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Evaluation of Pharmacist- or Nurse-driven Long-acting Insulin Titration Protocol in Adult Primary Care Patients with Type 2 Diabetes

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PATIENT SAFETY AND QUALITY IMPROVEMENT EXEMPLARS

Evaluation of nurse-or pharmacist-driven protocol for long-acting insulin titration in adult patients with type 2 diabetes

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Introduction: Studies have supported using a protocol to optimize insulin therapy with insulin titration. We implemented a protocol for long-acting insulin titration (LAIT), managed by registered nurse care managers (RNCMs) and clinical pharmacists (CPs), in a primary care setting. We aimed to determine if implementing a LAIT protocol managed by RNCMs and CPs would effectively improve the control of type 2 diabetes (T2D).

Methods: This retrospective analysis included patients who were receiving care at a primary care clinic within our health care system. Participants were 18 years of age and older with T2D and a hemoglobin A1C (A1C) > 8%. Demographic and A1C data were collected before and after enrollment in the protocol. The primary outcome was a change in A1C level between measurements taken before and after completing the protocol. The secondary outcome was achievement of the A1C goal.

Results: Participants experienced a significant decrease in A1C (9.97 ± 1.85% pre-protocol to 8.60 ± 1.67% post-protocol, P < .001). The median absolute change in A1C was -1.0 [interquartile range, -2.48 to -0.10]. Overall, 77 (37.7%) patients acheived an A1C < 8% and 31 (15.2%) achieved an A1C of < 7%. Barriers to adhering to the full protocol included needle phobia and lack of patient engagement.

Discussion: The LAIT protocol successfully improved glycemic control among patients with T2D. Future enhancements could focus on analyzing referral use and patient engagement.

Conclusions: The LAIT protocol allows RNCMs and CPs to significantly contribute to achieving glycemic goals in patients with uncontrolled diabetes.

Keywords: insulin titration, primary care, insulin therapy, type 2 diabetes

In the United States, over 30 million people (9.4% of the population) are living with diabetes.[1] While managing diabetes and associated hyperglycemia can help to prevent microvascular and macrovascular complications, many patients with diabetes do not optimally control their diabetes due to the complexity of their disease and clinical inertia.[2,3] The Standards of Medical Care in Diabetes recommend using a collaborative approach to managing diabetes in the primary care setting, which includes pharmacologic therapy.[3] When patients are not achieving their hemoglobin A1C (A1C) target, despite oral antihyperglycemic therapy, basal insulin is a potential next step. In the outpatient setting, demands for a provider's time and attention may lead to inconsistent methods for initiating and managing insulin therapy.

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The American Diabetes Association recommends that a long-acting insulin regimen be adjusted once or twice weekly until fasting blood glucose (FBG) targets are achieved.[3,5] Although studies have supported using a protocol to optimize insulin therapy with insulin titration,[4,6] there are limited studies that address efficient titration of basal insulin by healthcare providers other than the primary care provider (PCP). The purpose of this quality improvement (QI) project was to evaluate

the implementation and performance of a protocol for long-acting insulin titration (LAIT) in the primary care setting. The insulin titration was managed by registered nurse care managers (RNCM) or clinical pharmacists (CPs).

METHODS

Our retrospective analysis of this QI project included patients participating in the LAIT protocol between July 1, 2016 and January 23, 2019. The patients were managed at 10 primary care practices in Southern Maine. These practices were staffed by 10 RNCMs and 3 CPs during the project. Patients eligible for enrollment were 18 years of age or older with type 2 diabetes (T2D) and an A1C of > 8%. Patients enrolled agreed to self-monitor their blood glucose daily, maintain contact with RNCMs or CPs every 3-7 days for titration, and adhere to insulin therapy (self-reported by the patient). At the start of the protocol, patients new to insulin therapy were started on 10 units of long-acting insulin nightly, while patients already being treated with long-acting insulin were maintained on their current dose. Insulin doses were increased by 2 units every 3–7 days until a FBG goal of 80-150 mg/dL was reached. Patients were allowed to continue their current oral antihyperglycemic agent(s) and non-insulin injectables as prescribed by their PCP. Providers were contacted in the case of hypoglycemic episodes (Figure 1).

Demographic data, such as age, practice location, and referral date, were obtained and used to collect accurate pre- and post-protocol A1C values from the electronic medical record. These data were summarized with descriptive statistics. The primary outcome measure for protocol performance was the change in A1C level between measurments taken before and after completing the protocol. The secondary outcome was the percentage of patients who achieved their A1C goal, defined as an A1C < 8% and < 7%. Pre- and post-protocol A1Cs were calculated as mean ± standard deviation or median (interquartile range, IQR), as appropriate, for continuous data and as frequency (n, %) for categorical data. Post-protocol A1C was analyzed if the collection occurred at least 3 months after the initial A1C. If patients had multiple A1C measurments during the protocol, the A1C furthest from the start of protocol was analyzed. Paired differences in pre- and post-protocol A1C was evaluated by the Wilcoxon signed rank test. All statistical analyses were performed using SPSS Statistical software, version 25 (IBM SPSS Inc, Armonk, NY). This study followed Squire guidelines and was deemed a QI project by the Maine Medical Center Institutional Review Board.

