Efficiency of insulin pump and free style libra in therapy of children with diabetes mellitus tip 1

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Abstract— In the last couple of years, sensors have appeared on the market. They practice a new, more accurate method of measuring glucose in the intercellular fluid. One of the more famous is the Free Style Libre. The advantages of the device are numerous. In recent years, a novelty in the treatment of type 1 diabetes has been with the help of an insulin pump, which enables 24-hour delivery of insulin

Index Terms— Diabetes, Isulin, Free Style Libre, Insulin pump, Measuring,

1.INTRODUCTION

According to the older classification, type 1 diabetes was called juvenile diabetes. However, it can occur at any age. According to today's classification, type 1 diabetes is defined by a lack of insulin with or without an indication of autoimmune destruction of the islet cells of the islets of Langerhans. It is usually stated that it is a disease of fulminant onset, with symptomatic hyperglycemia and the development of ketoacidosis. However, there are growing indications that type 1 and type 2 diabetes are not so different. Two pathophysiological mechanisms underlie glucose intolerance and diabetes: insulin deficiency and insulin insensitivity. Insulin deficiency is caused by beta-cell depletion: the current view is that in type 1 diabetes, with an appropriate genetic predisposition under the influence of environmental provocation, initiates preoperative period, it is most effectively administered by continuous intravenous infusion of short-acting insulin. Over the past decades, the prognosis of people with type 1 diabetes has improved significantly. Attempts at prevention have so far yielded no results. The goals of today's research are: to improve existing care, and to find better and safer ways to replace insulin. The goal for the future is to find a cure and develop prevention (1). The epidemiology of type I diabetes expressed by prevalence and incidence varies widely between countries, within countries, and among particular ethnic groups. Most data for this type were obtained from various studies conducted in Europe. It is worrying that the results of most studies demonstrate an increase in the incidence of type I diabetes in recent decades. This trend is most pronounced in the age group of children 0–5 years of age, and this phenomenon is explained by the increasing occurrence of unknown environmental factors and increased susceptibility to type I diabetes (2).

the autoimmune process. Beta-cell destruction and consequent insulin deficiency predominate, but according to the accelerator hypothesis, insulin insensitivity may accelerate this process (1). In younger people, the disease often begins abruptly, with symptoms of hypoglycemia (thirst, polyuria, polydipsia). In the elderly, the onset of the disease is usually slower, it looks like it is type 2 diabetes. In recent years, the term LADA (latent autoimmune diabetes in adults) has been proposed for this type of disease. Strict glycemic control can delay the onset of diabetic complications. It is performed with basal-bolus treatment: multiple injections of insulin or continuous subcutaneous infusion with self-monitoring of glycemia and dose adjustment to treatment results. Maintenance of normoglycemia in severe conditions requiring intensive treatment, as in the

1. Modern approach to treatment

The approach to insulin treatment is determined by the type of diabetes. The purpose of treatment is to achieve a glycemic level as close as possible to normoglycemia, achieve a normal metabolism (prevent a chain of metabolic changes), prevent frequent and extreme hypoglycemia, reduce the risk or slow the development of chronic complications, achieve normal growth and development, improve quality of life and prolong its life expectancy. Treatment of diabetes most often includes patient education, proper nutrition, self-monitoring and physical activity, regular follow-up examinations, and treatment with insulin / oral antidiabetics (3). The treatment of type 1 diabetes mellitus in children and adolescents is very complex due to the lifelong duration of the disease and the dynamic metabolism and psyche in the period of growing up.

1. Insulin pump

In recent years, a novelty in the treatment of type 1 diabetes has been with the help of an insulin pump, which enables 24-hour delivery of insulin (5). After the discovery of insulin, the insulin pump is the greatest achievement in T1DM therapy. In the last twenty years, it has undergone a transformation from a complicated huge apparatus to a highly sophisticated device the size of a mobile phone. Its functioning is most similar to the physiological secretion of insulin. Reducing the number of injections by 10-15 times during insulin pump therapy compared to intensive insulin therapy (4 doses of insulin per day) is very important for the patient. Instead of a needle prick for each dose of insulin in IP therapy, insulin is continuously released through a thin plastic tube placed subcutaneously, which is changed every 3-4 days (4).

The insulin pump programming mechanism provides the ability to continuously deliver a small dose of insulin during the day and night (basal dose) and a bolus dose to meet the body's need for insulin between meals. An insulin pump is given before each meal with a bolus dose, the amount of which depends on the individual insulin requirement, the measured GUK level and the sum of carbohydrate intake per meal. The insulin pump consists of a container containing insulin and an infusion set (plastic tube) through which insulin is delivered to the subcutaneous tissue (abdomen, upper arms, lower legs, gluteal region). The place of application and infusion set should be changed every 3-4 days, in order to avoid insufficient delivery of insulin and possible infection at the place of the applied set.

The use of an insulin pump reduced the number of applications to the subcutaneous tissue from 365-1825 to 125-140 per year (insulin pump = 1 application / 3 days). Criteria for selecting patients for insulin pump treatment are: duration of type 1 diabetes longer than 6 months, recurrent moderate / severe hypoglycemia, HbA1c> 9% (with frequent changes in insulin dose), unpredictable glycemic oscillations that are difficult to resolve by changing the dose, reversible ketoacidosis severe hyperglycemia not due to poor cooperation, puberty and adolescence when insulin requirements increase sharply due to hormonal changes and accelerated growth, constant daily parental supervision, strong parental motivation, ability to understand technology, frequent glycemic control. Special indications are: diabetic gastroenteropathy, infants, young children, active athletes…

Before introducing an insulin pump, the patient should be well educated about its technical capabilities and educated on the proper handling of the insulin pump. Once the patient has mastered the operation of the insulin pump, the medical team instructs the patient on the required amount of insulin for the basal and bolus dose, on calculating the required units of insulin with carbohydrate meal and correction in case of hyperglycemia, and using other insulin delivery programs. Insulin pump therapy is one of the most advanced technological methods for achieving normalization of blood glucose, and there are at least four benefits of treatment with continuous insulin infusion (5).

