ORIGINAL ARTICLE

Continuous Subcutaneous Insulin Infusion Placement in Preschool Children Newly Diagnosed with Type 1 Diabetes

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Abstract

Introduction: The incidence of childhood type 1 diabetes is increasing worldwide, especially in young children. According to international guidelines, continuous subcutaneous insulin infusion is the preferred method of insulin delivery for preschool children. This study aimed to evaluate the efficacy and safety of continuous subcutaneous insulin infusion treatment soon after diagnosis in preschool children with type 1 diabetes.

Methods: A retrospective study was performed from 2016 to 2019, including all preschool children who placed continuous subcutaneous insulin infusion system up to two months after the diagnosis of type 1 diabetes. These patients were followed up for 18 months.

Results: This study included 11 patients (median age of 2.55 years at diagnosis, 54.5% females). All patients had a low C-peptide at diagnosis with a median of 0.45 ng/mL (interquartile range 0.18-0.58 ng/mL). The median of hemoglobin A1c decreased from 9.5% (interquartile range 8.1%-10.4%) at diagnosis to 7.4% (interquartile range 7.1%-7.7%) after 18 months of follow-up. The median of the total daily insulin dose increased from 0.49 IU/kg/day (interquartile range 0.45-0.49 IU/kg/day) to 0.70 IU/kg/day (interquartile range 0.61-0.78 IU/kg/day). Based on glucometer records, the median of self-monitoring blood glucose varied between 6.15-7.95 measures per day. The mean ± standard deviation of glucose varied between 158.5 ± 68.5 and 186 ± 83 mg/dL. The median value of the coefficient of variation varied between 42.5%- 47.9%. During the 18-month follow-up, no patient experienced diabetic ketoacidosis, severe hypoglycemia, or local complications.

Conclusion: The continuous subcutaneous insulin infusion seems safe and effective as an initial therapeutic approach to type 1 diabetes in preschool-aged children.

Keywords: Continuous subcutaneous insulin infusion, Follow-up, Preschool-aged children, Type 1 diabetes

Keypoints

What is known:

- Type 1 diabetes is one of the most prevalent chronic illnesses diagnosed in childhood, and its incidence is increasing in preschool-aged children.
- Continuous subcutaneous insulin infusion is the most physiological therapy of insulin replacement; therefore, it is expected to associate with long-term improvement in the disease.
- All children with type 1 diabetes, regardless of age, should be potentially eligible candidates for continuous subcutaneous insulin infusion.

What is added:

- To the best of our knowledge, there are no published studies in Portugal about using continuous subcutaneous insulin infusion in preschool-aged children.
- The early age of diagnosis associated with low C-peptide values predicts a low residual β-cell function.
- Continuous subcutaneous insulin infusion is safe and effective as an initial therapeutic approach to type 1 diabetes in preschool-aged children.

Introduction

Type 1 diabetes is a multifactorial disease characterized by the destruction of islet β-cells that leads to insulin deficiency.[1,2] Type 1 diabetes is one of the most prevalent chronic illnesses diagnosed in childhood, and its incidence seems to be increasing at an alarming rate in preschool-aged children.[3] This challenging population is particularly susceptible to both hyperglycemia and hypoglycemia because of wide fluctuations in physical activity from day to day, unpredictable eating habits, frequent intercurrent infections, and difficulties in delivering very small doses of insulin.[3,4]

Treatment requires the administration of subcutaneous

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insulin in doses calculated according to carbohydrate consumption and blood glucose measurements. It also requires basal insulin replacement. Physical activity, illness, and stress also play a role in calculating the total daily insulin (TDI) dose.[5] The Diabetes Control and Complications Trial[6] provided conclusive evidence that strict glycemic control reduces the development and progression of late complications in patients with type 1 diabetes.[6] Continuous subcutaneous insulin infusion (CSII) increases flexibility and facilitates diabetes management, compared to multiple daily insulin injections.[7] All children with type 1 diabetes, regardless of age, should be potentially eligible candidates for continuous subcutaneous insulin infusion.[8] In recent years, to reduce complications and improve blood glucose control, continuous subcutaneous insulin infusion has been used as an option for diabetes management, especially in preschool-aged children.[9]

This study aimed to evaluate the efficacy and safety of continuous subcutaneous insulin infusion treatment soon after diagnosis in preschool children with type 1 diabetes. Another aim of the study consisted of evaluating the pancreatic reserve relating to the values of C-peptide and the total daily insulin dose.

