University of Babylon

College of pharmacy

Modern technology and prevent side effects of insulin

A Research Project Submitted

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Bechlor in Pharmacy

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(بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ)

وَقُل رَّبِّ زِدْنِي عِلْمًا

(صدق الله العظيم)

آية 114 سورة طه

DEDICATION

After 5 years of fatigue and hardship for the sake of knowledge, I carried within it the wishes of the nights, and my trouble became an apple to the eye.

With all love, I dedicate the fruit of my success and graduation to the one who beautified my name with the most beautiful titles and taught me that the world is a struggle and its weapon Is knowledge and knowledge (my father).

To the one whom God placed paradise under her feet and made adversity easy for me with her prayers (my mother)

To those who supported me with love when I was weak (my brothers and sisters)

To those whose presence was medicine, to the people of the House, peace be upon them

To the absent person who Is present with us, the rest of God on his earth, the one reserved to achieve justice, to the awaited Imam Mahdi, peace be upon him

To all those who provided me with strength and guidance, removed troubles from my path with their effort and knowledge, and brought me to where I am now (my teachers).

ACKNOWLEDGEMENT

At the beginning of my speech, I must first express my gratitude to God Almighty, who has enabled me to reach this high academic stage.

I also extend my thanks and gratitude to:

My dear father and my honorable mother, who were my first support in reaching what I have achieved.

I also extend my thanks to Asst lec SHAHAD AHMED ALHAMADANI her supervision and granting me a lot of time had the first hand in producing this scientific thesis in the form in which it appeared, and her guidance and advice played an essential role in completing my scientific studies.

Summary

Type 1 diabetes mellitus (T1D) occurs when the pancreas fails to produce insulin. Therefore, exogenous insulin therapy is critical to achieve glycemic control in patients with T1D and to prevent its complications.

Achieving and maintaining near-normal blood glucose and avoiding acute glycaemic complications remain challenging for many people with T1D, and solutions are often sought In devices such as Insulin pumps.While costly management options, these advances may ultimately prove cost-effective

According to national guidelines, IPT may be considered, and Is assumed to be most effective, for Individuals who fail to achieve an HbA1c of 7.0 % (53 mmol/mol) or experience recurring hypoglycaemia using MDI .

The main objective of our study was to compare insulin pump therapy, also known as continuous subcutaneous insulin infusion (CSII) with multiple daily insulin (MDI) in their efficacy of managing T1D in adult patients

The research employed a cross-sectional online survey utilizing questionnaires to gather data. The study population comprised individuals diagnosed with Type 1 Diabetes (T1D) who were undergoing treatment with MDI & with Insulin pump.

A total of 80 participants, with a age rang from 18_75 years , Were randomised (IPT, n = 40; MDI, n = 40) .

The results of our study were that using an insulin pump improves blood sugar levels, improves metabolic functions, delays the occurrence of complications that accompany diabetes, and improves quality of life.

Chapter one:

INTRODUCTION

1.1. Diabetes mellitus :- commonly known as just diabetes, is a group of metabolic disorders characterized by a high blood sugar level over a prolonged period of time. In order to maintain this blood glucose value In normal parameters, a careful monitoring of it and Insulin administration are necessary.(1)

1.2. Diabetes technology is the term used to describe the hardware, devices, and software that people with diabetes use to assist with self-management. **(2)**

This includes:

• Insulin delivery technology such as insulin pumps and connected Insulin pens

• Glucose monitoring devices meter (CGM system or Glucose meter) .

• More recently, Diabetes technology has expanded to include Hybrid devices that both monitor glucose and deliver Insulin.

• Also many Health Mobil Apps can provide diabetes self- management support

Diabetes technology, when coupled with education, follow-up, and support, can Improve the lives and health of people with diabetes.

Figure 1// Overview of diabetes technology over time: The journey to today

1. 3. Insulin is a hormone central regulating carbohydrate and fat metabolism in the body.

Insulin causes liver cells, muscle cells and fat tissue to take up glucose from the blood and store it as glycogen in the liver and muscle. (3)

1.3.1. Insulin Structure:

Insulin is a peptide hormone composed of 51 amino acids and has a molecular weight of 5808Da. (4)

Two chain polypeptide

A chain-21 AA , B chain-30AA . Held together by two disulfide bonds

•Insulin is produced and stored In the body as a hexamer, while the active form Is the monomer. (4)

1.3.2 Insulin Function

• Facilitates glucose transport across the cell membrane

• Facilitates AA entry and synthesis of protein In muscle

• Insulin and Its related proteins have been shown to be produced inside the brain, and reduced levels of these proteins are linked to Alzheimer's disease.

1.3.3 Insulin Related Diseases

1 .DIABETES MILLITUS

•An all-encompassing term for hyperglycemia or excessive blood sugar.

CLASSIFICATION:

•Type 1/Insulin dependent diabetes mellitus (IDDM)
•Type 2/Non insulin dependent diabetes mellitus (NIDDM)
•Gestational diabetes
•Impaired glucose tolerance and prediabetes. (5)

2. INSULINOMA

These are tumors of the pancreatic beta cells that lead to excess Production of Insulin and this results in hypoglycaemia .(6&7)

3. POLYCISTIC OVARY SYNDROME

A complex syndrome In women that includes features of anovulation, Excess androgens, hirsuitism, infertility etc .(8)

84. METABOLIC SYNDROME

•Dyslipidemia
•B.P$\geq$ 130/85
•↑waist measurements. (9)

1.3.4 Types of Insulin

There are several types of Insulin available for the management Of diabetes. Some common types include: **(10)**

1. Rapid-acting insulin analogs: These insulins have a fast onset Of action, typically within 15 minutes of Injection, and a Shorter duration of action compared to other types. Examples Include insulin lispro (Humalog), Insulin aspart (NovoLog), and Insulin glulisine (Apidra)
2. Short-acting insulin (Regular insulin): regular insulin takes Effect within 30 minutes to an hour after injection and has a Duration of action of 2-3 hours. It Is also known as soluble Insulin. An example of this is Humulin R
3. Intermediate-acting insulin: This type of Insulin has a slower Onset of action and a longer duration compared to rapid-Acting and short-acting insulins. Examples includee NPH insulin (Neutral Protamine Hagedorn) such as Humulin N and Novolin N. It typically starts working within 1-2 hours, peaks In 4-12 Hours, and lasts for up to 24 hours
4. Long-acting insulin analogs: These insulins provide a steady Release of insulin over an extended period, typically lasting 24 Hours or longer. Examples include insulin glargine (Lantus), Insulin detemir (Levemir), and insulin degludec (Tresiba)
5. Pre-mixed insulin: These insulins are a combination of rapid-Or short-acting insulin and intermediate-acting insulin in fixed Proportions. They provide both immediate and prolonged Sugar control. Examples include NovoLog 70/30, Humalog Mix 75/25, and Humulin 70/30

1.3.5. Adverse effects of insulin

1- Systemic advers effect

• Hypoglycemia: the most common and dangerous side effect. **(11)**
• Hypokalemia: insulin causes shift of K+ from extra- to Intracellular fluid.
• Hypersensitivity reactions: urticaria, Angioedema or anaphylactic shock. **(12)**
• Insulin resistance : failure of the body cells to respond to either Endogenous or exogenous Insulin. As a result, larger doses of Insulin are required to give the desired response. **(13)**

• wight gain

2- Local adverse effects:
• Allergy: at the site of injection, especially with animal insulin.
Treatment:Change the type of insulin. Local corticosteroids.
• Lipodystrophy: (atrophy or hypertrophy) of s.c. tissue after Repeated injections :
Treatment; rotating the injection site. **(14)**
• Local infection.

