHg; mean ± SD; *n* = 42)	135.6 ±15.5	119.1 ± 10.5	–16.5
DL cholesterol (mg/dL; mean ± SD, *n* = 35)	101.4 ± 31.8	74.5 ±17.0	–26.9
A1C (%; median [interquartile range]; *n* = 22)	6.5 (0.48)	6.4 (0.65)	–0.1

TABLE 4. Factors Associated With Increased Rate of Failure to Maintain Goal

Factor	HR	SD	*P*
SBP goal maintenance failure group			
Chronic kidney disease	13.16	7.48	0.026
Heart failure	3.839	3.73	0.019
Coronary artery bypass graft surgery	3.869	3.32	0.008
A1C goal maintenance failure group			
Older age at clinic enrollment	1.08	0.15	0.015
Higher A1C at clinic discharge	2.61	2.05	0.028

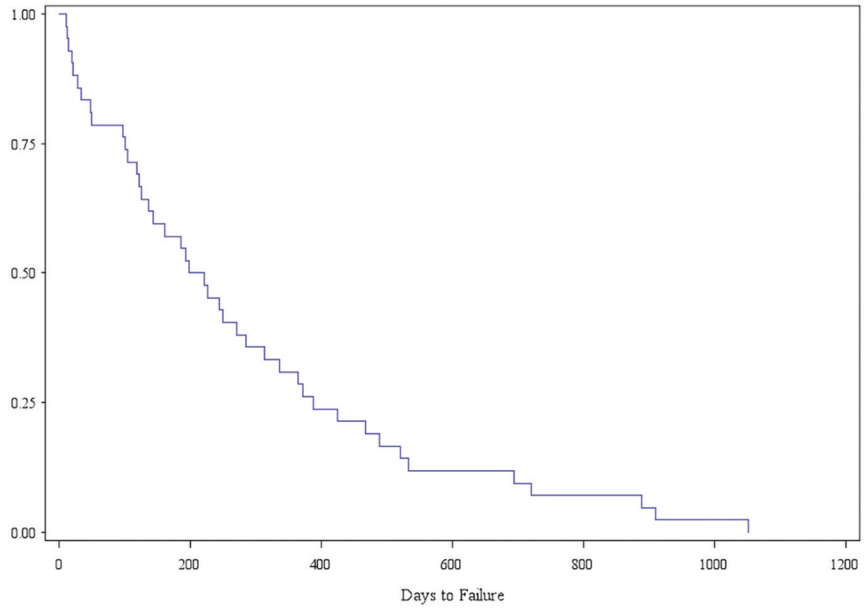

FIGURE 1. Kaplan-Meier curve for time to failure to maintain SBP goal (*n* = 42).

goals compared to both their baseline values and discharge values for the total study population. Because a clinical pharmacy may not have been consulted to manage all three problems for every patient (i.e., blood pressure, LDL cholesterol, and diabetes), some patients may already have been at goal for some of the three parameters and were being managed only for those not already at goal. For example, some patients with diabetes who were already maintaining their A1C goal were referred to a clinic for cholesterol management only. Table 2 summarizes the overall impact of clinical pharmacy services on SBP, LDL cholesterol, total cholesterol, and A1C for the duration of patients' clinic enrollment. Clinical characteristics of the patients being managed for each individual goal are shown in Table 3. The percentages of change from baseline to discharge for each clinical characteristic are shown in Tables 2 and 3. The largest changes were observed for total cholesterol (–15%) and LDL cholesterol (–13%) within the total study population. As shown in Table 3, substantial improvements were also seen in the individual groups of those failing to maintain SBP and LDL cholesterol goals (–12% and –27%, respectively).

Forty-two patients who were discharged from a clinic after achieving the SBP goal failed to maintain that goal later. At enrollment, the mean age in this group was 63.8 years old (SD 10.79 years), and the mean SBP was 135.6 mmHg (SD 15.48 mmHg). Figure 1 depicts the time to goal maintenance failure in this group, with a mean time to failure of 9.4 months (SD 8.75 months). As shown in Table 4, factors that were significantly associated with increasing a patient's rate of failure to maintain the SBP goal included history of CKD (HR 13.16, SD 7.48, $P = 0.026$), CABG (HR 3.869, SD 3.73, $P = 0.008$), or heart failure (HR 3.839, SD 3.32, $P = 0.019$).

Thirty-five patients who were discharged from a clinic after meeting their LDL cholesterol goal later failed to maintain this goal. The mean age at clinic enrollment was 64 years (SD 9.76 years). At discharge, the mean LDL cholesterol was 82 mg/dL (SD 27.45 mg/dL) and mean BMI was 32 kg/m^2 (SD 6.10 kg/m^2), and patients averaged four PCP visits until goal maintenance failure. Depicted in Figure 2, the mean time to failure for the LDL cholesterol goal was 25.8 months (SD 14.5 months). No characteristics were found to be statistically significant risk factors for LDL cholesterol goal failure.

