Original Work

Effect of Pharmacist and Nurse Practitioner Diabetes Focused Clinic Visits on Diabetic Outcomes and Statin use Within an Internal Medicine Department

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Abstract

Purpose: Diabetic patients seen by the nurse practitioner (NP) or pharmacist within the clinic setting have been shown to have improved patient outcomes. The objective of this study is to determine if diabetic patients seen by the NP or pharmacist have improved glycosylated hemoglobin (HbA1c), blood pressure control, and are receiving appropriate statin therapy, when compared to patients only seen by their primary physician. The new statin recommendations are based on recent American College of Cardiology (ACC) and American Heart Association (AHA) recommendation updates.

Methods: A retrospective analysis was conducted on diabetic patients who were seen by a provider two times within a nine-month period for a diabetes focused visit at the Internal Medicine department. The study group included patients seen by the NP or pharmacist and the control group was patients seen only by their primary physician.

Results: Eighty patients were included in the analysis. Patients seen by the pharmacist or NP for diabetes focused visits were statistically significantly more likely to be on the appropriate statin dose (p=0.021). There was no statistically significant difference between the two groups for HbA1c control (p=0.72 and 0.60), blood pressure control (p=0.38 and 0.24) or statin use (p=0.36).

Conclusions: Diabetes is a risk factor for the development of cardiovascular disease. Optimized management of diabetes can help to minimize this risk. Overall, management of diabetes by the pharmacist or NP was similar to that of physicians. Thus, showing the potential for management of diabetes by a multidisciplinary team.

The increasing number of people diagnosed with diabetes is creating a growing problem in the United States. According to the American Diabetes Association, in 2012 there were 29.1 million people living with diabetes with 1.7 million new diagnoses each year.[1] This puts an increased burden on the healthcare system as diabetes can cause long term complications that lead to increased morbidity and mortality. Included in this is an increased risk of cardiovascular disease. Mortality rates due to cardiovascular disease were 1.7 times higher in adults with diabetes compared to those without diabetes.[1] However, control of diabetes can decrease the risk of long term complications including the development of cardiovascular disease.[2]

One facet in the care of diabetic patients is based on recommendations from the 2013 ACC/AHA guideline updates on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults and the 2013 ACC/AHA guideline update on the assessment of cardiovascular risk.[3,4] These guidelines list diabetes as a risk factor when calculating whether a patient needs to be on statin therapy. When these guidelines were implemented this nearly doubled the number of patients eligible for statins.[5] Thus, statins are now recommended regardless of the presence of cardiovascular disease in patients with diabetes as they have been shown to reduce mortality due to cardiovascular events.[6-8] Statins slow and sometimes reverse the progression of plaque buildup in the body.[6-8] However, while statins are known for reducing cardiovascular risk, it is also important that patients with diabetes be seen by a healthcare provider on a regular basis to manage their glycemic control to further minimize short term and long term complications.[9]

The current climate of health care reform, coupled with a dubious economic environment, has led to inter-professional team management of patients.[10] Team-based care may improve patient outcomes in both acute and ambulatory practice settings. Specifically, pharmacists and nurse practitioners (NPs) have been shown to improve overall diabetes care and medication adherence via medication

therapy management visits.[11,12] This includes patients with diabetes and other diseases which require complex medication regimens.

Medication therapy management by a pharmacist is a useful part of team-based or multidisciplinary care that may be helpful in managing chronic conditions.[11] Pharmacist provided patient care services have demonstrated improvement in patient outcomes, demonstrating significant reductions in systolic and diastolic blood pressure, total cholesterol, low-density lipoprotein (LDL) cholesterol, body mass index and glycosylated hemoglobin (HbA1c) when compared to conventional care.[13,14] One study demonstrated a pharmacist-managed medication therapy service for diabetic patients had an overall reduction in HbA1c and an increase, from 14.8% to 43.2%, in the number of patients with an HbA1c at goal.[9]

Primary care NPs have been shown in numerous studies since the 1970's to be as efficacious as physicians in managing chronic disease.[15-19] Quality of care measurements have been examined over time to ensure patient management was at least equal between NPs and physicians. Frequently examined outcomes included blood pressure, HbA1c and lipids.[16,17,20,21]

The effectiveness of pharmacists is well documented in the areas of medication adherence, patient knowledge, quality of life measures, and in the prevention of adverse events.[13] Barriers to pharmacists providing patient care in a team-based setting have begun to fall away as the use of collaborative practice agreements (CPA) between physicians and pharmacists expands the pharmacist's ability to manage medication therapy.[22] The care of patients with chronic illnesses who require frequent monitoring, drug therapy adjustments and follow-up are well suited for the broad scope of services that a pharmacist or a NP can provide.

