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L. Vogt[1], K.-D. Kohnert[2], P. Heinke[2], A. Thomas[3], E. Salzsieder[2]

[1]Diabetes Service Center, Karlsburg, Germany;
[2]Institut of Diabetes «Gerhardt Katsch», Karlsburg, Germany;
[3]Medtronic, Meerbusch, Germany
(E-mail: vogt@diabetes-karlsburg.de)

Use of the KADIS-CSII program for adjusting insulin pump therapy in type 1 diabetes

Continuous subcutaneous insulin infusion (CSII) has become a standard for treatment optimization of type 1 diabetes (T1D). However, the transition from Multiple Dose Injection (MDI) to CSII therapy can be challenging. The objective of the present study was to use KADIS, the Karlsburg Diabetes Management System, for individual basal and bolus insulin adjustments in patients with type 1 diabetes while switching from MDI to pump therapy. We describe the extended KADIS-CSII program and its practical application for adjustment of insulin pump therapy. We conducted a pilot study including 12 patients with T1D who had received MDI therapy consisting of short- and long-acting insulin injections. Baseline HbA1c was 8.2±0.8 %, age 31.3±11.1 years, and diabetes duration 15.7±6.7 years (mean±SD). Data derived from continuous glucose monitoring (CGM) during MDI therapy were processed by the KADIS algorithm in order to characterise the patient's specific metabolic parameters. Those were used to estimate individual basal infusion rate patterns as well as insulin boluses based on carbohydrate consumption for the transition to CSII. Three months after transitioning from MDI to CSII based on KADIS guided therapy, the mean HbA1c value was reduced to 7.6±0.5 % (–0.6 % vs. baseline, $p<0.05$) and remained at this level until the end of the 6-month study. Likewise, time <3.9 mmol/L ($p=0.008$), glycemic variability indexes, such as SD around mean glucose ($p=0.010$), MAGE ($p=0.001$), and CONGA ($p=0.007$), were all significantly lower at study end. Consistent with these data, quality of glycemia measured by the GRADE index and a recently developed Q-score was also improved. The proposed KADIS-CSII program could become a practicable and efficient tool to support adjusting insulin pump therapy.

Key words: diabetes, insulin pump therapy, KADIS-program therapy, glycemia, glucose metabolism, HbA1.

Introduction

Several studies have shown that diabetic patients with poor glycemic control who are assigned to insulin infusion therapy achieve better improvements in HbA1c levels than those that remain on multiple injection treatment [1–5]. Compared with Multiple Dose Injection (MDI), the essential advantages of continuous subcutaneous insulin infusion (CSII) include adjustable basal rates and flexible delivery of short-acting insulin boluses for meals according to individual lifestyle preferences. While currently available conventional insulin pumps may differ by some specific features, all of them provide similar basic functionality allowing users to deliver pre-programmed pattern of basal insulin adjustable for times of lower and higher insulin demand, like during exercise or acute illness. Boluses are given before meals based on actual blood glucose levels and the anticipated food intake. Pumps can also provide decision support by calculating the insulin bolus dose needed to cover for the amount of carbohydrates to be consumed. The flexible use of short-acting insulin boluses at mealtimes and continuous basal insulin infusion around the clock does represent an acceptable compromise, closely mimicking physiologic pattern of insulin secretion. Consequently, if handled adequately users can achieve near-normoglycemia without extensive glucose fluctuations and without increasing the risk for hypoglycemia.

The transition from MDI to insulin pump therapy does allow for therapy optimization by determining individualized basal insulin infusion rate pattern, which differ from patient to patient and vary within periods of the day. The basal insulin dose is usually calculated as a percentage of the total daily insulin requirement. In order to establish variable rate pattern one can introduce fasting periods and compensate changing blood glucose levels by adjustments of the basal rates. In practice this procedure of compensation is cumbersome

and usually requires several days until blood glucose levels remain relatively steady. After a 24-h basal insulin profile has been established, meal boluses can be refined considering respective carbohydrate intake. The whole process of building up basal rate profiles and determining meal boluses correctly is rather time-consuming and represents a challenge for most family physicians as well as their patients.