Methods

An observational, retrospective study was performed on all preschool-aged children newly diagnosed with type 1 diabetes in our center (a level III hospital) between February 2016 and January 2019 (a three-year study). Subjects were selected from an institutional database of pediatric diabetic patients. The inclusion criteria were children with type 1 diabetes aged < 6 years at the time of diagnosis and continuous subcutaneous insulin infusion placement up to two months after diagnosis. During the study, 13 children were newly diagnosed with type 1 diabetes (under 6 years of age), and only two did not place an insulin infusion system after diagnosis (parental choice).

Data were retrospectively collected from medical records. The following variables were recorded at diagnosis: age, gender, presentation with diabetic ketoacidosis (DKA) *versus* diabetic ketosis without acidosis, fasting C-peptide levels, hemoglobin A1c (HbA1c), need for hospitalization on the inaugural episode, the moment of continuous subcutaneous insulin infusion placement, positive diabetes-associated autoantibodies: glutamic acid decarboxylase 65 autoantibodies (GADA), tyrosine phosphatase-like insulinoma antigen 2 (IA2), islet cell autoantibodies (ICA), and β-cell specific zinc transporter 8 autoantibodies (ZnT8). Diabetic ketoacidosis was defined by the presence of hyperglycemia (blood glucose > 200 mg/dL or 11 mmol/L), venous pH < 7.3 or serum bicarbonate < 15 mmol/L, and ketonemia (blood β-hydroxybutyrate ≥ 3 mmol/L).[10] Fasting C-peptide levels were measured on days immediately after diagnosis as soon as glycemic stability was restored. HbA1C at diagnosis was measured by ion-exchange high-performance liquid chromatography.

During a follow-up period of 18 months, the following data were recorded at each visit: HbA1c value, mean glucose and standard deviation (SD), coefficient of variation (%CV) obtained multiplying the ratio between the standard deviation and the mean glucose by 100, frequency of self-monitoring blood glucose (SMBG), total daily insulin dose (IU/kg/day) basal (%) and bolus (%), and acute complications (diabetic ketoacidosis, severe hypoglycemia, and continuous subcutaneous insulin infusion local complications). During the follow-up, HbA1c was measured by a finger stick blood sample with the DCA® 2000+Analyzer (GMI Inc.) device (monoclonal antibody agglutination reaction), following the manufacturer's guidelines. At each medical visit, the insulin pump and glucometer data were downloaded, allowing us to obtain the total insulin dose, and the frequency of self-monitoring blood glucose, mean glucose, as well as standard deviation. Severe hypoglycemia was defined as an incident of confirmed hypoglycemia that led to the loss of consciousness and/or seizure.[11]

Table 1. Demographic, clinical, and laboratory characteristics at diagnosis

Sex, n (%)	
Females	6 (54.5)
Males	5 (45.5)
Age (years), median (IQR)	2.55 (0.92-3.30)
Presentation form, n (%)	
Diabetic ketoacidosis	4 (36.4)
Ketosis without acidosis	7 (63.6)
Hospital admission, n (%)	9 (81.8)
Length of stay (days), median (IQR)	5 (4-6.5)
Fasting C peptide level (ng/mL), median (IQR)	0.45 (0.18-0.58)
Diabetes-associated autoantibodies, n (%)	
GADA +	7 (63.6)
IA2 +	8 (72.7)
ICA +	10 (90.9)
ZnT8 +	3 (27.3)
Moment of placement of CSII (days), median (IQR)	3 (1-21)

CSII - continuous subcutaneous insulin infusion; GADA - glutamic acid decarboxylase 65 autoantibodies; IA2 - tyrosine phosphatase-like insulinoma antigen 2; ICA - islet cell autoantibodies; IQR - interquartile range; ZnT8 - β-cell specific zinc transporter 8 autoantibodies.

