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EVALUATION OF GLUCOSE MONITORING TECHNOLOGIES FOR COST EFFECTIVE AND QUALITY CONTROL/MANAGEMENT OF DIABETES

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ABSTRACT

The diabetes epidemic in the United States (U.S.) has become a burden in regards to treatment, disease management, and associated costs. Key advancements in medical technology have been developed in efforts to mitigate this issue. We compare several types of glucose monitoring systems with respect to quality of care, management, and cost-effectiveness for type 1 and type 2 diabetics.

INTRODUCTION

Diabetes is a disease of metabolism: a disorder of how the body processes food. Most of the food eaten is transformed into glucose, which enters into the bloodstream, where cells use it as an energy source. Insulin, a pancreatic hormone, is required for the absorption of glucose into cells. Normally, when people consume nutrients, the pancreas produces the appropriate amount of insulin necessary for glucose to be absorbed from the blood stream into the cells. In individuals with diabetes, the pancreas produces either no or insufficient insulin, or the body's cells do not process the insulin which is produced properly. As a result the body loses its fuel source.

Two major types of diabetes exist: type 1 diabetes (formerly referred to as juvenile diabetes) and type 2 diabetes (formerly referred to as adult onset diabetes). Patients with type 1 diabetes account for about 5-10% of diagnosed diabetics in the U.S.; this condition occurs mostly in children and young adults but can become manifest at any age (ADA", 2012). It occurs because the body's immune system attacks and destroys the insulin-producing cells in the pancreas. If not diagnosed and treated with insulin, an individual with type 1 diabetes can lapse into a life-threatening coma.

About 90-95% of diabetics have type 2 diabetes, which is often associated with physical inactivity, older age, previous history of gestational diabetes, a family history of diabetes, obesity, and certain ethnicities. In 2010, type 2 diabetes was diagnosed in more than 25.8 million adults over the age of 20 in the U.S., while another 7.1 million went undiagnosed; 81.5 million had prediabetes (Roger et al., 2011). The prevalence of type 2 diabetes in all age, gender and ethnic groups in the U.S. is expected to more than double (from a prevalence of 5.6% to a prevalence of 12%) between 2005 and 2050 (Narayan et al., 2006).

Type 2 diabetes is increasingly being diagnosed in children and adolescent (Copeland et al., 2005; "Healthy Ohio", 2014. Patients with type 2 diabetes usually produce normal amounts of insulin, but this insulin is not used properly by the body and eventually a decrease in insulin production results. This results in the same situation as in the case of type 1 diabetes: blood glucose increases and the body cannot efficiently use of its main source of fuel ("Glucose", 2015).

Diabetes is associated with multiple long-term complications affecting virtually all parts of the body. The disease often leads to blindness, heart and blood vessel disease, stroke, kidney failure, amputations, and nerve damage (ADA, 2010). Before the discovery of insulin, a diagnosis of type 1 diabetes was a virtual death sentence – all patients died within a few years after diagnosis (Sattley, 2015). Insulin, while not a cure, was the first major breakthrough in the treatment of diabetes.

Treatments for type 1 diabetes include healthy eating, physical activity, and taking insulin; basic treatment for type 2 diabetes are the same as for type 1, except that oral medication may be substituted for insulin ("About Health", 2015). Blood glucose levels should be closely monitored through frequent blood glucose checking; patients with diabetes should also monitor blood glucose levels several times a year with a laboratory test called the HbA1c, results of which reflect average blood glucose levels over a 2-3 month period. This entire monitoring procedure has been characterized by many diabetics as complex (Kouris et al., 2010). The goal of diabetes management is to keep levels of blood glucose as close to the normal range as safely possible ("Goals of Treatment", 2015).

Diabetes was the 7th leading cause of mortality in the U.S. in 2007, with a reported 71, 382 death certificates listing it as the underlying cause of death. Actual contribution of diabetes to death is likely much more substantial, as an additional 160,022 death certificates in 2007 include diabetes as included under any-listed cause of death (ADA, 2011).

