Therapeutic education in diabetes

Therapeutic education for patients under treatment with subcutaneous continuous insulin infusion

Educarción terapéutica para pacientes en tratamiento con infusión subcutánea continua de insulina

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Abstract
The publication of results of The Diabetes Control and Complications Trial established a new paradigm in the treatment of diabetes mellitus type 1, causing a generalized use of intensive insulin therapy in clinical practice. With intensive therapy, therapeutic education acquires a fundamental role. Continuous subcutaneous insulin infusion is a treatment modality of intensive therapy. To implement it, certain knowledge and specific abilities of that therapy such as the technical handle of insulin pump functions, besides other theoretical aspects of diabetes treatment, are needed and usually given through structured educational programs. The treatment with continuous subcutaneous insulin infusion has shown a similar or higher reduction HbA\(_1c\) than treatment of multiple doses of insulin, with diminution of hypoglycaemic episodes and a better quality of life.

Keywords: therapeutic education, type 1 diabetes, continuous subcutaneous insulin infusion, metabolic control.

Introduction
The results of the study The Diabetes Control and Complications Trial (DCCT, 1993) demonstrated that an adequate glycemic control in persons with T1D reduces the risk of onset and progression of chronic complications.1 This improvement could be observed in the group of patients who underwent an intensive treatment, constituted by individuals both adult and adolescents. The intensive treatment was defined considering the increase of the number of insulin doses through the treatment with multiple dose insulin (MDI) in subcutaneous injections or with continuous subcutaneous insulin infusion (CSII), taking into account the increase of capillary glycemias, as well as the increase of the frequency of visits with the diabetes team. The therapeutic education in diabetes (TED) achieves at present a main role regarding to the control of the disease.2

During the last years, several meta-analyses have been published that prove that the treatment with CSII is more efficient than the treatment with MDI, both for the reduction of the glycosylated hemoglobin (HbA\(_1c\)) and for the acute complications.3-4 These patients need to acquire a series of knowledge and specific skills for this type of treatment, this is the need for a TED.

Therapeutic education in diabetes
The TED is the process in which the learning about the skills and necessary knowledge is facilitated to the patient and the family in order to assume an adequate attitude, as well as the necessary support to be an active part of the treatment.5,6 The health professionals who are responsible for the TED shall have an adequate training, and not only related to the disease, but also with knowledge on pedagogy and psychology, to be able to transmit the TED after adapting the teaching techniques to the individual rhythm of each family.7 In spite of the technological advances
which are available in the market, the patients continue taking decisions “in real time” about their treatment guideline, according to the changes that might occur in their daily routine. This generates the need of implementing structured TED programs according to the type of treatment they receive; these programs shall strengthen the basic knowledge and facilitate the learning of those new specific concepts that these patients should assume and dominate at short term.1

Structure of the CSII program Choosing the candidate
The treatment with CSII has demonstrated its effectiveness and at present it is another alternative in the treatment of the T1D. However, some studies prove that it is not a treatment which could be applicable to all the persons with T1D.2 Some regulatory agencies advise its use only in patients with T1D who do not achieve an adequate metabolic control in spite of the treatment with MDI, the use of slow insulin analogues and of having an adequate self-control of the DM.10 Moreover, other agencies point out the presence of frequent and/or unnoticed hypoglycemias.11 The New Technology Group of the Spanish Diabetes Society (SED) considers a series of indications12 (table 1). Some basic requirements should be added to the clinical inclusion criteria that will guarantee the therapy success.13,14 If some of these requirements are not fulfilled, we should set out to postpone the implantation of the CSII or even reject it (table 2).

The assistance team that controls the patient treated with CSII should count with a working team at the health site that might allow his care under day hospital regime and/or hospitalization, so as to be possible to start and adjust the treatment, to offer 24 hours attention and to make the permanent phone contact possible.12 Moreover, the patient, before accepting the commitment regarding to the implication in the CSII treatment, should know the advantages and disadvantages of carrying an insulin pump.15-19

As advantages of this therapy over the treatment with MDI we can quote the following ones: the infusion pump uses only fast action insulin (mainly analogues); when the insulin is administered in the same site during 2-3 days, the variability of its action is reduced and allows a higher flexibility in the diet as modifications can be done of the insulin doses in a more adjusted manner, however, the most relevant advantage is the reduction of serious hypoglycemia risk, both during the day as well as during the night.

As disadvantages we can mention the fact that the device is visible for other persons, the possible mechanical failures of the pump or the obstruction of the infusion systems, which can cause a higher risk of acute metabolic decompensation.