First, insulin is continuously delivered which can lead to improved glycemic control (5). Second, studies have shown improved glycemic control during the night and a reduced risk of the "dawn phenomenon," which causes blood glucose rise before

breakfast (6,7). Third, insulin pumps allow patients greater flexibility in their daily lives. Insulin pump therapy gives more freedom during meals, sleep and exercise, they do not have to adhere to a strict schedule, as is the case with multiple daily injections. Also, studies have shown that insulin pump treatment reduces the incidence of severe hypoglycemic episodes (8,9). Studies show that treatment with continuous subcutaneous insulin infusion - insulin pump leads to an improvement in glycemia, and thus a decrease in HbA1c (7). The disadvantage of using an insulin pump is the rapid development of hyperglycemia and ketoacidosis in the event of interruption of insulin delivery due to obstruction of the infusion set (12). Although rare, infections and allergic reactions at the site of the administered insulin catheter are possible, most commonly due to the patch that attaches it.

Insulin pump therapy was first introduced in the Federation of BiH at the Pediatric Clinic of the Clinical Center of the University of Sarajevo in February 2005. in the period 01.03.2005. to 01.09.2008. year, the insulin pump was placed in 39 patients, 24 males and 15 females, age up to 18 years, mean age 12.3 years. this number represents 20% of all pediatric patients with T1DM from Sarajevo Canton who are treated at the Pediatric Clinic in Sarajevo, while the share of patients with insulin pump in relation to all patients of the Diabetes Counseling Center of the Pediatric Clinic is 15%. Data from clinics in Sweden and Slovenia show that the share of patients on pump therapy is 12-60%, of the total number treated in these clinics (4).

2. Free Style Libre

In the last couple of years, sensors have appeared on the market. They practice a new, more accurate method of measuring glucose in the intercellular fluid. One of the more famous is the Free Style Libre. The advantages of the device are numerous. Thus, the device with the help of a flexible sensor that is constantly inserted into the skin and reads the level of glucose in the intercellular fluid and gives a display on the touch screen the size of a small mobile phone. The reading shows the glucose value numerically and graphically during the last eight hours with an added arrow indicating the speed and rise or fall of glucose. Also, glucose can be measured during sleep, and disease control is much better with constant information about glucose levels. This reduces the number of stitches, so measuring from the finger with the help of strips is necessary only in the event of sudden and rapid changes in glucose levels. The device is practical and comes in a package with a small sensor the size of a 5 KM coin, from which a thin thread comes out in the middle and goes under the skin. The sensor application is done with a simple inserter that performs the procedure simply and quickly. The sensor is waterproof, so the sick person can take a shower, swim, exercise, and the duration of the sensor is 14 days. Another of a number of advantages is the ability to scan over clothing (13).

Research question: is an insulin pump more effective in controlling type 1 diabetes mellitus than free style libre?

2.HYPOTHESES

Zero Hypothesis

Is an insulin pump more effective in controlling type 1 diabetes mellitus than free style libre?

Working hypothesis

An insulin pump is not more effective in controlling type 1 diabetes mellitus than free style libre?

3. OBJECTIVES OF THE WORK

To determine the efficiency of the insulin pump and free style libre in the control of type 1 diabetes mellitus and the impact on the quality of health of these children by scientific review of the literature (by isolating key studies, coding of separate studies and interpretation of records).

4. MATERIAL AND METHODS

The research part of the paper is designed as a non-experimental qualitative research (scientific review of the literature), in the part related to the modern therapy of diabetes mellitus using insulin pumps and free style pounds which are in charge of continuous monitoring of sugar concentration. Relevant databases were searched, including Pub Med, Google Scholar, Medline, Hamster, Beaver,

Science Citation Index and on request with the keywords "insulin pumps", "free style books", "modern therapy", "diabetes mellitus type 1" .

5. DISCUSSION

5.1. Coding of isolated studies according to the use of an insulin pump

I a) Author

Skrabic V, Milanovic M, Cvjetkovic N.

I b) Name of the study

Insulin pump in the treatment of type 1 diabetes mellitus

I c) Type of the study

Experimental study

I d) Objectives of the study

To determine differences in HbA1c values before and after the use of an insulin pump in the treatment of subjects with type 1 diabetes

I e) Research method

Patients were monitored in the period from 2003 to 2007. The study included 29 subjects who received an insulin pump in their treatment.

I f) Results

Statistically significantly lower last and average values of HbA1c after pump application (t-test for dependent samples: $t = 6.84$; $p < 0.001$). Mean HbA1c values before insulin pump administration were 8.8 ± 1.07 (mean ± SD) and after its administration 7.5 ± 0.83 (mean ± SD). The last value of HbA1c before the introduction of insulin pump was 8.9 ± 1.21 (mean ± SD) and after 7.5 ± 0.96 (mean ± SD).

I g) Conclusion

The authors confirmed that the insulin pump, as one of the ways to treat insulin in patients with type 1 diabetes, is a good choice and that its use achieves better regulation of glycemia.

II a) Author

Hasanbegovic S.

