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The Impact of Continuous Glucose Monitoring in the Management of Type II Diabetes

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Abstract

According to the American Diabetes Association (ADA), approximately 36 million Americans have a diagnosis of type II diabetes (T2D). Among these patients with T2D, nearly forty percent have glycated hemoglobin A1c (Hgb A1c) values above the target goal of 7%. Many patients with T2D utilize self-monitoring blood glucose (SMBG) systems to monitor day-to-day fluctuations in blood glucose values. However, SMBG systems can be cumbersome and may result in lower patient compliance. With many patients struggling to achieve their target Hgb A1c, methods to improve glycemic control are needed to prevent long-term diabetes-related complications. This literature review aims to investigate the benefits of initiating continuous glucose monitoring (CGM) in patients with T2D receiving various treatment regimens. A literature review was performed using electronic search databases PubMed, CINAHL, and Embase from May 5 to September 15, 2021. Keywords were diabetes mellitus, type 2, type 2 diabetes, cgm, continuous blood glucose monitoring, Freestyle Libre, and Dexcom. The search yielded around 387 articles. Exclusion criteria consisted of specific articles which focused on specific patient populations including type I diabetes (T1D) rather than T2D, along with pregnant, hemodialyzed, inpatient, and elderly patients with T2D. A total of 13 research articles were reviewed. Current literature suggests that initiating CGM in patients with T2D results in significant reductions in Hgb A1c, regardless of treatment regimen. Given the prevalence of T2D, applying this research with clinical application could help patients achieve their target Hgb A1c and subsequently reduce the risk of long-term diabetes-related complications.

Key Words: Type II Diabetes, Continuous Glucose Monitoring, CGM

Introduction

T2D is estimated to affect approximately 32 million people in the United States, compared to T1D which affects approximately 1.6 million people. Uncontrolled T2D, assessed by elevated Hgb A1c, is the greatest risk factor for diabetes-related complications. Medical providers commonly rely on SMBG systems for patients with T2D to manage glycemic control outside the office. The purpose of this literature review is to reveal the effectiveness of personal real-time continuous glucose monitoring (RT-CGM) systems and flash continuous glucose monitoring (F-CGM) systems in the outpatient management of T2D.

Statement of the Problem

Over time, SMBG systems became the standard of care in patients with both T1D and T2D to monitor glycemic control. One caveat to SMBG systems is that it only provides a one-time blood glucose measurement. This method can be cumbersome and may result in lower patient compliance, as it requires the patient to perform a capillary finger-stick each time a blood glucose measurement is obtained. Over the last two decades, the accuracy of CGM has improved significantly and its use in the management of T1D has become the standard of care, as these patients require frequent blood glucose monitoring to adhere to their insulin treatment regimen. However, the data on the effectiveness of CGM initiation in patients with T2D continues to evolve. Among patients with T2D, treatment regimens can differ significantly from patient to patient. Treatment regimens for patients with T2D vary from lifestyle modifications alone, to oral hypoglycemic agents alone, to insulin alone or in combination with oral hypoglycemic agents. The use of CGM in patients with T2D receiving multiple daily insulin injections has become more common over the last decade. However, utilizing CGM for more frequent blood glucose measurements in patients with T2D not on intensive insulin therapy may seem trivial.

With the wide range of disease severity and treatment regimens amongst this patient population, it can be difficult to decipher what option is best for patients to monitor glycemic control. Medical providers managing T2D in the outpatient setting need to be aware of the most efficacious modality for patients to monitor glycemic control in this patient population.

Research Question

In adult patients with T2D, is there a significant difference in Hgb A1c when using either RT-CGM or F-CGM as opposed to standard SMBG by capillary finger-stick monitoring?

Methods

A literature review was performed using electronic search databases; PubMed, CINAHL, and Embase. Both keyword and mesh terms were used to define a set of the literature discussing the use of CGM in the outpatient management of T2D. Keywords were diabetes mellitus, type 2, type 2 diabetes, cgm, continuous blood glucose monitoring, Freestyle Libre, and Dexcom. The search revealed a total of 387 studies. There were several studies excluded as they solely looked at T1D instead of T2D. Multiple other studies were excluded as they dealt with specific patient populations including pregnant, hemodialyzed, inpatient, and elderly patients with T2D. 13 studies met the final criteria.

