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ORIGINAL ARTICLE

Sensor-Augmented Pump Therapy: description of pediatric patients with Type 1 Diabetes Mellitus (T1D) and initial metabolic outcomes

Uso de microinfusor de insulina con sistema integrado en pacientes pediátricos con diabetes tipo 1: resultados metabólicos iniciales

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What do we know about the subject matter of this study?

The integrated insulin pump system (SAPT) allows automatic suspension of insulin when hypoglycemia is predicted, mainly reducing the risk of severe and inadvertent hypoglycemia and enabling microdosing administration for a better adjustment of treatment.

What does this study contribute to what is already known?

This pilot study provides some preliminary findings on efficacy and adverse effects of SAPT for metabolic control in pediatric patients with T1D treated at a referral center of the Chilean public health system.

Abstract

The insulin microinfuser with integrated system (SAPT) for patients with type 1 Diabetes Mellitus (T1D) is included in the national financial protection system for high-cost treatments. **Objective:** To describe the initial and first-year metabolic outcomes and epidemiological and nutritional characteristics of T1D pediatric patients treated with SAPT. **Patients and Method:** Retrospective, descriptive and analytical study of clinical records from 2017 to 2019, of 12 patients with T1D users of SAPT, attended in a referral hospital. Variables: age at program entry, time of evolution of the disease, type of insulin treatment and type of glucose monitoring (capillary: sample or Continuous Glucose Monitoring [CGM]) at program entry, cause of application to the program, nutritional status, rural or urban origin, educational level of the main guardian, HbA1c at application and in the last month of each quarter after SAPT installation, over a 12-month period. HbA1c analysis was venous sample by High-Performance Liquid Chromatography and follow-up was capillary sample by Latex Particle

Keywords:
Type 1 Diabetes Mellitus;
Insulin Pump;
Sensor Augmented Pump Therapy;
Continuous Glucose Monitoring;
Time in Range;
Time Above Range;
Time Below Range

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Agglutination Inhibition. **Results:** The median variables at 12 months of treatment were Total Daily Dose (TDD) 0.74, %Basal (%B) 49%, Time In Range (TIR) 39%, Time Below Range (TBR) 1%, and HbA1c 7.7%. The sensor usage time was met in all cases and only half of them achieved a correct execution of hyperglycemia and hypoglycemia treatment. Inadvertent severe hypoglycemia was the main cause of application to the program. **Conclusion**: TDD and %B increased, approaching physiological requirement, although without statistical significance, which could be attributed to the administration of adequate insulin with lower risk of hypoglycemia due to predictive suspension and CGM. TIR presented a favorable increase, although not significant, nor reaching the target range, attributable to the short observation time, difficulties in understanding and execution of our patients, and the learning process of the treating clinical team. SAPT was effective in hypoglycemia management and effective in improving HbA1c.

Introduction

Worldwide, the incidence of T1D has increased[1]. In Chile, whereas the 2004 incidence of T1D was 6-7/100,000, it reached 12/100,000 inhabitants in 2014[2].

In the 1970s, a Continuous Subcutaneous Insulin Infuser (CSII), known as an insulin pump, was first used. Subsequently, continuous glucose monitoring (CGM) emerged and has now achieved real-time recording. CSII and CGM were combined resulting in the integrated insulin pump system "Sensor-Augmented Pump Therapy" (SAPT), which allows suspending insulin automatically when hypoglycemia is predicted[3-4].

Chile, Law 20,850, known as *Ricarte Soto Law*, guarantees treatment with a subcutaneous insulin pump with integrated system for patients with T1D according to two standardized criteria described in the 2019 Public National Health Service protocol[5].

Currently, the Western Metropolitan Health Service of the country treat a population of 245,594 patients under 15 years old. The geographical characteristic includes a population with medium-high rurality, according to the 2017 Census[6], which is relevant to analyse the results, considering the educational level and training of the caregiver that it was required for the treatment. In December 2019, there were 184 children and adolescents diagnosed with Diabetes Mellitus monitored in the Pediatric Nutrition and Diabetes Unit of the *Hospital San Juan de Dios* (HSJD), a reference center for this pathology.

