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IMPACT OF BASELINE DIABETES KNOWLEDGE ASSESSMENT ON BIOMARKERS IN A PILOT DIABETES EDUCATION PROGRAM

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Abstract: Diabetes is a pressing public health concern, with a continuous rise in its prevalence, impacting approximately 9.4% of the U.S. population. If current trends persist, projections suggest that diabetes could affect one in three U.S. adults by 2050, further emphasizing the urgency of effective glycemic management. The prevalence of diabetes escalates with age, with approximately 25.2% of individuals aged 65 or older being diagnosed. Diabetes is associated with a spectrum of complications, including retinopathy, neuropathy, and an elevated risk of cardiovascular events.

Central to patient-centered glycemic management is Diabetes Self-Management Education and Support (DSMES), which is pivotal in improving outcomes and reducing healthcare costs. This form of education demonstrates several benefits, such as lowered hemoglobin A1C (A1C) levels and enhanced diabetes knowledge. Accredited DSMES programs adhere to national standards set by the American Diabetes Association and the American Association of Diabetes Educators, offering adaptable curricula to address the specific needs of participants, emphasizing the development of individualized education plans tailored to each participant's unique requirements.

Keywords: Diabetes, Glycemic management, Diabetes Self-Management Education and Support (DSMES) Complications, Patient-centered care.

1 Introduction

The latest statistics report from the Centers for Disease Control estimates that 9.4% of the United States population (30.3 million) has diabetes.[1] The prevalence of diabetes has continued to steadily increase every year since 1990 with projections that one in every three adults in the United States could have diabetes by 2050 if current trends continue.[2] The prevalence of diabetes increases with age, with an estimated 25.2% of patients 65 years or older being diagnosed with diabetes.[1] Common complications of diabetes include retinopathy, neuropathy, and an increased risk of cardiovascular disease, heart attack, and stroke.[3]

An important component of patient-centered glycemic management highlighted in the most recent Standards of Medical Care in Diabetes includes Diabetes Self-Management Education and Support (DSMES).[4] Numerous benefits of DSMES are shown in the research including, but not limited to, lower hemoglobin A1C (A1C), improved diabetes knowledge, and reduced health care costs.[5-8] There are national standards recognized by the American Diabetes Association (ADA) and the American Association of Diabetes Educators (AADE) regarding guidelines that all accredited and recognized DSMES programs must meet.[7] Standard six within this resource gives guidance on the curriculum content, including core content areas which educators can adapt to meet the

individual needs of the participant.[7] This format allows for flexibility and creativity among various education programs, with a focus on developing an individualized education plan containing components applicable to the participant.

One resource that may be helpful to educators in identifying knowledge gaps to better structure the education plan is an assessment of the participants' baseline diabetes knowledge. Previous studies have shown that an increase in diabetes knowledge correlates to a decrease in fasting glucose, cholesterol, and A1C, and has shown to improve selfcare behaviors.[9-13] Validated diabetes knowledge scales and assessments are available for educators to utilize but they tend to measure different aspects of self-care making it challenging to determine which is most appropriate to use.[14] Other pilot programs have used a psychometrically validated tool, not yet available nationally to providers, to assess a patient's knowledge of their diabetes, lifestyle requirements, and medication-taking strategies.[15] The multiple-choice questionnaire allows patients to work through assessment levels from Beginner to Proficient to Advanced providing a clear path for additional education sessions as the providers continue to work with their patients.[15] Initial use of this tool in an interdisciplinary care program showed improvements in A1C, low-density lipoprotein (LDL) cholesterol, and systolic blood pressure (SBP) levels, an increase in preventative care services received (flu vaccines and eye and foot examinations), and also showed improvement in patient satisfaction and a reduction in overall healthcare costs after 12 months.[16] The Diabetes Ten City Challenge then scaled this model and also demonstrated similar clinical and economic results.[17] Most recently the model has been used in Project IMPACT: Diabetes with 25 communities utilizing the tools with patients disproportionately affected by diabetes.[18] Final results from this study showed statistically and clinically significant reductions in A1C, and statistically significant reductions in LDL cholesterol, triglycerides, and total cholesterol.[18] An increase in patients receiving eye examinations, foot examinations, influenza vaccinations, and who quit smoking was also observed.

