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## Insulin Pump Therapy in Young Children With Diabetes

### In Brief

Insulin pump therapy has been shown to be beneficial in pediatric patients with type 1 diabetes; however, there is little data on very young children with regards to the risk/benefit ratio of pump therapy. This article describes the outcomes of insulin pump therapy in young children in our center at Childrens Hospital Los Angeles and the criteria for patient selection.

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Since the introduction of continuous subcutaneous insulin infusion (CSII) in the late 1970s, it has become apparent that the use of insulin pump therapy has many potential benefits for patients with type 1 diabetes.<sup>1,2</sup> Because it offers a more physiological way to deliver insulin and, therefore, potentially improves long-term outcome,<sup>3</sup> our center began to investigate its use in pediatric patients in the mid-1980s. Once it was shown that pump therapy had benefit in older children and adolescents with regard to improving glycemic control,<sup>4,5</sup> reducing hypoglycemia,<sup>6</sup> allowing for resumption of normal linear growth,<sup>7</sup> and decreasing episodes of recurrent diabetic ketoacidosis (DKA),<sup>8</sup> we became increasingly interested in evaluating its use in preschool and early school-aged children with diabetes. This article describes our experience at Childrens Hospital Los Angeles with insulin pump use in young children.

#### Patient Selection

To select pump patients at our center, we have employed standard criteria that span medical, educational, and psychological domains (Table 1). These are essentially the same for all potential pump candidates, including young children whose parents, rather than the child, must meet all of the educational criteria. From a psychological standpoint, all patients, regardless of age, must agree to wear the pump, and they must have tolerated

catheter insertion before obtaining the pump to ensure that they understand what this basic component of CSII entails.

Our center has established four medical indications for CSII (Table 1). These include:

1. To optimize basal/bolus insulin therapy. Patients using basal/bolus regimens who desire CSII and want to avail themselves of the latest technology to aid in intensive diabetes management should be considered valid and appropriate pump candidates. This is particularly relevant in young children in whom basal therapy, when done with two injections/day of intermediate-acting insulin, often results in extremes of glycemic excursion due to the unpredictable and unreliable duration of action of this insulin.

**Table 1. Standard Criteria for Pump Selection**

#### Medical Criteria

To optimize basal/bolus therapy  
To improve diabetes control  
To reduce recurrent severe hypoglycemia  
To reduce recurrent ketoacidosis

#### Educational

Has attained diabetes competency level 5  
Has viewed pump video, read pump manual

#### Psychological

Agrees to pump therapy—patient and parent  
Has inserted and tolerated pump catheter  
Has realistic expectations of CSII

- To improve diabetes control. Patients with suboptimal diabetes control despite optimal home management behaviors should be considered for CSII as a means to decrease glycemic excursion and lower HbA<sub>1c</sub> levels.
- To reduce episodes of severe hypoglycemia. For subjects with recurrent severe hypoglycemia, insulin pump therapy can be used to ameliorate this problem without deteriorating overall diabetes control.
- To reduce episodes of recurrent DKA. By giving a reliable basal infusion rate, CSII can reduce DKA episodes.<sup>8</sup>

For success with CSII, patients/families must have the requisite skills and knowledge, as well as the appropriate attitude to learn pump therapy.<sup>9,10</sup> The skills and knowledge required beyond learning how to insert, disconnect/suspend, protect, and program the pump include understanding and successfully using carbohydrate management/counting, correcting blood glucose levels outside the target range, sick-day management, and how to adjust for exercise and changes in activity pattern. For young children, all of these must be done by the parent(s) and adult(s) who supervise the young child. As shown in Table 2, our center has developed an eight-stage competency system. The parent(s) of pump candidates must reach the fifth level to be considered capable of managing CSII for their young children.

#### Advantages and Disadvantages of CSII in Young Children

CSII has some potential advantages and disadvantages for young children. For many young patients, it is easier and more convenient to take multiple daily doses of insulin with CSII than with a syringe or insulin pen. Because of erratic eating patterns, subjects can dose after eating and/or use a square wave bolus to better match food absorption and insulin delivery. The pump can deliver doses as small as 0.1 U, and insulin can be diluted conveniently. By using only rapid- or short-acting insulin, one does not have to deal with the unpredictable action and duration of action profiles of intermediate- and long-acting insulins.