II b) Name of the study

Indications for the introduction of insulin pump therapy in children and adolescents with type 1 diabetes mellitus

II c) Type of the study

Experimental study

II d) Objectives of the study

The aim of this paper is to present medical and non-medical indications for the inclusion of insulin pump therapy in T1DM patients at the Pediatric Clinic of the Clinical Center of the University of Sarajevo.

II e) Research method

The study included all patients of the Pediatric Clinic with diagnosed T1DM 1 in whom insulin pump therapy was included in the period from 01.03.2005. to 01.09.2008. years. The age of the patients included in the study is up to 18 years of age at the time of inclusion of insulin pump therapy. Indications for selecting patients to include insulin pump therapy were: medical and non-medical

II f) Results

Insulin pump therapy has been successfully introduced in 39 children and adolescents with TYPE 1 DM under the age of 18 who are patients of the Pediatric Clinic of the Clinical Center of the University of Sarajevo. This number represents one fifth of all pediatric patients with TYPE 1 DM from Sarajevo Canton who are treated at the Pediatric Clinic in Sarajevo, while the share of patients with insulin pump in relation to all patients of the Diabetes Counseling Center of the Pediatric Clinic is 15%.

II g) Conclusion

After analyzing all relevant literature data related to indications for the introduction of insulin pump therapy, and in accordance with the problems in the therapy of children and

adolescents with TYPE 1 DM that we encounter, the insulin pump team of the Pediatric Clinic of the Clinical Center of the University of Sarajevo made its own original indications. We believe that the selection of patients for the introduction of IP therapy based on our indications will be adequate to achieve better results of metabolic control of diabetes while improving the quality of life of children and adolescents with TYPE 1 DM.

III a) Author

Ursina Scheidegger, Sabin Allemanna, Karl Scheidegger, Peter Diema.

III b) Name of the study

Continuous subcutaneous insulin infusion therapy: effects on quality of life

III c) Type of the study

A prospective, longitudinal study

III d) Objectives of the study

Compare the specificity of quality of life in people with type 1 diabetes treatment with multiple daily injections (MDI) compared to subjects on continuous subcutaneous insulin infusion (CSII).

III e) Research method

Quality of life for diabetes as measured by a standardized DSQOLS questionnaire in 81 adults with type 1 diabetes on insulin therapy and in 78 subjects on continuous subcutaneous insulin therapy (cross-sectional study). In addition, 19 subjects were monitored prospectively, measuring quality of life before and after the transition from MDI to CSII (longitudinal study).

III f) Results

Satisfaction score with treatment with preference was significantly higher in subjects on continuous subcutaneous insulin infusion compared to subjects with daily insulin injections. Respondents feel more comfortable when it comes to nutrition, leisure flexibility and overall quality of life

III g) Conclusion

Subjects with type 1 diabetes on a continuous subcutaneous insulin infusion have a better quality of life than type 1 diabetics on daily insulin injections. They are more satisfied with the treatment in relation to their metabolism, goals as well as psychosocial factors, physical performance and protection from long-term complications and hypoglycemia. In addition, CSII respondents experience greater flexibility in their daily routine, and free time.

IV a) Author

Stojanovic J, Milosevic D, Antovic I, Sekulic G, Beljic-Zivkovic T.

IV b) Name of the study

Influence of different insulin therapy regimens on the quality of life of patients with type 1 diabetes mellitus.

IV c) Type of the study

Cross-sectional study

IV d) Objectives of the study

Given the high psychological burden of patients with DM, the aim of this study was to examine the impact of different regimens of insulin therapy, the quality of glycoregulation and the presence of vascular complications on the subjective assessment of patients about their quality of life.

IV e) Research method

Patients treated for type 1 DM (n = 122) controlled in the endocrinology clinic of the Clinical Hospital Center "Zvezdara" were classified into four groups according to the regimens of insulin therapy: 26 patients were on continuous subcutaneous insulin infusion with a insulin pump, 30 patients on conventional insulin therapy , 33 on intensified human insulin therapy and 33 on intensified insulin analogue therapy. The quality of life assessment was performed using three questionnaires: WHO-5 (for assessing emotional well-being), SF-36 (general health

survey) and ITAS questionnaire (for assessing attitudes towards insulin therapy). Assessment of metabolic control was performed by analysis of glycosylated hemoglobin (HbA1c), lipid status, and the presence of glycosylated complications. The following statistical analysis methods were used in this cross-sectional study:

IV f) Results

Patients on the insulin pump had significantly better metabolic control than other patients, especially those on conventional therapy (HbA1c on the pump 7.07 ± 1.48% vs. HbA1c on conventional therapy 10.04 ± 1.44; p = 0.000) . No difference was observed between the groups on intensive therapy with human insulins or insulin analogues. Good metabolic control significantly affected the quality of life. The existence of retinopathy and nephropathy significantly reduced physical well-being, and polyneuropathy and cardiovascular complications both physical and mental well-being

IV g) Conclusion

The choice of insulin therapy regimen significantly affects not only the metabolic control, but also the quality of life of the patient.

V a) Author

Petrovski G., Dimitrovski C., Milenkovic T.

V b) Name of the study

Insulin pump therapy with continuous glucose monitoring improves metabolic control in brittle typ 1 diabetes

V c) Type of the study

Cross-sectional study

V d) Objectives of the study

Evaluate the combination of insulin pump therapy and continuous glucose monitoring in metabolic control outcome in patients with fragile type 1 diabetes

V e) Research method

Insulin pump therapy was started in eleven type 1 diabetics with poor metabolism control (mean Hba1c = 9.6%). Metabolic control was assessed with CGMS and HbA1c over the next 6 months.

