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TECHNOLOGY IN THE TREATMENT OF DIABETES

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INTRODUCTION

The goal of the treatment of diabetes mellitus (DM) is to achieve the best compensation without severe hypoglycaemia or hyperglycaemia. This rule was valid in the last century and it still is. What has been changing and improving is the technology in diabetology.

There are many studies that describe the positive contribution of the treatment with an insulin pump in relation to the values of glycated haemoglobin (HbA1c). Glycated haemoglobin is a long-term indicator of diabetes mellitus compensation. The target values of diabetes mellitus type 1 (DM1) are established at under 60%.

The results of the clinical study DCCT (Diabetes Control and Complications Trial) confirmed that if we decrease HbA1c by 1%, we decrease the risk of complications in minor arteries by up to 40%. The study from 2008 proved the decrease of severe hypoglycaemia during the treatment with insulin pump and the improvement of glycated haemoglobin. It was compared to the use of an insulin pen.

Insulin pump is suitable for stabilizing the so-called labile diabetes. It decreases the incidence of hypoglycaemia and provides better balance in the values of night hypoglycaemia and morning hyperglycaemia. A long-term continuous monitoring of glucose helps to keep glycaemic values within a satisfactory range. Patients also benefit from the safety system, which protects them from hypoglycaemia. Insulin pumps with a hybrid closed-loop system regulate the basal insulin dose. Their goal is to keep the patient's goal values of glycated haemoglobin.

What do(n't) we know about diabetes?

Many people associate diabetes with the excessive sugar intake from food. However, this not so regarding diabetes mellitus type 1. Diabetes mellitus type 1 occurs because beta cells in pancreatic islets stop producing insulin. This condition is auto-immune, i.e. one's own immunity attacks these cells. When glucose is absorbed into the blood after a meal and glycaemia increases, there is no command to use glucose as a source of energy. Glucose circulates in the blood and glycaemia is high (hyperglycaemia). In order to use glucose efficiently as an energy source, we need insulin, which serves as a key (in layman's terms) to allow glucose to enter the cells.

This type of diabetes mellitus is most common in children, adolescents, and young adults. It can occur at a later age as well, and the only treatment is the lifelong application of insulin. Diabetes mellitus type 1 is not associated with age, being overweight or obese, or the excessive consumption of sweet food. On the other hand, diabetes mellitus type 2 mostly occurs at older age (senile diabetes) – and this is the case in most diabetics.

Types of treatment of diabetes mellitus type 1

Patients with DM1 have two possibilities to supply their body with insulin. The first option is an insulin pen. A diabetic applies insulin with a prolonged effect 5 times a day, and short-term insulin 3–4 times a day before meals or to balance glycaemia. The second option is an insulin pump – which will be discussed further later.

What is an insulin pump?

What does an insulin pump look like?

A modern insulin pump looks like an older type of mobile phone or an MP4 player. This device contains a tank with short-term insulin. A piston presses the tank bottom and provides doses of insulin. The other side of the tank is connected by a tube (approximately 60cm long), which is linked to a cannula. The cannula is inserted in the subcutis, where insulin is absorbed. It is changed every 2–3 days. The necessary parts of the pump are the display and control buttons. The source of energy is mostly a regular battery.

Dosing insulin

Insulin pumps mimic a healthy pancreas. On a daily basis, a healthy pancreas produces micro doses of insulin. When we start eating, the pancreas produces a larger dose to cover the carbohydrates from food. Insulin pumps are based on the same principle. It is simple, isn't it?

The basis of the insulin pump therapy is the insulin dose (established by a doctor on the basis of individual needs), the so-called *basal dose*, which covers the period between meals and during the night. Another dosing type is *bolus dose*, which covers carbohydrates from food or balances hyperglycaemia (balance bolus).

The history of insulin pumps

The first insulin pump, which was the size of a backpack, was produced in 1963. The first commercially used pumps were the size of a brick and became part of diabetes mellitus therapy at the end of the 1980's. In the Czech Republic, the history of the insulin pump goes back to 1983, when such a pump was used in wrongly compensated patients. In 1985, the first diabetic was discharged for outpatient treatment with an insulin pump.