The purpose of this case-control, quasi-experimental study was to implement a pilot baseline diabetes knowledge assessment developed specifically around the AADE7 Self-Care Behaviors[19], of which this site's program is accredited, to assess the impact on health outcomes in persons with diabetes.

2 Methods

2.1 Design

The Biomedical Institutional Review Board at the University of Toledo reviewed and approved this study. The pharmacist-led Diabetes Self-Management, Education, and Training (DSMET) Program at the University of Toledo serves adult patients with diabetes in an urban area and is nationally accredited by AADE. There is one pharmacist educator with diabetes educator certification (CDE) within the structure of the program. Pharmacy students on their advanced clinical rotations in their last year of school also deliver components of education to patients under the direct supervision of the lead educator. Patients enrolled in the DSMET Program scheduled to attend an individual education session between September 1, 2017, and September 1, 2018, were recruited for inclusion in the study. Participants in the intervention group completed the diabetes knowledge assessment either before coming to their appointment or at the start of their session. The assessment was available to participants as an electronic or paper version. After completion, the educator determined the priority areas of patient knowledge deficit as determined by the lower scores in each of the AADE7 Self-Care Behavior categories on the knowledge assessment and focused on that content in the education session. Baseline clinical biomarker results (within the past 3 months of the visit) were collected from the electronic medical record including, A1C, blood pressure (SBP, diastolic blood pressure (DBP)), and lipid panel (total cholesterol (TC), LDL, high-density lipoprotein (HDL), triglycerides (TG)) for participants who provided consent to be in the study. Sex, age at the time of study enrollment, and baseline knowledge assessment score were also tracked. Follow-up (at least 3 months after the visit, or up to annually for lipid panel) results of the same clinical biomarkers were also recorded for the participants. A control group of participants who attended at least one individual session of diabetes

education but who did not take the knowledge assessment test were also tracked along the same timeline for the same demographic and clinical biomarkers. The purpose of the control group was to assess the impact of education when areas of focus were identified objectively by the knowledge assessment scores compared to those identified subjectively by the educator or participant themselves.

2.2 Evaluation Instruments

The diabetes knowledge assessment developed for this study was a 53 question multiple choice test scored out of 49 points. Four questions on the assessment were subjective in nature (healthy coping) with no right or wrong answers. The assessment had a Flesch-Kincaid Grade Level of 6.7 which falls within the recommendations of health literacy for medical information.[20] Questions were evenly distributed among the seven AADE7 Self-Care Behavior categories (healthy eating, being active, monitoring, taking medication, problem solving, reducing risks, healthy coping) and an additional "General Diabetes" section (8 sections total). Every question had a choice labeled "I don't know" in order to minimize the chance of the participant guessing the correct answer and falsely elevating the score.

The assessment was developed in both a paper and online format allowing participants to take the survey at home before their appointment and also offered the flexibility for them to choose the format they were most comfortable with.

2.3 Outcomes

The primary outcome of this study was the difference in follow-up A1C for patients who attended at least one session of diabetes education and took the knowledge assessment test compared to those who did not take the test. The secondary outcomes were a difference in clinical biomarkers (A1C, BP, lipid panel) from baseline for each study group and difference in follow-up biomarkers (BP, lipid panel) when comparing groups.