V f) Results

HbA1C showed a decrease of 1.4% at 6 months after initialization of pump therapy. Physical activity, various foods and insulin were tested with CGMS. There was no severe hypoglycemia. During the next 6 months of pump therapy, patients successfully "managed" diabetes

V g) Conclusion

Insulin pump therapy can be initiated and used effectively in fragile type 1 diabetics to improve metabolic control and quality of life. When diabetes and cougar use are appropriately individualized, this type of therapy can help type 1 diabetics achieve and maintain metabolic control. Flexibility of life, to improve the quality of life, and independence can be maintained at a young age.

VI a) Autor

Deiss D, Hartmann R, Hoeffe J, Kordonouri O

VI b) Name of the study

Assessment of glycemic control by continuous glucose monitoring system in 50 children with type 1 diabetes starting on insulin pump therapy

VI c) Type of the study

Experimental study

VI d) Objectives of the study

Check the experience with the Continuous Glucose Monitoring System (CGMS) and identify the factors that affect glycemic control in a large group of children and adolescents with type 1 diabetes and change insulin pump therapy by continuous subcutaneous insulin infusion (CSII).

VI e) Research method

In 50 patients (21 boys, 29 girls; mean age 12.6 years (range: 1.3–16.4 years); duration of

diabetes 5.0 yr (0.2–13.3)], hemoglobin A1c (HbA1c)) and outpatient CGMS were performed before and 6 weeks after the onset of CSII.

VI f) Results

In the overall cohort, HbA1c improved from 8.1 ± 1.2% at baseline to 7.7 ± 0.9% after 6 weeks of CSII ($p < 0.001$). This effect was more pronounced in boys (8.0 ± 1.4 versus 7.5 ± 1.1%, $p = 0.007$) compared to girls (8.1 ± 1.1 versus 7.8 ± 0.7%). , $p = 0.039$) as well as in patients with poor glycemic control (HbA1c> 8.0%) at baseline (8.9 ± 0.6 vs. 8.1 ± 0.8%, $p < 0.001$) and in patients older than 12 yr (8.2 ± 1.2 vs. 7.7 ± 1.0%, $p < 0.001$).

VI g) Conclusion

With the change through continuous subcutaneous insulin infusion, HbA1c significantly improved after 6 weeks of therapy. The use of a continuous glucose monitoring system provided additional information on glycemic control in these patients

VII a) Autor

Sulmont V, Sounchon PF, Gouillard- Darnaud C et al

VII b) Name of the study

Metabolic Control in Children with Diabetes Mellitus Who are Younger than 6 Years at Diagnosis: Continuous Subcutaneous Insulin Infusion as a First Line Treatment?

VII c) Type of the study

Experimental study

VII d) Objectives of the study

Assess long-term metabolic outcomes in children diagnosed with diabetes at <6 years of age.

VII e) Research method

The cohort included 66 children with diabetes that lasted at least 5 years and was diagnosed before 6 years of age. Thirty-four children were treated at diagnosis with multiple daily subcutaneous insulin injections (MDI), and all but 3 of these children switched to continuous subcutaneous insulin infusion (CSII; group A). Thirty-two children received CSII as initial treatment (group B).

VII f) Results

HbA1c values were significantly lower in patients receiving CSII than in MDI during all 8 years of follow-up except one year. The incidence of severe hypoglycaemia was significantly reduced for the CSII group. In group A, HbA1c values increased during the study period, and in group B they increased only during the first 2 years and remained constant thereafter. Only 9.1% of patients did not use or quit CSII.

VII g) Conclusion

Continuous subcutaneous insulin therapy in children under 6 years of age provides better long-term metabolic control and reduces the risk of severe hypoglycaemia compared to insulin injections.

VIII a) Autor

Hermanides J et al

VIII b) Name of the study

Sensor-augmented pump therapy lowers HbA1c in suboptimally controlled Type 1 diabete

VIII c) Type of the study

Randomized control study

VIII d) Objectives of the study

To investigate the efficacy of sensor-augmented pump therapy in relation to multiple daily injection therapy in patients with suboptimally controlled type 1 diabetes.

VIII e) Research method

In this study, launched by a research multilingual study (Eurythmics Trial) in eight outpatient centers in Europe, we randomized 83 patients with type 1 diabetes (40 women) who are currently being treated with multiple daily injections, aged 18 to 65 years and HbA1c

≥% (≥ 66 mmol / mol) up to 26 weeks of treatment with either a sensor-augmented insulin pump (n = 44) (Paradigm® REAL-Time) or continued with multiple daily injections (n = 39). Changes in HbA1c between baseline and 26 weeks, endpoint derived from sensors, and patient-reported outcomes were assessed.

VIII f) Results

The study was completed by 43/44 (98%) patients in the group with an increased insulin pump and 35/39 (90%) patients in the group with multiple daily injections. Mean HbA1c at baseline and 26 weeks ranged from 8.46% (sd 0.95) (69 mmol / mol) to 7.23% (sd 0.65) (56 mmol / mol) in the sensor-enhanced group. insulin pump and from 8.59% (sd 0.82) (70 mmol / mol) to 8.46% (sd 1.04) (69 mmol / mol) in the group with multiple daily injections. The mean difference in HbA1c change after 26 weeks was -1.21% (95% confidence interval -1.52 to -0.90, P <0.001) in favor of the sensor group - increased insulin pump.