The main disadvantage of pump therapy in young children is that neither the pump nor the child is autonomous. Until CSII is a closed-looped system, pump therapy must

only be considered for children who are cared for by a parent or another adult willing and able to learn how to manage all aspects of the pump.

This is often easier to achieve for preschool rather than primary-school-aged children. Preschool children are home with a parent or in a day care center already committed to successful diabetes management. Most primary schools do not have an on-site school nurse or another adult, such as a teacher or office worker, willing or able to assume the responsibility of caring for a child with an insulin pump.

#### Methods for Pump Initiation

We have modified the six-step pump initiation guidelines so that they are tailored for young children.<sup>9,11</sup> These six steps are:

- Determine how much insulin to use in the pump by averaging the total units of insulin used/day for 2 weeks. Decrease by 20% for hypoglycemia, by 10% for euglycemia, and make no reduction for hyperglycemia.
- Divide the total dosage in half—50% for basal and 50% for bolus.
- Divide the portion for basal by 24 to determine the hourly basal rate.
- Check midnight and 3:00 a.m.

blood glucose levels for 2 weeks before pump placement for evidence of night or early-morning abnormalities of glycemia. For hypoglycemia, reduce the nighttime basal rate by 10%. For hyperglycemia, increase the 3:00 a.m. by 10%.

- Determine the carbohydrate-to-insulin ratio. (Divide 450 by the total units/day to determine the number of grams of carbohydrate for 1 U insulin.)
- Determine the correction dose for elevated glucose levels. (Divide 1,800 by the total units of insulin/day to determine the mg/dl that 1 U insulin decreases the blood glucose value.)

Patients/families then monitor glucose levels eight times/day and call for help with management issues daily until the desired glycemic pattern is achieved. On average, patients/families will need to call daily for 2–3 weeks, after which weekly contact is maintained for 3 months. At 3 months, a follow-up HbA<sub>1c</sub> level is obtained to ensure that pump therapy has maintained or improved glycemic outcome. Once it has been validated that CSII is efficacious, blood glucose monitoring can be done four to six

**Table 2. Competency Level Scale, from 1–8, Used in Our Center to Determine Appropriateness of CSII (For CSII, Level 5)**

Competency	Characteristics	Number
Safety	Initial information, injections, blood testing, treatment for hypoglycemia	1
Basics	Blood glucose targets, actions for levels out of target, glucagon, action of different types of insulin, diet and carbohydrate	2
Carbohydrate management	Determine quantity of carbohydrates in food, use of a plan for carbohydrate intake	3
Correction	How to correct glucose out of target	4
Daily changes	Decision-making about changes in daily routine adjusting insulin and carbohydrate intake, strategies to prevent hypoglycemia and DKA	5
Base dose adjustments	Make base dose adjustments, review blood glucose values to observe overall effects of treatments	6
Advanced diabetes management	Understand hormone pathways and food absorption, know about strategies to reduce complications	7
Maximized control, basal and bolus therapy	Independence in multiple injections/day or CSII to maximize control, flexibility, and freedom	8

times per day, as is advised in all of our type 1 diabetic patients.

In our experience, pump therapy does not induce patients/families to display more compulsive behavior than what they had shown previously. For example, the families who choose to routinely monitor more than four to six times/day are those who had done so before CSII. In addition, the relatively low number of basal rates (mean  $2.9 \pm 2.1/24$  h) used by our young children indicates that families do not appear to feel the need to micromanage pump therapy.

To make pump placement acceptable to our young pediatric subjects, we use local anesthetic cream, such as EMLA (Astra, Westborough, Mass.) to numb the area before catheter insertion. Our catheter of choice for young children is the Silhouette Infusion Set (Maersk Medical, Denmark) This requires hand insertion and enters the abdominal wall at an angle rather than straight. The catheter can then be threaded under the subcutaneous tissue in children who do not have a lot of subcutaneous fat rather than abutting the abdominal fascia, resulting in failure of insulin delivery.