We have previously developed the personalized counseling program KADIS® (Karlsburg Diabetes Management System) [6–8]. The program is based on a mathematical model describing the glucose metabolism in the form of a coupled system of differential equations. The individual metabolic situation, including food intake, insulin therapy, anti-diabetic medication, physical activity, and lifestyle, is reflected by a so-called «Metabolic Fingerprint» for each patient. Endogenous factors, such as insulin sensitivity and insulin reserve are identified during the process and responsible for the individual expression of the fingerprint profile.

Based on CGM measurements and patients' metabolic control data, we have expanded the KADIS program for implementation in CSII therapy to determine individual basal insulin rates and meal boluses. Here we are presenting a pilot study using the expanded KADIS program supporting the optimization of basal/bolus insulin delivery by pump with focus on T1 while switching from MDI to CSII.

Research Design and Methods

KADIS-based adjustment of CSII therapy. For this purpose, the original KADIS-program was extended and implemented in the CSII therapy, as further referred to as KADIS-CSII. The KADIS-CSII therapy support was implemented as follows: First, CGM measurements and patient's self-control data (CHO-meals, insulin doses, time etc.) were entered into the KADIS software to generate the «Metabolic Fingerprint», as demonstrated in Figure 1*a*. The «Metabolic Fingerprint» represents an *in silico* copy of the patient´s metabolic status. Second, as shown in Figure 1*b*, an initial setting of the basal rate was performed on the computer, omitting meals and insulin boluses (switch off within the software). Taking the pharmacokinetic differences between basal insulin infusion and bolus injections into account, the basal insulin rate, sufficient of predicting the glycemic curve residing in the normal range, was calculated by the KADIS specific mathematical algorithm. Third, meal effects were included in the computer simulation estimating appropriate insulin boluses in relation to the carbohydrate intake (Fig. 1*c*).

Setting and Patients

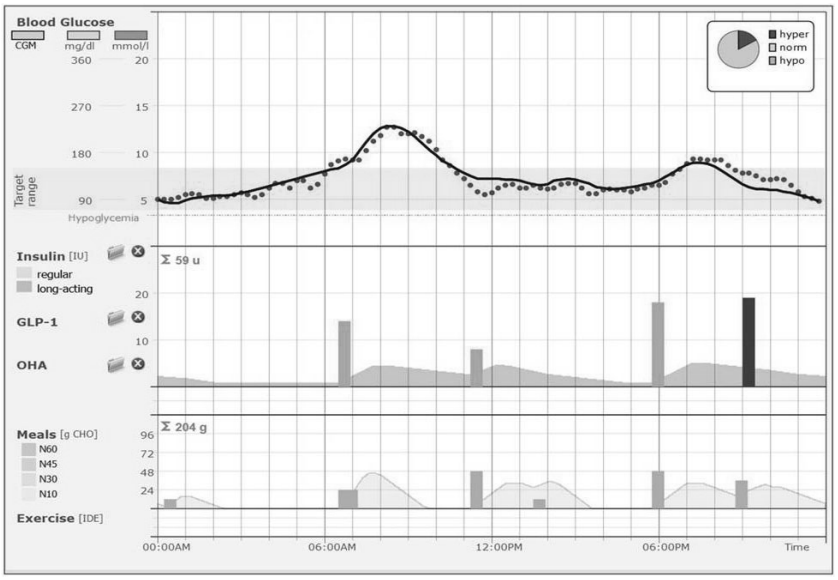
The pilot study was carried out at the Clinic of Diabetes and Metabolic Diseases Karlsburg, Germany, between February and December 2012. Twelve patients with type 1 diabetes on MDI therapy for a minimum of 2 years were included. MDI therapy consisted of either short-acting insulin Humalog (n = 4), Novorapid/Actrapid (n = 5), Liprolog (n = 2) or Huminsulin (n = 1) in combination with long-acting insulin Lantus (n = 9), Levemir (n = 2) or Huminsulin basal (n = 1). Exclusion criteria included clinically significant nephropathy, neuropathy, retinopathy, and women who were pregnant or breast feeding. Mean age of the participants was 31.3 ± 11.1 years, diabetes duration 15.7 ± 6.7 years, and baseline HbA1c 8.2 ± 0.8 %.