2.4 Statistical Analyses

A power analysis was performed to determine a 1% difference in average A1C from baseline among intervention and control groups. A 1% difference for our power calculation was decided to be practical considering our patient population and based on research indicating that diabetes education has shown to reduce A1C levels by up to 0.8% compared with usual care alone.[21] A sample of 32 participants (16 in each group) was needed to obtain 80% statistical power with a standard alpha level of 0.05.[22] Categorical variables were analyzed using the chi-square test. Continuous variables compared between groups were analyzed using the Independent-Samples t-test if the data was normally distributed, and reported as mean ± standard deviation. The Mann-Whitney U test was used for not normally distributed continuous data, with results being reported as median and interquartile range. Normally distributed baseline and follow-up clinical biomarkers within the same group were analyzed using the Paired t-test, and reported as mean ± standard deviation. The Wilcoxon signed rank test was used for not normally distributed data within a group and results were reported as median and interquartile range. P values less than 0.05 were determined a priori to be statistically significant. All statistical analyses were done using SPSS Statistics for Windows, Version 23.0, Armonk, NY (IBM Corp., Released 2015).

3 Results

3.1 Outcomes

There were a total of 40 participants included in the study (intervention group, n=20, control group, n=20). There were no significant differences at baseline between the two groups in terms of demographics or baseline clinical biomarkers (Table 1).

Table 1. Baseline Characteristics

	Intervention (n=20)	Control (n=20)	p-value
Gender (male / female) (%)	50/50	40/60	.525

Original Article

Age (years) ± SD	54.2 ± 10.94	55.8 ± 14.26	.693
Type of Diabetes (type 1 / type 2) (%)	10/90	20/80	.376
A1C (%) ± SD[a]	8.87 ± 1.8 (n=19)	9.17 ± 1.72	.602
SBP (mmHg) ± SD	136.05 ± 14.97	134.35 ± 18.56	.752
DBP (mmHg) ± SD	78.8 ± 12.73	76.75 ± 12.98	.617
TC (mg/dL) ± SD[a]	159.36 ± 38.38 (n=14)	161.68 ± 40.44 (n=19)	.869
LDL (mg/dL) ± SD[a]	90 ± 39.53 (n=14)	82.68 ± 37.29 (n=19)	.591
HDL (mg/dL, median (IQR))[a]	36.5 (29.5-43.5) (n=14)	38 (35-50) (n=19)	.402
TG (mg/dL, median (IQR))[a]	148.5 (110.5-200) (n=14)	153 (100-276) (n=19)	.702
Knowledge score (number correct of 49, median (IQR)) (%)	34(26.75-39)(69.4)	N/A	N/A

[a] = data not available for all participants; SD=Standard Deviation; IQR=Interquartile Range; A1C=Hemoglobin A1C; SBP=Systolic Blood Pressure; DBP=Diastolic Blood Pressure; TC=Total Cholesterol; LDL=Low-density Lipoprotein; HDL=High-density lipoprotein; TG=Triglycerides

A total of 20 patients attended an initial diabetes education visit and completed the baseline knowledge assessment test (Table 2). There was a significant reduction in average A1C percentage from 9.06% ± 1.64% at the initial diabetes clinic visit to 8.0% ± 1.83% at a 2.7 to 17-month follow-up result (n=18, $t = 3.309$, $P < 0.05$). Overall, 88% (n=16) of patients had a lower A1C at the follow-up time-point from baseline, and 38% (n=7) had an A1C less than 8%. There was a significant reduction in average SBP from 137.56 mmHg ± 14 mmHg at the initial diabetes clinic visit to 128.6 mmHg ± 18 mmHg at a 2.3 to 13.9-month follow-up result (n=18, $t = 2.158$, $P < 0.05$). At followup, 66% (n=12) of patients had the same or lower SBP, and 66% (n=12) had a SBP less than 140 mmHg. There were no differences in patients' DBP or lipid values between baseline and follow-up visits ($P > 0.05$).