Pharmacist and NP assistance in medication management can help alleviate the strain on valuable primary care and specialty care physicians, and in turn meet new financial incentives from Medicare and private insurers.[22] Current medical literature has little in the way of studies which examine inter-professional team care versus that of the traditional physician approach. Our internal medicine department piloted an innovative health care delivery model which utilized a team of professionals including the pharmacist and NP. The goal of this study was to examine if this newly formed team was making an impact on diabetic outcomes. This study analyzed how patient goals for HbA1c, blood pressure, statin use, and appropriate statin dosing through pharmacists and NP visits affected diabetes outcomes when compared to standard of care with the physician within the internal medicine department.

TABLE 1. Baseline Patient Characteristics in the Control and Study Groups

	Control (N=40)	*Study (N=40)*	*Total (N=80)*	*p Value*
Age (years), mean (SD)	64.0 (9.8)	63.0 (8.7)	63.5 (9.2)	0.63
Gender				0.64
Males	26 (65.0%)	24 (60.0%)	50 (62.5%)	
Females	14 (35.0%)	16 (40.0%)	30 (37.5%)	
Race				0.31
White	39 (97.5%)	40 (100.0%)	79 (98.8%)	
Other	1 (2.5%)	0 (0.0%)	1 (1.3%)	
Smoker				0.24
Yes	2 (5.0%)	5 (12.5%)	7 (8.8%)	
No	38 (95.0%)	35 (87.5%)	73 (91.3%)	
ASCVD 10 year risk (at first visit), mean (SD)	23.0 (15.8)	22.7 (14.9)	22.8 (15.2)	0.9271

Methods

A retrospective chart review was conducted on 80 patients with diabetes who were seen by an internal medicine physician, NP, or pharmacist provider at the clinic two times within a nine-month period for a diabetes focused visit. The study group (n=40) included patients who were seen by either the NP or pharmacist for at least two diabetes focused visits within the nine-month time period (i.e. team-care or multidisciplinary). If medication changes were identified by the pharmacist, these were approved by the patient's physician as no CPA was in place during the study. The control group (n=40) included patients who were seen only by the primary physician for all diabetes focused visits (i.e. primary physician only). At least two visits were required to measure changes in diabetic outcomes. If more than two visits occurred within the nine-month time frame the first and the last visit within the nine-month time period were used for analysis. The visits were standard clinic visits that focused on diabetes. Patients were identified through data collected by population health, an internal department that monitors diabetic outcomes, and the schedules of the pharmacists, NPs, and primary physicians within the internal medicine department.

Patients included in the study were:

- 18 years of age and older
- Seen by a NP or pharmacist for two visits where diabetes was a focus (study group) or seen by their primary physician for two visits where diabetes was a focus (control group)

Patients excluded from the study and all analysis if they were:

- Pregnant or breastfeeding
- Less than 18 years of age
- Allergic to statins
- Newly diagnosed with type 1 or type 2 diabetes mellitus three months

TABLE 2. Comparison of HbA1c, Statin Use, Statin Intensity and Blood Pressure Between the Control and Study Group at Final Diabetes Focused Visit in Comparison to First Visit

	Control (N=40)	Study (N=40)	Total (N=80)	p Value
Final HbA1c in control (if initial HbA1c not in control)				0.72
Yes	5 (20.8%)	6 (17.1%)	11 (18.6%)	
No	19 (79.2%)	29 (82.9%)	48 (81.4%)	
Final HbA1c in control (if initial HbA1c in control)				0.60
Yes	12 (75.0%)	3 (60.0%)	15 (71.4%)	
No	4 (25.0%)	2 (40.0%)	6 (28.6%)	
Statin Use				0.36
Yes	35 (87.5%)	32 (80.0%)	67 (83.8%)	
No	5 (12.5%)	8 (20.0%)	13 (16.3%)	
Correct Statin Intensity				0.021
Yes	12 (34.3%)	20 (62.5%)	32 (47.8%)	
No	23 (65.7%)	12 (37.5%)	35 (52.2%)	
Blood Pressure[1]				
Systolic Blood Pressure	129.72	127.08		0.38
Diastolic Blood Pressure	74.67	72.35		0.24

[1]Average blood pressure comparison between control and study groups after adjusting for initial blood pressure measures

prior to the study date
- Inadequate medical records with any missing data
- Patients where statin use would be contraindicated
- Patients who received a higher level of care such as nursing homes or assisted living facilities
- Referred out of primary care for diabetes management

Data collected included age, gender, HbA1c, statin use, statin dose, statin intolerance, weight, height, serum creatinine, blood pressure, cholesterol panel, baseline aspartate aminotransferase (AST), race, hypertension diagnosis, treatment for hypertension, smoking status, 10-year atherosclerotic cardiovascular disease (ASCVD) risk, provider seen for visit, and reason for visit. This data was used to calculate the 10-year ASCVD risk. Data regarding how often new medications were started, medications dose changes and emphasis on lifestyle modifications were not collected due to limited ability to collect this information.

