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Enhancing Diabetes Management Through the Integration of CGM and Insulin Pumps

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Abstract: This report provides an overview of diabetes with corresponding treatment, especially emphasizing the rising technology, coupling of continuous glucose monitoring (CGM), and insulin pumps. The report first provides some background information on diabetes. Then, it introduces the CGM and insulin pump technology with their basic mechanisms and functions, major players, and products. Moreover, the report examines the coupling of insulin pumps with CGM sensors, highlighting this combination as a more efficient and convenient method for maintaining blood sugar levels. The basic mechanisms of this coupling and the key companies involved are discussed. Moreover, the clinical safety and effectiveness of combining CGM and insulin pumps are addressed. Finally, the paper discusses current challenges and potential solutions for these advanced diabetes management technologies. The paper aims to offer a comprehensive understanding of how these devices enhance patient outcomes and the dynamics of their operational mechanisms.

Keywords: diabetes management, continuous glucose monitoring, insulin pumps, technology integration

1. Introduction

Diabetes is a chronic disease caused by insufficient insulin production in the body or dysfunctional insulin usage. Insulin is a hormone responsible for regulating blood sugar levels. High blood glucose, also called hyperglycemia, can cause damage to body systems, especially nerves and blood vessels [1].

Diabetes can be categorized into type 1, type 2, and gestational diabetes [2]:

Type 1 diabetes, or insulin-dependent juvenile/childhood-onset diabetes, is characterized by insufficient insulin production. Patients need to inject insulin daily. The cause and means of prevention for type 1 diabetes are currently unclear.

Type 2 diabetes, or non-insulin dependent adult-onset diabetes, refers to the body's inability to utilize insulin properly and efficiently. More than 95% of diabetes patients have type 2 diabetes. Factors contributing to type 2 diabetes include being overweight, insufficient exercise, and genetics. Early diagnosis is crucial to prevent severe effects.

Gestational diabetes refers to blood glucose levels being above normal but below the diagnostic standard for diabetes during pregnancy. Women with gestational diabetes and their children have a higher risk of developing type 2 diabetes after delivery. Gestational diabetes can be diagnosed through prenatal screening.

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According to the World Health Organization, the number of people with diabetes rose from 108 million in 1980 to 422 million in 2014, with a quicker prevalence increment in low- and middle-income countries [3]. Severe complications from diabetes include blindness [4], kidney failure, heart attacks, stroke, and lower limb amputation. In 2019, diabetes and kidney disease due to diabetes caused an estimated 2 million deaths [5]. Thus, it is crucial to provide effective management and prevention of diabetes for human health.

Continuous Glucose Monitoring (CGM) systems are a rising technology used in diabetes management. CGM devices can measure blood glucose levels continuously. In the meantime, insulin pumps store and transport insulin. Combining CGM and insulin pumps allows patients to measure their blood glucose levels and provide insulin at necessary times, offering a revolutionary solution for better management and improved quality of life.

This review paper focuses on CGM technology, insulin pumps, and their coupling for diabetes management. Topics include a brief introduction, basic principles, major companies and their products, development processes, and the effectiveness and safety of CGM systems and insulin pumps to provide readers with fundamental knowledge to explore the field of diabetes management further. This paper also discusses current technologies with their pressing challenges and potential solutions. This paper argues that the integration of CGM and insulin pumps represents a transformative advance in diabetes management, significantly improving patient autonomy and safety.

2. Continuous Glucose Monitoring Systems

2.1. Introduction of Continuous Glucose Monitoring Systems [6]

Continuous glucose monitoring systems are devices that measure blood glucose levels. CGM helps patients monitor their blood sugar at any time for their intake reference. CGM is specifically useful for patients with diabetes to monitor their blood glucose levels. They can be prescribed by doctors for adults and children. “Real-time” CGM devices send data to a smartphone or receiver automatically. The first “real-time” CGM was the Glucowatch Biographer from Cygnus, Redwood, CA. “Intermittent-scan” CGM devices estimate glucose levels continuously, but users need to scan the CGM with a separate receiver every few hours to view and store the data. Another type of CGM sends data to doctors for downloading and reviewing. Some CGMs have a feature that can send an alarm when glucose levels are out of range to inform patients or others to take action.