1.4. Insulin pumps

An insulin pump Is a small device that delivers Insulin through a small plastic tube (catheter). The device pumps insulin continuously day and night. It can also deliver Insulin more rapidly (bolus) before meals. Insulin pumps can help some people with diabetes have more control In managing blood glucose. **(15,16)**

The pump provides insulin to the body in two ways: **(17)**

1. Background (basal) insulin

Small amounts of insulin that are released continuously throughout the day.

2. Mealtime (bolus) insulin

Additional insulin can be delivered on demand to match food intake or to correct high blood sugar.

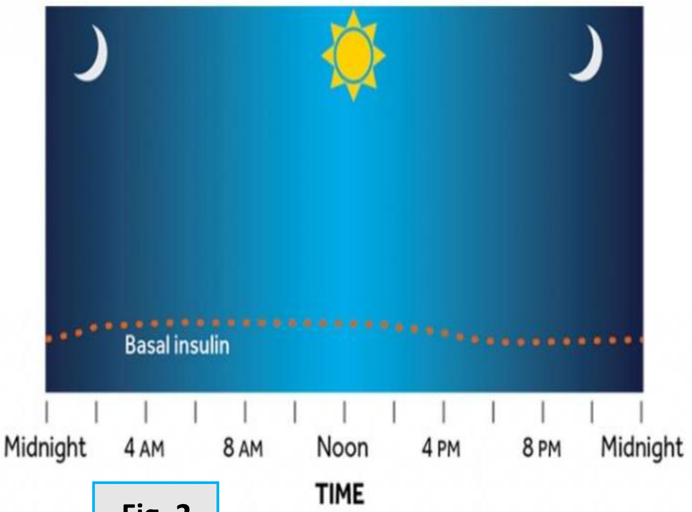


Fig. 2

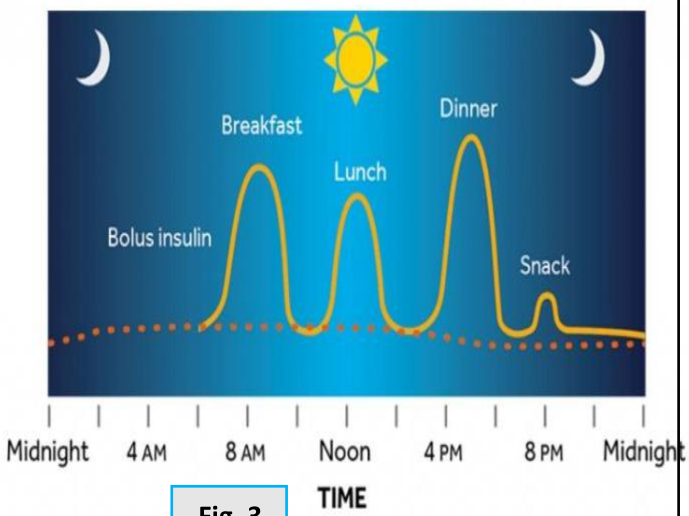


Fig. 3

1.4.1How does an insulin pump work? **(18)**

The pump sends insulin through a narrow plastic tube (a catheter) that ends in a tiny needle. The needle goes into skin. The tube and needle are called an infusion set. With most infusion sets, the needle pulls out, leaving a tiny flexible tube called a cannula under skin.

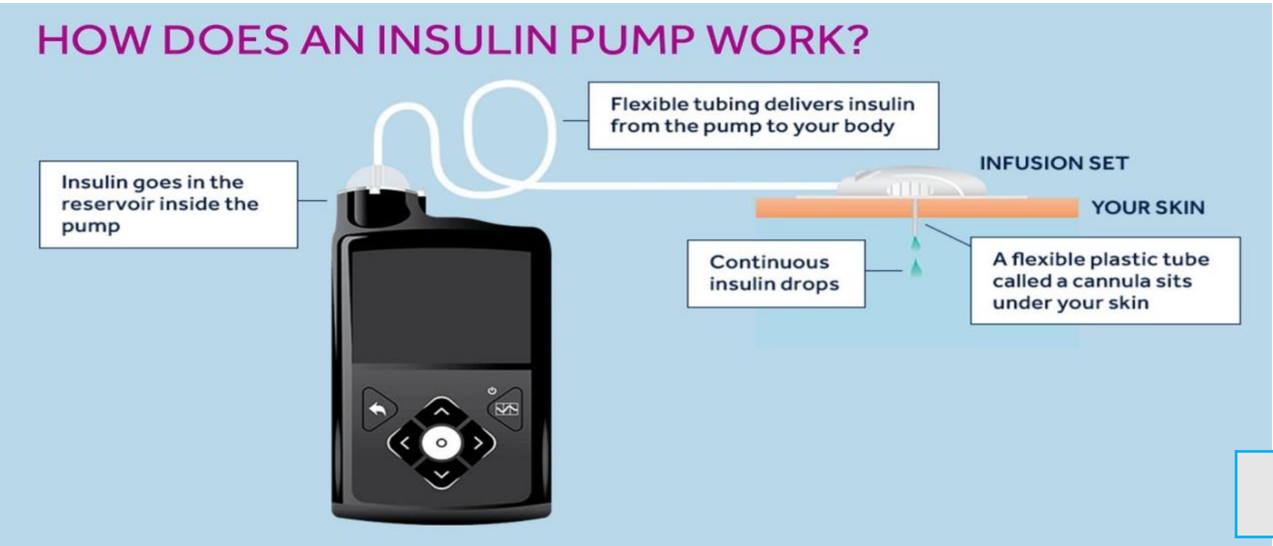


Fig. 4

Insulin must be stored at a temperature not exceeding 8°C. How Is insulin stored in insulin pumps even though temperatures may exceed 40°C?

To ensure insulin stability and efficacy, insulin pumps employ several mechanisms to preserve insulin at the appropriate temperature, even in changing air temperatures.

1.Internal Refrigeration.