Implementation of the CSII therapy
Once the patient has been chosen, and following the recommendations of different scientific societies12-20 and some authors,21,22 the education of the patient starts on the CSII therapy. It should be divided in three phases: 1) individual assessment of the starting point of the patient and his family through the active hearing, showing assertiveness with them at any moment; 2) training in the different techniques, both in the use of devices and in the diabetes self-care, with specific materials and 3) process follow-up. At the end of each session, it is important to do a theoretical synthesis and submit the information in a written document.

Previous phase to the implantation of the insulin pump
The experience demonstrates that for a candidate patient who is to start treatment with CSII, to know other patients that already use it suggests a positive strengthening. The previous education

<table>
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<tr>
<th>Table 1. Indications recommended by the New Technologies Group (SED) in order to implement a CSII therapy12</th>
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<tbody>
<tr>
<td>• Inadequate metabolic control (HbA1c &gt;7%) in spite of good compliance of MDI</td>
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<tr>
<td>• Presence of serious hypoglycemia’s, as well as nocturnal, unnoticed and recurrent hypoglycemias</td>
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<tr>
<td>• Difficulty to keep the normoglycemia during the night period. “Dawn phenomenon”</td>
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<td>• Wide glycemic variability regardless of the HbA1c</td>
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<tr>
<td>• Optimization of the glycemic control during the pre-gestational period and the pregnancy in absence of an adequate control with MDI</td>
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<tr>
<td>• Existence of gastroparesis</td>
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<tr>
<td>• Need of lifestyle flexibilization (in case of great flexibilization of hours), intake and exercise</td>
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<tr>
<td>• Very low insulin requirements (&lt;20 units/day)</td>
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<tr>
<td>• In childhood (at any age with motivated parents and collaborators)</td>
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<tr>
<td>• Phobia to needles</td>
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<td>• Competition athletes</td>
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CSII: continuous subcutaneous insulin infusion; HbA1c: glycosylated hemoglobin; MDI: multiple dose insulin.

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<th>Table 2. Basic requirements of the patient in order to obtain good results with CSII12</th>
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<tr>
<td>• To have real expectations on the treatment (essential)</td>
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<td>• High level of motivation in the use of the system and real involvement in the self-control optimization</td>
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<tr>
<td>• To demonstrate knowledge about T1D, as knowing how to take decisions to solve unforeseen situations in the acute decompensations</td>
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<tr>
<td>• Capability in the quantification of CH per servings</td>
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<td>• To perform monitoring of the CG, detailed record of CH intake and of administered insulin doses</td>
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<tr>
<td>• To assume the commitment of attending the follow-up visits with the different diabetes team members</td>
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<tr>
<td>• Physical and intellectual capacity for the learning, both of the technical aspects of the insulin pump and the theoretical aspects</td>
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<tr>
<td>• To have a certain level of emotional stability and absence of problems of psychiatric nature</td>
</tr>
<tr>
<td>• To have a good family support and of the patient’s environment. This point is especially relevant in pediatrics</td>
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CG: capillary glycemia; CH: carbohydrates; CSII: continuous subcutaneous insulin infusion; T1D: diabetes mellitus type 1.
to the implantation of the pump might be extended in time with a minimum of three visits of 1-3 hours each.13

It is important to revise and reach a consensus on a series of aspects with the patient:

- Diet habits, needs and timetables,13
- The patient should dominate the system of carbohydrates (CH) servings interchange, as well as the concept of insulin/serve of CH. It is advisable, throughout the week previous to the implantation, that the patient follows the agreed diet and records both the servings he takes and the performed glycemic profile.13

In this way, the patient will practice the diet plan per servings, which will help him to adapt the starting guideline to the treatment with CSII.

- To examine the puncture region and assess if an adequate rotation is done which should be part of the daily routine in the attention of the patients with diabetes.20 Before starting the treatment with CSII, we should be sure about the absence of lipodystrophies in the areas chosen for the puncture of the catheter (abdomen, gluteus or thighs). The frequency of the change of catheter shall depend on each individual case, though in most of the patients it is done each 2-3 days. The most adequate model of catheter is also chosen considering the adipose pannicule of the individual as it is important to guarantee the insertion catheter and skills to adapt himself to the new specific treatment lexical, as well as the handling of the basic functions of the pump. To give this training during group sessions, facilitates the optimization of the devoted time to the assistance team.20,21

  - **Baseline**: Units of insulin that are programmed in the device, which will administer in a continuous manner to cover the basal needs of the individual.

  - **Bolus**: insulin units that are administered before each meal adjusted to the CH servings (“meal bolus”) and/or extra dose to control the hyperglycemia (“corrector bolus”) with the aim of avoiding the glycemic fluctuations.