In 2012, the total expenditure for U.S. diabetes care was $245 billion, $176 billion for direct medical costs and $69 billion in productivity reduction (ADA, 2014). Between 1988-1994 and 2011-2012, the prevalence of diabetes increased in the overall U.S. population and in all subgroups evaluated, although the prevalence did appear to stabilize between 2007-2008 and 2011-2012 (Menke et al., 2015).

TECHNOLOOGY

Technological advancements in medicine have been developed in an effort to mitigate the diabetes epidemic in the U.S. Self-monitoring of blood glucose provides useful information for the management of diabetes. It can help the patient understand how well he/she is accomplishing treatment goals; how diet, exercise and other factors (e.g., illness, diabetes medication) affect blood glucose; and identify when blood glucose is too high or low (Mayo Clinic, 2015).

Traditional Blood Glucose Testing

Traditionally, the most common way (Vashist et al., 2011) to check blood sugar levels has been for the patient to: (1) prick the finger with a small, sharp needle; (2) transfer the drop of blood to a test strip; (3) place the test strip into a glucose meter; and (4) read the blood glucose level displayed on the meter. This self-monitoring approach is an "integral component of effective therapy" (ADA, 2015, S33). Although these Self-Monitoring Blood Glucose (SMBG) devices are generally simple to use, many patients often do not fully adhere to their provider's monitoring regimen. Lack of adherence is generally due to the inconvenience of testing multiple times daily, the cost of monitoring supplies, and the pain associated with multiple finger pricking (D'Archangelo, 2009). While the glucose meter itself is relatively inexpensive ($40 is not unusual), test strips for SMBG can cost up to $100 per month ("Guidelines", 2015). Globally, sales of blood-glucose monitors peaked in 2011 and has declined since then (Wall, 2013), but this is not sufficient to conclude that the business is souring since the majority of sales do not come from the blood glucose monitors but from the blood glucose strips themselves (Lund, 2014). The SMBG market was estimated at $3.99 billion for 2013 and is projected to grow to $4.18 billion by 2016 (Frost & Sullivan, 2015).

Continuous Glucose Monitoring

A technological advance in the field of glucose monitoring has been the development of Continuous Glucose Monitoring (CGMS) systems. CGMS include a tiny sensor that is surgically inserted under a diabetic's skin and used to monitor glucose levels. This sensor can stay in place for up to one week. Glucose levels are transmitted via radio waves to a wireless monitor (NIDDK, 2015). Unlike conventional SMBG monitoring, CGMS devices have the ability to more easily identify trends and fluctuations regarding direction, duration, magnitude, and frequencies in blood glucose levels that are difficult to monitor effectively using traditional glucose monitoring methods (Klonoff, 2005).

CONTINUOUS GGLUCOSE MONITORING CLINICAL RESULTS

Benefits of Continuous Glucose Monitoring in Diabetes Treatment: Studies of Type 1 Diabetes

Continuous glucose monitoring (hemoglobin level) can be associated with improved glycemic control in adults with type 1 diabetes (Tamborlane et al., 2008). Hirsch et al. (2008) demonstrated that type 1 diabetics with greater sensor utilization showed a greater improvement in A1C levels, but reduction in HgA1c was not significantly different between test (CGM) and control (SMBG) groups.

CGM technology has increased that capability to accurately recognize hypoglycemia and hyperglycemia in type 1 patients. CGM has offered sensitivities that have reached over 80% for threshold alerts alone, which had improved to well over 90% when combined with predictive alerts (Mastrototaro, Welsh and Lee, 2010). CGM has been shown to be associated with decreased HbA1c levels and time spent in hypoglycemia in individuals with type 1 diabetes (Battelino et al., 2012). Peyrot and Rubin (2009) reported that in a survey administered to 162 patients using a CGM device and 149 patients using SMBG to monitor blood glucose levels, found that the patients using CGM were more satisfied with their treatment and had better quality of life. The ADA found that CGM can be extremely useful in patients greater than the age of 25, due to evidence that CGM results were weaker on children and young adults (Steck et al., 2014).

Wojciechowski et al. (2011), in a review of 14 randomized clinical trials of the use of CGM for type 1 diabetes, found that CGM, particularly its real-time system, had a favorable effect on blood glucose control and decreased the incidence of hypoglycemic episodes in both adult and pediatric patients.