Today's goal is not only to produce pumps that dose insulin. Modern technologies are focusing on closed loop, i.e. devices that regulate insulin for themselves on the basis of glucose levels.

Why are insulin pumps magical devices?

Pumps are not only interesting due to the way they copy the secretion of insulin from a healthy pancreas. There are many functions that help their users to achieve better compensation better. We can use a metaphor to explain a diabetic's life better.

Imagine a man walking on a rope. He needs his arms to maintain balance. With diabetes, it is necessary to maintain the balance between the factors that increase glycaemia (food, stress) and those that decrease it (in-

The first insulin pump
(*source:* www.timestoast.com)

sulin, physical activity). When this balance is disrupted, hypoglycaemia or hyperglycaemia occurs. The goal of the treatment is to maintain the balance between these factors for as long as possible so that acute and later complications do not occur.

Hypoglycaemia is a life-threatening condition when there is insufficient glucose in the body. The most frequent cause is the excessive amount of insulin, insufficient carbohydrates, excessive physical activity, or alcohol. Hypoglycaemia is manifested in different ways – most frequently by sweating, restlessness, confusion, and unusual behaviour. The longer a diabetic suffers from diabetes, the harder it becomes for them to recognize the symptoms and they are not aware of hypoglycaemia (so-called hypoglycaemia unawareness syndrome). Severe hypoglycaemia can lead to unconsciousness or death. Repeated severe hypoglycaemia can cause permanent consequences for the brain cells.

A layman would ask if the hypoglycaemic state is better. It is not. Long lasting hypoglycaemia damages the eyes, kidneys, nerve fibres or heart and arteries. These complications can quietly develop and make life very uncomfortable after a few years. Hyperglycaemia occurs when the insulin level is insufficient.

Flexibility, or I can eat, sleep and be physically active when I want

Insulin pump treatment has significant advantages over insulin pens. The pens require a diabetic to maintain time intervals for the application of long-term insulin. They have to be mindful of when they eat and plan their physical activities.

In normal circumstances (when the patient is not ill or excessively physically active), a basal dose in an insulin pump should maintain a normal level of glycaemia. In theory, if a patient decides not to eat all day, a basal dose should maintain the target level of glucose. Thus, it is not necessary to look out for the time of injecting insulin or having a snack. If a patient decides to sleep longer, the basal insulin in the pump enables this. Thus, it is not necessary for the diabetic to carefully consider their eating time. A diabetic that has an insulin pump can eat when they want. They only need to inject bolus insulin. This advantage is mostly valued by teenagers and patients who are busy.

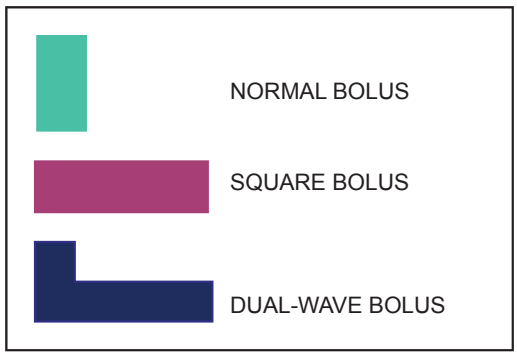
A significant asset of insulin pumps is the function of *"temporary basal"*. There are situations that change in the life of a diabetic. These mainly include physical activity (lesser need of insulin) and illness (larger need of insulin). This function enables a patient to, e.g., decrease the basal speed of insulin during the day because they are going cycling. They can set the time interval, select the percentage of dosing, and the pump will decrease the basal speed of insulin. This step decreases the risk of hypoglycaemia during sport and does not interfere in the setting of the basal dose by a doctor. There are cases when "temporary basal" is used during shopping, housecleaning, or dog walking. It is always best to consult with a diabetologist about the setting and use.

Other assets of insulin pumps include the calculation of bolus, combined and disassembled bolus, or remote or easy bolus.