  - **Preparation of the infusion equipment**: the equipment is made up of a reservoir and a catheter. There are several reservoirs in the market of different capacities (1.8; 2; 3 and 3.15 mL) according to the pump model. The reservoir should be filled with insulin, connected to the catheter and put in the compartment of the corresponding pump. It is important to purge the whole equipment in order to avoid the appearance of air bubbles.

  - **Daily life**: one of the initial concerns of many patients is how to carry the pump, both during the day and when going to bed. The devices count with clips, covers and other accessories that allow its adaptation to different situations. The patient should learn how to switch off from the device during short periods of time (shower, sexual intercourse, etc.).

  - **Solution of acute complications**: as from the moment that the CSII starts, there is the risk of suffering an imbalance amongst the meals, the performed activity and the administered insulin; therefore the patient should know how to solve the problems that might appear (table 3).24,25

- In order to avoid the overlap between the basal dose administered with the pump and the long-acting insulin administered on the previous day, the insulin guideline of the previous day should be modified to the start of the CSII.13

### Table 3. Solution of acute complications for patients under CSII therapy

<table>
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<tr>
<th>Acute Complication</th>
<th>Management</th>
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<tr>
<td><strong>Hypoglycemia</strong>: besides taking the recommended CH, the pump offers different possibilities in case of having a very low value of glycemia. The administration of insulin can be discontinued during 30 minutes. However, there is the risk that the patient gets confused and delays the restarting of the infusion excessively. For this reason, it is important to know the function of the “temporal basal”, that allows reducing the scheduled basal in a temporal manner during a determined period of time: in this case to 0% of basal during half an hour. In case of serious hypoglycemia, besides administering glucagon, the family should know the way of interrupting the insulin infusion. Probably, the safer way is to remove the cannula from the skin.</td>
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<td><strong>Hyperglycemia</strong>: it is considered that the values of the CH higher than 250 mg/dL should be corrected immediately, as they can lead towards a metabolic decompensation by DKA. The attitude that should be considered in this situation is:</td>
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<td>– To prove the insertion catheter point, the connection of the infusion team, the absence of air bubbles in the equipment and the functioning of the pump</td>
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<td>– To administer a corrective bolus. Basic rules shall be given to the patient at the beginning. Further on, the concept of “sensitivity factor” shall be introduced (quantity of plasmatic glucemia in mg/dL that is reduced in 2-3 hours after the administration of 1 unit of fast-acting insulin in bolus form). The use of the sensitivity factor allows estimating with more precision the corrective dose that should be administered</td>
<td></td>
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<tr>
<td>After one hour, a CG control should be performed. In case the glycemia lowered, the usual guideline will be followed. However, the ketonemia should be measured if the glycemia was not reduced (normal in lower values than 0.5 mmol/L). In case of sustained hyperglycemia and/or positive ketosis, the corrective dose should be applied with pen or syringe and the infusion equipment should be changed and follow the recommended “ketosis guideline”</td>
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<tr>
<td>Another way of correcting a moderate hyperglycemia is using the basal-temporal function, as it allows increasing the scheduled basal in a temporal manner during a determined period of time. This concept will be introduced progressively during the education program</td>
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**Notes**

CS: capillary glycemia; CH: carbohydrates; CSII: continuous subcutaneous insulin infusion; DKA: diabetic ketoacidosis

### Day of the pump implantation

The time dedicated to an education session on the pump implantation is of 2-4 hours. To implant the pump under day hospital regime allows adapting the treatment guideline as from the first moment to the patient’s “real” life rhythm. To perform a follow-
up of several hours provides safety to the patient, especially in
the pediatric population. On the implantation date, the patient
shall apply all the learning knowledge on the basic functions of
the pump, as well as the resolution of acute complications,
among which the prevention of infections in the puncture region
should be included.

Another essential point to obtain a successful result of the ther-

apy with CSII is to determine the control objective with the pa-
tient and the number of capillary glycemas (CG) that the patient
should undergo.13

At the beginning, 7-8 daily glycemic controls are necessary to
be performed, pre and postprandial in the three main meals, and
before going to bed (if it does not match with the dinner post-
prandial) and a nocturnal one, approximately at 3 am. In daily
life, at least 4 daily CG controls should be done.

The initial dose is estimated for 24 hours as from the reduction
of 20% of the total dose used at the moment with MDI.12 “An
alternative guideline with MDI” should also be submitted in writ-
ing and instruct the patient in its use in case of adverse situations
in which the disconnection of the pump might be necessary. It is
important to provide the contact phone numbers for consultations
in case of emergency, both medical and technical.

