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The Intersection of Carbohydrate Insulin Coverage, Delivery System Technology, and Glucose Sensing: The Need for Critical Thinking

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Abstract

Technology in Diabetes Mellitus has been available in the form of insulin pump delivery systems for almost 40 years and glucose sensing technology for over 20 years. It is just the last 10 years there have been broad adoptions of both pumps and personal sensors and more recently integrated delivery systems that are bringing us closer to physiologic dynamic control of diabetes that strives to replicate glucose control similar to persons without diabetes (who have normal glucose control mechanisms). Data from this technology is part of routine clinical practice in anyone caring for persons with diabetes especially in the type 1 space. This is a new avenue for clinical research but also a new area of challenge for providers and staff caring for patients with this technology. There is slowly emerging research that focuses on this clinical data specifically available from personal sensors. This discussion will briefly review what this looks like in clinical practice and a sampling of data from research in this new technology. Then we will discuss how providers, educators, patients, and other stakeholders should work as a team to focus on critical thinking as an essential skill set.

Keywords

Insulin Pump, Personal Glucose Sensor

1. Introduction

Both patients and clinicians frequently joke that simply taking food out of the equation would make diabetes management so much easier. With the increasing use of continuous glucose monitoring systems (CGMS) over the last 20 years the variability in glucose control inherent in especially the type 1 space has been brought into sharp focus. The act of simply taking nutrition and controlling post prandial glucose is now more than ever demonstrated by sensor technology to be infinitely challenging and for many a daily frustration. This discussion will focus on that challenge and how diabetes educators, providers, as well as patients with diabetes need to collectively share this new dynamic information and understand the complexity and critical thinking needed to achieve better glycemic control. Educators and providers continue to instruct and coach persons with diabetes with each encounter. Likewise these same patients are teaching us—if we pay attention to the information they bring with this new technology. This new source of trending data requires and does not replace critical thinking skills. I also half-jokingly share with patients that you spend your entire life trying to "figure it out" but in the end you never do because of the many physiologic and life variables.

2. Materials and Methods

This discussion will review information obtained from Tandem Corporation as well as Medtronic Inc. and is available as common source from online publications available to the general public as well as professionals. Other material was sourced from searching publications on how to interpret personal sensor information both with and without sensor powered pump technology and how to interpret the expansive data that comes to both provider and patient. Diabetes education information in general comes from multiple sources including the American Diabetes Association Standards of Care.

3. Results

Cellular physiology requires a nutritional source of energy more specifically glucose metabolism to sustain life literally minute by minute. Our bodies have the ability to maintain euglycemia in both the fasting state by gluconeogenesis as well as storing and using energy supplies when there is oral nutrition intake. Patients with inadequate insulin—both type 1 patients and type 2 patients with declining beta cell reserve—require exogenous insulin to transport glucose across the cellular membrane by facilitated diffusion. This process uses the transporter GLUT4 under the influence of insulin to supply cells with their needed energy source: glucose. Fine tuning of glycemic control utilizes insulin released in a bimodal first and second phase, GLP-1, amylin, and multiple counter-regulatory mechanisms.

Peripheral insulin administration requires significant effort to try to reproduce normal insulin physiology complicated by a myriad of complex variables some under the control of the patient and many not. The most significant fixed and uncontrolled variable is the time/action curve of currently available insulin administered either by a device or MDI insulin. Current insulin burdens patients with relatively slow absorption and onset of action and then unfortunately a long tail with relatively long duration of insulin action—much better now with analog insulin compared to human insulin but still far from physiologic.

Superimposed on this major barrier to reproducing normal beta cell function are the many injection variables. Just a few include timing of injection, type of insulin, time of day, the location or depot of the subcutaneous peripheral injection, absorption rates which can be impacted by lipodystrophy, temperature variables, injection technique, accuracy of insulin measurements before injection, and rarely even insulin that has lost potency and/or is outdated.

