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RESEARCH ARTICLE

A REVIEW ON GLUCOSE MONITORING DEVICES – REVOLUTION IN THE WORLD OF DIABETES

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ABSTRACT

Diabetes is one of the most chronic diseases affecting millions across the globe, mainly in aging populations and sedentary lifestyles. Continuous glucose monitoring is essential for blood sugars and avoiding significant micro and macrovascular organ damage. The field of research has come up with major developments in glucose monitoring technologies over decades. However, the area of glucose biosensors still faces significant challenges. The traditional methods of glucose monitoring, such as hemoglobin A1c, seemed to provide little benefit in day-to-day glucose monitoring and the need for changing therapies. Researchers have come up with modern methods of non-invasive glucose monitoring, which are more efficient, robust and affordable for individuals of all ages. Continuous glucose monitoring(CGM) is one of the most reliable and clinically valuable methods that demonstrated the reducing risks of hypo/hyperglycemia, glycemic variability and improving the target blood glucose levels. In this article, we emphasize the advantages and limitations of CGM in diabetic and non-diabetic individuals, recent advancements in non-invasive technology and the significance of point-of-care glucose testing.

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INTRODUCTION

The management of diabetes depends on correctly measuring glucose concentration levels using suitable biosensors. Continuous glucose monitoring (CGM) is the most useful technology established in 1980. This technology has been beneficial to diabetic patients both clinically and economically in measuring optimistic glucose levels (1) Diabetes is a chronic disease that requires continuous management from physical activity to proper drug/insulin therapy. These can be done by correctly measuring the blood glucose levels with accurate glucose biosensors. Blood glucose monitoring is divided into two types- invasive and non-invasive, with the former being most convenient and practical to use in a hospital setting. Although the results are precise and important for the diagnosis of diabetes, it is unfit for continuous monitoring of glucose. Hence, self-monitoring of glucose has been put into action by discovering various non-invasive technologies, making it feasible for diabetic patients to monitor their blood glucose levels (2) ADA recommends assessment of overall glucose levels by CGM metrics (overall glucose management index) as an estimate of Hba1c derived from a 14-day CGM report for routine assessment of blood glucose levels (3).

CONTINUOUS GLUCOSE MONITORS

CGM measures interstitial glucose continuously and updates the levels every 5 minutes. It consists of a sensor inserted into the skin and a transmitter that transmits sensor data to the monitor (4) FDA approved the first CGM called Dexcom G5(Fig-01) in 2016 for stand-alone use. Mastrototaro et., al proposed that -The first three commercial CGMs were made available in late 2005- Medtronic Guardian (Medtronic Minimed, Northridge, CA, USA), the Dexcom Seven Plus (Dexcom, San Diego, CA, USA) and the Abbott Navigator (Abbott Diabetes Care, Alameda, CA, USA)(5) CGMs can provide both retrospective and real-time glucose measurements which is why the need for sensitivity and specificity of these devices are still under investigation. A CGM has three main parts: sensor, transmitter, and monitor. A small sensor is inserted under the skin, arm, or belly. A thin tube or a needle pierces the skin measuring the electrical current signal generated by a glucose-oxidase reaction(Fig-02) proportional to the interstitial glucose. The sensor is connected to a transmitter that allows the system to send blood glucose readings wirelessly.

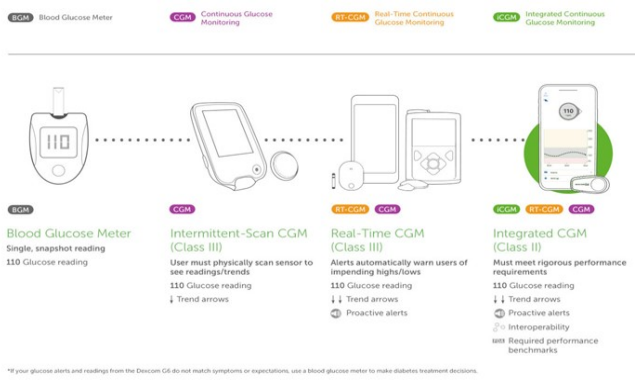

Fig. 01. Progression of Dexcom CGM biosensor device

The monitor displays information to the user. Sensors need to be changed every 10-14 days to maintain the accuracy of the results.