RESULTS

Among 463 patients with T2D who enrolled in the protocol, 205 patients aged 26-88 years (mean 60.0 ± 11.8 years) from 10 practices were eligible for inclusion in the analysis. Patients not meeting inclusion criteria were excluded. Figure 2 documents the process for identifying the final study group. Patients enrolled in the LAIT protocol showed a significant decrease in A1C (9.97 ± 1.85% pre-protocol to 8.60 ± 1.67% post-protocol; $P < .001$). The median absolute decrease in A1C was 1.0% [IQR, -2.48 to -0.10%]. Overall, an A1C of < 8% was achieved in 77 (37.7%) patients. Of these, 31 (15.2%) patients achieved further control with an A1C < 7%.

DISCUSSION

Interprofessional teams provide patient-centered care for diabetes. The LAIT protocol allows RNCMs and CPs to substantially contribute to achieving glycemic goals in patients with uncontrolled T2D. This QI project resulted in a significant 1% reduction in A1C among patients enrolled the LAIT protocol. Antihyperglycemic agents currently recommended by practice guidelines provide a comparable reduction. For example, sodium-glucose cotransporter 2 inhibitors (SGLT-2i) reduce A1C by an average of 0.5-1.0%, and dipeptidyl peptidase 4 inhibitors (DPP-4i) reduce A1C by as little as < 0.7%.[7] Thus, the LAIT protocol, carried out by a RNCM or CP, may more effectively reduce A1C than starting an additional oral antihyperglycemic agent. Previous work compared pharmacist- versus physician-managed insulin titration. For example, in a retrospective, matched, case-control study, Pitlick and colleagues compared pharmacist-managed insulin titration versus standard care in a primary care clinic serving ethnically diverse, underserved patients. Standard of care was described as patients who were managed by the PCP group and excluded if they had any interaction with a CP or endocrinologist. At 6 months, the investigators found a significant difference in the mean A1C between groups, favoring pharmacist management (1.0%, 95% CI, 0.2 to 1.6, $P = .009$).[6] Our study and previous work support the use of insulin titration by other members of the health care team, such as a

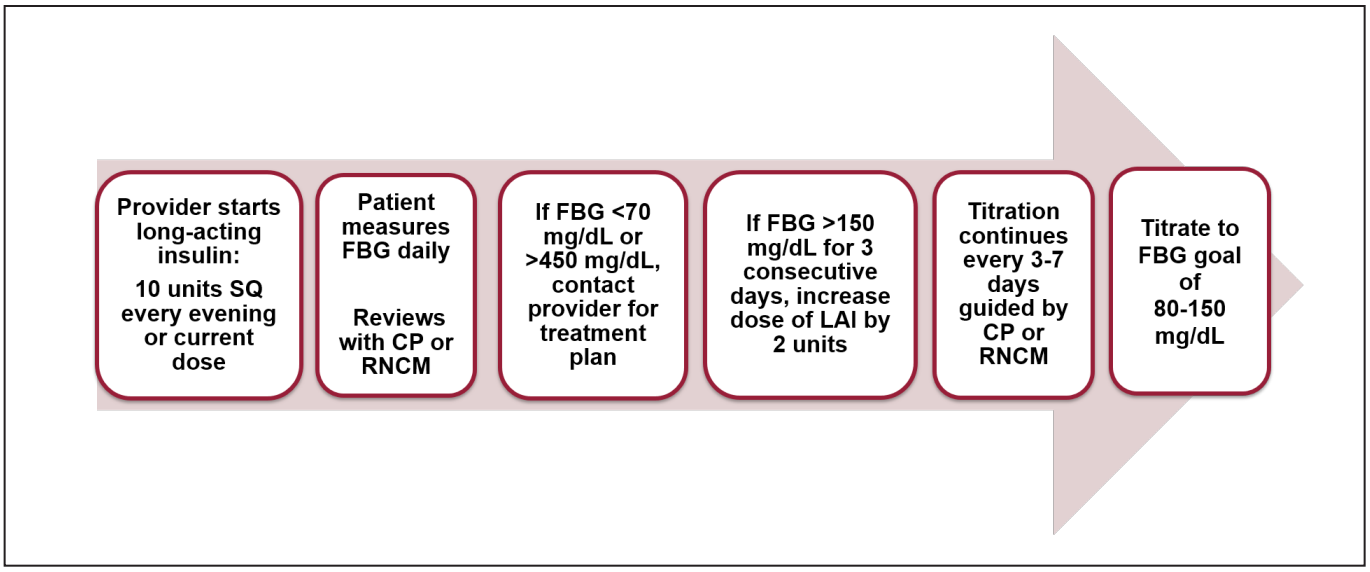

Figure 1. Algorithm for long-acting insulin titration.
SQ: subcutaneously, FBG: fasting blood glucose, CP: clinical pharmacist, RNCM: registered nurse care manager

