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Implementation and Evaluation of Clinical Pharmacy Services on Diabetes Care in an Endocrinology Clinic

Katherine Fukunaga, PharmD, APh; Candace Tan, PharmD, BCACP

Abstract

Purpose

Diabetes impacts a significant population in the United States, with uncontrolled diabetes leading to serious adverse health effects and substantial cost to the healthcare system. Diabetes management by clinical pharmacy services (CPS) demonstrating positive clinical outcomes has been well-established in the primary care setting. However, there is little data evaluating the impact of CPS in specialty clinics such as endocrinology, which may provide additional opportunities for pharmacists to improve outcomes in a complex patient population. The purpose of this study is to describe the implementation of CPS in an ambulatory endocrinology clinic and to evaluate the impact of pharmacist care on diabetes management.

Methods

This was a retrospective, pre- post- descriptive study. Patients were enrolled into the study during a 6-month period and followed for a minimum of 6 months. The primary endpoint was mean change in hemoglobin A1c (HbA1c) between the pre- and post- pharmacist intervention phase. Secondary endpoints included blood pressure outcomes, statin appropriateness, rates of hospital and Emergency Department (ED) admissions due to severe hyper- or hypo-glycemia, and rates of retinal screening exams.

Results

A total of 101 patients were included in the study population. The mean baseline HbA1c was 9.11% and at six months 8.27%, with mean change of 0.84% (p-value <0.01). Descriptive statistics showed that blood pressure control, as well as statin and retinal screening rates, were high at baseline, with CPS making limited interventions in these areas.

Conclusion

This study demonstrated that pharmacist interventions in diabetes care is associated with improved HbA1c for a complex patient population in an endocrinology clinic.

Objectives

As of 2017, the Centers for Disease Control and Prevention estimated that there were 30.3 million people in the United States who have diabetes mellitus. Furthermore, the total direct and indirect estimated cost of diabetes in the U.S. was $245 billion in 2012.[1] This number is expected to be higher today with the increased prevalence of diabetes. Previous research has shown that diabetes management by pharmacists in primary care settings have been beneficial and cost-effective.[2,3] Similar research, such as Jacobs et al. (2012), showed significant impact of pharmacist care on glycemic control when compared to physician-managed patients.[4] In a systematic review of randomized control trials to evaluate the effectiveness of pharmacist interventions in the management of type 2 diabetes, the authors concluded that pharmacists have a positive influence on glycemic control, blood pressure management, lipid profile, body mass index, 10-year coronary heart disease risk, medication adherence, and quality of life.[5] This broad-scale review examined the pharmacist role in all practice areas, including community, ambulatory care, and hospital settings.

However, there is little information regarding the role of pharmacists in specialty clinics such as endocrinology, where the most high risk and complex patients with diabetes are seen after failing usual measures in primary care. Morello et al. (2016) describes a pharmacist-endocrinologist diabetes management clinic in a Veterans Affairs (VA) facility. Although impact of pharmacist care showed significant improvement in HbA1c, the data was not generalizable to a large population as the study consisted of primarily Caucasian males.[6] On the other hand, Kaiser Permanente has a diverse population of type 1 and type 2 diabetes patients, with a more distributed age, gender, and race profile. Finally, Hill et al. (2014), described Kaiser Permanente Colorado's CPS model, where pharmacists under protocol manage diabetes as well as other endocrine-related disease states as part of a multidisciplinary team.[7] However, clinical outcomes data were not reported for this CPS.

The intent of this study is to describe the integration of pharmacist services into an endocrinology clinic and evaluate the impact of pharmacist care on diabetes and related co-morbidity outcomes. The primary endpoint was mean change in HbA1c between the pre- and post-pharmacist intervention period. Secondary endpoints examined the impact of pharmacist care on blood pressure, statin appropriateness, hospital and ED admissions due to diabetes, and retinal screening exams. Ultimately, this study serves to evaluate the impact of CPS in endocrinology and demonstrates the potential for expanding the role of clinical pharmacy into this specialty area.

