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Research Article

Cost-Effective Non-Invasive Blood Glucose Monitoring System with Mobile Application for Management of Diabetic Patients

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ABSTRACT

Introduction: Diabetes is a significant health concern worldwide. The current methods of monitoring the glucose level include invasive and minimally invasive methods, which cause pain and have some limitations too. We have discussed different methods of blood glucose detection.

Aims: The aim of the study is to develop a low-cost, non-invasive device, especially for the rural public, to ensure diabetes management can be done at home.

Methods and Material: This article uses an infrared-based technique for non-invasive blood glucose measurement. The trials were conducted on 18 healthy and two diabetic patients. We developed an experimental setup for controlling blood glucose levels within a prescribed range using insulin and glucagon delivery. The system sends data to the caregiver using an Internet of Things approach.

Results: Our non-invasive system's error was around 12.5%, tested through clinical trials, making it a viable option for further testing in medical applications. The student's t test shows a good correlation of 0.45 between blood glucose levels measured using the developed device and the traditional Accu-Chek active device. The entire process time is around 300 sec. The range tested for the non-invasive method is 50–600 mg/dL, with a response time of 10 sec.

Conclusions: The developed system can monitor glucose levels in real time and inject insulin or glucagon as needed. The system is user-friendly and affordable, and it can be monitored remotely using IoT and can save patients time, particularly in rural areas, especially in developing countries. More clinical trials are needed to verify the results. There are challenges associated with the development and implementation of IoT-based injection systems, including accuracy.

Keywords: Diabetes Management, Non-Invasive, Blood Glucose Level, Internet of Things

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Introduction

Diabetes is a global health problem that is increasing at an alarming rate. The number of diabetic patients is expected to reach 783 million by 2045,[1] and the estimated health expenditure on the disease could be one trillion US dollars. There are two main types of diabetes: type 1 and type 2. Type 1 diabetes is caused by the body's inability to produce insulin, while type 2 diabetes is caused by the body's inability to properly utilise insulin. Both types of diabetes can lead to serious health complications, so it is important to manage the condition carefully.

The invasive method is traditional and causes daily pain for the user. So in the future, this method will become obsolete. The minimal invasion method is divided into three main categories: electrochemical biosensors,[2] implanted microsystems, and iontophoresis. These tests require small incisions, are less painful than invasive methods, and have better accuracy.[3] The third category of methods is based on non-invasive techniques. These are based on continuous monitoring of aldohexose.[4] There are several non-invasive glucose sensing techniques based on near/ mid-infrared[5] absorption spectroscopy[6], optical polarimetry[7], Raman spectroscopy[8], and photoacoustic principles[9]. All the methods have different shortcomings like accuracy for photoacoustic or very costly like Raman spectroscopy. Accuracy is the only problem with the near-infrared method, and in this work, we will check to find the accuracy of the non-invasive procedure.

For diabetes management, certain hormones play an essential role in balancing blood glucose. Out of these, insulin and glucagon are crucial. Insulin is a hormone secreted by the pancreas beta islet cells to reduce the blood glucose level (BGL) in the cell. So, if the blood sugar level goes above the normal range, insulin is secreted more to make it down and vice-versa, and if the BGL goes below a certain level, the pancreas alpha islet cells release glucagon hormone, which tells the liver to convert the stored glycogen into glucose and make the blood glucose in the acceptable range.[10] There are some preferred methods which are more useful than insulin injections. And these are insulin pens, pumps, jet injection devices, and inhaled insulin. Some problems are associated with these insulin delivery systems, so safety precautions are required. One person should not use the insulin pens used by another patient to avoid the risks of infection with blood-borne pathogens.[11] Another method includes the inhaled form which requires more dosage and affects tissues on their way to contact. The dry form of insulin also creates problems as it may stick with breathing passage to the lungs.

Existing BGL monitoring systems are expensive, require finger pricking, and do not transfer data to healthcare teams in real time. To solve the real-time transfer of data issues Internet of Things (IoT) technology can help. IoT is a rapidly growing network of physical devices that are connected to the internet and can collect and exchange data. IoT devices are already being used in a variety of healthcare settings, including hospitals, clinics, and nursing homes. These systems are made specifically to release medication automatically based on a patient's health status, minimising human mistakes and guaranteeing the best dosage at the appropriate time.[12] So to accommodate all the features, we developed an IoT-based non-invasive BGL monitoring and management system that injects glucagon and insulin automatically based on non-invasive BGL values.

Methodology

The study was conducted on 18 healthy and 2 diabetic patients to monitor their non-invasive glucose levels. It was done at the symposium, and a free health checkup camp was organised for diabetic/ non-diabetic persons by the Department of Biomedical Engineering, VSB Engineering College, Karur on October 6, 2022. Informed consent was obtained from all participants.