Pumps with external control devices that can be locked by the parent are also preferable in this age-group. We use a number of belts and pouches to secure placement, including some that have been devised by parents themselves. Overall, the duration the catheter will function in young children is the same as in our older patients (~3 days). Occasionally, there are patients who are unable to use some, most, or all catheters longer than 2 days; however, we find this in all of our pump patients, regardless of age.

To facilitate diabetes management with CSII, we have developed a handheld plastic Insulin Dosage Guide<sup>12</sup> that displays how much insulin to give for meals and snacks (carbohydrate counting) and how to correct blood glucose levels outside of the target range. This guide uses an algorithm for increasing the dosage of insulin for every 50 mg/dl that the blood glucose level is above the upper limit of the patient's target range. The guide has been adjunctive in helping patients in our center achieve a significant reduction in mean HbA<sub>1c</sub> with CSII (Table 3).

The guide was originally developed to help patients/families with diabetes management when they first started CSII or other intensive regimens.

**Table 3. 1999 Data on CSII for Pediatric Subjects at Childrens Hospital Los Angeles**

	Pre-CSII	CSII	P value
HbA <sub>1c</sub>	8.4 ± 1.8%	7.8 ± 1.2%	0.01
BMI	22.8 ± 4	23.2 ± 5	NS
Hypoglycemia events/patient/year	0.09	0.04	0.05
DKA events/patient/year	0.15	0.09	0.05
Knowledge	82 ± 10	92 ± 6	0.001
Adherence	77 ± 9	82 ± 6	0.003
Responsibility	1.9 ± 0.4	2.2 ± 0.4	0.003
Integration	79 ± 12	90 ± 6	0.01
Quality of life	3.9 ± 0.4	4.2 ± 0.3	0.005

However, ~50% of our pump patients/families continue to use it for >3 months after pump placement to be sure that the dosage they are giving is correct.

We have previously emphasized the importance of having a diabetes team that is familiar with CSII and able to teach pump management to patients/families as the key to success.<sup>9,10</sup> These physicians and advanced practice nurses with pump training and certification are the ones in our center who follow patients from start to finish, providing the daily adjustments and ongoing teaching.

Although some of this could be performed through fax and e-mail, the certified diabetes educators in our center prefer daily phone contact so that an open dialog can be maintained. This obviously requires a significant time commitment, most of which is not reimbursed by third-party payers. Maintaining a pediatric center capable of supporting pump therapy is difficult and can be a financial drain.

#### Longitudinal Results of CSII Experience at Childrens Hospital Los Angeles

Since 1994, we have followed our patients on CSII longitudinally to determine short- and long-term outcomes. We have tracked multiple measures, such as age, duration of

diabetes, reason for pump placement, HbA<sub>1c</sub>, severe hypoglycemic events and DKA, insulin dosage, growth parameters, and validated measures of knowledge, adherence, responsibility, integration, and quality of life.

In 1999, 83 patients had been on insulin pump therapy in our center for a mean of 2.2 years. The mean age of subjects was  $13.6 \pm 3.9$  years, with a mean diabetes duration of  $5.3 \pm 3.2$  years. Of these, 55% were placed on CSII because they desired optimal basal/bolus management, 30% were given insulin pumps to improve glycemic control, 7% were placed on pumps to ameliorate severe hypoglycemia, and 8% started pump therapy because of recurrent DKA.<sup>9,10</sup>

Table 3 shows the pre- and post-pump HbA<sub>1c</sub>, body mass index (BMI), and hypoglycemia and DKA rates in our overall cohort as well as results on the validated measures listed above. As shown, there were significant improvements in all measures and no change in BMI. Included in our patient population at this time were six children ≤7 years of age.

Because of this overall success, by the end of 2000, our pump population had increased to 210 subjects (14% of our type 1 diabetic subjects), and we had pre- and post-pump data of at least 6 months' duration on 11 subjects ≤7 years. These data are

**Table 4. Data on Patients ≤7 Years of Age Using CSII**

	Pre-CSII	CSII	P value
HbA <sub>1c</sub>	8.5 ± 0.8%	7.4 ± 1.1%	0.01
Blood glucose ± SD	157 ± 64 mg/dl	92 ± 31 mg/dl	0.03
Severe hypoglycemia	0.18 events/patient/year	0.09 events/patient/year	ND
Family activity	74 ± 8	86 ± 6	0.003
Family cohesion	82 ± 6	90 ± 5	0.009
Parent impact	70 ± 5	87 ± 5	0.001

shown in Table 4. They show a decrease in HbA<sub>1c</sub> and mean blood glucose levels. The smaller standard deviation of the mean blood glucose level indicates that there was less glycemic excursion with the pump. These lower mean blood glucose and HbA<sub>1c</sub> values were obtained at the same time there was a reduction in the severe hypoglycemia rate.