Methods

This study was a single-center, retrospective chart review to evaluate the impact of pharmacist care on patients with diabetes in the endocrinology clinic at Kaiser Permanente West Los Angeles Medical Center. The Kaiser Permanente Southern California Review Board formally reviewed and

provided approval for the study protocol which included patients at the Kaiser Permanente West Los Angeles Medical Center who were enrolled into pharmacist care in the endocrinology clinic during the study period between March and September 2017.

A need for CPS in the endocrinology clinic was identified due to a physician staffing shortage and increased focus towards improving diabetes health outcomes. Patients meeting criteria for endocrinologist care included those with type 1 and type 2 diabetes failing to reach HbA1c goal through primary care efforts and either on maximally tolerated oral medications and insulin (or repeatedly declining insulin) or on high insulin doses per provider clinical judgment. One pharmacist operating at a 1.0 equivalent (40 hours per week) integrated into the interdisciplinary team consisting of physicians, registered nurses, licensed vocational nurses and medical assistants, and worked under physician-directed protocol to manage patients' diabetes and related co-morbidities. During initial service development, referrals were made based only on the endocrinologists' discretion without set referral criteria with the majority of patients referred having HbA1c over 8%. All patients were accepted if determined to be appropriate by physicians for additional diabetes care and there were no exclusions at the time except for those on pump-based insulin therapy. The endocrinologists also set individualized HbA1c treatment goals for patients. During the study period, there was no supportive pharmacy personnel to assist the pharmacist with administrative tasks.

The majority of pharmacist-patient encounters were telephone-based, with occasional in-person office visits for those patients with poor ability to provide reliable history over the phone, such as individuals with dementia or poor cognition. Glucometer and device teachings were also done in person. Pharmacist interventions included medication management (initiating, titrating and discontinuing medications for diabetes or related co-morbidities), device teaching, lab ordering and monitoring, patient education, and addressing care gaps (i.e. annual diabetic foot exams, retinal screenings). Frequency of CPS follow-up ranged from days up to 4 weeks depending on patient needs and diabetes control. Patients continued usual care with their endocrinologist and were seen every three to six months; the pharmacist acted as a provider-extender, providing additional patient touches in between physician visits. Patients also continued usual care with their primary care provider with follow-up frequency depending on health care needs, although once referred to endocrinology typically diabetes management was deferred to specialty services. Any patients who did not respond to a minimum of three attempts via a combination of telephone, email and letter outreach were discharged from pharmacy services and referred back to the endocrinologist for continued care.

Patients were identified retrospectively for the study using Health Connect, Kaiser Permanente's electronic medical record system. Patients were included in the study if they were being followed by an endocrinologist, diagnosed with either type 1 or type 2 diabetes, enrolled into CPS between March 15, 2017 and September 15, 2017, and followed by CPS for at least 6 months. All patients were 18 years or older as younger patients were followed by pediatrics. Of the 188 patients referred to CPS during the enrollment period, 68 patients were excluded due to failure to successfully establish telephone contact despite repeated attempts. Patients were also excluded if they were referred to CPS for hypoglycemia management (4), missing a baseline HbA1c within 6 months of the index date (1), not followed for at least 6 months (9), or were missing a 6-month follow-up HbA1c (5). The final study population after exclusions consisted of 101 patients.

Baseline characteristics were gathered for the study population, including a baseline HbA1c within 6 months of the index date. The primary endpoint HbA1c was the HbA1c at 6 ± 2 months. Secondary endpoints included blood pressure and statin appropriateness as well as the retinal screening health maintenance measure at 6 months. It also included hospital and ED admissions due to severe hyper- or hypo- glycemia, which were identified by ICD-9/10 codes used during the study period.

Statistical analyses used paired t-tests for both the primary and secondary endpoints of mean HbA1c and blood pressure change ($\alpha = 0.05$). Descriptive statistics were used to describe the other secondary endpoints.