A CGM machine has three parts [7]: First, a tiny disposable sensor that can be inserted under the skin, often on the belly or arm, with a sticky patch. Another type of sensor, an implantable sensor, is placed inside the body. These sensors measure glucose levels in the fluid between cells, which is similar to the glucose level in the blood. The sensors need to be replaced depending on the conditions. Second, a transmitter sends the information wirelessly to the third part. Last but not least, a software program on a smartphone, insulin pump, or separate device called the receiver. Differences between CGM models include ways of sensor placement, whether on the skin or implanted, frequency for the sensor replacement, warm-up time, and ways to adjust the program settings.

2.2. Companies with CGM Products [8]

Dexcom: Dexcom is the dominant leader in both the personal and professional CGM market, attributed to the strong performance of the G6. G6 sensors have a labeled usage life of ten days, and the G6 and G5 transmitters have a labeled usage life of three months. Dexcom acquired TypeZero Technologies, the manufacturer of the inControl diabetes management system.

Medtronic: Medtronic is the second leader in the overall CGM market. They offer MiniMed 670G, an integrated CGM pump that automatically adjusts basal insulin delivery based on glucose readings

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measured every 5 seconds. They also offer the iPro2, a professional CGM system used in retrospective clinical studies.

Abbott: Abbott is the third leading competitor within the professional CGM market. Abbott offers its FreeStyle Libre Pro device, which excludes finger prick calibration and the regular training process for physicians. The sensor records glucose levels every 15 minutes and can be worn for up to fourteen days.

3. Insulin Pump

3.1. Introduction of Insulin Pump

Insulin is a peptide hormone made by the pancreas's beta cells of the islets of Langerhans, important for blood sugar control. Insulin moves glucose from the blood into cells, maintaining blood sugar levels and providing sufficient energy for the cells' work. Insulin is a common medication for the treatment of diabetes mellitus type 1 and 2 [9]. An insulin pump is a wearable medical device that provides insulin underneath the patient's skin. It is a management tool for patients with diabetes who require insulin supply.

Insulin pumps work in two ways: basal insulin and bolus insulin. The basal insulin pump provides small and continuous insulin doses according to the basal rate. For example, patients may need different basal rates throughout the day, such as more insulin in the morning hours than in the evening due to cortisol secretion in the morning. Thus, they need to change the basal rates over the entire day. Insulin pumps can adjust the insulin provided based on the patient's glucose level and settings programmed by the healthcare provider. For bolus insulin pumps, they manually provide insulin when patients are eating to adjust the blood sugar. Patients will enter information about their carbohydrate intake and blood sugar level to calculate the bolus insulin needed, which the pump then delivers into their bodies.

There are two main types of insulin pumps: with or without tubing. Tubed insulin pumps have a long, thin tube that connects the pump to a cannula under the patient's skin to deliver insulin. The pump is usually made of durable plastic and metal with a screen to view settings and data. It also contains a cartridge of insulin with a replaceable or rechargeable battery. Patients will fill it up every two or three days based on how much insulin they need and the type of pump. The tube connects the insulin reservoir in the pump to an infusion set on the patient's skin. The infusion set sticks to the skin with a cannula underneath and can be placed on the upper arm, belly, hip, buttock, or thigh. Tubeless insulin pumps, on the other hand, integrate the insulin reservoir and the cannula as an adhesive patch on the patient's skin without external tubing. They are operated wirelessly with a handheld controller. Unlike tubed insulin pumps, patients can wear tubeless insulin pumps while bathing or swimming [10].

3.2. Companies with Insulin Pump Products

iLet® Bionic Pancreas System (tubed pump); Medtronic MiniMed™ (multiple tubed pumps); Omnipod® (multiple tubeless pumps); Tandem® t:slim (multiple tubed pumps); Accu-Chek® Solo Micropump System (tubeless pump).

4. Coupling CGM and Insulin Pump

4.1. Introduction of Coupling CGM and Insulin Pump

Continuous glucose monitoring (CGM) sensors can measure the glucose level in a patient's bloodstream continuously, like every 5 minutes. These sensors are based on a needle electrochemical

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sensor implanted in the subcutaneous tissue of the arm or abdomen. The sensor can detect and transmit the real-time blood sugar level to a portable receiver and send an alarm if the level goes beyond the defined range. Combined with the insulin pump as an integrated system, CGM sensor functions can be better utilized by patients and healthcare providers. CGM sensors and insulin pumps can work together like an artificial pancreas to maintain proper glucose levels (70-180 mg/dl) in patients. This coupling helps patients avoid the difficult task of manually controlling their glycemia in daily life.