In addition, there were no episodes of DKA. The risk of DKA had been a potential concern because without a depot of intermediate- or long-acting insulin, it was believed that if the pump catheter dislodged or the pump malfunctioned, DKA would rapidly ensue. However, this did not occur in our patients.

Results of scores on validated measures from the Child Health Questionnaire<sup>13</sup> revealed that the impact that diabetes had on family functioning, family activity, and family cohesion was significantly improved with CSII.

Six young subjects were placed on CSII to optimize basal/bolus therapy, three because of recurrent hypoglycemia, and two to improve glycemic control. The number of pump basal rates was less in young children compared with the older cohort of pump patients in our center ( $2.9 \pm 2.1$  for children  $\leq 7$  of age vs.  $4.1 \pm 1.8$  for children 8–13 years,  $P = 0.05$ ). There was no difference in the insulin dosage between the young cohort and older subjects ( $0.55 \pm 0.13$  U/kg/day vs.  $0.62 \pm 0.17$  U/kg/day,  $P = \text{NS}$ ).

Over the past 8 years, ~10% of the patients we started on CSII have gone back to injection therapy. This has been because of inability to wear the pump, failure to comply with the regimen, or lack of family support. All subjects who have discontinued have been teens; none were young children.

Because the pump is a health care expense, we were concerned that pumps would be more easily lost or damaged by young children who developmentally lack the ability to care for possessions. This has not been the case. Overall, very few pump accidents have occurred, and there has been no difference in the low rate of pump damage or loss (<5%/year) among age-groups (young children, school-aged children, and teens).

### Use of the Pump at Night for Young Children

Although we have found CSII to be of benefit in young preschool and

school-aged children, we have questioned the developmental capability of some children 7–10 years of age to manage the pump 24 h/day. These children are away from their parents and must assume some responsibility for pump management, in contradistinction to younger children who cannot be expected to perform any of the tasks required to manage CSII.

In these children 7–10 years of age, we evaluated the efficacy of insulin pump treatment only at night.<sup>14</sup> This concept had originally been put forth by Schiffrin and Belmonte<sup>15</sup> and Kanc et al.<sup>16</sup> in an older cohort of children who had reduced HbA<sub>1c</sub> levels, less hypoglycemia, and more normal fasting blood glucose levels with night insulin pump treatment. In our study of 10 children 7–10 years of age, nighttime CSII appeared to be beneficial.<sup>14</sup>

Our study cohort had on entry a mean diabetes duration of  $3.4 \pm 1.6$  years and a mean HbA<sub>1c</sub> of  $7.6 \pm 0.9\%$  and took a mean of  $0.9 \pm 0.3$  U of insulin/kg/day. Our study entailed a crossover design between three injections/day and CSII at night.

The results showed that, compared with baseline levels, the use of the pump resulted in a significant decrease in the mean average blood glucose ( $186 \pm 31.9$  vs.  $160 \pm 19.6$  mg/dl,  $P = 0.001$ ), breakfast ( $197 \pm 31.2$  vs.  $125 \pm 31.3$  mg/dl,  $P = 0.0001$ ), and 3:00 a.m. ( $173 \pm 48.8$  vs.  $132 \pm 25.2$  mg/dl,  $P = 0.003$ ) blood glucose levels. In addition, there was a decrease in the percentage of blood glucose levels less than the target range ( $21 \pm 10.0\%$  vs.  $15 \pm 6.3\%$ ,  $P = 0.01$ ), a decrease in fruc-

tosamine values ( $386 \pm 56$  vs.  $345 \pm 36.6$   $\mu\text{mol/l}$ ,  $P = 0.01$ ), and an increase in the percentage of blood glucose values within the target range ( $36 \pm 7.5\%$  vs.  $44 \pm 6.7\%$ ,  $P = 0.03$ ). There were no adverse events during the pump portion of the study. Specifically, there were no episodes of severe hypoglycemia.