Benefits of Continuous Glucose Monitoring in Diabetes Treatment: Studies of Type 2 Diabetes

Historically, patients with type 2 diabetes, particularly patients on diet or oral medications, test blood glucose levels much less frequently than patients with type 1 diabetes (Joyce and Pick, 2013). The Harman-Boehm study (2008) described multiple indications for the use of CGM among those patients with type 2 diabetes:

- to determine when and for how long patients have low, normal or high blood glucose
- to map fluctuations-direction, magnitude, duration, frequency, causes
- to facilitate adjustments in treatment to optimize control
- to determine response to adjustments in therapy.
- to determine the impact of lifestyle modification on control.
- to determine the impact of diet composition on control
- to diagnose and avoid hypoglycemia

CGM has many advantages to patients with type 2 diabetes. Harman-Boehm (2008), suggested that CGM provided an answer for some of the insufficiencies attributed to SMBG (e.g., CGM has the ability to detect postprandial glucose excursions, and nocturnal hyperglycemia not easily detected by SMBG). In a study in 2012, it was found that quality of life using the CGM, showed scores mainly unchanged for both the treatment and the control group, however, fear of hypoglycemia was reported in the study to be lower by 7.4% while wearing CGM (Mauras et al., 2012).

Patients with type 2 diabetes using CGM on an intermittent basis of 3 days a month for 3 months showed significant decreases in calorie consumption from total calories per day of 1858 calories to 1690 calories, an increase in exercise time from 188.2 minutes per week to 346.6 minutes per week and a decrease in the HbA1c levels from 9.1% to 8.0% (Yoo et al., 2008). The patients in this study also demonstrated decreased total daily calorie intake, weight, body mass index (BMI), and postprandial glucose level, and a significant increase in total exercise time per week after 3 months.

Allen et al. (2008) demonstrated a positive correlation between educating patients with type 2 diabetes on the impact of their physical activity on their glucose results using the data from the CGM device and the patients' increase in moderate activity by 5 minutes a day and also showed a statistically significant decrease in HbA1c.

When evaluating the use of CGM in a small sample (n=10) of poorly controlled type 2 diabetics, patients showed a mean reduction of 20% in HbA1c at the end of the first 90 days of monitoring, with an additional 1% reduction achieved to an average of 7.72% among those participants who continued to use CGM (Thielen et al., 2010). Cosson et al. (2009-0k) found a statistically significant decline in the HbA1c of type 2 diabetics using CGM compared with controls in a self-monitoring control group. No significant reduction in HgA1c was found for type 1 diabetics. Vigersky et al. (2012) in a randomized controlled trial of 100 type 2 diabetics, found significant reduction of HgA1c after 12 weeks with results persisting after 40 weeks. A 52-week study (Ehrhardt et al., 2011) found that RT-CGM improved glycemic control better than self-monitoring of blood glucose (SMBG) in patients with type 2 diabetes who were not taking prandial insulin.

Barriers to Continuous Glucose Monitoring Implementation

Some disadvantages that were reported included the complex task of inserting and calibrating the sensor, troubleshooting device malfunctions, and responding to alarms that became a burden that reduced the benefits from the technology (Wolpert, 2010).

The use of CGM requires the insertion of sensors under the skin, and many patients experience pain and/or discomfort from the sensor, transmitter, or tapes which are used to secure the device to the body. Also, the user was tasked with reading the CGM data once an alarm sounded and often, patients were not taught how to interpret and use the data, which cause patients to be dissatisfied with their results (Mastrototaro, Welsh and Lee, 2010).

Reimbursements for CGM devices have been limited by insurance or government payers. Insurance companies have been demanding rigorous evidence about continuous monitoring before they would pay for this technology (Klonoff, 2005). Usually, the sensors that have been used for CGM struggled to provide an accurate measurement of blood glucose; the devices had to be calibrated to the patient's blood glucose level by finger pricking, the more traditional method (Heinemann, 2006).