Block Diagram of IoT-based Injection System

The electronic components used in the development of the non-invasive glucose management system are shown in Figure 1. The system contains the 8-bit microcontroller from the microchip company (part number is PIC 16F877A) and has all the required input/ output ports and protocols for the data exchange between different electronic components. The system contains the 940 nm Infrared (IR) light emitting diode (LED) (IR-333A) as the light source and phototransistor (PT333C) to check the intensity of IR LED. The basic principle of the developed prototype system is that increasing BGL in the aqueous solution decreases the refractive angle of the IR light ray.[5] After proper signal conditioning by a signal control unit (SCU), the signal obtained from the phototransistor goes to a microcontroller. The mathematical algorithm is embedded in the microcontroller, calculating the glucose level. Depending on the range, the ULN2003 driver IC activates relays. The system uses two 12V DC relays to control the direct current (DC) motor attached to the syringes. These injections provide insulin or glucagon infusion when required. The system uses the IoT module with part number ESP8266. This module communicates with the smart mobile of the user to send the data in real time over the internet. The step-down transformer-based power supply helps in generating the system's 12V and 5V DC supply. The 7805 and 7812 ICs regulated the 5v and 12v DC power supply, respectively.

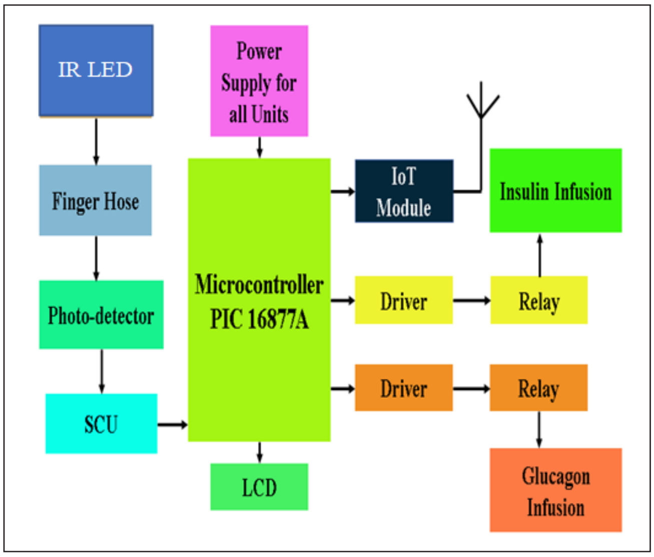

Figure 1.Block Diagram of the Developed Prototype

The 16*2 alphanumeric liquid crystal display (LCD) was used in the system to display all the patient's real time data. 1 mg/mL of glucagon and 100 units/mL of insulin were used in the syringes. Both the syringe volumes are 1 ml each. The length of the needle of the syringe is 1.27 cm. These are the standard plastic disposable syringes we procured from the local pharmacy. The insulin (Huminsulin R 100 IU injection 1x10 ml) and the glucagon 1 mg/mL kit (GlucaGen® HypoKit®) were procured from the online Netmeds website.[13]

Procedure of IoT-Based Control System

The procedure for using the developed IoT system is shown in Figure 2. First, the user has to put their index finger on the attached sensor. Then, the optical sensor reads the data, which goes to the microcontroller, which calculates the current value of the user's non-invasive BGL and then displays it on the LCD using Equation 1, which was taken from Narkhede et al.[5]

Non-invasive BGL (mg/dL)

= 2.998*v2 - 157.73*v + 335.55 (1)

Where v is the voltage coming to the microcontroller after the signal conditioning circuit is used in the system. After getting the glucose concentration, the system checks what chemical is required for the user to inject, whether glucagon or insulin. To calculate the insulin, we have used the Basal insulin dose method for diabetic patients.[14] According to them, for every 50 mg/dL glucose above the normal range of 60–120 mg/dL in fasting conditions, we have to inject 1 unit of insulin. So, the units of insulin required for the diabetic person in fasting conditions were given by Equation 2.

Units of insulin required

= (non-invasive BGL-120)/50 (2)

A 1 ml injection contains 100 units of insulin. The motor and the gear are adjusted to calculate the difference in providing 1ml of insulin in 500 seconds. The time required on the DC motor to deliver the necessary amount was calculated by Equation 3.