Literature Review

A review of the data has shown that CGM initiation may be an effective way for patients with T2D to improve glycemic control, regardless of treatment regimen. Significant reductions in Hgb A1c have been observed in patients with T2D on treatment regimens varying from lifestyle modifications alone, to oral medications alone, to insulin alone or in combination with oral hypoglycemic agents. CGM initiation has also been associated with significant reductions in diabetes-related distress, diabetes-related acute hospitalizations, all-cause hospitalizations, episodes of severe hypoglycemia, body weight, and BMI. Increased exercise time and treatment satisfaction was also found with CGM initiation. As a primary care provider, it is essential to understand how CGM initiation can improve outcomes in patients with T2D.

CGM as a Modality to Manage Diabetes

In the last decade, CGM technology has revolutionized diabetes management. A CGM system consists of a disposable sensor, a transmitter, and a receiver. The sensor, which needs to be replaced weekly or biweekly depending on the manufacturer guidelines, measures glucose concentrations in the interstitial fluid. A reusable transmitter is attached to the sensor and wirelessly transmits glucose values to a receiver. The receiver, either a factory provided handheld device, or an app downloaded on a smartphone, displays the blood glucose values for the patient to view. It is important to understand the differences between RT-CGM and F-CGM. With RT-CGM, blood glucose values are available continuously on the receiver and patients are not required to scan the sensor with the receiver. On the other hand, with F-CGM, the patient must scan the sensor with the receiver to view their blood glucose value and can do so as often as they wish. Both types of CGM systems allow patients to have better control of their disease and numerous studies have assessed its impact on Hgb A1c. This technology has become widely accepted as an effective way for patients with T1D to manage glycemic control, however studies showing the efficacy of CGM in patients with T2D continue to develop (Beck et al., 2017).

For patients with T2D, personal blood glucose meters are an essential tool for managing their disease. Everyday life variables including diet, exercise, stress, and illness can cause drastic fluctuations in blood glucose values in this patient population. Hgb A1c is the gold standard method in evaluating glycemic control in patients with T2D, and it has been reported that nearly forty percent of all patients with T2D have values above the accepted goal of 7% (Vigersky et al., 2012). Even with an optimized diabetes treatment regimen, many patients must monitor their blood glucose at an appropriate frequency to achieve their target Hgb A1c.

A potential obstacle in initiating CGM in patients with T2D is the uncertainty of the device's dependability. Some patients who have grown custom to SMBG may be reluctant to try a new technology such as a CGM system. The accuracy of CGM continues to expand and randomized clinical trials have shown the device to be a dependable way to achieve glycemic control. Boscari et al. (2017) performed a prospective, single center, randomized, crossover study that evaluated the accuracy of the FreeStyle Libre (Libre) and the Dexcom G4 Platinum (DGP4), two of the most popular CGM systems available on the market today. The Libre is classified as a F-CGM and the DGP4 is classified as a RT-CGM. The purpose of the study was to assess the mean absolute difference (% MARD) during glycemic excursions induced at a clinical research center and during home use without induced glycemic excursions. The lower the %MARD is, the closer the CGM reading is to the actual blood glucose measurement. Results during at-home use showed similar performance between Libre and DG4P (%MARD 13.7 ± 3.6 vs. 12.9 ± 2.5, $p = 0.392$). Results during CRC admissions for induced glycemic excursions showed there was also similar performance between Libre and DG4P (%MARD 14.9 ± 5.5 vs. 18.1 ± 8.1, $p = 0.062$). However, the results of this study may provide promising information to patients who are hesitant to try a CGM system. (Boscari et al., 2017).