Second session
Tackling into account that the catheter change is performed each
2-3 days, such sequence can be used as an advantage in order to
appoint a visit with the education team, which would allow the
patient to carry out the first change of the infusion equipment un-
der supervision. Besides calming the patient down, this guaran-
tees the detection and later correction of possible mistakes, in
case of occurrences, after 48-72 hours of having started the treat-
ment. However, as mentioned before, the patient should get in
touch with the care team in case of adverse situations, specially
during the first hours of therapy. Both during this visit and the
following ones, the knowledge and skills trained previously shall
be reinforced and the patient shall be started in the concept of
“sensitivity factor”.

Follow-up sessions in the starting of CSII therapy
The follow-up period of the CSII implantation has a variable dura-
tion (from some weeks to some months), adapting itself to the rhythm
and learning capacity of the patient and/or the family. The different
education objectives are strengthened during this period.13

• Adaptation of the insulin/CH-serving ratio. In order to do
this estimation, we need that the patient performs an exhaust-
ive record of the CH servings he takes, of the administered
meal bolus and of the pre and postprandial controls. This in-
dex is usually different for each individual and in the differ-
ent meal timetable.22 The models of the present pump count
with systems of bolus estimation. These functions help the
patient to estimate the quantity of insulin that he has to ad-
minister himself or herself more precisely according to the
CH and the CG control. Previously, all the necessary param-
eters for the estimation shall be programmed in the pump:
insulin/CH serving ratio, sensitivity factor, control targets
and duration of the insulin action (“active insulin”). The use
of this function is associated to a higher satisfaction of the
patients and to an improvement in the pre and postprandial
CG values; besides, it helps to apply a lower number of cor-
rector bolus and to reduce the number of hypoglycemias due
to the excessive administration of insulin.26 However, it is
important that the patient is trained manually as regards to
the estimation of the bolus as the proposed dose by the
pump should be modified usually.27

• Physical exercise. To undergo a therapy with CSII should not
hinder the practice of exercise. The patient shall determine the
CG before and after the practice in order to apply the correction
of the most adequate guideline to each situation according to
the intensity, the time, if it is scheduled or not, the type of exer-
cise, etc. The pump offers different possibilities. “A temporal
basal” is usually used reduced in 10-50% during a previous
hour and during the practice and also after the exercise in order
to avoid post-exercise hypoglycemias. The patient can also take
CH and apply a bolus reduced 30-50% of the dose that would
be administered in an exercise absence situation. Another possi-
bility, practiced usually in children, is to remove the pump. In
case of positive ketonemia, no exercise should be done until its
resolution.2,13

• Days of sickness. In case of suffering an intercurrent illness,

it should be foreseen that the glycemias values are higher,
mainly in case of showing infections, increasing the risk of
decompensation due to diabetic ketoacidosis (DKA). The
needs of insulin increase in the incubation period and during
the illness due to the insulin resistance. A tendency can be ob-
served towards hypoglycemias in processes with vomit and
diarrhea that might cause the reduction of intake and an inad-
quate absorption of the food. Though the patient does not
take food, he still needs the input of basal insulin. The bolus
doses should be adjusted according to the intake and the CG
values. As long as a patient with T1D shows vomits, it is es-
tential to prove the presence of ketonic bodies and increase
the CG controls. In case of resulting positive, insulin should
be applied by means of a pen and follow the action guideline
of a hyperglycemia process.26

• When traveling. In special situations as trips could be, it is im-
portant to check that all the necessary material is taken in order
to follow the CSII therapy (reservoirs, catheters, insulin), CG
meters, food that contain CH both of fast and slow absorption,
as well as insulin pens in order to use the alternative guideline
with MDI, if necessary. In case of flying in a plane, the insulin
should not be checked in, given that it might get lost and it
would be exposed to extreme temperatures. In order to avoid
problems during shipment, the patient has to count with a doc-
ument, which identifies himself as user of an insulin pump. If
the journeys are to areas of hour change, the timer of the pump
has to be changed to the hour of the destination place. If the
guideline of the basal insulin is very variable, it is better to
change the infuser timer progressively.
Incorporation of the program and regular visits to the usual consultation

At the end of the program, the patient and/or parents/guardians, considering the age, should be able to demonstrate a series of skills (table 4). As from that moment, the patient shall go on with the regime of usual visits in the diabetes practice.

