



# A randomized, crossover pilot study comparing glycemic control and satisfaction with an indwelling catheter (I-PORT Advance) for insulin administration in children and adolescents with type 1 diabetes on basal-bolus treatment



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## Background

It is known that an intensive insulin treatment allows to achieve a good metabolic control and prevent the long term microvascular complications. Basal-bolus regimen is considered as the best treatment for type 1 diabetes (T1D) in the pediatric age. However, to be adherent to the basal-bolus schedule, in everyday life children with T1D and their families have to inject insulin several times for meals, snacks and corrections for hyperglycaemic peaks. The needle-fear and discomfort felt by the child and parents/caregivers in insulin administration is one of the main obstacle to a good therapeutic compliance.

## Objective

To compare glycaemic control and satisfaction with a new injection port (I-PORT Advance), through which insulin can be injected subcutaneously from a syringe/pen without repeated needle punctures of the skin, to multiple daily insulin administration (MDI).

## Population and Study design

Twenty subjects (5 M, mean age  $9.5 \pm 2.6$  years, mean T1D-duration  $3.1 \pm 2.3$  yrs) were enrolled.

They were randomly assigned to group A (starting using I-PORT) and B (on traditional MDI).

Participants were trained to change the device every 3 days and to inject both basal and bolus insulins through it.

Subjects were invited to move to a strict basal-bolus regimen (requiring more insulin injections for meals, snacks and hyperglycaemic peaks).

After 8 weeks the 2 groups switched to the other arm.

HbA1c was detected at baseline, before the cross-over and at the end of the study (16 weeks).

A questionnaire was provided to collect satisfaction about the new device.

## Results

Two participants dropped out and were excluded from the analysis. Mean baseline HbA1c was  $8.02 \pm 1\%$  ( $64 \pm 11$  mmol/mol), mean HbA1c after I-PORT period  $7.53 \pm 0.7\%$  ( $58 \pm 8$  mmol/mol) whereas mean HbA1c on traditional MDI  $7.92 \pm 0.9\%$  ( $63 \pm 9.3$  mmol/mol) ( $p=0.06$ ). No dka or severe hypoglycaemic episodes occurred. At the end of the study 15/20 (75%) of participants appreciated I-PORT and decided to maintain it.

## Conclusions

In this pilot study I-PORT has proven to be safe and seems to improve metabolic control in children during real-life setting and, attenuating the discomfort of multiple injections through the device, allowed to follow more strictly basal-bolus regimen. Children and adolescents seem to tolerate and appreciate this new device.