VIII g) Conclusion

Sensor-enhanced pump therapy effectively lowers HbA1c in patients with type 1 diabetes who are suboptimally controlled with multiple daily injections

5.2. Coding of selected studies according to the use of Freestyle libre

I a) Author

Edge J, Acerini C, et al

I b) Name of study

An alternative sensor-based method for glucose monitoring in children and young people with diabetes

I c) Type of study

Cross-sectional study

I d) Objectives of the study

Determine the accuracy, safety and acceptability of the FreeStyle Libre Flash glucose monitoring system in the pediatric population.

I e) Research method

Eighty-nine participants aged 4 to 17, with type 1 diabetes, were enrolled in 9 diabetes centers in the UK. A factory-calibrated sensor was inserted into the back of the upper arm and used for up to 14 days. Sensor glucose measurements were compared with capillary blood (BG) glucose measurements. Sensor results are masked for participants.

I f) Results

Participants were in the target glucose range (3.9–10.0 mmol / L) 50% of the time (mean 12.1 hours / day), with a mean of 2.2 hours / day and 9.5 hours / day in hypoglycemia and hyperglycemia, respectively. Sensor use, device use and comparison with blood glucose self-monitoring were positively assessed by the majority of participants (84.3–100%). Five device-related adverse events were reported at different ages of participants.

I g) Conclusion

The accuracy, safety and acceptability of users of the FreeStyle Libre system have been proven for the pediatric population. The characteristics of the subject did not affect the accuracy of the system, which makes it suitable for a wide range of children and young people with diabetes.

II a) Autor

A Kafi E.S, Aldeen A.M, Khadwardi R.H.

II b) Name of the study

Flash glucose monitoring system may benefit children and adolescents with type 1 diabetes during fasting at Ramadan

II c) Type of the study

Prospective, pilot study

II d) Objectives of the study

Evaluate the benefits of using the Flash Glucose Monitoring System (FGMS) in children and

adolescents with type 1 diabetes mellitus (T1DM) during Ramadan fasting.

II e) Research method

A prospective pilot study of 51 participants, conducted at a pediatric clinic in children diagnosed with type 1 diabetes at King Abdulaziz University Hospital, Jeddah, Kingdom of Saudi Arabia from June to July 2016. Hypoglycemia is defined as a glucose value below 70 mg / dL, while hyperglycemia is a glucose value greater than 150 mg / dL for all participants based on the institute's protocol.

II f) Results

Participants were able to fast 67.0% of the total number of days of Ramadan, which met the conditions for fasting, until they fasted 33% of the day, of which due to hypoglycemia (15.4%) or some other reason not related to diabetes (17.6%). None of the participants developed severe hypoglycemia. The mean number of hyperglycemic episodes in the fasting hours was 1.29 per day, which was more than the hypoglycemic episodes (0.7). None of the participants developed diabetic ketoacidosis (DKA). Glycemic control with an average estimate of HbA1C during Ramadan (8.16 ± 1.64% [before the study]) at 8.2 ± 1.63% [after the study] p = 0.932.

II g) Conclusion

Children and adolescents with T1DM who use FGMS could quickly be at risk of life-threatening episodes of severe hypoglycemia or diabetic ketoacidosis during Ramadan. Adequate education and good glycemic control before Ramadan are important strategies combined with the use of FGMS to achieve a better outcome.

III a) Autor

Buckingham B.

III b) Name of the study

Use of the Direct Applied Treatment Algorithm (DATA) for diabetes management with a real - time continuous glucose monitor (the FreeStyle Navigator)

III c) Type of the study

Cross-sectional study

III d) Objectives of the study

Evaluate the use and effectiveness of data in children with diabetes using a continuous real-time glucose sensor (FreeStyle Navigator).

III e) Research method

30 children and adolescents (mean ± standard age deviation = 11.2 ± 4.1 years) receiving insulin pump therapy. Respondents were instructed to use DATA and were asked to download their Navigator weekly to review glucose patterns. The algorithm satisfaction questionnaire was completed at 3, 7, and 13 weeks.

III f) Results

At 13 weeks, all subjects and all but one parent were of the opinion that DATA provided good, clear instructions for insulin dosing, and felt that the guidelines improved postprandial glucose levels. In response to alarms, 86% of patients used DATA for at least 50% of the time for 3 weeks, and 59% did so for 13 weeks. Similar results were observed in the use of DATA to adjust the insulin bolus dose.

III g) Conclusion

These results demonstrate the feasibility of implementing DATA data when real-time continuous glucose monitoring is initiated and support its use in future clinical trials of real-time continuous glucose monitoring.

IV a) Autor

Massa G.G.

IV b) Name of the study

Evaluation of the FreeStyle® Libre Flash Glucose Monitoring System in Children and Adolescents with Type 1 Diabetes

IV c) Type of the study

Cross-sectional study

IV d) Objectives of the study

Evaluate the accuracy and usability of FGM in children with type 1 diabetes (DM).

IV e) Research method

67 children with DM 1 type of which (35 girls) aged 4 to 18 years were included. Subjects wore a sensor on the back of their upper arm. For the first 14 days, they regularly measured their blood glucose levels with their usual BG meter [Accu-Chek® Mobile [ACM], Roche [n = 24]; Contour® Next Link [CNL], Bayer [n = 26].]; OneTouch ® Verio® IQ [OTV], LifeScan [n = 17]) followed by a glucose scan of the sensor. Glucose scan readings were compared with blood glucose values. Consensus error analysis (CEG) measurements; mean difference (MD), mean relative difference (MRD), mean absolute difference (MAD) and mean absolute relative difference (MARD) were calculated. After 14 days, respondents were asked to complete a FGM usability questionnaire.