The coupling of CGM and basal insulin pumps works by automatically attenuating/suspending basal insulin infusion. This is categorized in two ways: attenuation/suspension determined by the detection of hypoglycemia or by the prediction of incoming hypoglycemia [11].

In detection-based attenuation methods, the CGM measures the blood sugar level. Once the level falls below the pre-defined threshold for hypoglycemia (e.g., 70mg/dl), the insulin pump reduces insulin delivery. When the CGM readings return to the normal range, insulin delivery is restored. Limitations of this method include its inability to prevent hypoglycemia from occurring and an intrinsic delay in the patient's body receiving the insulin until it works. Thus, there will be time differences between the actions of insulin delivery/suspension and the real physical reactions for blood sugar levels to increase/decrease.

Prediction-based attenuation methods can overcome the limitations mentioned above. Prediction-based methods use the predicted CGM data instead of the current CGM data to switch on/off insulin delivery. Prediction-based methods also use other input data such as insulin doses to forecast blood glucose levels. If hypoglycemia is predicted to occur (e.g., glucose level falling below the pre-defined threshold of 70mg/dl), the insulin pump reduces insulin delivery to avoid hypoglycemia. When the glucose level returns to normal, insulin delivery is restored. Another key parameter is the prediction horizon (PH), which refers to how much time in advance the hypoglycemic event would be predicted. A larger PH value is preferred to compensate for the delay of insulin action, but if the PH value is too large, it can cause a false positive event, which is undesirable.

4.2. Companies with Coupling Products

Medtronic Inc.: Medtronic focuses on both detection- and prediction-based suspension. It launched the first integrated medical device (MiniMed Paradigm REAL-time system) in 2006. Later products include Medtronic Paradigm Veo, MiniMed 530G, 630G, 640G, and 770G systems.

Two key algorithms for Medtronic products are low glucose suspend (LGS) and threshold suspend (TS), also called "suspend on low." LGS refers to the feature that suspends basal insulin delivery for up to 2 hours when the CGM value falls below a threshold between 40 and 110mg/dl. The system reactivates for 4 hours [12]. TS is similar to LGS, but the threshold range is limited to 60-90 mg/dl [13]. Prediction Low Glucose Management (PLGM), also called "suspend before low," is another algorithm from Medtronic Inc. that automatically suspends basal insulin delivery when glucose concentration is predicted to fall below the threshold in the next 30 minutes and restarts insulin delivery automatically when the predicted glucose value recovers [14]. Users can manually interrupt these algorithms to restart basal insulin delivery at any time.

Other products with similar functions include the Omnipod® 5 Automated Insulin Delivery System and the Tandem® t: slim Insulin Pump.

4.3. Clinical Effectiveness and Safety

The effectiveness of the integrated CGM and insulin pump system refers to the ability of the algorithm to reduce or prevent the occurrence of hypoglycemia. This is normally measured as the number/rate of hypoglycemic events, time spent in hypoglycemia, and so on. The safety of the system refers to

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the algorithm's ability not to produce adverse events and hyperglycemia. This is often measured by mean glucose concentration, glycated hemoglobin, and other indicators.

For the Medtronic LGS/TS algorithms, both single-arm and randomized controlled clinical trials support their effectiveness [15, 16, 17]. They showed reduced occurrence of hypoglycemia and reduced rate of hypoglycemic events, such as coma and seizure, without significant changes in HbA1c. The PLGM algorithms were assessed in both experimental and real-life conditions, showing significant effectiveness in reducing hypoglycemia [18, 19, 20]. The superiority of PLGM compared to LGS/TS was demonstrated by reducing excursions of hypoglycemia [21].

Non-commercial algorithms such as Kalman filter prediction-based suspension [22] also showed effectiveness in reducing overnight hypoglycemia in all age groups without serious adverse events [23, 24]. The attenuation algorithms Brakes and Power Brakes showed effectiveness in reducing hypoglycemia, with Power Brakes demonstrating a better ability to prevent hypoglycemic events than Brakes. Combining Power Brakes and 15g of rescue carbohydrates showed a promising effect in preventing hypoglycemic events. Adding historical CGM data improved Brakes' effectiveness in preventing hypoglycemia as well [25]. However, more realistic and long-duration clinical investigations are needed for such algorithms to further ensure their safety and effectiveness.

5. Discussion about current CGM products with their challenges

Though CGM acts as a promising tool for diabetes patients' management, there are some pressing issues that need further examination to provide better experiences for patients.