These insulin issues are significant but it is variables not directly related to insulin that effect glycemic control to a much greater extent in many of our patients. These issues are addressed by diabetes education and understanding them is critical for success in newly diagnosed patients—especially newly diagnosed type 1 patients. Some of these factors are listed below but first some comments are in order. Like many human endeavors: music, art, sports, and academics—one spends a lifetime learning to improve and refine your skills, but in the beginning basic concepts and techniques must be mastered. This is why we have coined the phrase "survival skills" when first teaching our newly diagnosed patients. Basic insulin skills are required, and to not confuse and overwhelm patients we focus on mastering basic skills of glucose monitoring and insulin injection with carb coverage using fixed dose insulin. We then layer on correction insulin and start the process of maximizing glycemic control not just with insulin adjustment but with carb control and carb counting. This educational journey starts by defining carbohydrates ("carbohydrates come from the ground"), and recognizing the three types of carbohydrates: starches, sugars, and dietary fiber [1]. Estimating the carbohydrate content of common foods requires familiarity with phone and computer apps and/or software included in new pump technology, formal training by a nutritionist, expertise in reading labels, identifying what is rapidly absorbed (high glycemic index-HGI) or more slowly digested and absorbed through the gut (low glycemic index-LGI).

Analog insulin led to the refining of basal/ bolus insulin in the first part of this century. It was not until personal sensor technology became broadly available in the last decade that we had more insight into the many variables affecting glycemic control and the nuanced nature of covering carbohydrates with insulin [2]. The following **Table 1** and **Table 2** include some of the recognized variables.

Current nutrition recommendations for individuals with diabetes stress the importance of implementing mealtimes interventions that reduce post prandial glucose (PPG) excursions. Yet doing so has been extremely challenging when checking glucose pre-prandial and again 2 hours after the start of a meal to determine their glycemic response to the meal. This method often underestimates the peak glucose value (something as simple as breakfast cereal) and fails to identify the duration of the PPG excursion (the classic example of a pizza meal) which is typical for high fat meals with carbohydrates.

Table 1. Glucose control issues related to nutritional intake [3] (see results paragraph 5).

Glycemic index
Food combinations
Insoluble fiber content
Proportion of protein and timing of protein intake at the meal (earlier and more is better?)
Proportion of fat content
Concentrated glucose drink consumption (fruit juice)
Timing of carbohydrate intake through the day
Complexity of carb counting—grams vs. carb choices
Inaccurate carb labeling on food products
Complexity of carbohydrate intake and insulin coverage in high intensity sports and physical activity
Complexity of glucose control in patients with many gastrointestinal comorbid issues including gastroparesis, supplemental feedings including tube feedings, TPN when patients are not eating, and post bariatric surgery
Cultural and religious preferences in food
Post bariatric and other gastrointestinal nutrient absorption issues
Total parenteral nutrition and tube feedings
Food restrictions such as gluten intolerance

Table 2. Glucose control issues related to the individual.

Level of diabetes education and medical sophistication
Quality of the patient's diabetes education
Variable engagement of the patient with his/her diabetes
Degree of insulin resistance often secondary to obesity
Genetics
Stress level
Gut microbiome
Variable physical activity and timing of activity—example shift worker challenges or jobs involving unanticipated physical activity superimposed on sedentary activity
Willingness or ability to engage in physical exercise (*i.e.* 150 minutes per week minimum as per ADA guidelines)
Underlying cognitive or psychiatric comorbid diagnosis (closed head injury, schizophrenia, depression)
Physical impairments (hand dexterity, visual impairment, tremor etc.)
Economics and insurance barriers
Access issues
Vegan and vegetarian diets
Minimal personal food preparation (eating prepared food outside the home)
Poor or no relationships providing support, marginal coping skills with a lifelong chronic illness, frustration and "burnout" especially when perceived personal effort is not leading to improved glycemic control, frank denial of diabetes as a coping mechanism
Language barriers including the deaf and blind
Literacy
Cultural, family, and faith-based practices that impact on caring for their own health with diabetes
Negative experiences with the health care system
Racial and ethnic bias—explicit and implicit; local and personal, national and systemic and gender bias
Age of the patient, age at the time if diagnosis, length of diabetes diagnosis
Family dysfunction

Improving glycemic control and safety in patients on insulin requires using glycemic response to carbohydrates—modified by appropriate insulin coverage—to be successful. But response to carbohydrates and glucose information in the past has been a static exercise at one point in time and did not have the context of trending. Collating all of this information (critical thinking skills) was confounded by this static information until technology did allow glucose trending in real time. Hemoglobin A1c was noted to be increased in patients with diabetes by Samuel Rahbar *et al.* in 1969 and gave an overarching 90-day picture of glycemic control and helped paint a picture of overall diabetes control. But POCT of glucose gave minimal information for immediate feedback as to the success or lack of success when trying to apply insulin coverage to meals.