Results

Baseline characteristics for the final study population are reported in Table 1. The mean age of the study population in years was 66.9, with a range from 39 to 91. Over 50% of the study population was Black, with the remaining population distributed among White, Hispanic and Asian/Pacific Islander descent. Sixty-six patients (65.4%) were classified as obese (body mass index of 30 or greater). Other co-morbidities included 84 patients (83.2%) with hypertension, 51 patients (50.5%) with cardiovascular disease and 35 patients (34.7%) with chronic kidney disease. 74 patients (73.3%) had an atherosclerotic cardiovascular disease (ASCVD) risk score of 7.5% or greater.

Out of the 188 referred patients, 4% or 18 patients had type 1 diabetes. Of these, seven patients were enrolled into CPS with four patients meeting inclusion criteria for the study. Of the 11 patients with type 1 diabetes not enrolled in CPS due to non-response, the average age was 39.

Baseline diabetes medications including the variety of orals and injectables are reported for the patients with type 2 diabetes only, as type 1 diabetes patients are insulin-dependent (Table 2). Patients with type 2 diabetes were on an average of 2.66 medications with 66% of patients on a combination of both oral medications and insulin. Thirteen patients (13.4%) were solely on oral medications. Eighty-one patients (83.5%) were on basal insulin at baseline, and fifty-one patients (52.6%) were also on prandial insulin.

The mean HbA1c was 9.11% (range 7 to 14.4, SD 1.3) at baseline and 8.27% (range 5.9 to 13, SD 1.41) at 6 months. The mean change in HbA1c between the pre- and post-pharmacist intervention period was 0.84% (p-value <0.01), meeting statistical significance (Figure 1).

There was no significant change in mean blood pressure between the pre- and post- pharmacist intervention period. Since the service was primarily telephone-based, baseline blood pressures were evaluated from most recent readings done from other outpatient visits and patients were scheduled for repeat blood pressure checks if interventions were made. Mean systolic blood pressure at baseline was 132.5 mmHg (SD 15.21) and diastolic blood pressure was 69 mmHg (SD 10.42). At the 6-month endpoint, the mean systolic blood

pressure was 133.6 mmHg (SD 14.85) and mean diastolic blood pressure was 68 mmHg (SD 11.36). The mean systolic blood pressure from baseline to 6-month follow-up increased by 1.1 mmHg (p-value 0.44) while the diastolic blood pressure decreased by 1.1 mmHg (p-value 0.31) (Figure 2).

Table 1. Baseline Characteristics (n = 101)

Age (years), Mean (SD)	66.9 (11.46)
Male, n (%)	48 (47.5)
Ethnicity/Race, n (%)	
Black	54 (53.5)
White	27 (26.7)
Hispanic	11 (10.9)
Asian/Pacific Islander	7 (6.9)
Other/Unknown	2 (2)
Baseline HbA1c (%), Mean (SD)	9.11 (1.3)
Baseline BP (mmHg), Mean (SD)	
SBP	132.5 (15.21)
DBP	69.1 (10.42)
BMI (kg/m^2), n (%)	
Mean (SD)	32.7 (7.36)
Normal BMI (18.5-24.9)	18 (17.8)
Overweight (25-29.9)	17 (16.8)
Obese (≥ 30)	66 (65.4)
Diabetes Classification, n (%)	
Type 1	4 (4)
Type 2	97 (96)
ASCVD risk score	
Mean (SD)	23.4 (13.57)
≥ 7.5%, n (%)	74 (73.3)
< 7.5%, n (%)	9 (8.9)
Not able to calculate, n (%)	18 (17.8)
Co-morbidities, n (%)	
Hypertension	84 (83.2)
Cardiovascular disease	51 (50.5)
Chronic kidney disease	35 (34.7)
Stage 1	0 (0)
Stage 2	14 (13.9)
Stage 3	15 (14.9)
Stage 4	4 (4)
Stage 5	2 (2)

Table 2. Baseline Medications Type 2 DM (n = 97)