Twenty-two patients who were discharged from a clinic after meeting the A1C goal subsequently failed

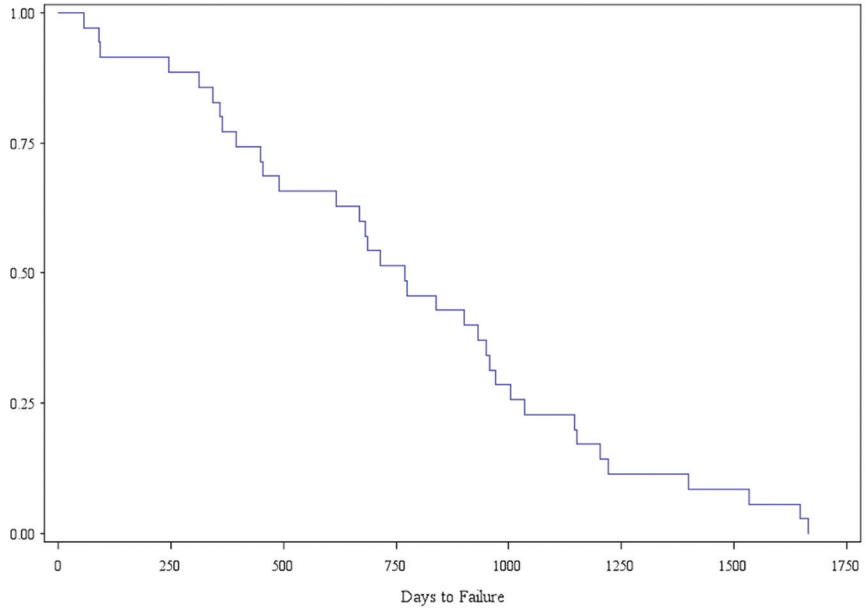

FIGURE 2. Kaplan-Meier curve for time to failure to maintain LDL cholesterol goal (n = 35).

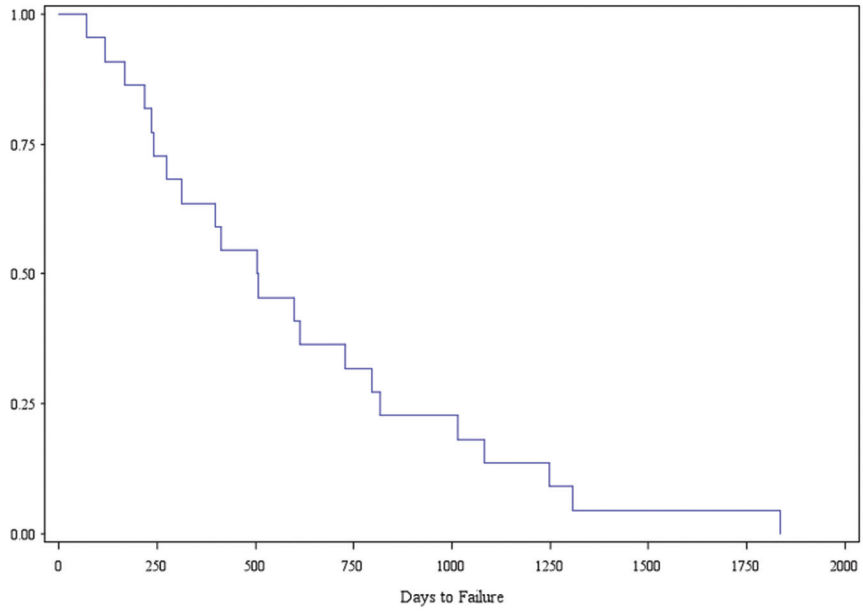

FIGURE 3. Kaplan-Meier curve for time to failure to maintain A1C goal (n = 22).

to maintain that goal. The mean time to failure was 20.4 months (SD 15.1 months). Figure 3 shows the Kaplan-Meier curve associated with this failure. Factors that were significantly associated with a shorter time to failure of the A1C goal are shown in Table 4. Age at clinic enrollment (HR 1.08, SD 0.15, P = 0.015) and A1C at clinic discharge (HR 2.61, SD 2.05, P = 0.028) demonstrated statistical significance. The mean age at clinic enrollment was 63.4 years old (SD 8.39 years) and mean A1C at discharge was 6.42% (SD 0.52%).

Discussion

Consistent with other studies (2–5, 11–15), the results of this study support the value of clinical pharmacists in disease state management, and specifically in assisting people with type 2 diabetes with improving glycemic control, blood pressure, and cholesterol levels. Within the individual goal failure groups, improvements were seen during clinic enrollment, although the improvement in A1C was modest. Given that the median A1C was 6.5% at clinic enrollment for those in the individual A1C goal failure group, this small improvement to 6.4% at discharge may have been attributable to the fact that many patients had well-controlled glycemia upon enrollment and were referred for hyperlipidemia or hypertension management, in which case there was little room for A1C improvement. On average, patients were taking 13 medications, and ~40% of patients were using insulin. Polypharmacy and the need for aggressive glycemic therapy may be factors that have some bearing on the difficulty in achieving and sustaining glycemic control in this population.