Time required to on the DC motor (sec) = (non-invasive BGL-120)/10 (3)

If the time calculation is less than 1 second, then the DC motor will not be on, and the display shows no requirement to inject the insulin dose. The subject then put his hands near that injection, as suggested by the LCD. The insulin can be injected into the back of the upper arms as shown in Figure 2 and then the motor stops. If the BGL value calculated from Equation 1 is less than 60 mg/dL, glucagon will be injected using Equation 4. According to DailyMed, 1 mg/mL of glucagon can increase the 79.3 mg/dL of glucose in the human body in 10–15 minutes.[15]

Glucagon required (mg/mL)

= (50-non-invasive BGL)/79.3 (4)

The 1 mL injection contains 1 mg of glucagon. The motor and the gear are adjusted to provide 1 mL of liquid in 500 seconds. The time required to turn on the DC motor to deliver the needed amount of glucagon is given by Equation 5.

Time required to on the DC motor (sec)

= (50-non-invasive BGL)*6.31 (5)

If the time calculated is less than 0.2 seconds, then the DC motor will not be on, and the display shows no requirement to inject the glucagon dose. The subject then puts their hand near the injection as per the instructions displayed on the LCD (Figure 2). Then, the glucagon can be injected into the upper arms. The 1.27 cm length of the needle was sufficient for the insulin/ glucagon to cross the dermis layer of the body and get absorbed in the shoulder of the patient. After the proper dosage of medicine delivery, the system stops. The medicine takes around 15 minutes to increase the level. If the condition still does not improve, a doctor should be contacted immediately, as this could be life-threatening for the diabetic patient. Until the health care arrives and the patient's condition does not improve, retake the reading for BGL, and the same procedure can be repeated after waiting 15 minutes from the first reading. After delivering the chemical, the DC motor reversed and the LCD instructed the patient to remove their arm. The IoT-enabled system also sent non-invasive BGL values to the patient's mobile, which could be accessed by the caretaker and doctor. The data could also be stored for future medical use, such as tracking non-invasive BGL history to provide better dosing and diet suggestions.

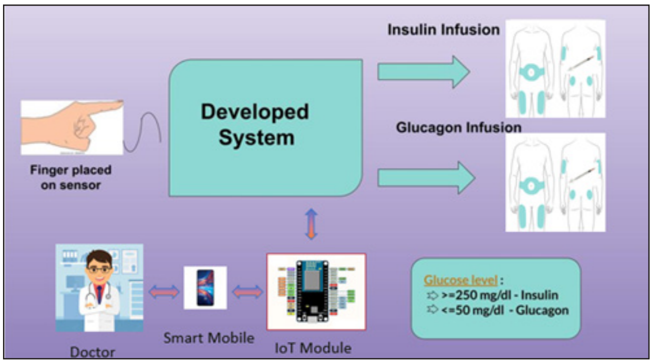

Figure 2.Block Diagram of the Procedure for the Diabetic Patient

Flowchart of IoT-Based Control System

The flowchart of the developed hardware is shown in Figure 3. It explains the working model of the proposed chemical injection system. The system works when the patient's blood glucose exceeds or below a particular range. First, the power is on, and then the microcontroller initialises with all the electronic parts attached to it, including LCD, relays, DC motors, optical sensors and IoT modules. The system asks the user to place the syringe's needle into the patient's upper arm. It then asks the user to put his forefinger in the hose made for the non-invasive blood glucose measurement. Then the microcontroller reads the non-invasive blood glucose level and then, based on the non-invasive blood glucose reading on the desired injection motor. For example, the time for insulin injection is based on Equation 3, and glucagon is based on Equation 5. The microcontroller also sends the data to the smart mobile via the IoT module in a specific format. After that, the motor returns to its initial value, and the loop repeats.

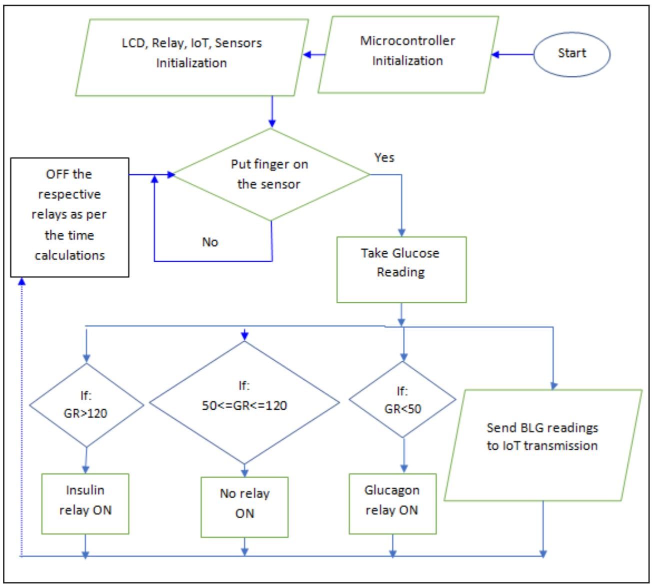

Figure 3.Flowchart for the Microcontroller Programme of the IoT System (Glucose Reading (GR))