Statistical Methods

The study groups (team-care or multidisciplinary vs primary physician only) were defined by the first visit within the time frame under study. This practice was used to avoid potential selection bias based on a patient's clinical outcome. This approach is akin to an intention-to-treat analysis in a clinical trial.

Descriptive statistics are reported as frequencies and percentages for categorical variables, and means with standard deviations (SD) for continuous variables. Categorical outcomes at the second visit were compared between study groups using Pearson's chi-square or Fisher's exact test. Continuous outcomes at the second visit were compared between study groups using two-sample t-tests. Regression analysis was used to compare blood pressure between groups at the second visit after adjusting for the patients' initial blood pressure measures.

We anticipated having approximately 80 patients, with approximately 40 in each group. Forty patients in each group allowed us to detect a difference in means of 0.634 standard deviations for any continuous outcome with 80% power using a two-sided t-test with alpha level of 0.05.

Results

Data was collected for 80 patients during the time period of January 1, 2016 to March 30, 2016. Patients were excluded prior to full data collection if they had any statin allergy or intolerance documented.

The average patient age in the control group was 64 (SD=9.8) years old compared to 63 (SD=8.7) years old in the interventional group (p=0.63). The percentage of male participants in the control group was 65% compared to 60% in the interventional group (p=0.64). Nearly all the patients in the study were Caucasian. There was no statically significant difference between the two groups in terms of smoking status (p=0.24) and ASCVD 10-year risk at first visit (p=0.93) that could impact baseline risk of cardiovascular disease. Baseline patient information is presented in Table 1.

The first primary outcome was a comparison of a patient's HbA1c at their last visit compared to their first visit. This was first measured by stratifying patients in each group based on whether HbA1c was at goal (less than 7.0%) or not at goal (greater than or equal to 7.0%) at the first visit. HbA1c at the last visit was then compared to the first visit and patients were categorized on whether they had remained in goal or not at goal, or, if they had moved to be at goal or not at goal. Among the patients that were at goal HbA1c at their first visit, there was no significant difference

TABLE 3. Examples of Statins Based on Intensity

High-Intensity	*Moderate-Intensity*	*Low-Intensity*
Atorvastatin 40-80 mg	Atorvastatin 10-20 mg	Fluvastatin 20-40 mg
Rosuvastatin 20-40 mg	Fluvastatin 40 mg twice daily	Lovastatin 20 mg
	Fluvastatin XL 80 mg	Pitavastatin 1 mg
	Lovastatin 40 mg	Pravastatin 10-20 mg
	Pitavastatin 2-4 mg	Simvastatin 10 mg
	Pravastatin 40-80 mg	
	Rosuvastatin 5-10 mg	
	Simvastatin 20-40 mg	

in the percentage of patients who were at goal HbA1c at the last visit between the two groups (interventional: 60% vs control: 75%, p=0.60). Among the patients that were not at goal HgA1c at first visit, there was no significant difference between the two groups of patients in terms of who were at goal at the last visit (control: 21% vs interventional: 17%, p=0.72). The second primary outcome was statin use. There was no significant difference in statin use between the two groups (control: 87.5% vs interventional: 80%, p=0.36; see Table 2).

The first secondary outcome compared correct statin intensity between the two groups based on each patient's ASCVD 10-year risk at the first visit. There was a statistically significant difference between the two groups. Patients seen by the pharmacist or NP for a diabetes focused visit were more likely to be on the correct intensity of statin (interventional: 62.5% vs control: 34.3%, p=0.021; see Table 2; Statins listed by intensity is included in Table 3).

The final secondary outcome compared systolic and diastolic blood pressure control between the two groups. There was no difference in systolic and diastolic blood pressure control between the two groups after adjusting for the patients' blood pressure at their first visit (p=0.38 and p=0.24, respectively; see Table 2).