Some advanced insulin pumps feature an integrated cooling system or refrigeration unit.

2.Insulated Casing: Most insulin pumps have an insulated casing that helps shield the insulin reservoir from external temperatures.

3. Insulin Cartridge or Pod Design: The insulin cartridges or pods used in insulin pumps are designed to maintain insulin at the optimal temperature for an extended period. Some cartridges or pods use temperature-controlled environments to ensure insulin remains stable, while others are designed with materials that help insulate the insulin.

4.emperature Alerts: Insulin pumps come with temperature alerts to notify users when the insulin temperature is outside the recommended range. When the temperature reaches a preset limit, the pump may stop delivering insulin, alert the user, or both.

1.4.2. types of insulin pump:

There are several brands of insulin pumps, but the two main categories are tubeless and tubed pumps.(19)

1. Tubless('tethered')pump uses a fine tube to connect the pump to the cannula; the pump is worn in a pocket or clipped to a belt.
2. patch pump or micro pump has no tubing or a very short tube, and the pump is usually stuck on to the skin .

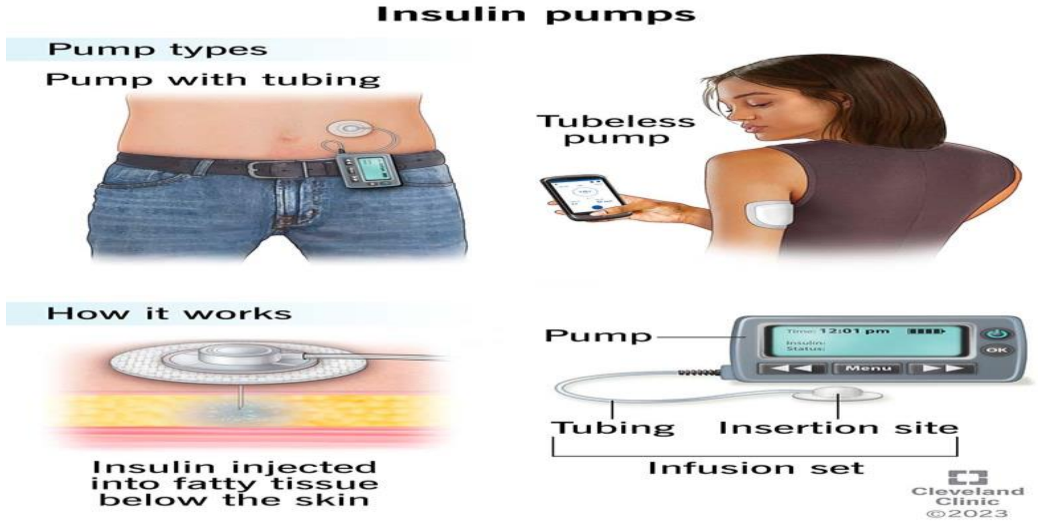


Fig. 5

1.4.3. Insulin pump and insulin adverse effects

-Insulin pumps can prevent or reduce many side effects of insulin through various mechanisms, including: (20)

- ❖ Hypoglycemia :-
  Insulin pumps can help prevent hypoglycemia in several ways. One key feature of an insulin pump is its ability to deliver insulin in small, precise increments, allowing for better control and avoidance of sudden drops in blood sugar levels. The pump can be programmed to deliver different basal rates of insulin throughout the day, mimicking the body's natural insulin secretion patterns and reducing the risk of hypoglycemia. Insulin pumps also offer customizable features such as temporary basal rates and insulin sensitivity settings. This means that users can adjust their insulin delivery to match their activity levels, meal times, or changes in insulin sensitivity. By having more control over insulin delivery, individuals with diabetes can better manage their blood sugar levels and lower the risk of hypoglycemia.
- ❖ Lipodystrophy:-
  Insulin pumps can help prevent lipodystrophy, a condition characterized by the loss of subcutaneous fat at injection sites, by providing consistent insulin delivery and allowing for proper site rotation. Lipodystrophy occurs when the same injection site is used repeatedly, causing damage to the subcutaneous tissue and leading to fat redistribution.

- allergic reactions
  insulin pumps can help prevent allergic reactions by offering different types of insulin infusion sets. These sets include various cannula and infusion options, such as stainless steel needles or flexible plastic catheters. This allows users to choose the type of infusion set that works best for them and reduces the likelihood of allergic responses to specific materials.

- Inconsistent insulin absorption:
  Insulin absorption can vary from one injection site to another, leading to inconsistent blood glucose control. Insulin pumps provide continuous and stable infusion of insulin, promoting more consistent blood sugar levels and reducing the risk of high or low blood sugar fluctuations caused by absorption inconsistencies.

- Over/under-dosing errors:
  With insulin pens or syringes, there is a potential for dosing errors due to manual calculations or incorrect insulin measurements. Insulin pumps allow for precise programming of insulin doses, reducing the likelihood of errors and enhancing overall accuracy. This occur by many mechanisms
  - Basal rate : Allows for continuous background insulin delivery at set rates throughout the day and night
  - Bolus delivery : Enables the user to deliver an extra boost of insulin to cover meals or correct high blood sugar levels
  - Carb counting : Allows for precise insulin dosing based on the number of carbohydrates consumed
  - Temporary basal rate : Lets users adjust their basal rate for specific situations, such as exercise or illness
  - Insulin on board (IOB) : Calculates the amount of insulin still active in the body from previous boluses and prevents insulin stacking, which can lead to hypoglycemia

A study compared insulin pumps and the use of insulin injections

Question

Are the rates of severe hypoglycemia and diabetic ketoacidosis lower with insulin pump therapy than with insulin injection therapy in young patients with type 1 diabetes?

Findings

In this population-based observational study including 30 579 young patients with type 1 diabetes, pump therapy, compared with injection therapy, was associated with significantly lower rates of severe hypoglycemia (9.55 vs 13.97 per 100 patient-years) and ketoacidosis (3.64 vs 4.26 per 100 patient-years), and with lower hemoglobin A1c levels (8.04% vs 8.22%) in a propensity score–matched cohort.