Results

Prototype Model

The program for the microchip microcontroller used in the system was developed in C language using a microchip C compiler (open source), and the hex file was uploaded into the microcontroller's memory using Pickit 3 programmer. All the electronic components were connected as per the block diagram mentioned in Figure 1. The developed hardware prototype model is shown in Figure 4. The Infrared LED blood glucose monitor (IRLBGM) device has four main components: a 940 nm IR LED transmitter, a photo-sensor, a microcontroller, and an LCD. Once the system initiates, the patient can place their finger in the finger hose. Then, the IR beam travels through the finger, and the glucose level is calculated using Equation 1 and displayed on the LCD. The size of the prototype model is around 35*35*6 cm^3. The response time of the optical sensor was 10 sec. The overall hardware cost of the system was around 100$. The overall one-cycle time of the system was around 300 seconds.

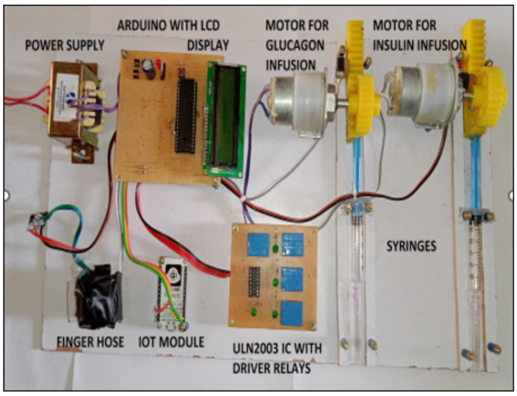

Figure 4.A Photograph of the Developed Prototype

The non-invasive BGL need to be calibrated at least one time before it is to be used by the diabetic patient. To calibrate the non-invasive BGL device from Accu-Chek Active (optical method instrument) was used to calibrate the non-invasive BGL. The developed system has an energy consumption of 1 wH. The range tested for glucose is 50–600 mg/dL. The shelf life of the developed system is in years as the system uses all the electronic components to measure non-invasive blood glucose. The limit of detection for the non-invasive BGL was found to be around 10 mg/dL. The system asks the user to put the needle into the patient's shoulder. If the needle goes the wrong way by the user's hands, the user can remove his hands from the place and re-enter the needle; after that, it will start the system. For the extreme readings of the findings for the non-invasive blood glucose, like in case of readings below 50 mg/dL, the system will alert the user and the caregiver mobile to send first aid for that person. In case the BGL values are in the medical concern zone, the system will also send an alert message to the caregiver and the doctor.

Software Platform

The open source platform name Cayenne software[16] was used as the smart mobile app for the caregiver. It helps interface the IoT devices to the smart mobile, and through this method, we get different data from the optical sensor on the smart mobile in real time using IoT technology. Figure 5 shows the graph obtained on the smartphone application using the IoT application. The higher values of non-invasive blood glucose levels on the graph are for the diabetic person post two hours after the food, and the lower values are for the healthy person taken before the food intake. The IoT-based system provides several advantages. First, the developed system uses a secure hash algorithm standard to ensure the authenticity of the user. The method is verified for the end user with the help of a real-time sample database and cloud storage. The test result shows that altering the patient's health record was identified immediately, and the patient's history remains safe from any false prescription. Finally, the monitoring of the BGL can be done in real-time with the help of IoT, which benefits the diabetic patient from further spreading the complications that arise from diabetes.

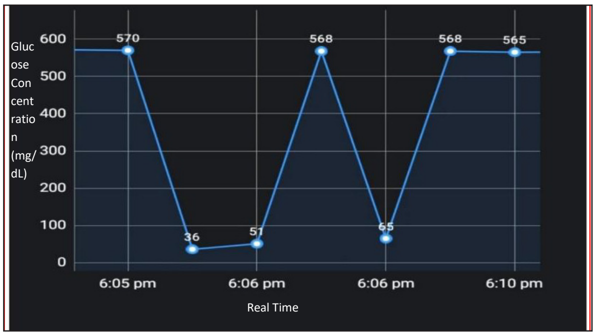

Figure 5.Readings of Non-Invasive Blood Glucose for the Person with Diabetes and the Healthy Persons