MiniMed CGMS was introduced in 1999, a three day retrospective sensor, and began to validate some of the theories on the glycemic effects of various foods and provided some unexpected discoveries. Today, real time CGM systems display glucose readings every few minutes throughout the day and night, giving clinicians and patients a glimpse of information previously unavailable or difficult to ascertain through self-monitoring of blood glucose (SMBG). Glucose values, trend arrows, line graphs, and alarms viewed on the screen reveal real-time perspective. HGI and LGI carbohydrates can be monitored in complex meal selections with variable fat and protein intake and the responses noted. Glycemic response to food and analyzing trends and patterns from this data provide an opportunity to improve skills in glycemic control from the very first day of sensor wear. I am reminded of a physician patient who in his mid-thirties was struggling with control of his type 1 diabetes and was frustrated by A1c's in the 9% range. The first visit back to me after starting personal sensor wear produced an A1c of 7% for the first time. His first remark was memorable: "I learned more about taking care of my diabetes in the first week of wearing my sensor than I learned in the previous 20 years of having diabetes."

The literature now documents the importance of CGM in persons with diabetes using insulin—both for safety and improvement in A1c. CGM also provides new information never available in the days of SMBG. Glucose variability is of major importance and has been of concern and a focus of clinical research for over 3 decades. Beyond issues focusing on overall glycemic control are issues of well-being, quality of life for the patient, and reducing risk of hypoglycemia in patients with significant glucose variability especially those with high A1c values. Glucose variability has been shown to be an independent predictor of severe hypoglycemia in type 1 patients and also predictive of non-severe hypoglycemia in type 2 patients. Oxidative stress occurs with glucose variability and it is widely held this is another important issue related to end organ disease including vascular disease. Original CGM research demonstrated that the same A1c can be achieved by patients with both high and low variability: high variability patients even though treated to appropriate A1c levels are not safe. This is seen daily in clinical practice using CGM and often is our focus when coaching carb control and managing insulin safely. A comment on excessive basal insulin by both MDI and pump management is in order to be complete. Excessive basal insulin use was recognized after insulin glargine came to market and diabetes thought leaders such as Udaya Kabadi MD and Bruce Bode MD published and spoke to this issue repeatedly during the early years of refining basal/bolus insulin therapy. This remains a significant problem in clinical practice that is not always recognized. Excessive basal doses often lead to defensive eating, eating uncovered carbohydrates, and by necessity giving inadequate bolus insulin for carbs in order to avoid "late" hypoglycemia 3 - 4 hours after eating because of excessive insulin on board. This then is seen on CGM as highs and lows with high glucose variability with frequent rescue of hypoglycemia with carbohydrates and not rarely then treating the high sugars that follow with correction doses. Breaking this cycle can be challenging as often A1c's are high and patients are redescent to reduce basal insulin. There are exceptions but basal rates over 50% of total insulin are usually excessive.

Time in range is another concept made possible by CGM which dealt with glucose variability to some degree and pointed out excessive unsafe hypoglycemia not necessarily accounted for by POCT glucose and A1c.

Nutritional decision making is part of having diabetes and obviously is a major part of what makes diabetes challenging. The influence of the total amount of carbohydrates as well as the ratio of carbohydrates to fat and protein continues to be studied and CGM data continue to be researched and will be briefly and not exhaustively reviewed for this discussion [4]. Let's review some of that information.