Table 2. Glycemic control during follow-up period

	Diagnosis n = 11	3 months n = 11	6 months n = 11	9 months n = 11	12 months n = 11	18 months n = 11
HbA1c (%), median (IQR)	9.5 (8.1-10.4)	8.5 (8,1-9)	7.6 (7.4-7.9)	7.7 (7.4-8)	7.7 (7.5-8.1)	7.4 (7.1-7.7)
TDI (IU/kg/day), median (IQR)	0.49 (0.45-0.5)	0.53 (0.47-0.61)	0.62 (0.55-0.7)	0.70 (0.62-0.75)	0.72 (0.62-0.8)	0.70 (0.61-0.78)
Basal (%)	48	52	55	54	51.5	55
Bolus (%)	52	48	45	46	48.5	45
SMBG (measures / day), median (IQR)	--	6.7 (6.03-7.2)	6.15 (5.4-8.73)	7.1 (5.4-10.7)	7.95 (5.45-10.6)	7.55 (5-10.55)
Mean glucose ± SD (mg/dL)	--	182.5 ±78.5	160 ±68.5	186 ±83	173 ±77	158.5 ±79.5
%CV, median (IQR)	--	45.9 (36.1-51.6)	42.5 (37.4-46.5)	47.9 (40.1-49.4)	45.8 (40.4-48.3)	46.1(40.8-52.6)
DKA (episodes / year)	--	0	0	0	0	0
Severe hypoglycemia (episodes / year)	--	0	0	0	0	0
Local complications, n (%)						
Infection	--	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Lipodystrophy		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

%CV - coefficient of variation; DKA - diabetic ketoacidosis; HbA1c - hemoglobin A1c; IQR - interquartile range; SD - standard deviation; SMBG - self-monitoring blood glucose; TDI - total daily insulin dose.

Statistical analysis was performed using the IBM SPSS statistics software (version 26®). Continuous variables were characterized by mean ± SD and median (interquartile range, IQR) if they had symmetric or asymmetric distribution, respectively, and categorical variables by absolute and relative frequencies.

Results

Eleven patients were included in the study, 54.5% (n = 6) females. The demographic, clinical, and laboratory characteristics at diagnosis are summarized in Table 1.

The median age at diagnosis was 2.55 years (minimum 9 months and maximum 4.27 years). Regarding the presentation form, 36.3% (n = 4) had diabetic ketoacidosis, and the remaining patients presented with ketosis without acidosis. Patients who required hospital admission in the inaugural episode were 82% (n = 9) with a median length of stay of five days (IQR 4-6.5 days).

The median fasting C-peptide level at diagnosis was 0.45 ng/mL (IQR 0.18-0.58 ng/mL). Regarding autoimmunity, most patients (n = 10) had two or more positive autoantibodies. The ICA was present in 90.9% of patients (n = 10), followed by IA2 in 72.7% (n = 8), GADA in 63.6% (n = 7), and finally, ZnT8 in 27.3% (n = 3). A family history of type 1 diabetes was also present in six patients (54.5%).

The continuous subcutaneous insulin infusion treatment started at a median of three days after diagnosis (IQR 1-21 days). The median HbA1c decreased from 9.5% (IQR 8.1%-10.4%) at diagnosis to 7.4% (IQR 7.1%-7.7%) after 18 months of follow-up, as presented in Table 2. On the other hand, the median total daily insulin dose increased from 0.49 IU/kg/day (IQR 0.45-0.49 IU/kg/day) to 0.70 IU/kg/day (IQR 0.61-0.78 IU/kg/day) (Table 2).

Based on glucometer records, the median of self-monitoring blood glucose varied between 6.15-7.95 measures per day. The mean glucose ± SD varied between 158.5 ± 68.5 mg/dL and 186 ± 83 mg/dL (Table 2). The median value of %CV varied between 42.5%-47.9%.

During the 18 months of follow-up, none of the patients had diabetic ketoacidosis or severe hypoglycemia. There were also no local complications, such as lipodystrophy or infection at the catheter insertion site. However, two hospital readmissions occurred during the follow-up due to ketosis without acidosis related to intercurrent illness (febrile intercurrence with oral intolerance).