RT-CGM in Patients with T2D on Multiple Daily Insulin Injections

Beck et al. (2017) performed a 24-week, randomized, multicenter clinical trial comparing RT-CGM versus SMBG in adult patients with T2D receiving multiple daily insulin injections. The purpose of this study was to evaluate whether RT-CGM improves clinical outcomes in patients with T2D. Of the 158 adult patients selected for the trial, 79 were randomly selected to the RT-CGM group and 79 were randomly selected to the SMBG control group. The primary clinical outcome for the study, change in Hgb A1c, was measured at baseline, 12 weeks, and 24 weeks. At baseline, mean Hgb A1c was 8.5% (SD, 0.6%) in the RT-CGM group and 8.5% (SD, 0.7%) in the SMBG group. After the first 12 weeks of the study, mean Hgb A1c in the RT-CGM group and the SMBG group was reduced to 7.5% (SD, 0.7%) and 7.9% (SD, 0.8%), respectively. From 12 to 24 weeks, Hgb A1c increased slightly in both the RT-CGM and the SMBG groups, 7.7% (SD, 0.7%) and 8.0% (SD, 0.9%), respectively. The adjusted difference in mean change in Hgb A1c from baseline to week 24 was -0.3% (CI, -0.5% to 0.0%) (p = 0.022). In participants with the highest baseline Hgb A1c (≥ 9%), the RT-CGM group experienced a much greater reduction in Hgb A1c versus the SMBG group, 1.4% vs 0.7%, respectively. Observing participants with the highest baseline Hgb A1c achieve greatly improved glycemic control is important when evaluating the effectiveness of RT-CGM. These individuals are at greatest risk for diabetes-related complications and discovering techniques to better control their disease is essential (Beck at al., 2017).

Gilbert et al. (2021) performed a real-world prospective study that analyzed the impact of RT-CGM initiation on Hgb A1c and quality of life (QoL) in patients with both T1D and T2D receiving multiple daily insulin injections. The thought is that QoL improvments in patient with diabetes will result in a reduction in Hgb Alc and diabetes-related complications. Of the 248 patients who completed the study, 66 were patients with T2D. Patients provided their Hgb Alc measurement and answered the QoL questionaire at baseline and after 12 weeks of RT-CGM initiation. Among patients, Hgb A1c mean ± standard deviation decreased from 8.5% ± 2.2% to 7.1% ± 1.1% (p < 0.001) after 12 weeks of RT-CGM initiation. Markers of emotional distress, regimen distress, interpersonal distress, hypoglycemic anxiety, and hypoglycemic avoidance dropped significantly ($p < 0.001$) after RT-CGM initiation. The results of this study showed that RT-CGM initiation in patients with T2D on multiple daily insulin injections experience benefits beyond reductions in Hgb A1c alone. The improved confidence and reduction in diabetes distress observed after RT-CGM initiation seems to allow patients to take control of their disease and assist in improving their health (Gilbert et al., 2021).

Jackson et al. (2021) evaluated studies that reported the role RT-CGM plays in improving glycemic control, assessed by Hgb A1c, in patients with T2D receiving multiple daily insulin injections. The authors assessed an observational study that found a 0.4% reduction in Hgb A1c among patients with T2D receiving multiple daily insulin injections. Jackson et al. (2021) also evaluated a meta-analysis of 5 RCTs that compared Hgb A1c outcomes in a RT-CGM intervention group versus a SMBG control group. The meta-analysis found a significant improvement in Hgb A1c (pooled mean difference of 0.25%) with the use of RT-CGM versus SMBG. The literature reviewed by the authors overwhelmingly supported the use of RT-CGM in patients with T2D receiving multiple daily insulin injections (Jackson et al., 2021).