IV f) Results

2,626 scanned glucose were read and matched to blood glucose values. Freestyle libre readings were highly correlated with blood glucose levels ($r = 0.926$, $p < 0.001$). 80.3% of data pairs were in zone A (= no effect on clinical activity), and 18.4% were in zone B (= altered clinical effect with little or no effect on clinical outcome.

IV g) Conclusion

The results showed a reasonable agreement between the readings of the Freestyle libre scanned glucose and the measurement of capillary glucose in children. However, there was great interindividual variability. Wearing the sensor requires special attention. Further studies in children are imperative to document the accuracy and safety of FGM in the pediatric population.

V a) Autor

Hulse A, Rai S, Prasanna Kumar K.

V b) Name of the study

Evaluation of accuracy of ambulatory glucose profile in an outpatient setting in children with type 1 diabetes

V c) Type of the study

Section study

V d) Objectives of the study

Evaluate the accuracy of ambulatory glucose profile (AGP) data in children with type 1 diabetes compared to laboratory blood sugar (RBS) levels, capillary blood glucose (CBG) measured by a hospital glucometer, and home blood sugar (SMBG) monitoring.

V e) Research method

The observed RBS, CBG, and AGP data were analyzed for 51 patients who wore AGP sensors for 2 weeks. Simultaneous venous and CBG samples were collected on the first and 14th day. SMBG at home was reviewed and recorded by patients to optimize insulin doses. Precision measures (mean absolute deviation, mean absolute relative difference (MARD), and AGP linear regression coefficient on RBS, CBG, and home-monitored SMBG were calculated.

V f) Results

Seventy paired RBS, CBG, and AGP data and 362 paired home SMBG and AGP data were available. The MARD was 9.56% for AGP versus RBS and 15.07% for AGP versus CBG. The coefficient of linear regression of AGP above RBS was 0.93, and AGP over CBG 0.89 ($P < 0.001$). The accuracy of AGP over SMBG was assessed in four ranges: <75, 76-140, 141-200, and> 200 mg.

V g) Conclusion

In this study, AGP data correlated significantly with RBS and CBG data in children with type 1 diabetes. However, a large number of samples in the research environment would help document the reproducibility of the results.

VI a) Autor

Rai S, Hulse A, Kumar P.

VI b) Name of the study

Feasibility and acceptability of ambulatory glucose profile in children with Type 1 diabetes mellitus: A pilot study.

VI c) Type of the study

Pilot study

VI d) Objectives of the study

Investigate the use of ambulatory glucose profiles in children

VI e) Research method

AGP was used in 46 children with type 1 diabetes. Feasibility was measured in terms of data and sensor failure. Eligibility was measured using a questionnaire

VI f) Results

Forty-six children (22 girls and 24 boys) with a mean age of 10.07 years and a mean duration of diabetes of 3.4 years were included in this study. In this cohort, for 30 (65.21%) subjects, the sensor remained on site for a total of 14 days. In addition to minor discomfort, AGP is well accepted by most children and their parents.

VI g) Conclusion

AGP is a feasible option for monitoring glycemic status in children with diabetes with a high acceptance rate.

VII a) Autor

Ziegler R, Heidtmann B, et al

VII b) Name of the study

Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes.

VII c) Type of the study

Experimental study

VII d) Objectives of the study

The aim of this study was to link the frequency of blood glucose self-monitoring (SMBG) with the quality of metabolic control, measurement (HbA1c), frequency of hypoglycemia and ketoacidosis, and to see whether associations between SMBG and these outcomes are affected by patient age or treatment regimen.

VII e) Research method

Data from the DPV-Wiss database of 26,723 children and adolescents aged 0–18 years with type 1 diabetes recorded in the period 1995–2006 were analyzed. The estimated variables were gender, age, duration of diabetes, treatment regimen, insulin dose, body mass index - standard deviation (BMI-SDS), HbA1c, hypoglycemia rate, and ketoacidosis.

VII f) Results

In the youngest age group of children under 6 years of age, the incidence of SMBG was highest compared with children aged 6 to 12 years or children aged> 12 years: 6.0 / d vs 5.3 / d versus 4.4 / d ($p < 0.001$). The frequency of SMBG also differed significantly in different treatment groups ($p < 0.001$), but only for the group with continuous subcutaneous insulin (CSII) the frequency was significantly higher: 5.3 / d (CSII) versus 4.7 / d (multiple daily) . 4.6 / d (conventional therapy).

VII g) Conclusion

A higher frequency of self-measurement of blood glucose was associated with better metabolism control. But only in adolescents older than 12 years, metabolic control (HbA1c) was significantly improved with two or more blood glucose measurements.

VIII a)Autor

Fokert MJ, et al

VIII b) Name of the study

Performance of Freestyle libre glucose monitoring system in patients with type 1 and 2 diabetes

VIII c) Type of the study

Prospective study

VIII d) Objectives of the study

Evaluate the accuracy and usability of freestyle pounds by comparing its scanned results in subjects with type 1 and 2 diabetes, and in subjects without diabetes

VIII e) Research method

In this prospective study, a reasonable precision of freestyle libri readings in the upper arm was demonstrated relative to capillary values monitored and aligned with recognized laboratory reference values.

VIII f) Results

However, certain things need to be considered when using freestyle pounds in daily life, including observed lower values in lower ranges and higher values in higher ranges, and underestimating the effect of meals on glucose response. These weaknesses can be partially overcome by optimizing the available user manuals.