Average # of DM Medications (n)	2.66
Diabetes Medications, n (%)	
Oral only	13 (13.4)
Oral + Insulin	64 (66).1)
Insulin only	20 (20.6)
Basal Insulin	81 (83.5)
Prandial Insulin	51 (52.6)
Insulin U-500	2 (2.1)
Other Injectable Medication	3 (3.1)

During the study period, there were six changes made to statin doses. Of note, all of the patients in the study period were already on a statin at baseline unless they did not tolerate or refused to take statins. Ninety-five patients were up-to-date on their retinal screenings at the end of the study period. Of these, 53 patients were not yet due for screening, 27 patients completed screening, and 15 patients had an intervention by the pharmacist to complete one. Finally, there were 16 hospital and ED admissions related to uncontrolled diabetes, from either severe hyper- or hypo- glycemia instances.

Figure 1. Primary Endpoint: mean change in HbA1c

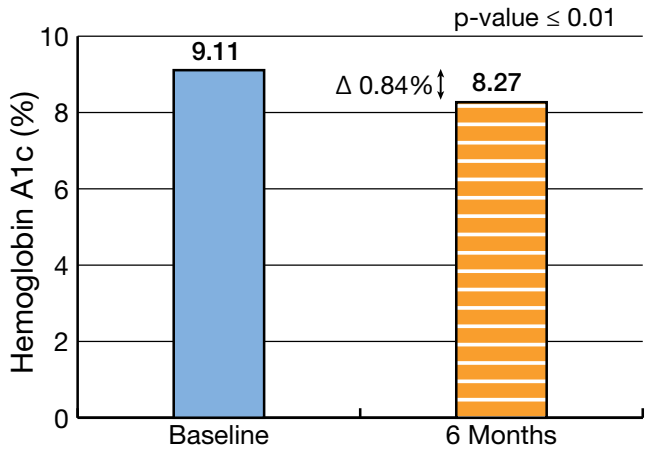
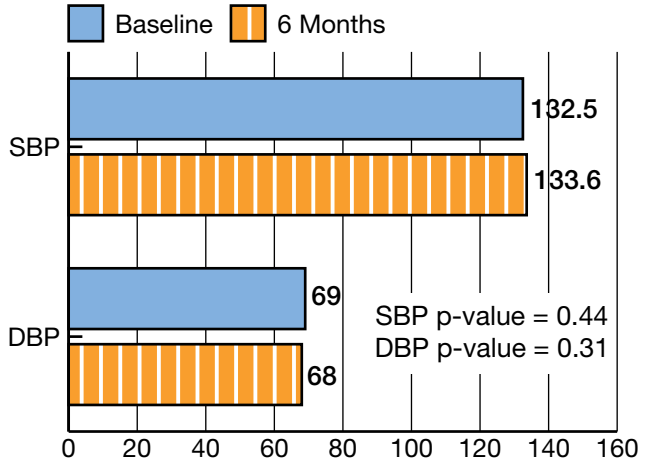


Figure 2. Secondary Endpoint: mean change in blood pressure



Discussion

This study was designed to measure the impact of pharmacist care on diabetes management in an ambulatory endocrinology clinic with a complex patient population. Outcomes of the study showed that CPS was associated with improved glycemic control.

Baseline characteristics and the necessity for referral to endocrinology showed that the population was a complex group of patients that may have been more difficult to manage than in a primary care setting. Because a majority of the patients in the study population were already on insulin and many on a combination of insulins, a significant amount of pharmacist interventions involved insulin titrations. Up-titrations were most common; however given the prevalence of patients with glycemic instability in this specialized setting, a refined and more subtle approach to insulin adjustment was often taken. Therapy adjustment also included addition of second- and third- line oral agents as well as changing between various insulins or to more concentrated formulations to optimize patient response. The impetus for adding glucagon-like peptide-1 receptor (GLP-1) agonists and sodium-glucose co-transport 2 (SGLT2) inhibitors to background therapy was gaining momentum at the time of the study, and has only become more aggressive in recent years given the rapidly changing landscape of diabetes care.[8] Down-titration and discontinuation of both oral medications and insulin occurred in settings of hypoglycemia, improving glycemic control from lifestyle changes or from changes in patient status. Alternative agents were attempted in patients who had lack of response or adverse reaction to add-on or current therapy. Under physician-directed protocol, the pharmacist intervened in a wide variety of therapy changes to improve glycemic control in this specialty population.