After hospital admission a continuous glucose monitoring was performed over 6 days, using the iPro system (Medtronic MiniMed). All participants performed a MDI therapy during this CGM. All participants signed informed consent prior to study entry. The main patient characteristics are shown in Table 1.

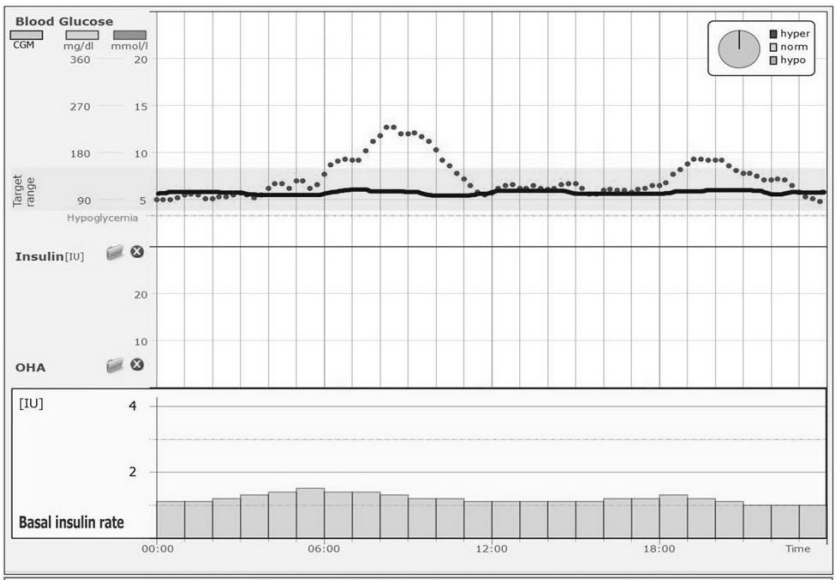
Table 1

Baseline characteristics of the study patients

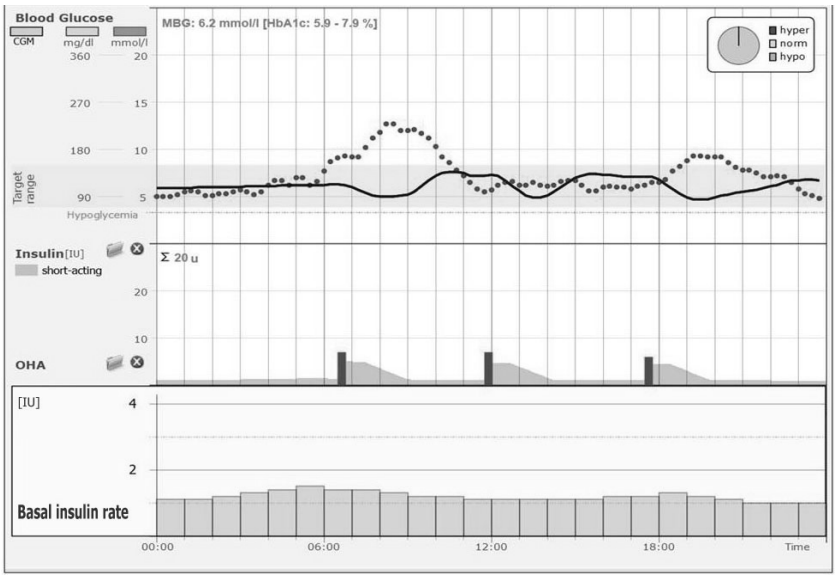
Patient	Age (years)	Gender	Diabetesduration (years)	HbA1c (%)	BMI (kg/m^2)	Insulinrequirement (U/day)
1	38	m	26	8.0	30.0	66
2	25	w	19	8.0	29.0	50
3	23	w	14	8.5	22.4	41
4	25	w	22	10.3	23.5	39
5	61	w	5	7.6	27.4	36
6	26	w	19	8.4	24.1	61
7	28	w	16	7.5	25.5	54
8	36	m	15	8.1	25.4	66
9	25	w	13	8.5	23.5	60
10	24	m	18	8.7	21.5	42
11	40	m	2	7.3	22.6	42
12	25	w	19	7.5	27.4	64
N = 12	31.3±11.1	8f/4m	15.7±6.7	8.2±0.8	25.2±2.7	51.8±11.4