To date, there is no precise information on the number of SAPT users, nor on their metabolic and epidemiological characteristics. This treatment is described as between 10-30% of the total number of patients diagnosed with T1D, varying according to the reality of each center[2,5].

Several studies demonstrate the beneficial effects of SAPT improving HbA1c, glycemic variability and prevention of severe and nocturnal hypoglycemia, mainly due to the function of the integrated system and the feasibility of these devices to deliver low doses to younger children, according to their requirements[9-12]. In addition, improved quality of life has been observed in users of CSII and SAPT compared with multiple-dose injection (MDI) therapy[13-15]. On the other hand, non-metabolic adverse effects of the device include transient or permanent pump dysfunction, infusion set failure, local effects such as skin infection, allergic skin reactions, lipohypertrophy or lipoatrophy, and caregiver and/or patient burnout[16-19].

Although there have been advances in glycemic control, most young people with T1D do not achieve control goals, as measured by HbA1c, according to international diabetes registries[20]. However, despite this parameter as a single indicator fails to detect glycemic fluctuations, it is still a predictive indicator of complications. The CGM allows the permanent measurement of interstitial glucose, through a sensor inserted in the subcutaneous cellular tissue, contributing to establish new indicators of metabolic control such as Time In Range (TIR), Time Below Range (TBR), Time Above Range (TAR), and % Coefficient of Variation (CV). Exact values of Total Daily Dose (TDD) of insulin and percentage of basal Insulin (%Basal) is provided by the use of insulin pump[21-25].

The aim of this research was to describe the baseline and 12-month metabolic variables and epidemiological-demographic characteristics of pediatric patients with T1D using SAPT.

Patients and Method

Retrospective, descriptive, and analytical study of clinical records of pediatric patients with T1D using SAPT treated at the Pediatric Nutrition and Diabetes Unit of the HSJD, between January 2017 and December 2019, according to one of the following inclusion criteria: insulin micro doses requirement, correct treatment compliance but, not achieving appropriate

glycemic control and/or presence of episodes of severe and unspecified cause of inadvertent hypoglycemia, despite treatment compliance[3].

The variables studied are: age of patient and time of disease at the beginning of the study, criteria to apply to the program, rural or urban origin, educational level of the main caregiver, number of complications associated with the treatment, and hospitalization causes after the initiation of therapy. Nutritional status and degree of metabolic control were determined at the baseline and quarterly follow-up. The treatment compliance was evaluated at the end of the period.

The results were registered into an Excel spreadsheet. Insulin pump users out of the aforementioned period and children with other types of diabetes were excluded. Variables were summarized in absolute numbers, proportions, and/or summary measures (means and medians). The statistical significance of the variables was analyzed through a t-test using theoretical target values for each variable (TIR 70%, TBR 1%, TAR 25%, CV 36%, insulin TDD 0.7 IU/kg/day, and basal 50%). The value of statistical significance was defined over 95%. The study was approved by the Pediatrics Service and the Scientific Ethical Committee (SEC) of the HSJD. It was not necessary the informed consent due to the nature of the research.

The 3 stages of the SAPT: 1. Assessment and training; 2. Application: registration on the platform, CGM (period of one to two weeks), venous and/or capillary blood HbA1c; and 3. Device set up and follow-up.

Studied variables: 1.Patient age; 2. Time of the disease, type of insulin treatment (MDI or pump), and type of glucose monitoring (capillary blood or CGM) at the beginning ; 3. Criteria to apply: a) microdose insulin need, b) severe inadvertent hypoglycemia, or both of them[3]; 4. Nutritional status defined by anthropometry at the start of the study and quarterly during the first year of SAPT , according to the WHO 2007 growth chart for children over 5 years old and the WHO 2006 growth chart in children under 5 years old[26]; 5. Rural or urban origin; 6. The educational level of the main caregiver (incomplete primary school, complete primary school, complete secondary school, complete superior education); 7. HbA1c at the beginning and quarterly after SAPT setting up during 12 months (4 quarters corresponding to 4 data downloads from the SAPT device).