Any barriers to medication adherence, including but not limited to personal patient challenges, financial difficulty, and need for additional medication assistance were also addressed as an essential component of care. Referrals to other departments such as social work, home health or financial assistance were made when appropriate.

In conjunction with medication adjustments and related counseling, the pharmacist engaged patients in diabetes education focusing on lifestyle modifications as a critical component of comprehensive diabetes care. Education provided during patient encounters included but was not limited to optimal diet options, individualized patient diet goals and basic carbohydrate counting. Additional resources for patient education included referrals to health education classes or individual nutrition consultations. These were made when appropriate, however the frequency of referrals and successful consults were not reported. Exercise plans based on national recommendations and tailored to individuals were also discussed.

The pharmacist interventions in medication therapy management, diet and lifestyle counseling, and other diabetes related factors correlated with a statistically significant reduction of HbA1c to 8.27% (SD 1.41) at 6 months. This mean HbA1c decrease of 0.84% brought patients closer to their individualized glycemic goals, typically between 7-8% based on American Diabetes Association recommendations.[9]

There were fewer opportunities for pharmacist interventions for the secondary endpoints. At baseline, the mean blood pressure was 133/69 mmHg, already meeting the goal blood pressure of <140/90 per American Diabetes Association guidelines.[8] Furthermore, since the majority of patients were already on a statin at baseline (unless they were intolerant or declined treatment), there were only 6 changes made to lipid-lowering therapy during the study period. Although the study did not specifically evaluate if these adjustments were due to pharmacist interventions, the pharmacist did address appropriate therapy when assessing patients, making changes based on American Diabetes Association guidelines as well as patient factors such as tolerability. Other providers may have had influence over the statins aside from the pharmacist, including the endocrinologist, primary care physician, etc. Finally, 94% of patients were up-to-date on their retinal screenings by the end of the study period, with the pharmacist intervening on 15 patients (14.8%) to schedule their retinal screening exam. We hypothesize that the secondary endpoints required minimal pharmacist intervention as patients received extensive primary and endocrinology care prior to and during the study period for comorbidity-related concerns.

For the type 1 diabetes population, treatment adjustments were focused on multiple dose insulin (MDI) injection therapy during the study period. There were distinct age pattern differences between the type 1 and type 2 diabetes patient populations, which may have been associated with varying success of contact rates as well as treatment strategies. Because the type 1 diabetes population is seen only by endocrinology for diabetes management, it was expected that there would be a higher proportion of type 1 diabetes patients than the 4% found in the final study population. However, there was a greater proportion of type 1 patients compared to type 2 patients that were not successfully enrolled in CPS due to a lack of response to CPS outreach. At an average age of 39 years for those who were not successfully enrolled, the type 1 diabetes patients were significantly younger than those in the final study group population. Therefore, alternative outreach strategies such as secured messaging services or text messaging can be considered for this younger patient population in order to boost contact rates for diabetes care. Since this writing, the referral rate for type 1 patients has also increased as the scope of practice for the pharmacist has expanded to include management of patients on continuous glucose monitors as well as insulin pumps.

This study also adds to the race data available for CPS services in endocrinology, which is currently limited to White populations. The study population was 54% Black, with this minority having higher morbidity and mortality rates from diabetes due to a variety of socio-economic, cultural and historical factors.[9] Chung et al. (2014) and Isetts et al. (2016) show that CPS in both diabetes and hypertension management is effective in improving outcomes for under-represented minorities.[10,11] This study corroborates the available data and demonstrates the potential to expand to specialty care areas as well.