a) **«Metabolic Fingerprint»** — After entering the measured data from continuous glucose monitoring (glucose curve with red dots), insulin dosing (3 x short-acting insulin, 1 x long-acting insulin; bar graph in the middle), and the meals as CHO (lower part of the figure), the model is fitted to the metabolic control of the patient and the glucose curve (blue) is finally simulated by the KADIS® model system



b) **KADIS®-based profile of the insulin basal rate** — After omitting the insulin bolus as well as meals, and considering the different pharmaco-kinetics of bolus insulin injections and continuous insulin infusion (CSII) is determined by simulation of the individual basal rate (bar graph)



c) **KADIS®-based transition to CSII therapy** — Meals are added again and the insulin boluses determined in relation to the amount of carbohydrates consumed. The expected glucose curve for the KADIS®-CSII setting of the individual basal rate and meal insulin boluses (red bar in the middle) is shown in blue

Figure 1. Procedure for KADIS® CSII-based assessment of the basal rate and the adjustment of boluses

The data flow for application of KADIS-CSII is shown in Figure 2. Comprising of:

(1) personalized mathematical adjustment to the acute individual metabolic situation «Metabolic Fingerprinting»;
(2) KADIS-based computer simulation of change of insulin injection from MDI to CSII therapy, taking pharmacokinetics under MDI and continuous insulin infusion into account;
(3) simulation of food omission and mathematical determination of individual basal insulin rate;
(4) simulation of meal insulin boluses dependent on food intake and changing circadian insulin sensitivity.

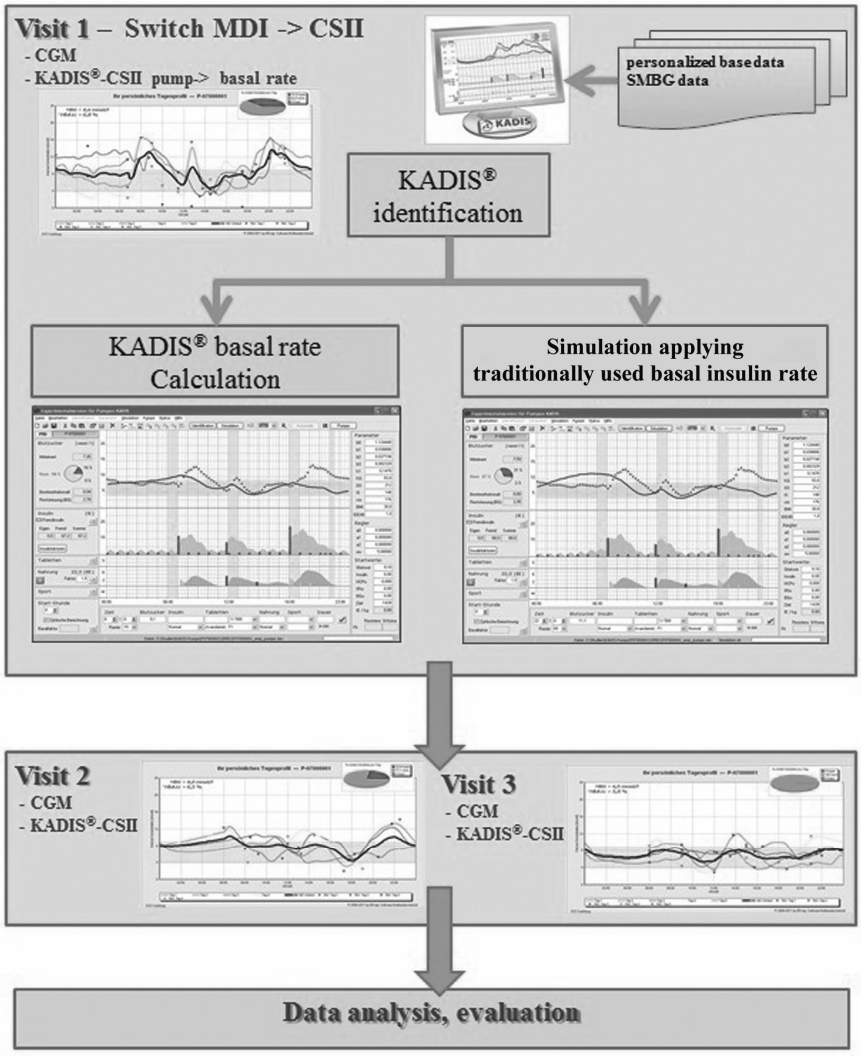


Figure 2. Flow chart of the KADIS-CSII study

Based on the result of the KADIS – CSII simulation a proposal was put forward to support the attending physician in adjustment of pump therapy.