RT-CGM in Patients with T2D not on Multiple Daily Insulin Injections

Ehrhardt et al. (2011) performed a prospective, two-arm, randomized 12 week trial comparing RT-CGM versus SMBG in patients with T2D not receiving multiple daily insulin injections. The primary outcome of the study was to evalutate the impact RT-CGM has on Hgb A1c. Ehrhardt et al. (2011) recruited 100 patients from the Walter Reed Health Care System, where 50 patients were selected for the RT-CGM group, and 50 patients were selected for the SMBG group. Patients in both groups were further divided into subgroups according to their diabetes treatment regimen, including diet and exercise alone, oral hypoglycemic agents alone, and long-acting insulin alone or in combination with oral hypoglycemic agents. Results of the study showed mean (± SD) Hgb A1c decrease by 1.0% (±1.1%) for the RT-CGM group and 0.5% (±0.8%) for the SMBG group ($p = 0.006$). The median change-from-baseline in the RT-CGM and SMGB groups were -0.75% and -0.4%, respectively ($z = 2.51$ and $p = 0.01$). Mean Hgb A1c reductions were constant across all treatment regimen subgroups, which ensures the effectiveness of RT-CGM was assessed on a broader patient population. This study suggested the use of RT-CGM in patients with T2D not on multiple daily insulin injections is superior to standard SMBG alone, regardless of treatment regimen (Ehrdardt et al., 2011).

Vigersky et al. (2012) conducted a post-trial follow-up on the randomized control trial performed by Ehrdardt et al. (2011). The purpose of this post-trial follow-up was to determine the long-term glycemic effect of RT-CGM versus SMBG after an active intervention phase. Change in glycemic control amongst the RT-CGM group versus the SMBG group was determined by measuring Hgb A1c quarterly after the initial 12-week intervention phase. The results of the trial showed an adjusted decline in Hgb A1c for the RT-CGM versus SMBG group of 0.9 vs. 0.4% from baseline to 12 weeks, 1.0 vs. 0.5% from baseline to 24 weeks, 1.1 vs. 0.5% from baseline to 38 weeks, and 1.1 vs. 0.5% from baseline to 52 weeks. The data discovered in this 40-week follow-up trial showed RT-CGM has a lasting effect on improved glycemic control (Vigersky et al., 2012).

Martens et al. (2021) performed a multicenter, randomized, open-label parallel-group trial which compared the effect of RT-CGM versus SMBG in 175 patients with T2D on long-acting insulin only. The primary outcome evaluated was the difference in the change in Hgb A1c 8 months after CGM initiation. The RT-CGM group experienced a significant reduction in Hgb A1c after 8 months (9.1% to 8.0%) compared to the SMBG group (9.0% to 8.4%), ($p = 0.02$). A key secondary outcome was monitoring the time spent with blood glucose values greater than 250 mg/dL in the CGM group compared to the SMBG group. The mean percentage of time greater than 250 mg/dL was 11% in the RT-CGM group versus 27% in the SMBG group. ($p <$ 0.01) (Martens et al., 2021).

Yoo et al. (2008) performed a prospective, open-label, randomized control trial which compared the effect of RT-CGM versus SMBG in patients with poorly controlled T2D. Out of the 65 patients recruited for the study, 56 patients were either on an oral hypoglycemic agent alone or in combination with a long-acting insulin. The primary outcome evaluated was the difference in the change in Hgb A1c after 3 months. The RT-CGM group had a significant reduction in Hgb A1c after 12 weeks (9.1 ± 1.0% to 8.0 ± 1.2%, $p < 0.001$). There was also a significant reduction of Hgb A1c in the SMBG group (8.7 ± 0.7% to 8.3 ± 1.1%, $p = 0.01$), though not as significant as the reduction seen in the RT-CGM group. Other outcomes evaluated by Yoo et al. (2008) included change in body weight, body mass index (BMI), and exercise time per week. After 12 weeks, the patients in the RT-CGM group experienced a significant reduction in both body weight ($p = 0.014$) and BMI ($p = 0.008$). Total exercise time per week was significantly increased in the RT-CGM group compared with the SMBG group ($p = 0.02$). This study showed the role RT-CGM plays in promoting lifestyle improvements. RT-CGM seems to act as a behavior medication tool, which eventually results in reductions in Hgb A1c values (Yoo et al., 2008).