This study showed that there was generally good durability of maintaining blood pressure, lipid, and glycemic goals in veterans with type 2 diabetes. However, this was less true for SBP, for which goal maintenance durability was ~9 months, compared to nearly 2 years for LDL cholesterol and A1C goals. Because SBP is likely the most volatile of these parameters, it is not surprising that the related time to goal failure was shorter than those of LDL cholesterol and A1C.

The mean times to goal maintenance failure in this study were comparable to those reported by Pirraglia et al. (17): A1C and LDL cholesterol failures of 21.3 months each and SBP failure of 6.9 months. SBP goal maintenance was slightly more durable in the present study than in the study by Pirraglia et al., given that our definition of SBP goal failure was stricter, requiring three consecutive above-goal readings versus a single above-goal reading.

Although this study did not find a significant association between baseline SBP and time to maintenance failure for that goal, patients with a history of CKD, heart failure, or CABG had a significantly shorter time to SBP goal failure. Because the definition for failure of this goal differed from that in the study by Pirraglia et al., it is not surprising that the factors significantly affecting time to goal maintenance failure also varied.

Given the marginal stability of SBP, the findings of this study indicate that hypertensive veterans with type 2 diabetes, and particularly those with a history of CKD, heart failure, or CABG, may benefit from continued follow-up with a pharmacist-managed clinic after achieving their goal instead of being discharged to usual care. Based on the study by Pirraglia et al. (17), the same consideration could also be given to patients with an elevated SBP level at the time of clinic enrollment. However, that study did not identify a specific SBP level that would be considered elevated and a risk for a shorter time to goal failure.

Although Pirraglia et al. identified insulin use as a risk factor for shorter time to LDL cholesterol goal maintenance failure, the present study found no similar risk factors. However, it did find that patients of advanced age or having higher A1C levels at discharge may be at higher risk for failure to maintain their A1C goal after clinic discharge. Because the study by Pirraglia et al. identified only BMI as a significant risk factor for time to A1C goal maintenance failure (17), the results of these two studies differ in terms of risk factors for these two outcomes. Although these factors may contribute to a shorter time to failure of maintaining an LDL cholesterol or A1C goal, most patients, including those with these potential risk factors, were able to maintain both goals for ~2 years. This should be kept in mind when considering whether to forgo clinic discharge in favor of continuing clinic follow-up for patients with these characteristics.

This study had some limitations. It included only patients with diabetes who had failed to maintain their clinical goals within 3 years of discharge from the pharmacy-based clinics. There was also a relatively small sample size; only 69 patients met study criteria to be included in the statistical analyses. This was ~30% of the population size in the study by Pirraglia et al., which may have contributed to the lack of accord in the risk factors identified in the two studies (17). In addition, it may have been helpful for this study to have a comparison group of patients with type 2 diabetes who maintained their clinical goals for 3 years after being discharged from the pharmacy clinic. Also, because this study was retrospective, it was not possible to control for all confounding factors that may have influenced its findings. Factors such as visits to other specialty providers, medication adherence, appointment adherence, diet, physical activity level, and patient literacy were not documented and could have potentially influenced the results. Interpretation of the results for SBP in this study is complicated by the fact that, in 2013, ADA changed its recommended SBP goal for people with diabetes from <130 mmHg to <140 mmHg (18). Finally, because this study was conducted on veterans with type 2 diabetes receiving care through a VA health care system, its findings may not be fully applicable to other patient populations.

In conclusion, this study provides further evidence that pharmacists can have a significant impact as part of the health care team in improving patient care in the diabetes patient population, and specifically in helping these patients achieving blood pressure, cholesterol, and glycemic goals. From these results, it can be concluded that, once achieved in a pharmacy-based clinic, LDL cholesterol and A1C goals are relatively durable, although the SBP goal does not have the same durability.

This study also adds new evidence that many patients may be safely discharged from a disease state management clinic and that resources can then be utilized to target those with specific risk factors for failure to maintain their clinical goals. These results may alter current practices and criteria for patient discharge, especially for patients who achieve their SBP goals but may still benefit from additional follow-up in the pharmacy-based clinic (e.g., patients with type 2 diabetes and CKD). Because the mean time to goal maintenance failure for SBP was 9.4 months, scheduling a follow-up appointment for 6–9 months after discharge seems reasonable. Additional research into the factors that encourage maintenance of blood pressure, cholesterol, and glycemic goals and reduce cardiovascular risk will be vital in determining optimal strategies for management of these chronic conditions.

Duality of Interest

No potential conflicts of interest relevant to this article were reported.

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Signed, Christian Kohler, Managing Director, Scholarly Journal Publishing.