First of all, the sensor accuracy and stability need to be further maintained over time. Especially when interacting with a subcutaneous environment, issues like sensor fouling and calibration drift reduce reliability and may require frequent recalibration or replacement. Enzyme-based biosensor glucose monitoring could lead to sensor fouling [26] due to biofouling layers that accumulate on implanted sensors, leading to signal degradation and calibration drift. Thus, using non-enzymatic materials, such as noble metals [27], and nanomaterials including carbon nanotubes and graphene [28], could reduce the issue of fouling and enhance stability. These nanomaterials show promise due to their high sensitivity, fast response times, and lower risk of fouling to significantly enhance the durability and accuracy of CGMs. Calibration drift is another issue that affects the accuracy of CGM. It can be caused by foreign body response and sensor degradation [29]. Some approaches to address this issue include biocompatible coating and enhanced sensor material.

Another issue with the coupling of CGM and insulin pumps is the lag time in insulin delivery, which means there's a delay between CGM glucose data and insulin delivery effectiveness [30]. This delay can be problematic for patients to manage sudden glucose fluctuations. As discussed above, prediction-based algorithms can alleviate the issue to some extent, but further improvement in predictive accuracy and response time could be explored with the rising field of machine learning models trained on individual patient data. For example, artificial pancreas systems that integrate AI algorithms for autonomous insulin delivery [31]. These systems could analyze continuous glucose data and predict glucose trends based on individual metabolic patterns, making real-time adjustments without manual input.

Last but not least, the cost of integrated CGM and insulin pump systems is relatively a burden for many patients, even with insurance coverage. For example, a CGM system, such as Dexcom G6, can cost between $1,000 and $2,000 annually, combined with sensors, transmitters, and receivers [32]. Insulin pumps, such as products from Medtronic or Omnipod, can cost between $3,000 to $6,000 for the device alone, without the cost of supplies like infusion sets, reservoirs, or patches [33]. The continuous expenses such as replacement for CGM sensors and relevant insulin pump supplies can add additional $400 to $700 monthly without insurance. Though these prices can be reduced by health insurance to some degree, coverage varies significantly among patients which can still make these

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devices financially inaccessible for them [34]. However, medicare recently expanded coverage for CGM devices with coverage limitations and restriction for some patients. In a broad overview, CGM and insulin pump technologies are often unavailable or extremely expensive in low- and middle-income countries due to limited market access, high import tariffs, and regulatory hurdles. The public healthcare system in these countries typically does not provide insurance for advanced diabetes technologies such as integrated CGM-insulin pump systems [35]. Potential solutions regarding this pressing issue include inventing more affordable, cost-effective CGM and pump alternatives, expanding government and insurance support, expanding non-profit and NGO programs such as the International Diabetes Federation and Life for a Child, and providing mobile and telemedicine guidance to patients.

6. Conclusion

In conclusion, CGM and insulin pump systems represent one of the most transformative advances in diabetes management, allowing people to monitor and adjust their glucose levels in near real-time. By continuously tracking glucose and delivering insulin as needed, these systems create a more responsive and precise approach than traditional methods, like finger-pricking and manual injections. This technology has the potential to dramatically improve quality of life, reducing both immediate risks like hypoglycemia and longer-term complications associated with poorly controlled blood glucose.

However, the integration of CGM and insulin pumps still facing various challenges. Issues like sensor accuracy, calibration drift, and insulin lag time remain technical hurdles that need to be addressed to improve system reliability and responsiveness. Furthermore, the costs are high, both for the devices themselves and for the ongoing supplies, making accessibility a major barrier. Additionally, managing these devices can be complex, requiring significant patient education and training to use them effectively and to interpret the data correctly.

From a future-oriented perspective, there is immense promise in emerging technologies that could address some of these limitations. For instance, advances in materials science—such as nanomaterial-based sensors—offer the potential for longer-lasting, more accurate CGMs. Similarly, predictive algorithms and machine learning could lead to more intelligent insulin delivery systems, reducing the impact of lag times and making glucose management even more precise. Innovations in alternative insulin delivery methods, like inhaled or oral insulin, could further transform how these systems function, potentially reducing the need for invasive pumps and minimizing device visibility and maintenance requirements.

Overall, CGM and insulin pump systems embody both the opportunities and challenges of modern diabetes care. The potential for improved glucose control, reduction in diabetes-related complications, and enhanced autonomy for patients are substantial, but achieving widespread accessibility and ease of use will require continued innovation, cost reductions, and support systems that make this technology feasible for all who need it.

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