Discussion

Very young children have a shorter but more aggressive prediabetes phase corresponding to the rapid and more extensive destruction of β-cells, relatively smaller β-cell mass, or less regenerative β-cell capacity.[12] Residual β-cell function can be assessed by measuring C-peptide concentration. A value of fasting C-peptide of 0.6 ng/mL was proven to be a meaningful cut-off point for residual β-cell function.[13] Most patients, after starting insulin therapy, have a transient improvement in β-cell function, which peaks between two and six months after diagnosis, known as the honeymoon phase. In our cohort, the fasting C-peptide was low (median at diagnosis 0.45 ng/mL, maximum 0.66 ng/mL), which means a low residual β-cell function. On the other hand, during the study period, there was an increase in insulin dosage (median total daily insulin increased from 0.49 IU/kg/day to 0.70 IU/kg/day). These findings reflect

more progressive and rapid destruction of β-cells, less residual insulin by at diagnosis, and the absence of a honeymoon phase in preschool-aged children.

The use of continuous subcutaneous insulin infusion therapy in type 1 diabetes has increased significantly in the last decade. One goal of the Portuguese national program for diabetes is the use of continuous subcutaneous insulin infusion in all children under 5 years. Several studies have demonstrated better metabolic control in preschool-aged children treated with continuous subcutaneous insulin infusion, compared to those treated with multiple daily insulin injections.[7,9,14,15]

A large meta-analysis demonstrated that continuous subcutaneous insulin infusion, compared to multiple daily insulin injections, is associated with lower HbA1c levels in children with type 1 diabetes.[9] In addition, a recent multicenter study showed that early initiation of insulin pump therapy provides better glycemic control (lower HbA1c values), decreases the risk of severe hypoglycemia, and leads to a better cardiovascular risk profile, compared to delayed treatment.[16] The results of the present study revealed a metabolic improvement with a decrease in median HbA1c from 9.5% at diagnosis to 7.4% after 18 months of follow-up, as described in the literature. According to the last recommendations of the International Society for Pediatric and Adolescent Diabetes,[17] the target HbA1c for all children with type 1 diabetes, including preschool children, is intended to be < 7%. Besides the value of HbA1c, regular self-monitoring blood glucose is essential for diabetes management for all children with type 1 diabetes. Hemoglobin A1c improvements with more frequent glucose measurements are due to better insulin dosing for the consumed carbohydrate and an improved ability to quickly correct out-of-target range glucose values.[17] The International Society for Pediatric and Adolescent Diabetes recommends at least six to 10 self-monitoring blood glucose per day for successful intensive diabetes management. This target was achieved in this study with the median of self-monitoring blood glucose between 6.15-7.95 measures per day. Probably, these results were undervalued because of the concomitant use of interstitial glucose monitoring systems. Although HbA1c remains the best measure of long-term glycemia within and between populations, several studies have shown that HbA1c has significant limitations when used in isolation to assess an individual's glycemic control. Glycemic variability is associated with a negative impact on brain volume and growth, and markers of cardiovascular morbidity in children with type 1 diabetes, despite the short disease duration.[18] The coefficient of variation is probably one of the most reliable markers to assess the amplitude of glycemic variability, and some investigators have established the coefficient of variation as a valid glycemic variability index.[19] According to a recent study,[19] a coefficient of variation of 36% appears to be a suitable threshold to distinguish between stable and unstable glycemia in diabetes because, beyond this limit, the frequency of hypoglycemia is significantly increased. In the present study, the median value of coefficient of variation varied between 42.5%-47.9%. Although these values are higher than recommended, they are similar to those described in a study in the same age group.[18]

In addition to good metabolic control, during the study period, there were no severe complications (diabetic ketoacidosis and severe hypoglycemia) and no local complications, such as lipodystrophy or infection at the catheter insertion site.

Despite the advantages already described in the use of continuous subcutaneous insulin infusion, challenges may arise in its placement soon after diagnosis. One barrier to the initiation of insulin pump therapy by parents for their children with type 1 diabetes is physical interference which may include physical discomfort, interference with activity, and concern for skin reactions. On the other hand, handling the insulin pump and the infusion tubing / catheter malfunctions are another challenge in the placement of continuous subcutaneous insulin infusion.[19] One limitation of this study lies in its design. As it is a retrospective study, it mainly relies on information from medical records, with possible inaccuracies and loss of data. Other limitations include the small sample size and the absence of a control group to compare results. Therefore, studies with larger samples are needed to support the present results.