Measures of glycemia

HbA1c levels were estimated from blood samples by standard procedure. The following measures were derived from CGM profiles: mean glucose concentration (MGC), standard deviation around mean glucose (SD), time spent in hypoglycemia and hyperglycemia, high blood glucose index (HBGI), low blood glucose index (LBGI), interquartile range, mean amplitude of glycemic excursion (MAGE), and continuous overall net glycemic action (CONGA). In addition, the quality of glycemic control was assessed by the Glycemic Risk Assessment Diabetes Equation (GRADE) score and a newly developed Q-score [9–10]. The Q-score does represent a combined value of various qualitative measures of glucose control that has been proven an effective determination of metabolic risk for an individual patient. Q-score evaluation criteria are depicted in Table 2.

Table 2

Q-Score evaluation criteria

Q-Score		Clinical evaluation of the quality of glycemic control
≥ 12.0	Poor	Glycaemia mostly outside the target range (>80 %), very high variability, presence of hypoglycaemic episodes
8.5–11.9	Fair	Glycaemia often outside the target range (50–80 %), high variability, hypoglycaemic episodes can occur
6.0–8.4	Satisfactory	Glycaemia partially outside the target range (20–50 %), reasonable variability
4.0–5.9	Good	Glycaemia mostly within the target range (80–100 %), low variability, no hypoglycaemic episodes
< 4.0	Very good	Glycaemia completely within the target range (80–100 %), negligible variability, no hypoglycaemic events

Primary outcomes were the HbA1c value and time in hypoglycemia (<3.9 mmol/L). Secondary outcomes included glycemic variability and quality of glycemic control.

Statistical analysis

Data are presented as mean±SD values unless otherwise specified. Individual comparisons within patients between MDI and CSII treatment were performed using the paired t-test and between group comparisons using analysis of variance. The mean area under the glucose curve (AUC) was calculated by the trapezoidal method. A P-value of <0.05 was considered statistically significant. Analyses were carried out using SPSS, version 12.0.

Results

Table 1 shows the baseline characteristics of the participants included in the study. Prior to CSII therapy HbA1c levels ranged from 7.3–10.3 % (56–89 mmol/mol). Switching to CSII therapy reduced HbA1c values by an average 0.6 % (p<0.052) during 3 month with no further decrease until the end of the study at 6 month. As shown in Table 3, CGM mean glucose was not significantly decreased, while time spent at glucose levels <3.9 mmol/L was reduced by a mean of 64 % (p = 0.008). This is consistent with a 62 % decrease in LBGI. The time glucose levels were in target range (3.9–8.9 mmol/L) increased overall from 73 to 86 % (p = 0.048). Four out of the 12 participants achieved 100 % with glucose levels spent in the target range. CSII therapy also decreased glycemic variability: SD 1.8 *vs.* 2.8 mmol/L (p = 0.010), MAGE 0.9 *vs.* 1.6 mmol/L (p = 0.001), and CONGA 2.7 *vs.* 4.3 (p = 0.007). It did not significantly decrease the GRADE score (5.6 *vs.* 7.3, p = 0.12) but did improve the quality of glycemic control as estimated by the Q-score (8.0 *vs.* 12.6, p = 0.001).