Finally, previous studies for CPS management in diabetes show populations with varying comorbidities. For example, in Benedict et al. (2018), at baseline, 7% of patients had cardiovascular disease (CVD), 55.6% had hypertension, and 62% were obese.[12] In comparison, this study population had higher rates of risk factors and other comorbidities including CVD (50.5%) and hypertension (83.2%). Implications of these comorbidities affected treatment strategy and goals of therapy in this complex patient population, often limiting medication choices and the degree of feasible dose adjustment. In addition, there were 16 admissions related to hypoglycemia- or

hyperglycemia- related complications during the study period with these patients requiring frequent follow-up and care, often up to several times per week initially after discharge.

Limitations

There were several significant limitations to the study that provide future opportunities for additional research. This was a retrospective, pre- post- descriptive study limited to a 6-month active study period. In the future, a longer duration would allow for better examination of HbA1c trends through pharmacist interventions. Additionally, evaluating the rate of adverse events, such as comparison of pre- post- ED/hospital admissions for diabetes-related complications would elucidate whether pharmacist care can reduce hospitalizations. Finally, matching a standard care cohort to a CPS cohort would more conclusively determine the impact of pharmacist care on diabetes outcomes.

A cost-data analysis would also evaluate the economic value of CPS in specialty care. Cost effectiveness was studied in the Veterans Affairs Diabetes Intense Medical Management "Tune-Up" clinic (DIMM clinic).[2] Although different in structure, the DIMM clinic provides another example of pharmacist care in an endocrinology clinic that improved glycemic control compared to primary care alone. Additional pharmacist management was associated with greater cost avoidance and a return-on-investment of $9.01 per dollar spent on the DIMM clinic.[2] For future studies of endocrine CPS, cost analyses could strengthen the value of pharmacists as provider-extenders in the endocrinology setting.

There were no specific referral criteria in place during the initial service development period, resulting in a high volume, diverse set of patients with varying needs exceeding the capacity of a 1.0 equivalent pharmacist. A needs assessment performed after the study period ended identified the highest-risk cohort, allowing the service to prioritize patients who would receive greatest benefit from pharmacist care. Another strategy to maximize pharmacist output and to practice most efficiently at their highest scope is to have support for administrative duties such as gathering blood sugar readings and medication history. There was no ancillary support during the study period with the pharmacist performing all tasks necessary to operate the clinical service. However, since this writing there is now an additional staff member operating at a 0.5 equivalent assisting in non-clinical tasks, thereby allowing the pharmacist to focus more on clinical interventions. Finally, the service has also replaced cold-calls with scheduled telephone appointments to increase successful contact rates.

Conclusions

CPS was associated with improved glycemic control in an endocrinology clinic. While prior care plays an important role for initial glycemic control and other diabetes management endpoints, pharmacist care may further improve HbA1c in a specialty service. Since the study conclusion, steps have been taken to target high-risk patients as well as isolate a population that would most benefit from CPS. Pharmacist scope of practice has expanded to include management of patients on continuous glucose monitors as well as insulin pump therapy. The results found in the current study support pharmacist care in one area of the specialty realm; however, there are many specialty care areas that may benefit from CPS. Pharmacists play key roles in specialized population management targeting high-risk patients that may lead to improved outcomes.

About the Authors

Katherine Fukunaga, PharmD, APh, was the PGY-1 Pharmacy Resident at Kaiser Permanente West Los Angeles Medical Center from 2017 to 2018. She continues to work for Kaiser Permanente as a pharmacist. Dr. Fukunaga has no conflicts of interest or financial interests to disclose.

Candace Tan, PharmD, BCACP, is an ambulatory care clinical pharmacist at Kaiser Permanente West Los Angeles Medical Center. She served as faculty at both the University of Hawai`i at Hilo, College of Pharmacy and at the University of Southern California before joining Kaiser Permanente. Dr. Tan has no conflicts of interest or financial interests to disclose.

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