In conclusion, continuous subcutaneous insulin infusion is safe and effective as an initial therapeutic approach to type 1 diabetes in preschool-aged children. Furthermore, the findings of a recent multicenter study provided evidence for improved clinical outcomes (better glycemic control, decreased risk of severe hypoglycemia, and a better cardiovascular risk profile) associated with the early initiation of insulin pump therapy in children with type 1 diabetes.[16]

The early age of diagnosis associated with low C-peptide values predicts a low residual β-cell function. In addition to HbA1c, concepts such as coefficient of variation and time in the range are increasingly used to assess metabolic control.

Compared to older children and adolescents, preschool children with diabetes represent a unique population. They require a flexible therapeutic regime, the responsibility of which rests entirely on their caregivers.

The use of continuous subcutaneous insulin infusion had a considerable impact on the quality of life of children and caregivers: fewer needle sticks, a scheme easily adjusted to the child's eating pattern, and the possibility of administrating small amounts of insulin.

Author Contribuitions

LT, JF, MJO and TB participated in the study conception or design. LT, VG and CR participated in acquisition of data. LT, VG, CR, JF, MJO and TB participated in the analysis or interpretation of data. LT and VG participated in the drafting of the manuscript. CR, JF, MJO and TB participated in the critical revision of the manuscript. All authors approved the final manuscript and are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of Interest

The authors declare that there were no conflicts of interest in conducting this study.

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Protection of human and animal subjects

The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki 2013).

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Confidentiality of data

The authors declare that they have followed the protocols of their work center on the publication of patient data.

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Colocação de Sistemas de Perfusão Contínua de Insulina em Crianças Pré-Escolares com Diagnóstico Recente de Diabetes Tipo 1

Introdução: A incidência de diabetes tipo 1 tem aumentado a nível global, especialmente em crianças pequenas. Segundo orientações internacionais, os sistemas de perfusão contínua de insulina são o método de eleição de administração de insulina na idade pré-escolar. O objetivo deste estudo foi avaliar a eficácia e segurança do tratamento com sistema de perfusão contínua de insulina logo após o diagnóstico de diabetes tipo 1 em crianças em idade pré-escolar.
Métodos: Realizado um estudo retrospetivo, entre 2016-2019, incluindo todas as crianças em idade pré-escolar que colocaram sistemas de perfusão contínua de insulina até dois meses após o diagnóstico e com um período de seguimento de 18 meses.
Resultados: Foram incluídas 11 crianças (mediana de idade 2,55 anos na altura do diagnóstico, 54,5% sexo feminino). Todos os doentes tinham peptídeo-C baixo ao diagnóstico com mediana 0,45 ng/mL (intervalo interquartil 0,18-0,58 ng/mL). A mediana da hemoglobina A1c diminuiu de 9,5% (intervalo interquartil 8,1%-10,4%) ao diagnóstico para 7,4% (intervalo interquartil 7,1%-7,7%) e a dose diária de insulina aumentou de 0,49 UI/kg/dia (intervalo interquartil 0,45-0,49 UI/kg/dia) para 0,70 UI/kg/dia (intervalo interquartil 0,61-0,78 UI/kg/dia). A mediana da automonitorização da glicemia variou entre 6,15-7,95 avaliações por dia. O valor da glicose média variou entre 158,5-186 mg/dL e o desvio-padrão 68,5-83 mg/dL. A mediana do coeficiente de variação situou-se entre 42,5%-47,9%. Durante o período de seguimento, nenhum doente teve cetoacidose diabética, hipoglicemia grave ou complicações locais.
Discussão: O sistema de perfusão contínua de insulina provou ser seguro e eficaz como abordagem terapêutica inicial em crianças com diabetes tipo 1 em idade pré-escolar.

Palavra-Chave: Cetoacidose Diabética/prevenção e controlo; Diabetes Mellitus Tipo 1/ tratamento farmacológico; Infusões Subcutâneas; Insulina/administração & dosagem; Pré-Escolar; Sistemas de Infusão de Insulina