Discussion

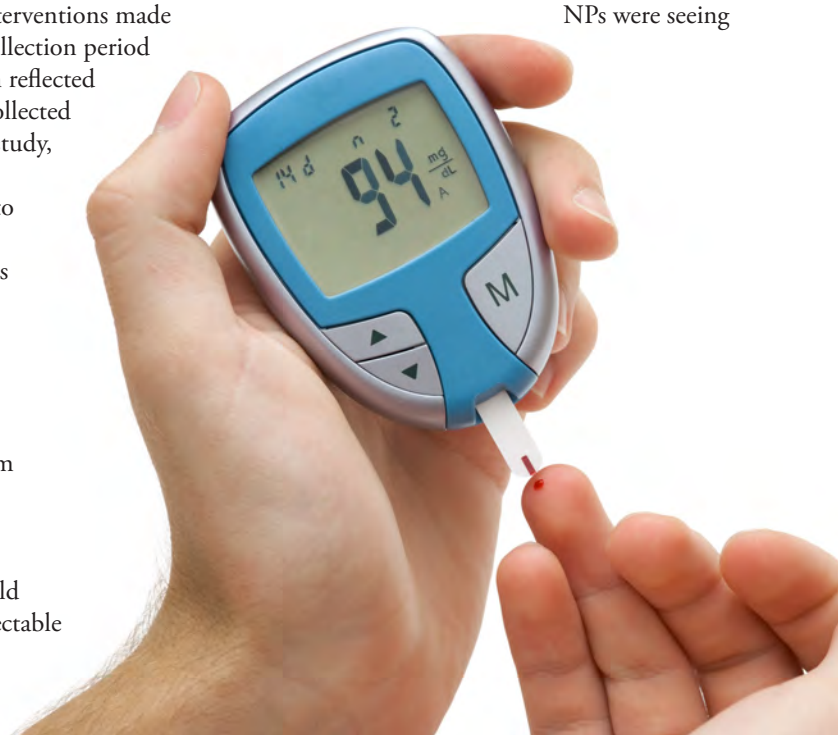
This study demonstrates that diabetes focused visits with the pharmacist and/or NP improve the use of the correct intensity of statin dose based on a patient's ASCVD risk score. This is important in patients with diabetes as they are at a higher risk for developing cardiovascular disease regardless of their baseline presence of cardiovascular disease.[6-8] While other study outcomes did not reach statistical significance, the pharmacist and NP achieved similar diabetes measures compared to solely physician managed diabetes. This supports the use of multidisciplinary care in managing diabetic patients as the demand for care of patients with chronic conditions rises.

There were several limitations to this study. Due to the retrospective nature, it was limited to using data that was previously collected. The quality of the data collected could impact the quality of the results. The retrospective design of this study may also limit some of the findings of this study, as interventions made later in the data collection period may have not been reflected in the lab values collected on the last day of study, such as HbA1c.

Secondly, due to the small design, limited conclusions can be made for a larger sample. In addition, patients may have seen providers outside of the health system internal medicine department to manage their diabetes. This would not have been detectable through the data collection methods used.

Thirdly, the 10-year ASCVD risk was calculated based on the data collected within the patient chart. The data collection was not blinded. This could have created unintentional bias with the data collection in the determination of 10-year ASCVD risk and correct statin intensity due to lack of blinding. Consequently, the lack of blinding during data collection could have had the potential to unintentionally impact the findings of the study, even though the statistical analysis was blinded.

A final limitation of this study was that the multidisciplinary care services performed by the pharmacists through the internal medicine department were newly implemented at the beginning of the study. The pharmacists and NPs were seeing



patients with diabetes more consistently at the end of the study period. The full effect of the multidisciplinary care model of patient care may not be represented in this short-term study that occurred early in the implementation phase before the pharmacist had a collaborative practice agreement with the physicians to change medications or doses without physician approval.

Conclusion

Diabetes is a known risk factor for developing cardiovascular disease. Management of diabetes and appropriate medication use can help minimize this risk. Diabetes focused visits with an NP or pharmacist can help to improve appropriate statin dosing based on the patient risk factors determined by the ACC and AHA. Overall, diabetes management by the NP or pharmacist had similar outcomes to management by the physician for HbA1c measures, statin use and blood pressure control. However, more research is required on this topic. The results of this study will be used to advance the use of pharmacists in managing diabetes and other complex medical conditions, where medication therapy is a significant part of managing overall patient health within the internal medicine and family medicine departments at the health system.

At the time the study was conducted: Kristen Kannel was a PGY-1 pharmacy resident at Mayo Clinic Health System in Eau Claire, WI. Catherine Lea was a pharmacist at Mayo Clinic Health System in Eau Claire, WI. Michele Denial was a nurse practitioner in the internal medicine department at Mayo Clinic Heath System in Eau Claire, WI. Ross Dierkhising was a biostatistician at Mayo Clinic in Rochester, MN.

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