F-CGM in Patients with T2D on Multiple Daily Insulin Injections

Bergenstal et al. (2021) performed a retrospective database study to assess the effects of F-CGM initiation on occurrence rates of acute diabetes-related events (ADE) and all-cause inpatient hospitalizations (ACH) in 2463 patients with T2D treated with multiple daily insulin injections. ADE were defined as inpatient events or emergency outpatient events due to hypoglycemia, hypoglycemia coma, clinical hyperglycemia, diabetic ketoacidosis, and hyperosmolarity. Results of the study showed a reduction in ADE from 0.180 to 0.072 events/patient-year (hazard ratio [HR] 0.39 [0.30, 0.51]; $p < 0.001$). ACH occurrences were reduced from 0.420 to 0.283 events/patient-year (HR 0.68 [0.59, 0.78]; $p < 0.001$). Among the cohort, the study also observed a significant decrease in hospitalizations from infections (41.7%), renal disease (48.5%), and liver disease (41.7%). Though data observed during this study did not evaluate the effect F-CGM has on Hgb A1c, a reduction in ADE is an indirect measurement of improved glycemic control in patients with insulin treated T2D (Bergenstal et al., 2021).

Haak et al. (2017) performed an open-label, randomized control trial on 224 adult patients with T2D receiving multiple daily insulin injections from 26 European diabetes centers. The primary outcome of the study was to compare the difference in Hgb A1c after 6 months in patients utilizing F-CGM versus standard SMBG. Secondary outcomes of the study included prevelance of hypoglycemia, effect of age, and patient satisfaction with F-CGM initiation. There was no difference in Hgb A1c reduction at 6 months between the F-CGM group and SMBG group (-0.29 ± 0.07% and -0.31 ± 0.09%; $p = 0.8222$). In fact, in the ≥ 65 years subgroup, the drop in Hgb A1c was more pronounced for the SMBG group compared to the F-CGM group (-0.49 ± 0.13% versus -0.05 ± 0.10%; $p = 0.0081$). Interestingly, in the ≤ 65 years subgroup, a significant reduction in Hgb A1c was observed in the F-CGM group compared to the SMBG group (-0.53 ± 0.09% versus -0.20 ± 0.12%; $p = 0.0301$). The time in hypoglycemia < 70 mg/dL, < 55 mg/dL, and < 45 mg/dL were reduced by 43% ($p = 0.0006$), 53% ($p = 0.0014$), and 64% ($p = 0.0013$), respectively for the F-CGM group compared to the SMBG group. The treatment satisfaction scores, assessed by the Diabetes Treatment Satisfaction Questionnaire (DTSQ), was significantly improved for the F-CGM group compared with the SMBG group ($p < 0.0001$). Even though time in hypoglycemia and treatment satisfaction was improved with F-CGM, this is the first study that did not find the system beneficial in reducing Hgb A1c in patients with T2D (Haak et al., 2017).

Krakauer et al. (2017) reviewed literature regarding the use of F-CGM in patients with T2D. During the review of evidence, the authors evaluated an open-label, randomized control trial which compared the effect of F-CGM versus SMBG on Hgb Alc in patients with T2D on multiple daily insulin injections. The evidence showed a signficant reduction in Hgb A1c among the F-CGM group versus the SMBG group. The mean changes from baseline to 10 weeks in Hgb A1c were -0.82% among the F-CGM group and -0.33% among the SMBG group ($p = 0.005$). Krakauer et al. (2017) also evaluated a retrospective real-world chart review that assessed the glycemic effect of F-CGM initiation on Hgb A1c in patients with T2D on multiple daily insulin injections. From baseline to 90 days after F-CGM initiation, there was a 0.9% reduction in Hgb A1c observed ($p < 0.0001$). The literature evaluated by the authors overwhelmingly supported the use of F-CGM in patients with T2D receiving multiple daily insulin injections (Krakauer et al., 2017).