Table 2. Study Results

Intervention Group Results	Baseline[a]	Follow-up[a]	p-value
A1C (%) ± SD (n=18)	9.06 ± 1.64	8.01 ± 1.83	.004
SBP (mmHg) ± SD (n=18)	137.56 ± 14.07	127.61 ± 18	.046
DBP (mmHg) ± SD (n=18)	78.78 ± 12.92	75.06 ± 20.72	.357
TC (mg/dL) ± SD (n=12)	155 ± 39.65	143.3 ± 44.06	.276
LDL (mg/dL) ± SD (n=12)	86.17 ± 41.59	69.25± 30.59	.086
HDL (mg/dL) ± SD (n=12)	36.67 ± 12.15	33.33 ± 11.66	.087

TG (mg/dL, median (IQR))(n=12)	148.5 (110.5-200)	148 (96-205.5)	.239
Control Group Results	Baseline (n=20)	Follow-up (n=20)	p-value
A1C (%, median (IQR))	9.05 (7.7-10.05)	8.05 (7.6-9.23)	.036
SBP (mmHg) ± SD	134.35 ± 18.56	136.9 ± 22.73	.629
DBP (mmHg) ± SD	76.75 ± 12.98	72.9 ± 14.07	.295
TC (mg/dL) ± SD(n=16)[a]	160.88 ± 43.69	163.94 ± 50.18	.668
LDL (mg/dL) ± SD (n=16)[a]	79.63 ± 39.54	80.75± 43.8	.879
HDL (mg/dL, median (IQR))(n=16)[a]	38 (35-50)	40.5 (33.5-52.25)	.296
TG (mg/dL, median (IQR))(n=16)[a]	153 (100-276)	146 (86.75-310.25)	.877
Comparison of Follow-Up Results	Intervention[a]	Control (n=20)	p-value
A1C (%) ± SD	8.2 (6.4-9.2) (n=18)	8.1 (7.6-9.2)	.872
SBP (mmHg) ± SD	127.61 ± 18 (n=18)	136.9 ± 22.73	.174
DBP (mmHg) ± SD	75.06 ± 20.72 (n=18)	72.9 ± 14.07	.707
TC (mg/dL) ± SD[a]	146 ± 43.27(n=13)	163.94 ± 50.18 (n=16)	.318
LDL (mg/dL) ± SD[a]	71.62 ± 30.5(n=13)	80.75± 43.8 (n=16)	.530
HDL (mg/dL, median (IQR))[a]	34(25-43) (n=13)	40.5 (33.5-52.25) (n=16)	.059
TG (mg/dL, median (IQR))[a]	148 (96-205.5) (n=13)	146 (86.75-310.25) (n=16)	.809

[a] = data not available for all participants; SD=Standard Deviation; IQR=Interquartile Range; A1C=Hemoglobin A1C; SBP=Systolic Blood Pressure; DBP=Diastolic Blood Pressure; TC=Total Cholesterol; LDL=Low-density Lipoprotein; HDL=High-density lipoprotein; TG=Triglycerides

The median diabetes knowledge score for the intervention group was 34 (26.75-39). The most frequently missed question was within the "Being Active" section. This question asked, "How much physical activity is recommended for those with diabetes?" Only three participants answered this question correctly. The least frequently missed question was in the "Healthy Eating" section and asked participants to "Choose which frozen meal is a better option based on total calories, total carbohydrates, protein, and fat" when comparing two nutrition labels. Eighteen participants answered this question correctly.

Original Article

A total of 20 patients attended an initial diabetes education visit and are included in the control group of participants who did not take the knowledge assessment test (Table 2). There was a significant decrease in median A1C percentage from 9.05% (7.7-10.05%) at the initial diabetes clinic visit to 8.05% (7.6-9.23%) at a 2.9- to 14.4month follow-up result (n=20, Z= -2.096, P< 0.05). Overall, 65% (n=13) of patients had a lower A1C at the followup time point from baseline, and 40% (n=8) had an A1C less than 8%. There were no differences in patient's blood pressure or lipid values between baseline and follow-up visits for the patients who received diabetes education without taking the knowledge assessment test at baseline (P> 0.05).