VIII g) Conclusion

Further evaluation is needed to identify the appropriate target population that is most likely to benefit from freestyle pounds

IX a) Autor

Campbell F, et al

IX b) Name of the study

Outcomes of using flash glucose monitoring technology by children and young people with type 1 diabetes in a single arm study

IX c) Type of the study

Prospective study

IX d) Objectives of the study

Evaluate blood glucose monitoring technology in children and adolescents with type 1 diabetes mellitus

IX e) Research method

A prospective single-arm, non-inferiority multicenter study to demonstrate time equivalence in the range (TIR [70-180 mg / dL]) by comparing 14-day masked sensor wear (baseline) with self-monitored blood glucose testing (SMBG) last 14 days.

IX f) Results

A total of 76 children and adolescents (46.1% men; age 10.3 ± 4.0 years, length of type 1 diabetes 5.4 ± 3.7 years; mean ± SD) participated with 10 locations. TIR improved significantly by 0.9 ± 2.8 h / d (P = 0.005) versus SMBG baseline. The time in hyperglycemia (> 180 mg / dL) was reduced by -1.2 ± 3.3 h / d (P = 0.004). HbA1c decreased by -0.4% (-4.4 mmol / mol), from 7.9 ± 1.0% (62.9 ± 11.2 mmol / mol) baseline to 7.5 ± 0.9% (58.5 ± 9.8 mmol / mol) at the end of the study (P <0.0001) with reductions in all age subgroups (4-6, 7-12 and 13-17 years). The time in hypoglycaemia (<70 mg / dL) was not altered.

IX g) Conclusion

Children with diabetes improved glycemic control safely and effectively with short-term flash glucose monitoring compared with the use of stand-alone blood glucose meters in one study.

X a) Autor

Bailey. T et al

X b) Name of the study

The Performance and Usability of a Factory-Calibrated Flash Glucose Monitoring System

X c) Type of the study

Experimental study

X d) Objectives of the study

The purpose of this study was to evaluate the performance and usability of the FreeStyle® Libre ™ Flash Glucose Monitoring System (Abbott Diabetes Care, Alameda, CA) for interstitial glucose scores compared to capillary blood scores.

X e) Research method

Seventy-two study participants with type 1 or type 2 diabetes were included in four clinical locations in the United States. The sensor was inserted on the back of each upper arm for up to 14 days. Three factory-calibrated sensor batches were used in the study. Sensor glucose measurements were compared with blood capillary glucose (BG) results (approximately eight per day) obtained using a BG meter built

into the reader (BG reference) and YSI analyzer reference tests (Yellow Springs Instrument, Yellow Springs, OH) at three clinic visits. (32 samples per visit). Sensor readings are masked for participants.

X f) Results

The accuracy of the results was proven in relation to the capillary glucose reference values in the blood, with 86.7% of the sensor results within Consensus Error Grid Zone A. The reading percentage within Consensus Error Grid Zone A on days 2, 7 and 14 was 88.4 %, 89.2% and 85.2%, respectively. The overall mean absolute relative difference was 11.4%. The mean delay time between sensor and YSI reference values was 4.5 ± 4.8 min. Sensor accuracy was not affected by factors such as body mass index, age, type of diabetes, clinical location, insulin administration, or HbA1c.

X g) Conclusion

Interstitial glucose measurements with the FreeStyle Libre system were found to be accurate compared to blood capillary glucose reference values, with an accuracy that remained stable during 14 days of consumption and unchanged patient characteristics.

XI a) Autor

Herman A, et al

XI b) Name of the study

Allergic contact dermatitis caused by isobornyl acrylate in Freestyle® Libre, a newly introduced glucose sensor

XI c) Type of the study

Experimental study

XI d) Objectives of the study

To report several cases of allergic contact dermatitis caused by FreeStyle® Libre, and to report isobornyl acrylate as an allergen

XI e) Research method

Fifteen patients had allergic contact dermatitis caused by FreeStyle® Libre. All but 1 were tested with the basic series and with parts and / or ultrasonic bath extracts (sticky part) of the glucose sensor. Isobornyl acrylate was tested in various concentrations and vehicles in 13 patients. Gas chromatography-mass spectrometry (GC-MS) of the sensor was performed.

XI f) Results

All patients responded to the adhesive portion of the sensor, and 12 patients showed that they were sensitized to isobornyl acrylate. Symptoms of a simultaneous reaction to other allergens are rarely observed. GC-MS showed the presence of isobornyl acrylate in the sensors.

XI g) Conclusion

Cases of allergic contact dermatitis caused by FreeStyle® Libre are becoming more and more common, and isobornyl acrylate is a relevant allergen. Reversible reactivity to other acrylates is rarely observed, but other, hitherto unidentified, contact allergens may still be present in the device.

XII a) Autor

Vivian A.

XII b) Name of the study

Continuous Glucose Control: Consensus of the Conference of the American Association of Clinical Endocrinologists and the American College of Endocrinologists

XII c) Type of the study

Scientific review of the literature

XII d) Objectives of the study

Barriers to continuous glucose monitoring (CGM) continue to hinder the adoption of this valuable technology for the treatment of diabetes.

XII e) Research method

The American Association of Clinical Endocrinologists and the American College of Endocrinologists convened a public consensus conference on February 20, 2016, to review available CGM data and propose strategies to expand the CGM approach.

XII f) Results

Conference participants agreed that the evidence supports the benefits of CGM in type 1 diabetes and that these benefits are likely to be applied whenever intensive insulin therapy is used, regardless of the type of diabetes. CGM is likely to reduce health resource utilization for acute and chronic complications, although realistic analyzes are needed to confirm potential cost savings and quality of life improvements.

XII g) Conclusion

Continuous glucose monitoring improves glycemic control, reduces hypoglycemia, and may reduce the overall cost of diabetes management. Expanding CGM coverage and use is likely to improve the health outcomes of people with diabetes.