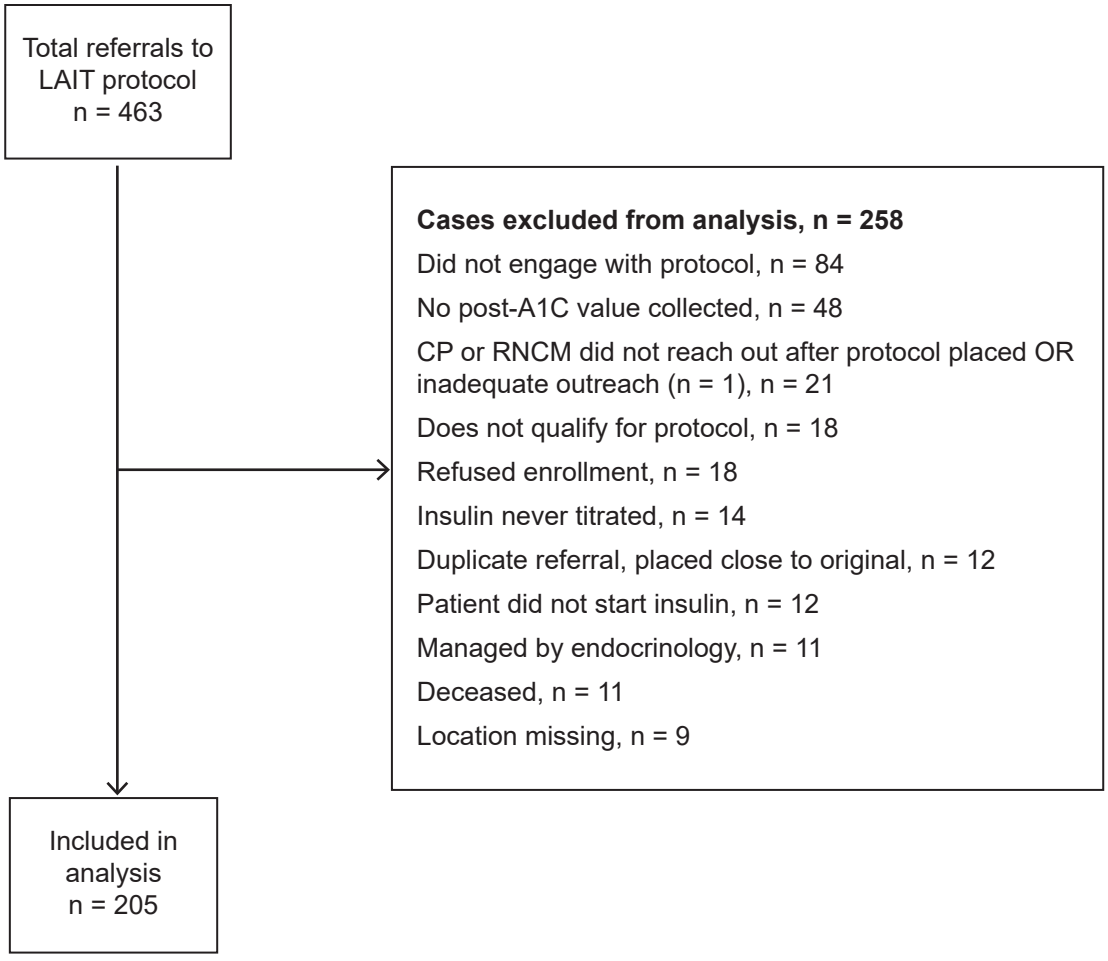

Figure 2. Selection process for study group

RNCM or CP. One advantage to using RNCMs and CPs for insulin titration is that patients can access them more easily than physicians. Most RNCMs and CPs have dedicated time for phone calls to follow up with patients more often, and they can better serve patients with higher needs, especially those with a high burden of disease. Their time is also less costly than a physician, further justifying the expansion of their role.

One limitation of this project is the inability to understand the use of other antihyperglycemic agents within the study population and the reported incidence of hypoglycemia. Additional limitations include failure to easily retrieve information regarding the number or frequency of calls made by the RNCM or CP, and the number of adjustments to the insulin dose. Barriers to effectively using the protocol involved lack of patient engagement, including needle phobia and failure to return phone calls or regularly monitor FBG. Future work should include increasing the size of the intervention population; investigating adverse outcomes, such as the frequency of hypoglycemia and emergency department use; and comparing patients on the LAIT protocol with standard care or new technologies, such as patient-driven phone applications.

CONCLUSION

The implementation of a LAIT protocol in the primary care setting significantly decreased A1C and may further improve the management of T2D. Our findings suggest that at our institution, care team members beyond the PCP effectively managed a LAIT protocol and helped patients with T2D better manage their disease and achieve their therapeutic goals.

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Conflicts of Interest: None

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