Yaron et al. (2019) conducted an open-label randomized control trial on 101 patients with T2D treated with multiple daily insulin injections. The primary outcome of the study was to compare diabetes treatment satisfaction, assessed by the DTSQ questionaire, in patients utilizing F-CGM versus SMBG. DTQS scores range from +3 (much more satisfied) to 0 (midpoint representing no change) to -3 (much less satisfied). Diabetes treatment satisfaction was similar among both groups. The mean (SD) score for treatment satisfaction was 2.47 (0.77) in the F-CGM group and 2.18 (0.83) in the SMBG group ($p = 0.053$). Patients in the F-CGM group found the device to be significantly more flexible (2.28 [1.25] vs 1.61 [1.04] in the control group, p = 0.023). The secondary outcome of the study was to compare the difference in Hgb A1c in patients utilizing F-CGM versus SMBG. At baseline, the mean Hgb A1c was 8.68% in the F-CGM group and 8.34% in the SMBG group. After 10 weeks, the mean (SD) changes in Hgb A1c showed a reduction of -0.82% in the F-CGM group and -0.33% in the SMBG group (p = 0.005). The proportion of patients with a reduction in Hgb A1c of at least 1% was 39.2% in the F-CGM group and 18.6% in the SMBG group (p = 0.023). This study was effective in showing the how F-CGM can improve diabetes treatment satisfaction and subsequently improve glycemic control, which was shown by significant reductions in Hgb A1c (Yaron et al., 2019).

F-CGM in Patients with T2D not on Multiple Daily Insulin Injections

Krakauer et al. (2017) examined a retrospective real-world study among patients with T2D on long-acting insulin or non-insulin therapy 6 months and 12 months after F-CGM initiation. The results of the study demonstrated a mean Hgb A1c reduction of 0.8% (from 8.5 to 7.7%) after 6 months and by 0.6% (from 8.5 to 7.9%) after 12 months of F-CGM initiation (both $p < 0.0001$). Interestingly, the greatest reduction in Hgb A1c was seen in the non-insulin group at 6 months (-0.9%) and at 12 months (-0.7%). Whereas a reduction in Hgb A1c seen in the long-acting insulin at 6 months and 12 months was -0.6% and -0.5%, respectively. This study serves as a good example of how disease progression and treatment regimen is not indicative of how a patient with T2D will respond to F-CGM initiation (Krakauer et al., 2017).

Wright et al. (2021) completed a retrospective observational study that evaluated the change in Hgb A1c after F-CGM initiation in patients with suboptimally controlled T2D treated with either long-acting or non-insulin therapy. Of the 1034 patients with T2D evaluated in the study, 728 received non-insulin therapy and 306 received long-acting insulin therapy. A significant reduction in Hgb A1c was observed amongst the entire conhort. From baseline to 60-300 days of F-CGM use, mean Hgb A1c was reduced from 10.1% to 8.6% ($p < 0.0001$), respectively. Patients receiving long-acting insulin achieved a Hgb A1c reduction of 1.1% and patients receiving non-insulin therapy achieved a Hgb A1c reduction of 1.6% (both $p < 0.001$). This study pointed to F-CGM as an effective strategy for improving glycemic control in patients with poorly controlled T2D on a variety of treatment regimens (Wright et al., 2021).

The Association of CGM Scan Frequency on Hgb A1c

Kraukeuer et al. (2017) assessed studies that evaluated the association of F-CGM scan frequency with Hgb A1c values in patients with T2D on a wide range of treatment regimens, from multiple daily insulin injections to lifestyle measures alone. The studies which were evaluated supported the notion that increased F-CGM scans per day results in a lower Hgb Alc. The authors reviewed a real-world analysis which found greater scanning frequency from 4.4 (lowest) to 48.1 (highest) scans per day was associated with a reduction in Hgb A1c from 8.0% to 6.7% ($p < 0.001$). Similarly, Kraukeuer et al. (2017) evaluated a study that showed increased scanning frequency was associated with a significantly lower Hgb A1c, demonstrated by a Hgb A1c of 6.7% among the highest scans per day versus 7.6% among the fewest scans per day ($p < 0.01$). These results showed increased F-CGM scan frequency facilitates improved lifestyle and treatment decisions throughout the day to improve glycemic control (Krakauer et al., 2017).