Clinical Results

The research presented a potential blood glucose monitoring IRLBGM device. It displays the blood glucose with a 10-second response time. The clinical study of the BGL to the non-invasive BGL values from IRLBGM was done for the twenty graduate students; the sample was collected during the symposium conducted by the Institute, and the consent forms were signed by the students whose BGL had been collected. 18 students from our college and two diabetic patients were tested to check the developed system's IRLBGM to BGL values, and the device's overall error range was 12.5% to 10.7% for the IRLBGM device. The results show that the developed system's data in the Clark A zone can be used in the medical field. The reference glucose levels were obtained with a finger-prick BGL device from the Accu-Chek optical model. The Student's t test value of 0.451 shows a good correlation between BGL and the non-invasive blood glucose values. Table 1 shows the BGL and the non-invasive blood glucose values for 20 subjects post-breakfast. To use the IoT-based injection system, the injection is inserted at the shoulder location and the size of the syringe needle is chosen so that it will release the chemicals in the desired part of the body only without husting other organs. To test the working of the injection system, we have used the plastic doll to simulate the human-based system. We had chosen the doll method due to the time constraint for the project work and the long clinical trials' approval procedure. To use the developed system, the user should clean the syringe and the site location, before use. It would be good if the device is shown to and tested on the user and its usage is explained in the presence of a medical expert, as it is intended to be used as a point-of-care device. The IoT will not cause any issues as it is being used only for the data transmission of non-invasive blood glucose.

Table 1.BGL and Non-Invasive Blood Glucose Values for Healthy and Diabetic Patients Taken at the Post-Breakfast Time

S. No	Sample Type (Diabetic/ Non-Diabetic)	BGL (mg/dL) (Post Breakfast)	Non-Invasive Blood Glucose (mg/dL) (Post Breakfast)	Error (±) (%)
1	Non-diabetic	120	115	4.2
2	Non-diabetic	110	100	9.1
3	Non-diabetic	115	120	-4.3
4	Non-diabetic	105	100	4.8
5	Non-diabetic	100	110	-10.0
6	Non-diabetic	125	135	-8.0
7	Non-diabetic	118	108	8.5
8	Non-diabetic	107	95	11.2
9	Non-diabetic	122	135	-10.7
10	Non-diabetic	100	95	5.0
11	Non-diabetic	90	95	-5.6
12	Non-diabetic	95	100	-5.3
13	Non-diabetic	105	100	4.8
14	Non-diabetic	110	105	4.5
15	Non-diabetic	115	110	4.3
16	Non-diabetic	112	115	-2.7
17	Non-diabetic	110	115	-4.5
18	Non-diabetic	108	113	-4.6
19	Diabetic	500	450	10.0
20	Diabetic	600	525	12.5

Discussion

A non-invasive blood glucose control system prototype has been developed for diabetes management. The system uses near-infrared spectroscopy to measure non-invasive BGL without the need for finger pricking. The system also has an insulin or glucagon injection system that can be used to automatically adjust BGL. The inclusion of glucagon in dual hormone closed loop systems appears to be effective in reducing overall hypoglycaemia and hypoglycaemia related to exercise. The system has been tested on a small number of subjects and has shown promising results in accordance with Hina and Saadeh.[17] However, more clinical trials are needed to verify the results along with system accuracy to assess the long-term safety and efficacy of the system. Precautions should be taken by the user while cleaning the site where the optical sensor and the syringe are to be inserted. The user must first be trained to use the system.

The system has several advantages over traditional invasive BGL monitoring systems which include providing more comfort to patients, as it does not require finger pricking, causes less pain and time consumption, and is associated with increased security, convenience, and enhanced patient engagement. It also has a broad market application prospect. It is also more affordable as the cost of the hardware was around 100$ and the software platform used was open source, also it does not require the use of disposable lancets. The system is also more portable, as it does not require a large, bulky device used in hospital settings.

Conclusion

The system has the potential to revolutionise the way BGL is monitored and managed. It could make non-invasive blood glucose monitoring more convenient and affordable for patients, and also help to improve patient outcomes in terms of better remote and self-monitoring of the patient in real time. The implementation of IoT-based injection systems could have a number of implications for healthcare management. IoT-based injection systems could help to improve the efficiency of healthcare delivery by reducing the need for people with diabetes to visit their doctor or nurse. IoT-based injection systems could help to improve patient outcomes by reducing the risk of hypoglycaemia and hyperglycaemia. IoT-based injection systems could help to lower healthcare costs by reducing the need for hospitalisations and other expensive treatments. In the future, controlling the complete system can be done by a doctor who is remotely controlling the device using IoT in real time. However, there are also a number of challenges like accuracy, and reliability associated with the development and implementation of IoT-based injection systems.

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Conflict of Interest: None

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