Carbohydrates are critical not only for glucose control but also for long term nutrition. In type 1 patients carbohydrate poor or ketogenic diets can be dangerous. There is no definitive research as to the appropriate total of carbohydrates, fats, and proteins nor what would be the ideal proportion. There are however publications [5] that can be used to guide these decisions. The most interesting ones use CGMS looking at glycemic responses and include the following observations:

- the optimal dietary protein to reduced glucose variability measured by MAGE measurement (<140 mg/dl) is 15% in patients with type 1 diabetes.
- keeping total carbohydrate intake less than 50% does improve glucose variability in patients with type 1 diabetes.
- when comparing diets with low glycemic index (LGI) vs. diets with high glycemic index (HGI) the HGI diets produced much more glucose variability as measured by MAGE specifically studied in a Chinese population that is referenced below [6].

Sensor technology demonstrates immediate feedback of carbohydrate and dietary selections so patients can themselves change variables of carbohydrate totals, HGI vs. LGI food and the influence of fat and protein on post prandial glucose. This critical thinking advanced skill seems intuitive but there is a limited evidence to on the best way to select dietary choices including the proportion of protein, fat, and carbohydrates and other factors including timing and sequencing of these foods. Patients need to be coached to be diligent observers and willing to make changes in their diets to promote the best control possible within the confines of personal choices, likes and culture specific diets. Trend arrows using sensors have produced these conventional guidelines and can be helpful especially when just starting sensor wear and are included for completeness (Table 3).

When patients are evaluating their glycemic responses by sensor they should be encouraged to start by evaluating their favorite meals without modification looking at which meals have the highest glycemic peak and why? How long does it take for the glucose to peak? Which meals have the longest PPG duration and why? How does one continue to improve carb counting skills? As these skills improve patients can start to maneuver variables again requiring significant critical thinking skills based on some of the factors that have been reviewed.

Restaurant foods are particularly challenging because of the difficulty in assessing nutrient composition and portion size. It is important for patients to understand how to interpret CGM results without drawing inaccurate conclusion. Patients need to keep the following in mind:

- Specific mixed meals need to be evaluated on more than one occasion
- The effects of a specific type of meal can vary at different times of the day
- Portion sizes must be consistent and estimated accurately (using labels and household measuring devices).

Because of the complexity and challenges of daily control-insulin pump technology has evolved to the point of being partial closed loop and can adjust for changes in blood glucose anticipating low and high blood sugars by complex algorithms. This can help improve glycemic control and can make adjustments and corrections when manual control is inadequate. The Medtronic Insulin pump—using 670G and 770G technology in auto mode—will adjust basal rates every 5 minutes and using trend calculations will adjust insulin based on the patient's last 6 days of readings wearing a Medtronic Guardian Sensor and is recalibrated every night at midnight. Even if a bolus is a bit off it can adjust insulin to correct glucose readings but still requires manual bolus intervention for carb coverage and for large mismatches. The Tandem T:Slim X2 Insulin Pump uses Control-IQ technology with the Dexcom G6 sensor and predicts what the glucose will be in 30 minutes and adjust insulin delivery accordingly. When glucose readings are predicted to be between 112.5 and 160 mg/dl basal rates remain unchanged. When glucose is predicted to be in 30 minutes greater than 160 mg/dl basal rates are increased to address the glucose change. When glucose is predicted to be less than 112.5 mg/dl 30 minutes in the future basal rates are decreased from your personal active profile. When Control-IQ technology predicts you will be low 30 minutes in the future (less than 70 mg/dl) insulin delivery is stopped although bolus insulin can be continued. Basal insulin will be resumed

Table 3. Trend arrow interpretation [4].

Glucose	Bolus
Rising > 2 mg/dl per minute	Increase by 20%
Rising > 1 - 2 mg/dl per minute	Increase by 10%
Decreasing > 2 mg/dl per minute	Decrease 20%
Decreasing > 1 mg/dl per minute	Decrease 10%

when Control IQ predicts glucose will be over 70 mg/dl 30 minutes in the future. Like-wise when glucose is predicted to be over 160 mg/dl 30 minutes in the future basal insulin will be increased. When Control-IQ technology predicts greater than 180 mg/dl and maximum basal rates are being delivered the pump will give a bolus to bring glucose down to the target range. As in the Medtronic system bolus insulin for carbohydrate intake and correction for large glucose mismatch is required. One last comment about pump therapy: in the past pump therapy was often given only to those deemed to be motivated, with some level of diabetes sophistication, and patients literally had to "earn" the right to this technology. The last 10 years has brought a more appropriate and enlightened point of view—this is just another tool and patients who can benefit should have access to pump and sensor technology in spite of past success or failure controlling their diabetes.