Discussion

As examined in this literature review, there is evidence that initiating both RT-CGM and F-CGM in patients with T2D may lead to reductions in Hgb A1c, regardless of disease severity and treatment regimen. Hgb A1c is recognized as the greatest predictor of long-term diabetes-related complications, and it is imperative that patients with T2D have the best resources available to improve and maintain glycemic control. Though Hgb A1c still remains the benchmark for monitoring the effectiveness of diabetes management, it is also important to evaluate other endpoints. Taking into consideration diabetes-related distress, diabetes-related acute hospitalizations, all-cause hospitalizations, hyperglycemia and/or hypoglycemia awareness, body weight, BMI, and exercise time are all useful measurements in evaluating the effectiveness of diabetes management.

Like the research on CGM initiation in patients with T1D, the evidence overwhelmingly supports CGM initiation in patient with T2D receiving multiple daily insulin injections. Success with CGM initiation in both T1D and T2D receiving multiple daily insulin injections is understandable, as treatment decisions are made endlessly throughout the day based on blood glucose variations. The ability to conveniently determine blood glucose values painlessly and almost effortlessly anytime throughout the day allows this patient population to make the necessary medication and food intake adjustments to manage their disease effectively (Beck et al., 2017; Bergenstal et al., 2021; Gilbert et al., 2021; Jackson et al., 2021; Krakauer et al., 2017; Yaron et al., 2019).

The use of CGM in patients with T2D not receiving multiple daily insulin injections continues to be a debated topic. These patients are on a set treatment regimen which does not require day-to-day medication adjustments. Interestingly, the research has shown this technology has a role in the management of T2D in patients not receiving multiple daily insulin injections. At a minimum, it seems CGM initiation in this patient population aids in a better understanding of how their disease process is affected by lifestyle variables. Awareness on how food intake, exercise, stress, and illness effect blood glucose values allow this patient population to make the necessary lifestyle and behavior modifications to improve glycemic control (Ehrdardt et al., 2011; Krakauer et al., 2017; Martens et al., 2021; Vigersky et al., 2012; Wright et al., 2021; Yoo et al., 2008).

Unlike other studies that have evaluated the ability of the CGM initiation to produce significant reductions in Hgb A1c in patients with T2D, Haak et al. (2017) found no significant change after 6 months. However, one of the secondary endpoints evaluated in that study still pointed to CGM as an effective tool for some patients. Although there was not a significant reduction in Hgb A1c in the CGM group compared to the SMBG group across the entire cohort, there was still significant improvements seen in those younger than 65 years. The reason this age group achieved significant reductions in Hgb A1c was uncertain by the authors of the study. It could be hypothesized that the pre-trial education for the CGM group was more accommodating for those younger than 65 years (Haak et al., 2017).

The study by Yoo et al. (2008) demonstrated the effectiveness of RT-CGM as a not only a tool to improve glycemic control measured by Hgb A1c, but also as a behavior modification tool. The significant changes in body weight, BMI, and exercise time per week show the ability of CGM to achieve benefits outside of improved glycemic control. The advantages of improved body composition and increased exercise time per week are multifaceted. These advantages vary from improved psychological health seen with enhanced self-confidence, to the cardiac benefits of an improved exercise workload, to potentially slowing the disease progression of T2D (Yoo et al., 2008).

Several studies have evaluated how quality of life and treatment satisfaction measurements correlate with Hgb A1c outcomes in patients with T2D after CGM initiation. Quality of life is a critical subjective measurement in patients with T2D, as diabetes-related distress often correlates with objective measurements such as glycemic control. Studies have consistently shown that CGM initiation in patients with T2D not only significantly improves Hgb A1c, but also significantly improves quality of life and treatment satisfaction. The improved confidence and reduction in stress observed with CGM initiation seems to allow patients to take command of their disease and contributions to improved health, which was confirmed by Hgb A1c reductions (Gilbert et al., 2021; Haak et al., 2017). The study by Bergenstal et al. (2021) which discovered that patients with T2D receiving multiple daily insulin injections experienced a significant reduction in ADE and ACH with CGM initiation, is also encouraging. Though data observed during this study did not evaluate the effect CGM initiation had on Hgb A1c, a reduction in ADE and ACH could be viewed as an incidental measurement of improved glycemic control in patients with insulin treated T2D (Bergenstal et al., 2021).