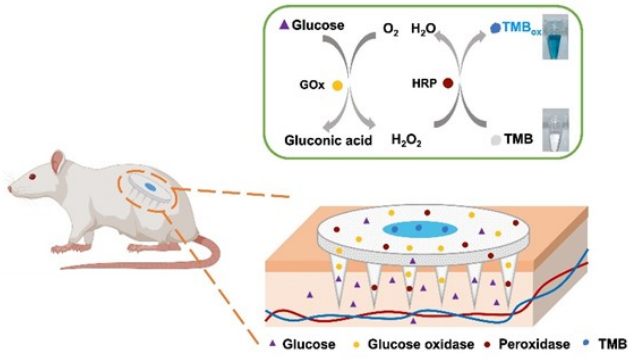

Fig. 02. A mice sample showing Glucose-oxidase reaction in CGM Transmitter

CGM Sensor Technologies: CGM has been tested with various glucose sensing mechanisms in an attempt to match all the fundamental requirements like sensitivity, specificity, and biocompatibility for extended in vivo use(6) Starting in 2005, the first three commercial biosensor CGM systems became available for personal use. A more significant and accurate sensor called Enlite was launched by Medtronic in the year 2011 however, FDA approved its use in 2013 declaring its use has shown more significant clinical and human factor improvements. A few changes have been made to this user-friendly devicesuch as decreasing the size of the sensor, extending wear time to 6 days, redesigning the electrode layout improving the usability and accuracy by reaching 13.6% MARD (7) A new and more accurate sensor, Guardian Sensor 3 was proposed by the same company which is used in Minimed 670G hybrid closed loop system (8). A fourth generation subcutaneous glucose sensor which was proved to be more accurate than the previous one in use.

Dexcom launched their new G4 Platinum Sensor with Share technology in 2015, which allows a secure wireless connection via Bluetooth between a patient's receiver and an app on the mobile phone. They have modified this technology into wireless communication to a smartphone without the need for a receiver by launching a new G5 Mobile CGM System in the same year (9) Abbott launched their new FreeStyle Navigator II CGM System (Fig- 03) in 2011 with a completely redesigned receiver, transmitter and reducing the warm-up time from 10hr to 1hr compared to first generation FreeStyle Navigator (10) This new sensor lasted for five days outnumbering the other CGM biosensors already in use.

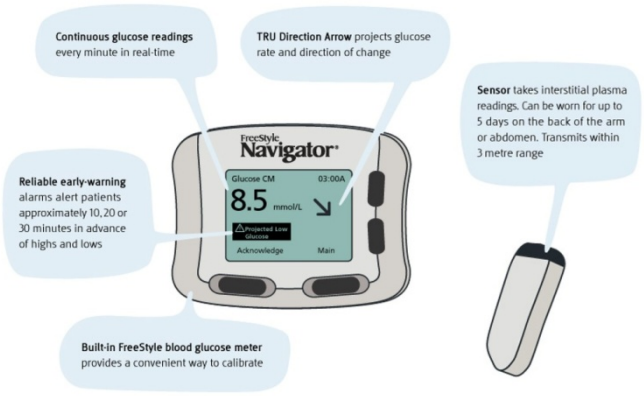

Fig. 03. Freestyle Navigator Biosensor device

Next Generation of CGM Biosensors: The smallest and long-lasting products have had the greatest appeal and success in the present generation of CGM Sensors. However, the size and lifetime of CGM biosensors are critical aspects of device development. Researchers are working on developing new technologies for the miniaturization of electrochemical biosensors as there are many limits associated with them- from sensor sensitivity to enzyme stability bringing the latest optical sensing technologies into use. Optical detection methods proposed so far include Raman spectroscopy for non-invasive detection and fluorescence-based sensors for implanted devices (11) A multicentre trial by Kropff and his team proposed the accuracy of Eversense sensor, an implantable CGM that provides glucose measurements through external coupled transmitter for a lifetime of six months which is currently being used in European countries(12)The Eversense CGM (Fig-04) has a lifetime of 90 days with accuracy of 11.4% MARD (13).

Fig. 04. EversenseCGM Biosensor Implantable device

The most crucial aspect to be considered for improvement of next-generation CGM sensors is the calibration requirement. CGM sensors need to be calibrated to convert the raw measurements like the electric current to glucose values, usually twice per day(14) Next generation CGM sensors need to be less caliber dependent with maintenance of sensor accuracy. According to Bailey et., aland team, the only available glucose sensor that is factory-calibratedis the Free Style Libre Flash glucose monitoring system (15). Recent research improvements in CGM technologies suggest the next-generation systems are more accurate, easy to use, less painful, long-lasting and user-friendly in terms of calibration requirements and smart feature data management. The accuracy of CGM sensors has improved a lot in recent years, and some of the devices were approved for use in Europe

(Abbott Navigator II, FreeStyle Libre Flash) and the United States(Dexcom G5 Mobile)(16) without confirmatory self-monitoring Blood Glucose testing(SMBG)These achievements have contributed to the increase in use of CGM biosensors in coming years.

CONCLUSION

CGM biosensors have revolutionized the treatment of diabetes in recent years with their accuracy, reliability and ease of use. The quality of glycemic control in both type I and II diabetes has dramatically improved reducing the dosages of bolus insulin regimens. CGM serves as a tool by assisting in medical therapy for diabetes, early detection of prediabetes and creating awareness in hypoglycemic patients. This paper is an overview of different CGM technologies and their impact on glucose monitoring.

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