The analytical biochemical method of HbA1c at the baseline was venous blood sampling with High-Performance Liquid Chromatography (HPLC) and at the follow-up was capillary blood sampling by Latex Agglutination Inhibition (LAI). The CGM was analyzed in the same periods as HbA1c. Four indicators were measured[24-25]:

1. Time in range (TIR): the percentage of time when the glycemia level is in the target range (70-180 mg/dl), with goal > 70% of the total time.
2. Time below range (TBR): percentage of time in which the glycemia level is below 70 mg/dL. The study's CGMs only had the description of range < 70 mg/dL with target < 5%. Current CGM systems allows to describe the hypoglycemia level 1 < 70 mg/dL, with target < 4% of total time, and the hypoglycemia level 2 < 54 mg/dL, with goal < 1% of total time.. To mitigate the limitation of the old system configuration, TBR < 1% was defined as target in our study.
3. Time above range (TAR): the percentage of time in which the glycemia level is above the target. It is defined as hyperglycemia level 1 > 180mg/dL with target < 25% of total time and hyperglycemia level 2 > 250mg/dL, with target < 5% of total time.
4. Percentage Coefficient of Variability (%CV): Measurement of fluctuations in frequency and duration of interstitial glucose, value showed by the sensor. The appropriate value is less than 36%.

The administered insulin was recorded as total daily dose (TDD) and expressed in IU/kg/day. The TDD goal was established according to the requirement by the age of the group. The basal insulin dose (%Basal) was expressed as a percentage of basal insulin in relation to TDD, with acceptable target < 50%.

The number and causes of hospitalizations due to treatment complications by SAPT during the study were evaluated. The degree of treatment compliance after 12 months of SAPT was also evaluated according to the variables registered in the data downloaded from the device: i. Number of infusion set changes per month: adequate value 1 every 3 days, with a minimum total of 10 monthly changes; ii. Management of the safety flowchart in hyperglycemias; iii. manegement of hypoglycemias; and iv. The sensor usage was more than 70% of the time.

Results

Clinical records of 12 patients were analyzed; 8 were female. The median age at the start to the study was 83 months (6 years and 11 months), with a minimum of 28 months and a maximum of 179 (14 years and 11 months). Three patients were adolescents (> 10 years). Eight were predominantly from rural areas. The main caregiver scholarship was predominantly secondary school and superior education (5 cases each) and, two reported cases of elementary scholarship (complete and incomplete). Severe inadvertent hypoglycemia was the main cause of application (11 cases). Only one

patient was admitted for microdose as the sole cause. The median of the time of disease at the beginnig was 25 months (range 7-72 months). Before starting the program 11 patients were using MDI plus SMBG and only one was using an insulin pump with SAPT. Seven cases presented malnutrition by excess and there was no undernutrition. (Table 1).

Regarding global metabolic variables at the time of application the median values were HbA1c 8.6%, TDD 0.59 IU/kg/day, %B 55, TIR 25.5%, TBR 5.5%, TAR 66%, and CV 41%. Table 2 shows the medians of the parameters indicated in quarterly follow-ups during the first year of SAPT.

The statistical significance analysis was performed between the average values at twelve months and the goal values (Table 3), which showed HbA1c 7.7% ($p < 0.05$), TDD 0.74 IU/kg/day ($p < 0.1$), %B 49 ($p < 0.7$), TIR 39% ($p < 0.99$), TBR 1% ($p < 0.05$), TAR 57% ($p < 0.99$), and CV 38% ($p < 0.1$).

About the treatment compliance , all patients complied with the time of device use. The monthly infusion set changes had a median of 10, but only seven patients reached that value. Six patients achieved a correct management of hyperglycemia and seven an optimal management of hypoglycemia (Table 4).

There were six hospitalizations in two patients, five events of ketoacidosis and one diabetic ketosis. There were no hospitalizations due to hypoglycemia. Complications were infectious intercurrences in five cases and only one due to infusion set failure. There were no hospital admission due to pump failure or problems at the cannula insertion site (Table 5).