The discovery by Kraukeuer et al. (2017), which showed how increased scan frequency with CGM was associated significant reductions in Hgb A1c, is what indeed demonstrates the role this technology plays in the management of T2D. Higher CGM scan frequency provides patients with the ability to make more precise day-to-day treatment adjustments in patients receiving multiple daily insulin injections. In patients not receiving multiple daily insulin injections, higher CGM scan frequency acts as an important education tool to aid in making improved lifestyle decisions. The improved compliance with more frequent blood glucose checks seems to result in an enhanced awareness of their disease process (Kraukeuer et al., 2017).

Several limitations for this literature review exist. Many of these studies received some degree of funding from either Abbott Diabetes Care or DexCom Corporation, the companies which manufacture the FreeStyle Libre F-CGM and DexCom RT-CGM, respectively. Due to this support, a certain amount of bias cannot be excluded. Another limitation is the lack of long-term data showing the impact of CGM initiation in patients with T2D. Evaluating outcomes after years of CGM initiation is important to determine if the advantages are sustainable and can reduce long-term diabetes-related complications. Reducing Hgb A1c over the course of several months is not enough and patients must maintain these improvements over their lifetime to reduce the risk of diabetic retinopathy, nephropathy, neuropathy, and cardiovascular disease. Among participants who are new to a CGM system, it is crucial to evaluate education level as this may play a role their ability to properly operate this technology. With this, addressing education level is a limitation to this literature review.

Conclusion

The conclusion of this literature review suggests that CGM initiation may improve Hgb A1c outcomes in patients with T2D. The data to support this point of view has been shown in patients with T2D on treatment regimens ranging from intensive insulin therapy to patients who manage their disease with simple lifestyle measure alone. However, few studies have studied the effects beyond one year of CGM initiation. At a minimum, a short-term trial of CGM in this patient population may provide patients with the essential education they need to better manage their T2D going forward. The data showed similar reductions in Hgb A1c with RT-CGM and F-CGM systems and the decision on which device is best for a certain patient should be based on individual preference.

Applicability to Clinical Practice

With the information provided in this literature review, the medical provider will be able to make an evidence-based decision on what modality is best to manage glycemic control in patients with T2D. It is worth noting that a CGM system may not be necessary for all patients.

For example, patients with T2D whose Hgb A1c is optimized on less intensive treatment regimens may see little benefit from CGM. These patients may manage glycemic control adequately with occasional blood glucose checks with a SMBG system. On the other hand, patients with T2D whose Hgb A1c is not at target goal may find a CGM system more beneficial. In these patients, the improved compliance of more frequent blood glucose checks with a CGM system can help support better glycemic control.

One of the downfalls to CGM is the cost to initiate and operate the system. Most insurance companies will not cover any expenses of a CGM system in patients with T2D not receiving multiple daily insulin injections. This becomes especially problematic for the patients who are receiving less intensive treatment regimens, as the cost of a CGM system may be unaffordable. Initiating a CGM system requires purchasing a transmitter and a receiver, which can include an upfront cost of up to $300. On top of that, CGM systems have an operating cost of up to $200 per month, which includes replacing the sensors on a weekly or biweekly basis. Fortunately, patients who are unable to afford a CGM system can seek out various discount and assistance programs that may help reduce cost.

Another option for patients wishing to achieve the benefits of CGM is to seek diabetes care at a clinic which offers professional CGM trials at no additional cost beyond the office visit charge. Professional CGM involves patients wearing a CGM device provided by their health care providers clinic for a short period of time. Patients return the sensor and equipment to the clinic, and data are downloaded and analyzed. Though patients may only be utilizing the CGM system for a period as short as two weeks, the knowledge patients acquire during a brief CGM trial can provide lasting effects on glycemic control in the long run.

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