1.5. Continuous glucose monitor (CGM)

A continuous glucose monitor (CGM) is a wearable device that tracks blood glucose (sugar) every Few minutes without the need for fingersticks, throughout the day and night. The readings are relayed in real time to a device which Can be read by the patient, caregiver or health-care provider, even remotely. This can be lifesaving for people who experience low glucose at night and risk not waking up in the morning .**(21)**

1.5.1. Work of continuous glucose monitor (CGM) **(22)**

CGM systems work by continuously measuring glucose levels in the interstitial fluid, which is the fluid surrounding cells in your body. Here's how it works in detail:

1. Sensor Placement: A small sensor, usually about the size of a quarter, is inserted just under the skin, usually on the abdomen or arm. The sensor has a tiny electrode that measures glucose levels in the interstitial fluid. **(23)**
2. Glucose Measurement: The sensor uses an enzymatic reaction to detect the glucose levels around it. The enzyme reacts with glucose, producing a small electrical signal proportional to the glucose concentration.
3. Data Transmission: The sensor wirelessly transmits the glucose readings to a receiver or a smartphone app. Some CGM systems use Bluetooth or other wireless technologies, allowing you to conveniently monitor your glucose levels on your phone or other compatible
4. Data Interpretation: The receiver or app processes the glucose data and displays it as real-time glucose readings on a graph or numeric display. You can see your current glucose level, as well as the trend over the past few hours. **(24)**
5. Alarms and Alerts: CGM systems often have customizable alarms and alerts that notify you when your glucose levels are too high or too low. This helps you take prompt action to prevent dangerous situations such as hypoglycemia or hyperglycemia.
6. Trend Analysis: By examining the glucose trend line, you can identify patterns and make informed decisions regarding insulin doses, diet, and physical activity. CGM systems can provide valuable insights into how your glucose levels respond to various factors, allowing you to adjust your diabetes management accordingly.

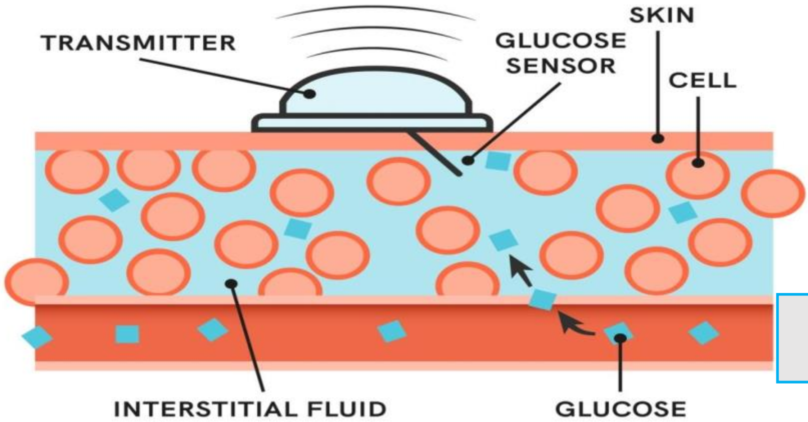


Fig. 6

CONTINUOUS GLUCOSE MONITOR (CGM)

There are a few different types of CGM (continuous glucose monitoring) systems available. Here are some common types:

1. Real-Time CGM: Real-time CGM systems provide continuous glucose readings in real-time. They typically consist of a sensor inserted under the skin and a receiver or smartphone app that displays the glucose data. This type of CGM allows you to monitor your glucose levels continuously throughout the day and night. **(25)**

2. Professional CGM: Professional or retrospective CGM systems are used in clinical settings or by healthcare professionals. They involve wearing a CGM device for a specified period, such as a few days or a week. After wearing the device, the collected glucose data is analyzed and used to assess your glucose patterns and make treatment adjustments if necessary. (26)

3. Flash Glucose Monitoring: Flash glucose monitoring systems, also known as "intermittent scanning" systems (without transmitter) also use a sensor placed under the skin. However, instead of providing continuous glucose readings, they require users to scan the sensor with a reader or smartphone app to obtain glucose readings. This type of CGM eliminates the need for fingerstick calinecessary. **(27,28)**

4. Integrated Insulin Pump CGM: Some insulin pumps have integrated CGM functionality. These systems combine insulin delivery and continuous glucose monitoring Into a single device, eliminating the need to carry separate devices.

5. Disposable Patch CGM: Disposable patch CGM systems use a small sensor patch that is worn on the body. The sensor patch is usually discarded after a certain period, such as one to two weeks, and replaced with a new one.

CGM categories

Professional	Personal
Blinded and unblinded (real-time feedback) options	Real-time feedback or scan for instant feedback (flash device)
Short term use (3-14 days)	Long term use
Continuous monitoring	Continuous monitoring
Alarms for hypo/hyperglycemia in select devices	Alarms for hypo/hyperglycemia in select devices
Insurance coverage for most people with type 1 or type 2 diabetes	Insurance coverage more limited to type 1 diabetes or those on MDI insulin
Not compatible with smartphones or insulin pumps	Compatibility with smartphones and insulin pumps with select devices
Not FDA approved for insulin dosing (must always confirm with a glucose meter)	Select devices approved for insulin dosing

Fig .7

1.5.2. The relationship between CGM and preventing insulin side effects

CGM does not directly prevent side effects of using insulin, it can provide valuable information and help individuals manage their blood sugar levels more effectively, potentially reducing the risk of experiencing certain side effects associated with Insulin therapy.

CGM devices provide real-time data on blood sugar fluctuations throughout the day and night. This information can help individuals make informed decisions regarding insulin dosing, diet, and physical activity. By having a better understanding of their glucose patterns, individuals may be able to fine-tune their insulin regimen and avoid extreme fluctuations in blood sugar that can lead to hypoglycemia (low blood sugar) or hyperglycemia (high blood sugar). **(29)**

Additionally, CGM systems can provide alerts and alarms to warn individuals when their glucose levels are reaching potentially dangerous levels. This can help prevent severe hypoglycemia or hyperglycemia and allow for timely interventions.

1.5.3. Relationship between CGM & Time in range

Time in Range

TIR is relatively new term used within the diabetes community , It describes the percentage of time the bloodglucose levels stay within a target range(Target range from 70 -180 mg/dl for most patient)

The goal for many non pregnant adults is TIRof at least 70 % with TBR <4% and TAR <25%. Meaning roughly 17 out of 24 hourseach day to be in range.

There is a direct relationship between continuous glucose monitoring (CGM) and time in range for people with diabetes. Time in range refers to the amount of time a person's blood sugar levels are within a target range. CGM devices play a crucial role in providing real-time glucose level data, allowing individuals to monitor and manage their blood sugar levels more effectively, ultimately aiming to maximize their time spent in the target range.