6. CONCLUSION

6.1. Conclusions for separate studies for the use of an insulin pump

6.1.1.

The authors confirmed that the insulin pump, as one of the ways to treat insulin in patients with type 1 diabetes, is a good choice and that its use achieves better regulation of glycemia.

6.1.2.

After analyzing all relevant literature data related to indications for the introduction of insulin pump therapy, and in accordance with the problems in the therapy of children and adolescents with TYPE 1 DM that we encounter, the insulin pump team of the Pediatric Clinic of the Clinical Center of the University of Sarajevo made its own original indications. We believe that the selection of patients for the introduction of IP therapy based on our indications will be adequate to achieve better results of metabolic control of diabetes while improving the quality of life of children and adolescents with TYPE 1 DM.

6.1.3.

With the change through continuous subcutaneous insulin infusion, HbA1c significantly improved after 6 weeks of therapy. The use of a continuous glucose monitoring system provided additional information on glycemic control in these patients.

6.1.4.

Continuous subcutaneous insulin therapy in children under 6 years of age provides better long-term metabolic control and reduces the risk of severe hypoglycaemia compared to insulin injections.

6.1.5.

Subjects with type 1 diabetes on a continuous subcutaneous insulin infusion have a better quality of life than type 1 diabetics on daily insulin injections. They are more satisfied with the treatment in relation to their metabolism, goals as well as psychosocial factors, physical performance and protection from long-term complications and hypoglycemia. In addition, CSII respondents experience greater flexibility in their daily routine, and free time.

6.1.6.

The choice of insulin therapy regimen significantly affects not only the metabolic control, but also the quality of life of the patient

6.1.7.

Insulin pump therapy can be initiated and used effectively in fragile type 1 diabetics to improve metabolic control and quality of life. When diabetes and cougar use are appropriately individualized, this type of therapy can help type 1 diabetics achieve and maintain metabolic control. Flexibility of life, to improve the quality of life, and independence can be maintained at a young age.

6.1.8.

Sensor-enhanced pump therapy effectively lowers HbA1c in patients with type 1 diabetes who are suboptimally controlled with multiple daily injections.

6.2. Conclusions for separate studies for the use of Freestyle libre

6.2.1.

The accuracy, safety and acceptability of users of the FreeStyle Libre system have been proven for the pediatric population. The characteristics of the subject did not affect the accuracy of the system, which makes it suitable for a wide range of children and young people with diabetes.

6.2.2.

Children and adolescents with T1DM who use FGMS could quickly be at risk of life-threatening episodes of severe hypoglycemia or diabetic ketoacidosis during Ramadan. Adequate education and good glycemic control before Ramadan are important strategies combined with the use of FGMS to achieve a better outcome.

6.2.3.

These results demonstrate the feasibility of implementing DATA data when real-time continuous glucose monitoring is initiated and support its use in future clinical trials of real-time continuous glucose monitoring.

6.2.4.

The results showed a reasonable agreement between the readings of the Freestyle libre scanned glucose and the measurement of capillary glucose in children. However, there was great interindividual variability. Wearing the sensor requires special attention. Further studies in children are imperative to document the accuracy and safety of FGM in the pediatric population.

6.2.5.

In this study, AGP data correlated significantly with RBS and CBG data in children with type 1 diabetes. However, a large number of samples in the research environment would help document the reproducibility of the results.

6.2.6.

An ambulatory glucose profile is a viable option for monitoring glycemic status in children with diabetes with a high acceptance rate.

6.2.7.

A higher frequency of self-measurement of blood glucose was associated with better metabolism control. But only in adolescents older than 12 years, metabolic control (HbA1c) was significantly improved with two or more blood glucose measurements.

6.2.8.

Further evaluation is needed to identify the appropriate target population that is most likely to benefit from freestyle pounds.

6.2.9.

Children with diabetes improved glycemic control safely and effectively with short-term flash glucose monitoring compared with the use of stand-alone blood glucose meters in one study.

6.2.10.

Interstitial glucose measurements with the FreeStyle Libre system were found to be accurate compared to blood capillary glucose reference values, with an accuracy that remained stable during 14 days of consumption and unchanged patient characteristics.

6.2.11.

Cases of allergic contact dermatitis caused by FreeStyle® Libre are becoming more and more common, and isobornyl acrylate is a relevant allergen. Reversible reactivity to other acrylates is rarely observed, but other, hitherto unidentified, contact allergens may still be present in the device.

6.2.12.

Continuous glucose monitoring improves glycemic control, reduces hypoglycemia, and may reduce the overall cost of diabetes management. Expanding CGM coverage and use is likely to improve the health outcomes of people with diabetes.

The authors confirmed that the insulin pump, as one of the ways to treat insulin in patients with type 1 diabetes, is a good choice and that its use achieves better glycemic regulation, that it is effective especially in children under 6 years of age, and that it increases quality of life. with diabetes mellitus.

The authors confirmed that glucose measurements with the FreeStyle Libre system give accurate results compared to blood capillary glucose reference values. Further evaluation is needed to identify the appropriate target population that is most likely to benefit from freestyle libre, and cases of allergic contact dermatitis caused by FreeStyle Libre have been increasingly noticed recently.

The key conclusion of the research would be:

It is recommended to use FreeStyle Libre but with an insulin pump, for continuous monitoring of glucose levels, and based on the presented facts, the working hypothesis is accepted: "Insulin pump is an efficacy in the control of type 1 diabetes mellitus, from FreeStyle Libre".

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