Discussion

SAPT is part of the group of high-cost treatments financed through the *Ricarte Soto Law*, which guarantees the universal access criterion, it was showed in the number of patients were from predominantly rural areas, traditionally with less availability of some benefits.

On the other hand, this treatment requires a high degree of understanding, reflected in the caregiver educational level[27].

Due to the abrupt implementation of this treatment, it was observed a wide variability of the time of disease.

Despite the frequent nutritional intervention of the patients with T1D, and especially in those that are using SAPT, there were seven cases of overweight or obesity, that remained after one year of treatment. However, all the patients had a normal height despite of the chronicity of the condition. This fact matched with the reality of the current pediatric population and also with T1D patients[28].

The advance of the CGM has provided new metrics of metabolic control, such as TIR, TBR, TAR, and CV. However, HbA1c remains being the principal predictive parameter for angiopathic complications[29].

This study showed a decreasing of TBR to 1% what is statistically significant ($p < 0.05$), according with the published data[24-25]. There were no hospitalizations associated with hypoglycemia, demonstrating the efficacy of the treatment for severe inadvertent hypoglycemia. Also SAPT achived the < 1% goal being more demanding than the 5% established by the international consensus.

The TIR had a positive increase although, it was not statistically significant and did not reach the target over 70%, possibly due to the short time observation, difficulties of understanding and development of our patients, the recent start up of the treatment and, the team learning . However, the TIR increase enhance daily time of good metabolic control and, therefore,

Table 1. Demographic characteristics and carer of 12 patients with T1D using SAPT at the beginning of the study

Variable	n
Age, median (min-máx)	83 meses (28-179)
Origin	
Predominantly urban	4 (33%)
Predominantly rural	8 (67%)
Tutor Education	
Basic (1-8) incomplete	1 (8%)
Basic (1-8) complete	1 (8%)
Secundary (1-4) complete	5 (42%)
Superior complete	5 (42%)
Duration of desease	
<1 year	3 (25%)
1-5 years	8 (67%)
>5 years	1 (8%)
Treatment and glucose monitoring before	
MDI + SMBG	11 (92%)
Insulin pump (SAPT)	1 (8%)
Rational	
1*	1 (8%)
2**	6 (50%)
Both of them	5 (42%)
Nutritional status.	
Eutrophic.	5 (42%)
Overweight	5 (42%)
Obesity	2 (16%)

MDI: Multiple daily injection. SMBG: self-monitoring of capillary blood glucose *Insulin micro-dose requirement. **inadvertent severe hypoglycemia.

Table 2. The medians of the variables (p25 y p75) of metabolic control in 12 patients with T1D using SAPT at baseline and quarterly for up to 12 months

Variable	0 month	3 months	6 months	9 months	12 months
Overweight/Obesity*	7	7	8	6	8
HbA1c (%)	8.55 (7.4-8.9)	7.9 (7.3-8.3)	7.8 (7.4-8.3)	7.7 (7.4-8.6)	7.7 (6.9-8.2)**
TIR (%)	26 (23-32)	28 (21-32)	31 (26-38)	43 (34-53)	39 (33-54)
TBR (%)	6 (1.8-9.3)	4 (0-5)	0 (0-3.5)	1 (0-1.7)	1 (1-6.2) **
TAR (%)	66 (57-74)	70 (61-78)	69 (58-73)	59 (46-62)	57 (45-64)
TDD (IU/kg/day)	0.59 (0.56-0.69)	0.72 (0.64-0.79)	0.86 (0.67-0.95)	0.71 (0.65-1)	0.74 (0.66-0.93)
Basal Insulin (%)	55 (50-62)	46 (42-55)	49 (43-62)	51 (38-55)	49 (42-52)
%CV sensor	41 (38-49)	38 (33-41)	37 (35-44)	40 (33-40)	38 (34-42)

HbA1c: Glycosylated hemoglobin A1c; TIR: Time in range; TBR: Time below range; TAR: Time above range, TDD: Total daily dose of insulin. %B: Basal insulin; %CV: Coefficient of variation, *Number of patients, **Statistical significance.