TIR is calculated automatically in the software that comes with the CGM deviceor mobile application .**(30 ,31)**

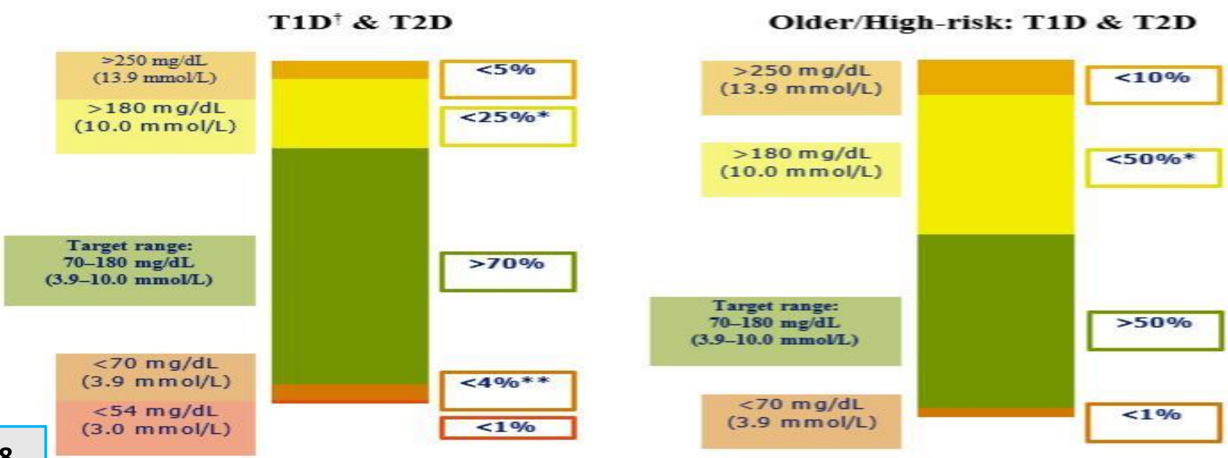
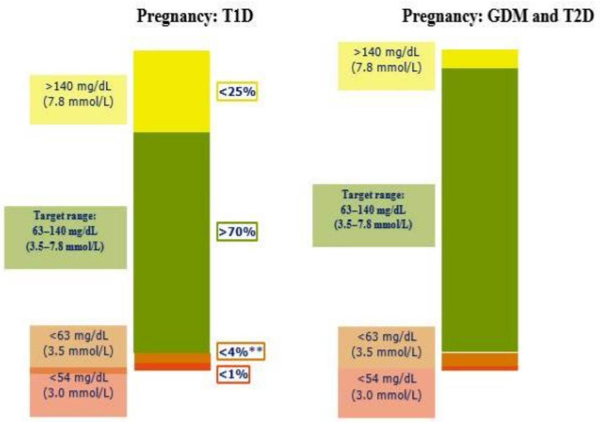


Fig. 8

Fig. 9



1.6. Artificial Pancreas

- The Artificial Pancreas Device system is a system of devices that closely mimicsthe glucose regulating function of a healthy pancreas.(32)

Sometimes an artificial pancreas device system is referred to as a "closed-loop "System, an "automated insulin delivery" system, or an "autonomous system for a Glycemic control." (33)

The first hybrid closed loop system, the Medtronic's MiniMed 670G System is the first FDA approved artificial pancreas. (34)

The FDA approved it for treating type 1 diabetes in people age 14 and older.

1.6.1. Artificial Pancreas components

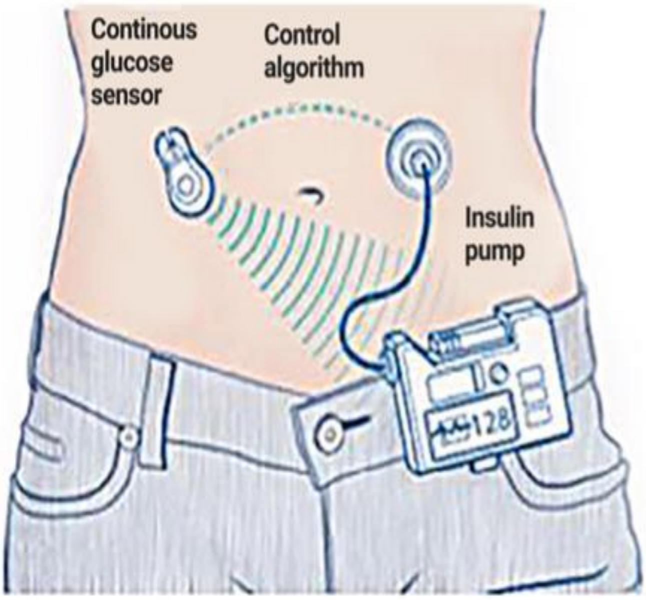
The artificial pancreas typically consists of four main components: (35)

1. Continuous Glucose Monitor (CGM): This device measures the glucose levels in the body continuously or at regular intervals. It provides real-time glucose data to the control algorithm.
2. Insulin Pump: The insulin pump delivers insulin into the body based on the instructions from the control algorithm. It can continuously provide basal insulin and also administer bolus doses for mealtime or correction.
3. Control Algorithm: The control algorithm serves as the intelligence behind the artificial pancreas system. It receives glucose data from the CGM and calculates the appropriate insulin dose based on various factors. The algorithm then sends instructions to the insulin pump.
4. Blood Glucose Meter: Some artificial pancreas systems include a separate blood glucose meter to cross-check the accuracy of the CGM readings. This helps ensure accurate insulin dosing decisions

1.6.2. Artificial Pancreas and insulin side effects

While the artificial pancreas system can help regulate Insulin delivery and Improve diabetes management, It may not completely eliminate all insulin side effects. Insulin itself can have potential side effects, including:

1. **Hypoglycemia**: The artificial pancreas system aims to prevent hypoglycemia (low blood sugar) by adjusting insulin doses based on real-time glucose measurements. However, there can still be situations where hypoglycemia may occur, such as during exercise, incorrect input of meal information, or system malfunctions.**(36,37)**
2. **Hyperglycemia**: Similarly, the artificIal pancreas system tries to avoid hyperglycemia (high blood sugar) by delivering appropriate amounts of insulin. However, not all factors influencing glucose levels can be accounted for, and there may be instances where hyperglycemia can occur.
3. **Insulin Absorption Issues:** Insulin absorption can vary from person to person, and factors like infusion site issues or insulin degradation can affect its effectiveness. While the artificial pancreas system can optimize insulin delivery, individual factors can still influence the overall impact.
4. **Allergic reactions or site irritations:** some individuals may experience allergies or skin irritations at the infusion site due to factors like adhesives or components of the system. It is important to be aware of these potential Issues and consult with a healthcare professional regarding any concerns.



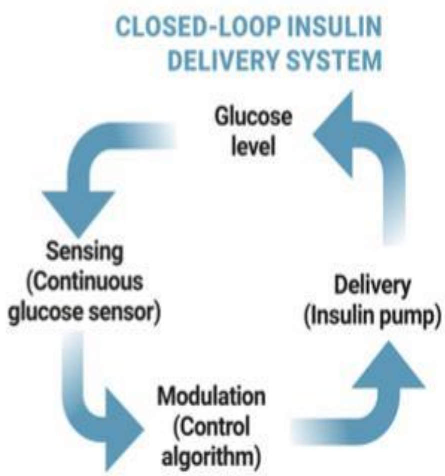


Fig. 10

1.7. Smart insulin pen

A smart insulin pen is a technologically advanced device used by individuals with diabetes who require insulin therapy. It is designed to help users accurately administer insulin doses, monitor their glucose levels, and track their insulin usage for better diabetes management.