Table 3

Comparison of glycemic parameters at baseline and after 3 and 6 months duration

Parameter	MDI baseline	CSII at 3 months	CSII at 6 months	P Value
HbA1c, %	8.2	7.6	7.6	0.052
MGC, mmol/l (mg/dl)	7.5 [135]	8.3 [149]	7.3 [131]	0.065
SD, mmol/l (mg/dl)	2.8 [50]	2.2 [40]	1.8 [32]	0.010
MAGE, mmol/l (mg/dl)	1.63 [29]	1.09 [20]	0.91 [16]	0.001
Time > 8.9 mmol/l, h/day	6.87	8.22	5.54	0.359
AUChyper, mg/dl×day	19.50	17.03	12.31	0.166
Time < 3.9 mmol/l, h/day	2.87	0.65	1.02	0.008
AUChypo, mg/dl×day	2.35	0.41	0.54	0.010
Glucose levels in target range, %	72.7	74.5	86.0	0.048
Glucose Range, mmol/l (mg/dl)	10.5 [189]	8.6 [155]	6.9 [124]	0.006
HBGI	2.51	2.59	1.94	0.166
LBGI	1.70	0.42	0.65	0.011
GRADE	7.27	6.89	5.61	0.115
CONGA?	4.34	3.63	2.65	0.007
Q-Score	12.6	9.7	8.0	0.001

MGC, Mean Glucose Concentration; SD, Standard Deviation of Glucose Concentration; MAGE, Mean Amplitude of Glucose Excursion; Glucose Range (Max/Min), HBGI, High Blood Glucose Index; LBGI, Low Blood Glucose Index; GRADE, Glycemic Risk Assessment Diabetes Equation; CONGA, Continuous Overall Net Glycemic Action; Q-score, Quality of glycemic control.

Comparison of the basal rate estimates using the KADIS-CSII algorithm e.g. with the default scheme proposed by Renner [11, 12] for setting the basal insulin rate did reveale significant differences (Fig. 3). The differences consisted in dose, which were on average lower than by the traditional method, and in dynamics/distribution of the basal rate. Fig 4 demonstrates an example in case of identical basal insulin dose recommendation resulting in differences of distribution between KADIS-CSII and the Renner method. The method by Renner suggested an average 26.6 ± 6.6 IU daily amount of insulin, whereas CSII-KADIS suggested 21.7 ± 5.7 IU (p = 0.35). With minor modifications implemented by HCPs under everyday conditions, the mean basal insulin dose at the end of the 6months period consisted of 20.6 ± 4.8 U/day (p = 0.24).

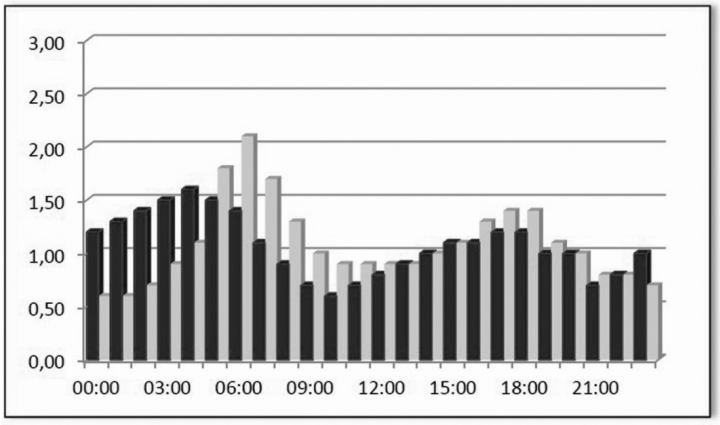


Figure 3. Basal rate profiles obtained for 26 IU with KADIS®-CSII adjustment (red) and after using the default profile by Renner et al. (light blue)