This study indicates that nighttime-only insulin pump therapy can be used to improve glycemia in young children who cannot be managed 24 h/day with CSII because they lack the developmental/cognitive skills to be independent when they are not cared for by their parents or other adults competent in pump management.

### Insulin Pump Therapy Coupled With the Continuous Glucose Monitoring System

We have recently used the continuous glucose monitoring system (CGMS) (MiniMed, Sylmar, CA) to evaluate the efficacy of pump therapy in our patient population (F.R.K., L.C. Gibson, M.H., S.C., L.K. Fisher, P.P., unpublished data). CGMS measures subcutaneous interstitial glucose levels continuously, recording values on average every 5 min within a range of 40–400 mg/dl.<sup>17</sup> Because the CGMS is a light-weight, portable, minimally invasive system, it was possible to employ this in our pediatric patients, including young children.

We compared the glycemic patterns over a mean of  $4.3 \pm 1.4$  days in 24 children on three to four injections per day with that of 23 children on CSII. There were more abnormal glucose patterns (defined as >50% of glu-

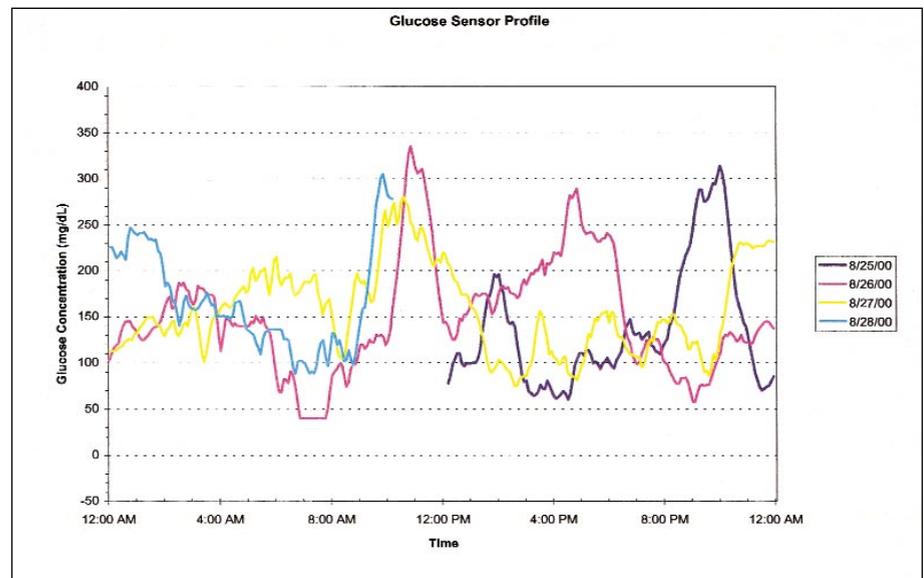


Figure 1. CGMS Tracing of a 4 year old with a high post-breakfast pattern.

cose values outside the target range during any of the nine time periods/day—three premeal, three postmeal, and three night periods [bedtime to midnight, midnight to 3:00 a.m., and 3:00 a.m. to waking]) with injection therapy compared with the pump (130 abnormal glucose patterns in the injection group compared with 80 abnormal patterns in the pump group).

Figure 1 shows an example of an abnormally high glucose pattern after breakfast in a 4-year-old patient on CSII. Figure 2 shows a tracing from a 6-year-old pump patient without an abnormal glucose value.

We have found that the information from CGMS can be used to alter insulin regimens, particularly the bolus insulin therapy, for pump patients. This has led to a decrease in HbA<sub>1c</sub> in patients selected because of glucose management problems.<sup>17</sup> We are in the process of evaluating the efficacy of obtaining CGMS on all CSII patients 2–3 months after starting on the pump. We hypothesize that this will improve our ability to regulate glycemia by ensuring that basal, bolus, and correction doses are optimal.

### Conclusions

Our experience with insulin pump therapy in young children, as well as our entire population on CSII, has been extremely positive. Our young patients have had a reduction in HbA<sub>1c</sub>, mean blood glucose levels, and glycemic excursion; a decrease in episodes of severe hypoglycemia; and an increase in family functioning around diabetes.