Smart insulin pens often come with features such as Bluetooth connectivity, built-in memory, and compatibility with smartphone applications. These features allow the pen to communicate wirelessly with other devices or apps, making it easier for individuals to keep track of their insulin doses and glucose readings.**(38,39,40)**

The Smart insulin pen consists of several parts, each serving a specific function. Here's a brief overview:

1. Pen Body: The main body of the pen holds the insulin cartridge and is responsible for delivering the correct dose of insulin.

2. Dosing Button: The dosing button allows the user to select and administer the desired dosage of insulin.
3. Display Screen: The display screen provides information such as the selected dose, injection history, and reminders. It helps users track their insulin usage and manage their diabetes effecinsulin
4. Bluetooth Connectivity: The Smart insulin pen is equipped with Bluetooth technology, allowing it to connect to a smartphone or other devices. This connectivity enables data transfer, including insulin dosage information and other important metrics.
5. Preferences and Settings: The Smart insulin pen may have additional buttons or controls for configuring various preferences and settings. These can include options for basal rate, mealtime insulin ratios, and reminders for blood glucose monitoring.
6. Memory Storage: The pen may have built-in memory storage to store historical data related to insulin doses, injection times, and other relevant information. This data can be accessed by healthcare professionals or used for personal record-keeping.
7. Sensor Technology: In some advanced Smart insulin pens, there may be built-in sensors to monitor blood glucose levels continuously. These sensors can provide real-time feedback and help users make informed decisions about their insulin dosage.
8. Battery: The pen may be powered by a rechargeable battery or disposable batteries, depending on the model. The battery ensures the pen's functionality and enables features like the display screen and Bluetooth connectivity.
9. Pen needle: It is the disposable, fine needle attached to the pen for injecting insulin. The needle is typically detachable and replaced for each injection.

Smart insulin pens

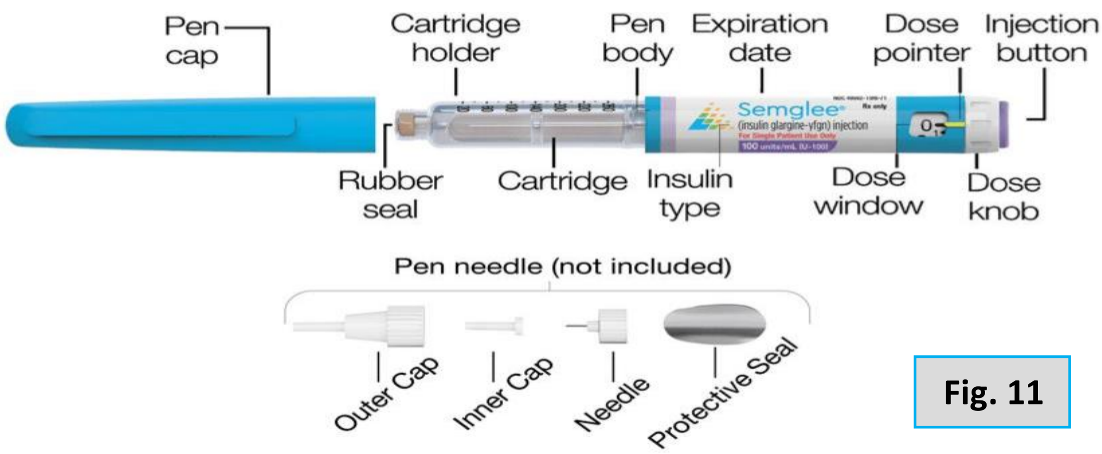


Fig. 11

1.7.1. Smart insulin pen and insulin side effects

• Hypoglycemia :- Smart insulin pens have been developed to help prevent hypoglycemia in individuals with diabetes. These pens are equipped with integrated technology that monitors blood sugar levels and delivers the appropriate insulin dosage based on the readings. By constantly monitoring glucose levels and adjusting the insulin doses accordingly, smart insulin pens can help individuals avoid episodes of hypoglycemia, which can be dangerous and potentially life-threatening.(41)

• Lipodystrophy :- smart insulin pens can indirectly help reduce the risk of lipodystrophy by providing features that promote proper injection technique and rotation of injection sites. These features can remind users to rotate injection sites regularly, preventing the accumulation of fat deposits in specific areas. Additionally, some smart insulin pens have built-in injection tracking and reminder functionalities to ensure that users follow proper injection.

• Weight gain:- Smart insulin pens themselves do not directly prevent weight gain.smart insulin pens can assist users in adhering to their prescribed insulin regimen and maintaining optimal blood sugar control. When blood sugar levels are well-managed, it may help prevent excessive hunger, cravings, and potential weight gain associated with fluctuations in glucose levels.

1.8. Needle free insulin delivery

Needle-free insulin delivery refers to alternative methods of administering insulin without the use of traditional injection needles. These methods aim to provide a more convenient and painless way for individuals with diabetes to receive their insulin doses. Here are a few examples of needle-free insulin delivery :(42,43)

1. Inhalable Insulin: This method involves delivering insulin through the lungs using an inhaler. The insulin is inhaled as a fine mist, allowing it to be absorbed directly into the bloodstream .(44)

2. Insulin Patches: These patches contain small microneedles that do not penetrate the skin. The microneedles dissolve upon contact with the skin, releasing insulin into the body. (45)

3. Insulin Jet Injectors: These devices use high-pressure streams of insulin to penetrate the skin and deliver the medication. The insulin is delivered as a fine jet, without the need for needles. (46)

4. Insulin Sprays: Insulin sprays are administered directly onto the skin, where it quickly absorbs into the bloodstream. This method eliminates the need for injection needles.

5. Insulin Pens: Insulin pens are devices that contain a cartridge of insulin and a disposable needle. The needle is inserted into the pen, and a dial is used to select the desired insulin dose. The insulin is then injected using a button or trigger.

6. Insulin Nasal Spray: This method involves delivering insulin through the nasal passages. Insulin is sprayed into the nose, where it is absorbed by the nasal mucosa and enters the bloodstream.

7. Insulin Pills: Currently, oral insulin pills are in development. These pills aim to deliver insulin through the digestive system, bypassing the need for injections entirely. However, they have yet to reach widespread availability, and more research is needed.

1.8.1. Types of Needle-Free Injection Devices

Several types of needle-free injection systems are available In the market, each with unique features and advantages .
They include-:
Spring-powered injectors, powder injectors,& jet injectors.
The most common type of needle-free injector is the jet Injector device, used for vaccines, insulin, hormones, and other pharmaceutical applications. InsuJet Is an excellent example of a needle-free jet injector.
Needle-free jet injectors are often called jet gun Injectors, air guns, or pneumatic injectors. They can either be single-use, also called DCIJs (disposable cartridge jet injectors) or multi-use, also called MUNJIs (multi-use nozzle jet Injectors).