When reviewing Table 1 and Table 2 it is clear that Diabetes Education is the foundation of keeping persons with diabetes safe, as well as establishing excellent glycemic control. Critical thinking skills need to be modeled as well as taught and techniques such as Motivational Interviewing need to be used to meet these goals. Scarce resources, both human and financial, have led to decreasing access to Diabetes Education both in the outpatient as well as in the inpatient setting. This issue goes beyond the discussion of this paper, but we all acknowledge lack of access to Diabetes Education is a major barrier to giving the best care for all persons diagnosed with diabetes.

All of this information, both basic and advanced, need to be included in diabetes education. Diabetes educators, medical providers, patients and other stakeholders such as family members need to collaborate and strategize individualized approaches to accomplish the best glycemic control for every patient. Advanced technology resources should be used when available and appropriate. Goals and choices of therapy will vary depending on patient preference as well as resources and individual demographics, but underlying this effort is a focus on individualized care and critical thinking skills. Technology is extremely helpful to accomplish each patient's best control but to maximize effectiveness ongoing skill refinement is needed in areas such as carb counting and dealing with the variables and challenges in just living out one's life. Basic concepts like consistent prandial insulin BEFORE meals not after, and adding protein to every carbohydrate intake can be very effective and evidence-based studies show A1c reduction and less hypoglycemia in patients using basal/bolus insulin or advanced closed systems. The focus is again reducing post prandial hyperglycemia [7]. Strategic and regular physical activity can dramatically improve glucose control and the immediate feedback from sensor technology when making changes accelerates and reinforces skill development in the pursuit of better glucose control. Pump and sensor technology can be exciting and engaging and reduce some of the burden of diabetes but also can be exhausting. The entire support structure for each patient, professional as well as family and friends, need to demonstrate empathy and understanding of the demands of diabetes (there is never a day off!). Each time the patient experiences unexpected high or low sugars critical thinking skills need to be taught and encouraged, but without criticism, so these events are minimized. With sensor technology it is common for patients to over correct and to address lows without pausing to consider the WHY of that event. This is something that should be discussed with every patient on insulin at every visit. It can be naturally discussed when reviewing pump/sensor/meter downloads at patient visits.

The experience of many providers (including this one) who prescribe sensor driven pump therapy as well as informal comments from patients suggests those who have highly (A1c < 7%) controlled diabetes in the type 1 space sometimes benefit less from this technology than those with only "fair" control (A1c in the 7.5% to 9% range). It is not unusual to see a 1% - 2% drop in A1c in those patients with only "fair" control for many reasons. One possible factor is better insulin administration using these "smart pumps". Patients are also often more engaged and more motivated to try harder for control when experiencing success. Insulin timing using set alarms, avoidance of both hypoglycemia and hyperglycemia by flexible alerts, and close monitoring add to safety as well as the reward of better control. Immediate glycemic feedback accelerates learning carbohydrate coverage skills using insulin therapy. Critical thinking when applied to this technology maximizes these rewards, reduces glucose variability, and adds to patient satisfaction on many levels.

4. Discussion

Improving Quality of Life and decreasing the burden of diabetes for our patients should be as important as A1c reduction. The principal goal for all persons with diabetes and those in their care circle should be keeping patients safe—especially on insulin—and specifically focusing on reducing hypoglycemia. Honing skills in self-care of diabetes and mastering diabetes technology using critical thinking skills moves each patient towards that goal of being safe. Hopefully in the future new insulin options and fully closed loop pump/sensor technology will move us further toward this goal. In the short and medium term we need to team up with our patients to give them the best and most sustainable therapy that is individualized for every patient. There is an opportunity going forward to study the impact of teaching critical thinking skills that would require some measure of patient engagement vs. a cohort of patients with a similar level of engagement not receiving the same critical thinking instruction to document that patients are safer with less hypoglycemia at the same or better level of glycemic control.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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