The MiniMed™ insulin pump has the integrated Bolus Wizard™ calculator, which helps to recommend bolus doses on the basis of current glycaemia and the quantity of carbohydrates that the patient is going to consume.

The Bolus Wizard™ calculator should enable patients to prevent their glycaemia level from exceeding the upper limit of the target glucose range. In its calculations, the calculator includes the necessary insulin to cover the food as well as balance bolus (the bolus dose that decreases glycaemia levels). It has been proven that using calculated bolus is an asset considering the compensation of diabetes mellitus

Useful bolus includes *dual-wave* and *square bolus*. It is necessary to realize that the absorption of carbohydrates is affected by other food parts, such as fats and proteins, which decrease the speed of digestion. Boluses serve



for insulin to copy the absorption of carbohydrates. An example is presented below.

Food rich in carbohydrates, fats, and proteins, such as pizza, is absorbed a little slower. When a diabetic injects a dose of insulin after a pizza, postprandial glycaemia physiologically increases and can hold a high level for several hours. Applying dual-wave bolus can be a solution. A pump user chooses the quantity of bolus that it divided in two doses. The first is injected immediately (this covers the first carbohydrate wave) and the second is gradually dosed in the subcutis. This way, the effect of bolus is prolonged, and a diabetic has better postprandial values.

The second of the mentioned boluses is the so-called disassembled bolus, which enables diabetics to participate in social events etc.

Other benefits of an insulin pump include *easy* and *remote bolus*. The easy bolus is mostly used when it is necessary to inject bolus "blindly". This way is suitable when social situations require a discreet bolus injection without taking the pump out of the pocket because bolus can be injected using one button. A similar way in which it is not necessary to use a button is remote bolus, when a glucometer works as a remote-control device for injecting bolus. Mainly clients who have the pump in the worst available places (underwear) appreciate this possibility.

All mentioned functions are available in the Minimed™ 640G and MiniMed™ Paradigm Veo insulin pumps.

Continuous glucose monitoring

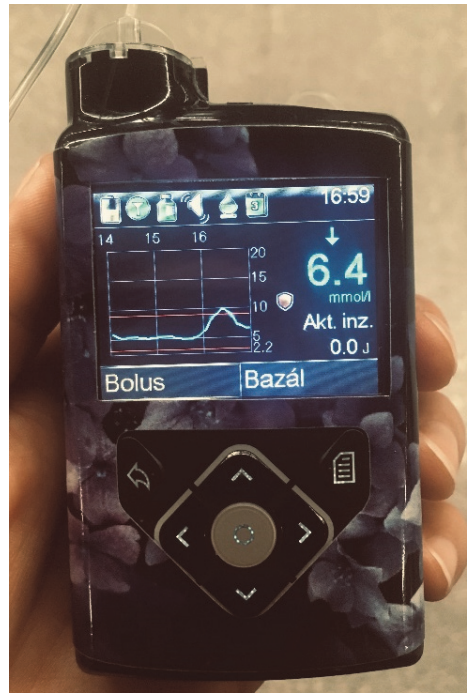
Besides insulin, what is the "daily bread" of a diabetic type 1?

You may have noticed someone in a restaurant or on a park bench puncturing their finger and attaching a small device to it.

This is a glucometer, which is an indispensable aid in a diabetic's life. It enables a diabetic to check on their glycaemia before and after a meal, during physical activities or during the night. Taking regular measurements (4× per day or more frequent) helps to maintain a healthy lifestyle.

What is continuous glucose monitoring?

CGM is the abbreviation for Continuous glucose monitoring, which has become an indispensable part of modern treatment of DM type 1. Glucose sensors are devices that measure the quantity of glucose in subcutaneous cells. Compared to glycaemia (concentration of glucose in blood), the value is delayed by approximately 10 minutes. Contemporary sensors can predict and indicate a decrease or increase of glucose level. The components of CGM include a glucose sensor, a transmitter, and a monitor. If the treatment includes an insulin pump, it has the function of a monitor. An independent device can also function as a monitor, such as a mobile phone, which is used especially by diabetics that are treated with insulin injections.