The number of times an injector can be used depends on the type of medication you take and the manufacturer.
For example, InsuJet, a multi-use injector, can be used up to 5,000 times to deliver your daily Insulin dose.

Fig. 12

1.8.2. Needle-free insulin delivery and insulin side effects

• lipodystrophy :- Needle-free insulin delivery systems, such as Insulin pens or insulin pumps, can help prevent lipodystrophy. These devices use fine needles or catheters to deliver insulin without the need for traditional Injections. By using alternative delivery methods, the risk of developing lipodystrophy is reduced.

Insulin pens typically use disposable needles that are thinner and shorter than traditional syringes, reducing the trauma to the skin and the risk of fat tissue damage. Insulin pumps, on the other hand, use a small catheter inserted under the skin, delivering insulin continuously or in programmed doses.

By avoiding repeated needle Injections in the same area, needle-free insulin delivery reduces the likelihood of lipodystrophy.

• weight gain :- Needle-free insulin delivery methods can potentially help prevent weight gain in individuals with diabetes. Traditional insulin injections can sometimes lead to weight gain due to factors such as increased appetite and insulin absorption issues. However, needle-free alternatives, such as insulin pumps or inhalable insulin, may offer more precise dosing and better glucose control, which can contribute to better weight management

Chapter 2:

Methodology

•Insulin pump therapy can improve quality of life and glycaemic control for many people with type 1 diabetes. people using insulin pumps achieve better metabolic outcomes compared with people using multiple daily injections (MDI) so in this study we compared between DM patients who use insulin pump & who use MDI .

We aimed to estimate effects of insulin pump therapy (IPT) on HbA1c level, and severe hypoglycaemia (SH),&BMI &Microvascular complications& Macrovascular complications compared with multiple daily insulin injections (MDI).

In Sweden , most individuals with T1D are seen in specialist diabetes outpatient clinics, and treatment is fully subsidised by the public healthcare system.

Objective: The main objective of our study was to compare insulin pump therapy, also known as continuous subcutaneous insulin infusion (CSII) with multiple daily insulin (MDI) in their efficacy of managing T1D in adult patients .

3.1. Material &Methods:-

Data sources & population :-

The data used in this study come from national Danish registries . We accessed the information through a group created on the Facebook platform, which included a number of type 1 diabetics residing in Sweden, where we contacted them and asked 40 people to fill out the questionnaire.

We identified all adults (≥18 years) who were alive and residing in Sweden as of 2023 who had ever been diagnosed with T1DM .

Methods:-

• The research employed a cross-sectional online survey utilizing questionnaires to gather data. The study population comprised individuals diagnosed with Type 1 Diabetes (T1D) who were undergoing treatment with MDI & with insulin pump. The participants may or may not have been utilizing Continuous Glucose Monitoring (CGM) .

• We identified a cohort of all adults with type 1 diabetes in Sweden using cross-sectional online survey these individual use either IPT (treatment) or MDI (control)

• We estimated treatment effects among population subgroups using treatment-staggered difference-in-differences.

•We evaluated the potential heterogeneity effects, we estimated the ATTs for each result for the following subgroups: male versus female, lower than average age, age groups (18 to 25 years, 25 to 50 years, 50 to 75 years old), lower vs higher educational achievement (primary, high school or vocational school versus short or medium higher education) .

Chapter 3:
RESULTS

Variable		Treatment arm	
		IPT(total person 40) person 40)	MDI (total
Age groups	18- 25	7 person (18%)	11 person (28%)
	25-50	23 person (58%)	20 person (50%)
	50- 75	10 person (25%)	9 person (23%)
Sex	male	27person (68%)	21 person (53%)
	female	13 person (33%)	19 person (48%)
Education	Primary	0	10 person (25%)
	High school or vocational school	2 person (5%)	13 person (33%)
	Short or medium higher education	38 person (95%)	17 person (43%)
Duration of type 1 diabetes (years)	< 25 years	26 person Without IPT(medium 15 years) With IPT (medium 9 years)	24 person (60%)
	≥ 25 years	14 person without IPT (medium 7 years) With IPT (medium 4 years)	16 person (40%)
Type of Insulin pump	Insulin pump with tubing	27 person (68%)	
	Insulin patch pump	13 person (33%)	

Variable		Treatment arm IPT(total person 40)	MDI (total person 40)
Use CGM with IPT		17 person (42 %)	
HbA1c % (CI)		7.2 (7.1-7.3)	7.6 (7.4 _7.7)
Severe hypoglycemia event in the past 6 month	0	26 person (65%)	19 person (48%)
	1	9 person (23%)	15 person (38%)
	2 or more	5 person (13%)	6 person (15%)
BMI		~ 28.1 (26.5 - 31.0)	~27.5 (26.7 - 31.3)
History of microvascular complications		15-16 person (40%)	21-22 person (52%)
History of macrovascular complications		6-7 person (15%)	9-11 person (22%)
Amputation of lower extremity		0	0

Results: A total of 80 participants, with a age rang from 18_75 years , Were randomised (IPT, n = 40; MDI, n = 40) .

27(68%)men and 13 (33%)women

• The Incidences of severe hypoglycaemia one time (IPT , 23%; MDI, 38% participants) .

• Among responders, 27 (68%) used an insulin pump with tubing and 13 (33%) used a patch pump.

• In our study the number of patients who used CGM with IPT were 42%

• The amount of HBA1C in IPT users 7.2 (7.1 – 7.3). For MDI users was 7.6 (7.4 – 7.7).

• The BMI was for IPT users ~ (28.1). For MDI users it was ~ (27.5).

As for the complications of diabetes, it was less common for IPT users compared to MDI users.

Discussion

The results of our study demonstrated that In our population with T1D, those who used CSII as a mode of insulin delivery have improved hemoglobin A1c levels and glycemic profiles compared to those who are on an MDI regimen. Most of the Improvement in HbA1c in the CSII group occurred during the first 3 months after Initiation of pump therapy.

Studies that compared CSII to MDI have shown that most of the improvement in HbA1c occurs in the first few months after Initiation of CSII, **(47-48)** . which is In agreement with our observations. The InItial prominent reduction in HbA1c after initiation of CSII may be related to intensification of insulin therapy during this time compared to the previous insulin regimens applied. However, further improvement in HbA1c does not typically occur after 6 to 12 months; and In some studies, this Improvement is not necessarily sustained,**(47,48,49).** This is likely due to an element of diabetes burnout**(50-51)** or due to loss of enthusiasm for the new technology. Generally the reason behind this Is not clear and needs to be further explored, as understanding factors that can positively influence motivation and compliance Is essential to appropriately manage individuals with T1D. However, the longer sustaInability of a positive effect of a pump could be reflected on the commitments of patients/family to Intensification of treatment.