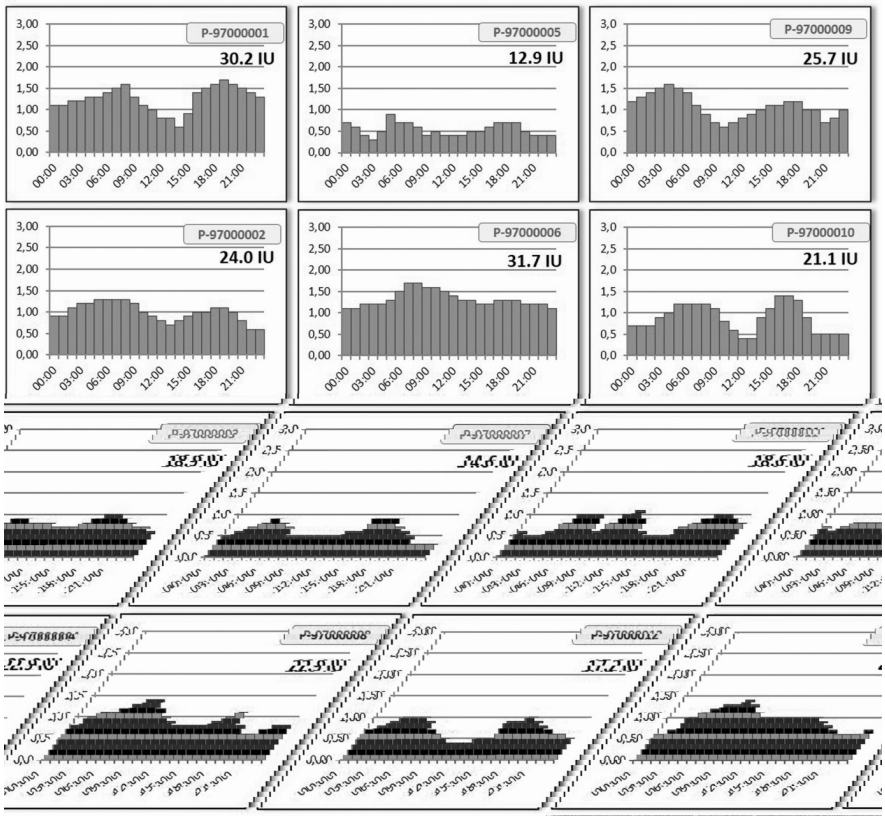


Figure 4. Samples of individual basal rate profiles with KADIS®-CSII of patients included in present study

Discussion

Our study shows that the KADIS-CSII program, which was specifically developed for recommendations of insulin pump therapy, is able to efficiently provide basal rates and insulin meal boluses. The capabilities of our algorithm outperform most widely used empirical approaches, which require several time-consuming meal omission tests until the basal insulin infusion profile can be established followed by adjusting meal boluses to minimize postprandial glucose excursions. The KADIS-CSII program, however, allows an instant assessment of basal insulin rate and meal boluses necessary to achieve glucose levels in target range by simulation, provided CGM profiles and respective inputs were recorded over a duration of several days. Herein, we have mainly used the iPro monitoring system to record glucose values over 6 days. It is conceivable that the longer the glucose monitoring time, usually 6–14 days, the more precise the «Metabolic Fingerprint» and thus estimation of basal and bolus insulin. Generating the «Metabolic Fingerprint» and calculation of the personalized basal rate setting for a patient by KADIS-CSII takes less than 10 minutes. This data does indicate that the use of KADIS would facilitate a successful transition from MDI to pump therapy within a much shorter period of time than considered traditionally. In addition, the use of KADIS by the clinician does offer checking out various treatment options or patient preferences by simulation in lieu of empirical implementation. It is also of note that the average daily insulin dose compared to MDI therapy could be reduced by 62 % (22 vs. 52 U/day) and was lower than suggested by the traditional method (22 vs. 26 U/day). Furthermore calculation of basal rates by KADIS-CSII results in personalized profiles/ distribution pattern for a patient whereas in case of the traditional method would result in identical pattern, including the same initial basal rate, for a given amount of insulin.

In addition, an important feature of the KADIS-CSII algorithm is the potencial to avoid hypoglycemia during adjustment of pump therapy. Using it is straightforward and requires users to input body weight, amount of carbohydrates, total daily insulin dose, and basal insulin infusion rate. Moreover, it is capable of discriminating between rapidly and slowly absorbed meals, and the variability in insulin sensitivity is assessed by model-based analysis. Limitations of the study are the small sample size, the dominance of female gender, and the broad age range (23–61 years) of participants.

The procedure of the program «KADIS®-CSII» on the identification of a «metabolic fingerprint» should be tested for other patients and age groups, which are known to have variable basal rate profiles. In particular, in children and adolescentsthis is known. The effectiveness of KADIS®-CSII in these groups of patients should be subject of further investigations.