This technology provides a continuous overview of the current glucose concentration. The sensor updates data every five minutes, which means that there are 288 glucose values per day. On average, the glucometer shows 4 glucose values a day. CGM also shows glucose values with a curve and informs about the speed of the fall or rise of the glucose value – the so-called trend pointer. In the attached picture of a pump display, there are two red lines in the square field, which show the margins of low and high glucose values. The margins are set by a doctor, as well as

the alarms that warn about high or low glucose values. In order for the treatment to be the most efficient in the long run, it is important to monitor the curve, trend pointers and make retrospective data assessments. Insulin pumps enable us to see data from the last 24 hours. To analyse older data, a therapeutic software Carelink™ is used, which continuously downloads the data from a pump. Theanalysis of this data can lead to a consultation with a doctor, who can then better establish or adjust the treatment.

SmartGuard™

The mentioned MiniMed™ 640G insulin pump, which was launched in the Czech Republic in 2015, disposes of the function of the predictive stop of insulin dispensation before reaching low glucose values. Due to this function, a pump (assuming it communicates with a sensor and the setting is appropriate) can stop insulin dispensation when glucose concentration decreases, and hypoglycaemia may occur. The algorithm has a safety zone, which ensures that hypoglycaemia (ideally) does not occur. The pump stops insulin dispensation for a minimum of 30 minutes, maximum 120 minutes, and reinstates it as soon as certain conditions are met. Of course, the user can restore it themselves. What is this function good for? At the beginning, we mentioned that some diabetics suffered from hypoglycaemia unawareness syndrome and SmartGuard™ technology helped them with it. Hypoglycaemia can occur anytime, even at night. Diabetics who do not suffer from hypoglycaemia unawareness syndrome do not have to wake up when hypoglycaemia occurs. According to the study SMILE (2019), the SmartGuard™ function of the MiniMed™ 640G system can prevent hypoglycaemia by 73%, and 83% of users can feel safer.

The technology of the future, i.e. the closed loop

Hybrid closed loop (HCL)

Creating artificial pancreas or beta cells is not a new idea. The contemporary research is directed toward a technological rather than biological treatment.

Globally, Medtronic is the largest producer of medical technology; thus, it has been developing a technology that is reminiscent of an artificial pancreas for several years. In this context, Medtronic has taken a series of steps. One of them is the predictive algorithm (PLGM: Predictive Low Glucose Management) of the MiniMed™ 640G system, which we have already mentioned. Another step Medtronic made was the first hybrid closed loop system, which was launched as MiniMed™ 670G. Since 2018, this system has been available in Europe in several countries, but not in the Czech Republic. The MiniMed™ 670G system can regulate basal doses of insulin by itself on the basis of the development of glucose levels. This year, Medtronic has received CE certification for the new and more advanced hybrid closed loop system, which this year will be launched in Europe (including the Czech Republic) as MiniMed™ 780G.

MiniMed™ 780G

This newest pump belongs in the group of hybrid closed loop systems. The pump can not only regulate the basal insulin dose by itself, but it also automatically dispenses bolus insulin to correct glucose levels (so-called automatic correction). The goal of this pump is to maintain glucose levels in the target range for as long as possible (3.9 to 10 mmol/l.)

Another asset of this pump is the ability to communicate with a mobile phone. Not only will it be possible to check one's values on a mobile phone, but, at the same time, it will automatically synchronize with the Carelink™ software. A part of this technology is the application for the nearest surroundings of the MiniMed™ 780G system user. This mobile phone application enables its user to remotely monitor the development of glucose levels in real time. Its assets can be valued mainly by the parents of small children or adolescents with diabetes mellitus.

CONCLUSIONS

Medical studies, findings, technological development, and the interest of diabetics – all of these can contribute to a better quality and (almost) full life of a person with diabetes mellitus type 1.

** The author is an employee of the company Medtronic Czechia s.r.o. Medtronic Czechia s.r.o. is one of several companies that sell insulin pumps and CGM systems in the Czech Republic.*

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