Based on the concept of metabolic memory, this persistent improvement in glycemic control during the study period should translate into a reduction of diabetes related complications such as retinopathy and nephropathy, which in turn should lead to reduced healthcare costs related to diabetes complications. It would be interesting to explore cost-effectiveness in future studies, comparing the cost of CSII with the long-term reduction in healthcare costs related to decreased burden of diabetes complications.

The improvement In HbA1c in the CSII group compared to the MDI group is related to many factors. Despite both groups having a similar total daily dose of insulin, the distribution of insulin administration in the CSII group matches carbohydrate intake better than in the MDI, with the majority of carbohydrate intake covered by rapid insulin. Additionally, compliance in the CSII group with prandial insulin is likely higher, with users administering rapid insulin for snacks especially since they do not require injections to be administered.

However, the CSII group have more frequent visits with specialized diabetes educators and dieticians in the clinic, particularly during the first few months after pump initiation. Diabetes education as well as frequent follow up have a positive impact on glycemic control.An additional factor to be considered is enthusiasm and motivation due to the novelty of the insulin pump and the use of new technology, which may contribute to better compliance to insulin administration. Understanding the factors that help drive patient motivation is essential to reduce rates of diabetes burn-out.

An increase in BMI was noted in both the MDI and the CSII groups in our study, which is an expected finding given the anabolic function of insulin.

In concordance with our findings, observational studies have found an association between the use of CSII and increased weight gain,**(52-53)** . A study conducted in Kuwait had a similar result despite a reduction in insulin daily dose. Kuwait's study stated that the significant increase in BMI in patients on CSII therapy may have been due to the liberty to eat without receivIng extra injections of Insulin, **(54)** .On the other hand, other studies including randomized controlled trials, large cohort-matched studies and systematic reviews, did not find a significant difference between CSII and MDI with regards to weight or BMI,**(55,56,57)** . The need of long-term studies is a necessity to determine the actual effect of both treatments on BMI.

Conclusion:-

The addition of CGM and the development of closed-loop systems may offer further improvement of glycemic control without the risk of hypoglycemia. While costly management options, these advances may ultimately prove cost-effective.

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جامعة بابل
كلية الصيدلة

التكنولوجيا الحديثة ومنع الاثار الجانبية للانسولين

مشروع بحث مقدم إلى قسم كلية الصيدلة / جامعة بابل استكمالاً لمتطلبات درجة البكالوريوس في الصيدلة

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2024 م

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الأهداء

بعد تعب ومشقه دامت 5 سنوات في سبيل العلم حملتُ في طياتها امنيات الليالي ، واصبح عنائي للعين قُرّة .

وبكل حب اهدي ثمرة نجاحي وتخرجي الى الذي جمّل اسمي بأجمل الالقاب وعلمني أنَّ الدنيا كفاح وسلاحها العلم والمعرفة(ابي)

الى من جعل الله الجنة تحت قدميها وسهلت لي الشدائد بدعائها (امي)

الى من ساندوني بكل حب عند ضعفي (اخوتي واخواتي)

إلى من كان وجودهم الدواء إلى اهل البيت عليهم السلام

إلى الغائب الحاضر معنا بقية الله في أرضه المدخر لتحقيق العدل إلى الإمام المهدي المنتظر علية السلام

الى جميع من امدّوني بالقوة والتوجيه وازاحوا عن طريقي المتاعب بجهدهم وعلمهم واوصلوني الى ما انا عليه الان (اساتذتي) .

شكر وتقدير

في بداية كلمتي لا بدّ لي من أتوجه اولاً بالشكر لله عزّ وجلّ الذي وفقني للوصول الى هذه المرحلة العلمية العالية .

كما انني أتوجه بالشكر والامتنان لكل من:

والدي العزيز ووالدتي الكريمة الذين كانوا السند الاول لي في الوصول الى ما وصلت اليه.

كما أتوجه بالشكر والامتنان الى الدكتوره شهد أحمد الحمداني فقد كان لإشرافها ومنحها الكثير من الوقت لي اليد الأولى في خروج هذه الرسالة العلمية بالشكل الذي ظهرت عليه، كما كان لتوجيهاتها ونصائحها دور أساسي في إتمام دراستي العلمية.

الخلاصه :-

يحدث داء السكري من النوع الأول (T1D) عندما يفشل البنكرياس في إنتاج الأنسولين. لذلك، يعد العلاج بالأنسولين الخارجي أمرًا بالغ الأهمية لتحقيق التحكم في نسبة السكر في الدم لدى مرضى T 1D ومنع مضاعفاته.

لا يزال تحقيق مستوى السكر في الدم شبه الطبيعي والحفاظ عليه وتجنب مضاعفات نسبة السكر في الدم الحادة يمثل تحديًا للعديد من الأشخاص المصابين بداء السكري من النوع الأول، وغالبًا ما يتم البحث عن حلول في أجهزة مثل مضخات الأنسولين. وعلى الرغم من أن خيارات الإدارة مكلفة، إلا أن هذه التطورات قد تثبت في النهاية فعاليتها من حيث التكلفة

وفقًا للمبادئ التوجيهية الوطنية، يمكن اعتبار العلاج IPT، ويُفترض أنه الأكثر فعالية، للأفراد الذين فشلوا في تحقيق مستوى HbA1c بنسبة 7.0% (53 مليمول/مول) أو الذين يعانون من نقص سكر الدم المتكرر باستخدام أجهزة الاستنشاق بالجرعات المقننة.

كان الهدف الرئيسي من دراستنا هو مقارنة العلاج بمضخة الأنسولين، المعروف أيضًا باسم التسريب المستمر للأنسولين تحت الجلد (CSII) مع الأنسولين اليومي المتعدد (MDI) في فعاليتهما في إدارة مرض السكري من النوع الأول لدى المرضى البالغين.

استخدم البحث مسحًا مقطعيًا عبر الإنترنت باستخدام الاستبيانات لجمع البيانات. يتألف مجتمع الدراسة من أفراد تم تشخيص إصابتهم بمرض السكري من النوع الأول (T1D) والذين كانوا يخضعون للعلاج باستخدام أجهزة الاستنشاق بالجرعات المقننة ومضخة الأنسولين.

تم اختيارهم بشكل عشوائي إجمالي 80 مشاركًا، تتراوح أعمارهم بين 18 و75 عامًا (IPT، n = 40؛ MDI، n = 40).

وكانت نتائج دراستنا أن استخدام مضخة الأنسولين يحسن مستويات السكر في الدم، ويحسن وظائف التمثيل الغذائي، ويؤخر حدوث المضاعفات التي تصاحب مرض السكري، ويحسن نوعية الحياة.