In summary, introduction of the KADIS-CSII program into clinical practice circumvents time-consuming meal omission tests to build up individual basal insulin rates and cover prandial insulin deficiency. It may thus increase efficiency and flexibility when switch from MDI to pump therapy is required to optimize glycemic control. KADIS-CSII is a program that can be effectively used for the conversion of patients on CSII or the optimization of an existing CSII. For this purpose, a variant already has been created, which implements the calculation in an iPad (TeleDIAB). This makes it possible for the first time in the presence of CGM data and a corresponding user access to transfer patients to a CSII therapy to support online. The clinical relevance of KADIS-CSII is the immediate achieve optimum adjustment of the insulin pump parameters. The economic relevance relates to the time savings for the diabetes team, but also for the patients without burdening meal omission and other tests as well as access to a telemedicine solution. Finally KADIS-CSII provides personalized basal rates considering the typical daily life style of patients. These advantages are to be confirmed in a randomized, controlled clinical trial with a larger number of patients.

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Л. Фогт, К.-Д. Конерт, П. Хайнке, А. Томас, Е. Зальцидер

1-Типті қант диабеті терапиясында инсулинді сорғышты қолдану үшін KADIS-CSII бағдарламасын пайдалану

1-Типті қант диабетін (T1D) емдеуде тері асты арқылы инсулинді (CSII) үздіксіз енгізуді оңтайландыру үрдісі стандартты болып табылады. Алайда бірнеше рет енгізген инъекциядан кейін CSII терапияға көшу қиынға соғады. Бұл зерттеудің мақсаты — инсулиндік сорғышта пайдаланатын инсулин терапиясының диабетті басқаратын KARLSBURG-KADIS жүйесін қолдану. Инсулин сорғыштарын пайдалану кезінде біз оның практикалық процесіндегі KADIS-CSII бағдарламасын ұсындық. Сондай-ақ инсулин қысқа және ұзақ мерзімді әсер ететін емнен тұратын MDI емін қабылдаған T1D-мен 12 науқастарды алдын ала зерттедік. HbA1c бастапқы деңгейі 8,2 ± 0,8 % құрады, емделушілердің жасы 31,3 ± 11,1 аралығында және қант диабетімен ауру ұзақтығы 15,7 ± 6,7 жылға тең болды. Науқастың нақтылы метаболитті көрсеткіштерін сипаттайтын MDI терапиясы кезінде глюкоза деңгейін үздіксіз бақылау (CGM) мәліметтері KADIS алгоритм көмегімен жүзеге асты. Үш ай өткен соң MDI-дан CSII-ға өту үшін негізгі терапия KADIS негізінде бақылынып, HbA1c орташа мәні 7,6 ± 0,5 % -ға төмендеді және алты айлық зерттеу соңына дейін осы деңгейде болды. Ұсынылған KADIS-CSII бағдарламасы инсулин сорғыш терапиясын өту үрдісінде нақты және тиімді нормативтік құрал бола алады.

Л. Фогт, К.-Д. Конерт, П. Хайнке, А. Томас, Е. Зальцидер

Применение программы KADIS-CSII для использования инсулинового насоса в терапии диабета 1 типа

Непрерывное подкожное вливание инсулина (CSII) стало стандартом в процессе оптимизации лечения диабета 1 типа (T1D). Однако переход от многократных инъекций к терапии CSII является непростым. Цель данного исследования состояла в том, чтобы использовать KADIS-KARLSBURG-систему управления диабетом при переводе терапии инсулином на использование метода его непрерывного введения. Нами представлена расширенная программа KADIS-CSII в процессе ее практического применения при использовании инсулиновых насосов. Проведено предварительное исследование, 12 па-

циентов с T1D получили терапию MDI, состоящую из инсулина короткого и длительного действия. Начальный уровень HbA1c составлял 8.2±0.8 %, возраст пациентов — 31.3±11.1 лет и продолжительность диабета — 15.7±6.7 года. Данные непрерывного контроля уровня глюкозы (CGM) во время терапии MDI были обработаны алгоритмом KADIS, чтобы характеризовать определенные метаболические параметры пациента. Спустя три месяца после перехода от MDI к CSII на основе управляемой терапии KADIS среднее значение HbA1c было снижено до 7.6±0.5 % и оставалось на этом уровне до конца шестимесячного исследования. Предложенная программа KADIS-CSII может стать реальным и эффективным регулирующим инструментом в процессе перехода к терапии инсулиновым насосом.