Cost-Effectiveness of Continuous Glucose Monitoring for Type 1 and Type 2 Diabetes

A cost effectiveness and resource allocation empirical study determined the cost-effectiveness of CGMS compared to SMBG and insulin therapy in type 1 diabetic adults, concluding that patients using CGMS achieved an expected improvement in effectiveness of 0.52 QALYs at an expected increase in cost of $23,552, resulting in an ICER of approximately $45,033/QALY. Based upon a willingness-to-pay of $100,000/QALY, CGM with intensive insulin therapy was deemed to be cost effective (McQueen et al., 2011). The CGMS combination also reduced the likelihood of disease progression, co-morbid complications, and mortality in subjects via its effect on HbA1c levels in comparison to SMBG (McQueen et al., 2011). Using the same willingness-to-pay hurdle, Huang et al. (2010) also reached the same conclusion for type 1 diabetics, although these researchers did note considerable uncertainty surrounding these estimates. Lifetime projections indicated that CGMS would lead to reductions in complications such as blindness, amputation, and kidney disease.

Research has indicated cost-effective results in type 2 diabetes patients as well. Vigersky et al. (2012) analyzed the short and long-term effects of CGMS in type 2 diabetic subjects not on prandial insulin, concluding that type 2 diabetic patients not taking prandial insulin had significant improvement in glycemic monitoring using CGMS (Vigersky et al., 2012). A base-case analysis projected the costs at five years using the same intervention that was used by Vigersky et al. (2012). Mosley et al. (2012) estimated that improved glycemic control from CGMS was projected to reduce average costs with the following complications: heart disease (-$177), kidney disease (-$141), and diabetic food complications (-$212), and that the overall cost/QALY was $10,071.

DISCUSSION

The analysis of the literature displays a need for CGM among patients with type 1 and type 2 diabetes. CGM is a viable treatment option that serves to assist in data collection for lifestyle adjustments and treatment adjustments.

Clinically, in multiple studies, CGM has been shown to be effective in reducing blood glucose and HgA1c. The studies suggest an improvement in lifestyle in terms of nutrition, exercise and glucose control. This shows that the individual's awareness of how their choices impact their glucose states which contributes to the willingness to accept the lifestyle modifications needed. Identifying the causes of blood glucose changes in a real-time environment using CGM contributes to greater confidence among those with type 2 diabetes when compared to SBG monitoring. This confidence allows for the user to confidently adjust their medication doses with much less fear of a hypoglycemic event (Joyce and Pick, 2013).

Despite evidence that CGM has the potential to benefit patients with type 1 and type 2 diabetes, widespread adoption of this technology has been limited. In patients with frequent hypoglycemic incidents, the quality of life benefits that were provided by continuous monitoring were offset by disadvantages.

CGMS technologies are able to detect critically low overnight blood glucose levels, reveal blood glucose change levels between meal consumptions, display early morning spikes in blood glucose, and evaluate how an individual's caloric intake and physical activity affect blood glucose levels (Vashist, 2013). They offer the potential to predict hypoglycemic events before their occurrence (D'Archangelo, 2009) and are compact, wearable, light-weight, portable, possess long sensor life spans, and are water-resistant (Vashist, 2013). CGMS are especially useful in intensive care units, where close monitoring of blood glucose is especially important (Vashist, 2013).

If further research continues to suggest that the use of CGM is a viable measure to battle the diabetes epidemic in the U.S., stakeholders of the health system need to ensure that the general population has affordable access to and the means to education on this clinical technology. Improvements in the ability to use CGM information appropriately, joined with improvements in the design of devices and their reliability will continue to help with diabetes management.

However, most commercially-available CGMS require training and education of the diabetic patient, and frequent fingerstick blood tests for calibration. They are also relatively expensive. Until these problems have been addressed, it is that CGMS devices will replace SMGB systems on a widespread basis (Vashist, 2013). According to WebMD ("How Does", 2015), new and improved types of CGMS are currently in clinical trials.

CONCLUSION

CGMS has been shown to be an effective and cost-effective option in terms of efficient treatment and disease management for type 1 and type 2 diabetic subjects. Further improvement in the design and reliability of CGMS technologies will enhance the management of diabetes.

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