We believe the success of our pump program in young children can be attributed to the fact that we have employed appropriate criteria for patient selection and have a standardized method to initiate pump therapy and to follow and support our patients/families. Our center has a sufficient number of experienced diabetes educators to be able to take daily phone calls and to perform ongoing teaching/validation over the weeks to months required to achieve stable glycemia. Our Insulin Dosage Guide, modification of the pump manual, use of CSII at nighttime only, and use of CGMS to evaluate glycemia and modify insulin dosages all have enabled us to maximize the benefit of CSII in young children with no apparent negative medical or lifestyle consequences.

To date, there have not been many reports to support advocating the use of CSII in young children. The recent Consensus Guidelines 2000 of the International Society for Pediatric and Adolescent Diabetes<sup>18</sup> advocated the use of external insulin pumps in young children. These guidelines stated that pumps have been proven successful in young infants in need of diabetes stabilization. However, there were no specific references given to support this statement.

This relative dearth of specific evidence supporting the efficacy of pump use in young children has led many pediatric endocrinologists to avoid CSII in children <6 years of age. To rigorously determine the role of CSII in this age-group, randomized trials should be conducted.

These should include cost/benefit analyses because pump therapy adds short-term cost to the economic burden of diabetes. However, there is evidence that the improvement in glycemic control appreciated with CSII may reduce the long-term cost of caring for patients with this devastating disease.<sup>3</sup>

At present, the results of our experience would suggest that CSII can be used with success in young children. Specifically, pump therapy should not be avoided in young children who meet one of the four medical indications; who have motivated parents with the appropriate knowledge, skills, and attitude; and who are cared for by a diabetes team expert in pump therapy. With no data to the contrary, CSII should be considered a viable diabetes management alternative in children of any age.

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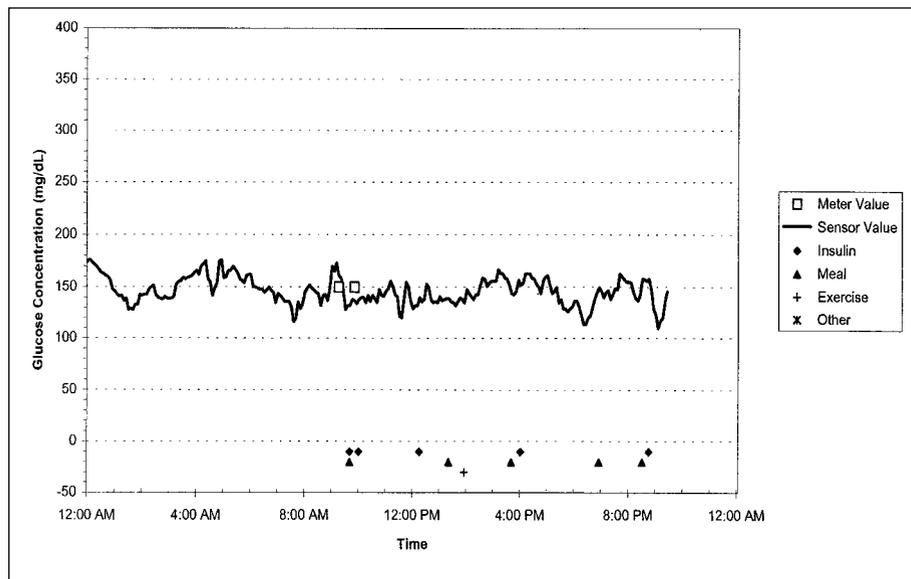


Figure 2. CGMS tracing of a 6-year-old with no abnormal glucose patterns.

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*Note of disclosure: Dr. Kaufman is a stock shareholder in MiniMed, Inc., which manufactures insulin pumps and the Continuous Glucose Monitoring System. She has served as an advisor or speaker's bureau member and has received research support from MiniMed, as well as Novo Nordisk and Eli Lilly, both of which manufacture insulin. Ms. Halvorson is a stock shareholder in MiniMed, Inc., and has received honoraria and research support from MiniMed, Eli Lilly, and Novo Nordisk. Ms. Carpenter is a stock shareholder in MiniMed, Inc.*