Table 3. Statistical significance between theorical value and the average of the variables at 12 months of treatment

Variables	Theorical value	Average value (min-max)	p value
HbA1c	7	7.7 (6.5-9.2)	0.013ᶜ
TIR %	70	40.8 (13-65)	2.488
TBR %	1*	3.3 (0-9)	0.020ᶜ
TAR %	25	55.8 (31-87)	2.185
TDD	0.7**	0.8 (0.6 -1.4)	0.057
%B	50	47.8 (20-80)	0.298
%CV	36	38.1 (29-49)	0.134

HbA1c: Glycosylated hemoglobin A1c; TIR: Time in range; TBR: Time below range; TAR: Time above range, TDD: Total daily dose of insulin. %B: Basal insulin; %CV: Coefficient of variation. *Consensus variable of inadvertent severe hypoglycemia. **Consensus variable of TDD by age. ᶜStatistical significance.

Table 4. Cause and number of 6 hospitalization in 2 T1D patients using SAPT during first year of treatment

Variable	n (%)
Complications	6
Ketoacidosis	5 (83%)
Ketosis	1 (17%)
Hypoglycemia	0
Causes	
Not asociated infections (SAPT)	5 (83%)
Infusion set failures	1 (17%)
Infusion pump malfunctions	0

Table 5. Treatment compliance of T1D patients using SAPT at the end of the first year of treatment

Variable	Patients (%)
Infusion set replacement[1]	7 (58)
Hyperglycemia management	6 (50)
Hypoglycemia management	7 (58)
Sensor usage over 70% of the time	12 (100)

[1]Ten monthly cannula replacement.

a lower risk of micro and macrovascular complications, reflected in the statistically significant decrease in HbA1c ($p < 0.05$).

The initial TDD was into the requirement range, although, after one year of treatment, it was observed that the infused dose was closer to the physiological, and the %B approached to the 50%. Both TDD and %B increased, although without statistical significance, which could be explained by an accurate insulin administration with a lower risk of hypoglycemia due to the predictive low glucose suspend system (PLGS). In adolescents, the system allowed better performance in their insulin treatment with greater safety given by the CGM.

CV reached 38%, approaching to the target but, without significant difference ($p < 0.1$), possibly due to the young age of the patients (median close to 7 years old with a minimum of 2 years old). In any case, it should be considered that the non-significant results could be due to the small sample size.

The capillary blood HbA1c for long term follow-up is supported by the strong evidence, compared with the laboratory HbA1c[30]. For this reason, the Unit uses capillary blood sample like a clinical practice especially for younger patients saving time and economic cost.

The treatment compliance was measured by 4 indicators, most of the patients accomplished 1 or more of them. However, only four patients fulfilled the evaluated criteria. A plausible explanation would be that one indicator is conditioned by the need for additional financing from the family (cannulas in the management of hyperglycemia). Another reason could be the caregiver burn out, which was not analyzed in this study. Besides, only one episode of six hospitalizations was attributable to infusion system failure.

In conclusion, this pilot study provided information about reality of SAPT implementation through the *Ricarte Soto Law*. eventually this information allowing improvements on terapeutical and educational strategies. The most significant outcome in this research was to recognize the beneficial and the effectiveness of SAPT in the prevention of severe hypoglycemia, achieving the TBR goal and being an accurate tool in long-term metabolic control with a statistical significance reduction in HbA1c.

The difficulties to achieve the treatment compliance reveal the importance of social support and educational reinforcement by the multidisciplinary team. This study did not evaluate quality of life or caregiver burnout, although those are relevant issues in chronic pathologies, it could be a study limitation.

The information value will increase with more data systematization, collaborative and analytical studies with a larger number of patients.

Will be possible to achieve metabolic control goals with more automated technologies, further of the human factor or educational level of the patient or caregiver.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors state that the information has been obtained anonymously from previous data, therefore, Research Ethics Committee, in its discretion, has exempted from obtaining an informed consent, which is recorded in the respective form.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

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