A comparison of the means of the follow-up results between the intervention and control groups showed no significant differences (Table 2). While the follow-up SBP and lipid values (TC, LDL, HDL, TG) were higher in the control group, there were no statistically significant differences among these results when comparing the intervention and control groups (P> 0.05). The follow-up A1C and DBP were higher in the intervention group, but not significantly so when comparing the intervention and control groups (P> 0.05).

4 Discussion

The importance of DSMES and the benefits of education on glycemic control have been well described in the literature.[4-8] Studies have shown that diabetes knowledge correlates with glycemic control so the use of a knowledge assessment tool may be useful to educators when developing individualized education plans for patients.[9-13] Use of a psychometrically validated multiple-choice questionnaire to guide diabetes education sessions has resulted in improvements in clinical biomarkers, receiving preventative services related to diabetes, patient satisfaction, and healthcare costs, however, this tool is not available for use by providers.[15-18] The purpose of this study was to demonstrate that use of a curriculum-specific knowledge assessment may have clinical importance in this population.

This study of the impact of incorporating a baseline knowledge assessment questionnaire in individual diabetes education sessions on health outcomes has multiple strengths. The pilot study met sample size based on power calculations and had a control group that was well matched to the intervention group in terms of baseline characteristics. Broad inclusion criteria with no exclusions produced a study population which was representative of the target population in the area, potentially allowing results to be more generalizable. Use of a control group in this study helped to determine the significance of the use of the knowledge assessment in this diabetes education program. The structure of the program having one main educator ensured that education sessions were likely similar from patient-to-patient, therefore, improving the reliability of the results. A unique factor to this study was the use of the knowledge assessment developed specifically around the concepts of AADE7 Self-Care Behaviors which aligned well with the curriculum already in use by this program.

There are various limitations in this pilot study to consider. First, this study did not assess some variables that were collected in similar studies which could have affected or impacted the results seen in this study. This study did not assess factors such as patient satisfaction, health care savings, medication-taking strategies, or engagement with preventative recommendations (vaccines, exams) for persons with diabetes so it is unknown at this time if the use of the knowledge assessment made any impact on these factors. Also not considered in this study was previous participation in a diabetes education program. Patients may have attended diabetes education prior to this study, either within the program or at another program in the area, which this study did not account for and could have had an impact on the results.

Future studies on this topic could track these elements in order to better assess the effect on outcomes in diabetes education sessions guided by the use of the knowledge assessment. There were several missing data points for the patients included in this study as well. Use of the electronic medical record within our institution helped streamline the gathering of demographic and clinical information, however, some patients used laboratories outside of our institution which posed a challenge to either contact the patient for that information or to request

and receive the clinical biomarker results from the outside facility. It was also found that patients did not always complete the tests ordered by their provider which also contributed to missing data in this study.
Including a required follow-up education session may have helped improve the tracking of this data. Finally, the knowledge assessment used in this study was long and not psychometrically validated prior to use. It took patients about 30 minutes on average to complete the assessment in its entirety. The number of multiple-choice questions could have deterred some patients from completing the assessment or they might have become fatigued by the end, marking questions as "I don't know" possibly skewing the results.

5 Conclusion

In the intervention group, there was a significant reduction in A1C and SBP from baseline. There was also a significant reduction in A1C from baseline in the control group. When comparing follow-up results among the two groups to determine if the knowledge assessment made a difference in outcomes, there were no significant differences among follow-up levels of clinical biomarkers found.
Diabetes education had an impact on lowering A1C levels from baseline, but the use of the knowledge assessment at baseline did not make a larger impact on clinical biomarkers than diabetes education alone in patients who attended at least one session of individual diabetes education. This may be because the knowledge assessment used in this study was very well aligned with the concepts already being taught in this specific program. Similar programs looking to find ways to help guide diabetes education sessions can apply the results of this study to make the content covered in a session specific to each patient's needs. To determine the clinical impact of the use of a knowledge assessment to guide diabetes education sessions, further studies should be done with a larger sample of patients, a shorter version of the knowledge assessment, and additional follow-up sessions of diabetes education.

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Original Article

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