Special considerations in small children and unweaned babies

The success of the therapy with CSII does not depend on the age. Excellent results with this therapy are described both in unweaned babies and in elder persons with a great family support. An improvement of the metabolic control has precisely been proved in small children along with a reduction of the serious hypoglycemia risk. In case of children who do not eat well, it is essential to take into account considering the different factors associated to age have an influence (mainly in unweaned babies). This can be of biological nature (hormonal, diseases typical of children’s age), psychological, cognitive and social. Moreover, the patients of these ages are characterized by having a high sensitivity to the insulin, unpredictable intake patterns and a great variability in the physical activity practice, what makes them especially vulnerable to suffer hypoglycemias. On the other hand, they also have a lower ability to detect and inform about the events, which have a greater repercussion on the cognitive ability. The stress and anguish that the parents suffer has to be taken into account considering the difficulty that it represents to try to control as best as possible the diabetes of their children. All this leads us to the need of more thorough follow-up and treatment.

The treatment with CSII in unweaned babies is very beneficial, as it offers the possibility of administering very low basal doses and varying them throughout the day, helping to minimize the hypoglycemia risk. In case of children who do not eat well, it is possible to fraction the administration of bolus in order to cover the intake in pre, intra and post-intake, so as to favor a major safety. In hypoglycemia situations with the use of MDI, the parents should administer a corrective dose that in many occasions they leave out in order to avoid a new shot. Moreover, the minimum dosage we count with is of 0.5 units. In turn, the CSII allows administering insulin without an extra shot and a dosage of corrective bolus in small quantities (up to 0.1 units), allowing a better control of the glycemic fluctuations.

In this age group, both the TED and the education CSII program are addressed to parents and/or guardians, and also to those who share part of the time with the child. The TED involves a higher inversion in time and effort for its control and an increase of the visits frequency at the beginning of the treatment with CSII for the adjustment of the basal doses and bolus. It also requires a direct phone contact during the first 24–72 hours with the assistance team. The pump material (reservoir, catheter, etc.) should be adapted to the child’s needs and it is essential to take into account the aspects that are detailed in table 5.

Conclusions

The use of structured programs of therapeutic education addressed to patients who are users of the CSII therapy is essential to achieve an adequate treatment adherence. These patients require skills and specific knowledge that they have to handle in a short period of time, as they shall have to take adequate decisions continuously about the treatment guideline in their daily life. The patient who shall receive CSII should know, before starting and in an exhaustive manner, the characteristics of this type of treatment, should have real expectations and fulfill a series of fundamental requirements in order to obtain good results. The experience shows us that the treatment with CSII improves the life quality of the patients.

Acknowledgements

We want to thank Dr. Suárez, Dr. Angulo and especially Dr. Torres for her critical and constructive reading, whose contribution improved the quality of this article.

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<tr>
<th>Table 4. Knowledge and skills that a CSII user patient should dominate</th>
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<tr>
<td>• Technical skills in the preparation and injection of insulin, and way of acting in case technical problems with the pump appear</td>
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<tr>
<td>• Prevention, detection and handling in case of acute complications and the use of the “alternative guideline” with MDI, both in case of problems with the pump and temporal disconnections</td>
</tr>
<tr>
<td>• Handling in case of intercurrent disease situations</td>
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<tr>
<td>• Use of modification algorithms of the new guideline: basal line, in case of repeated phenomena and corrective bolus using the sensitivity factor</td>
</tr>
<tr>
<td>• Administration of the adequate dose or insulin according to the insulin index/CH serving</td>
</tr>
<tr>
<td>• Handling in case of physical exercise practice</td>
</tr>
<tr>
<td>• Handling of special situations, as journeys, school, etc.</td>
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<table>
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<tr>
<th>Table 5. Relevant aspects in the implantation of CSII in unweaned babies</th>
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<tr>
<td>• To use anesthetic ointment in the insertion area in order to reduce the pain</td>
</tr>
<tr>
<td>• The use of an automatic inserter minimizes the impact of the insertion, facilitating the process to the parents</td>
</tr>
<tr>
<td>• Maximum control and rotation of the injection areas as they are limited to gluteus and thighs in small dimensions</td>
</tr>
<tr>
<td>• Use of the pump blocking system in order to avoid handling risk by the child</td>
</tr>
<tr>
<td>• Adaptation of the maximum safety doses in basal and bolus in order to minimize the over-administration of bolus in case of mistake</td>
</tr>
<tr>
<td>• Count with explanatory documentation about the concept of the CSII treatment and basic handling of the pump for professors in nurseries and schools</td>
</tr>
</tbody>
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CH: carbohydrates; CSII: continuous subcutaneous insulin infusion; MDI: multiple dose insulin.
Declarations of potential conflict of interests

Carmen Yoldi and Ana Gómez state that there are no conflicts of interest as regards to the content of this article.

References


