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# Position Statement: Continuous Subcutaneous Insulin Infusion in Very Young Children With Type 1 Diabetes

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## ABSTRACT

Insulin pump therapy has become increasingly popular for the treatment of type 1 diabetes in pediatric patients. Although significant experience has accrued with the use of this modality in older children and adolescents, much less data are available regarding continuous subcutaneous insulin infusion in the very young. Policies of individual physician practices and insurance companies vary widely, and there is currently no consensus regarding the appropriateness of insulin pump therapy in the under 6 age group. However, we have witnessed in recent years a significant increase in the number of clinical trials investigating the use of continuous subcutaneous insulin infusion in young patients, and reports of >100 pre-school-aged diabetic children treated with insulin pumps are available in the literature. Although these studies have been of relatively short duration ( $\leq 12$  months), the results are remarkably consistent. Although there is no evidence that insulin pump therapy results in a sustained improvement in glycemic control in this age group, risks associated with these devices in the hands of reliable adults who are managing diabetes in very young children are low. Parental satisfaction related to the increased flexibility that continuous subcutaneous insulin infusion affords anecdotally seems to be high, although formal examination of parental stress and health-related quality of life in this setting has been minimal. Important questions remain regarding selection of appropriate candidates for insulin pump therapy, whether benefits of continuous subcutaneous insulin infusion outweigh the costs, and what eventual outcomes will be in children treated with pumps from a very young age. Long-term follow-up of medical, psychological, and neurocognitive parameters in these young patients will be paramount. Our goal with this review is to summarize efficacy and safety of continuous subcutaneous insulin infusion in children  $\leq 6$  years of age, present potential pros and cons of using insulin pumps in this population, and propose clinical management guidelines that could be useful for both practitioners and third-party payers alike.

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### Key Words

diabetes, insulin pumps, children

### Abbreviations

CSII—continuous subcutaneous insulin infusion

MDI—multiple daily injections

HbA1C—hemoglobin A1C

DKA—diabetic ketoacidosis

QoL—quality of life

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THE FIRST REPORT of insulin pump therapy in children under the age of 6 was published >20 years ago.<sup>1</sup> In this uncontrolled, observational study, 6 patients with poorly controlled diabetes were treated with continuous subcutaneous insulin infusion (CSII) for 6 months, during which time they experienced significant improvements in glycemic control and frequency of hypoglycemic events. In the years after this initial account, the number of published reports of insulin pump therapy in pediatric patients has risen exponentially.<sup>2</sup> Although the vast majority have indicated favorable results,<sup>3-14</sup> few have focused specifically on toddlers and preschool-aged children. Of those studies that have targeted this age range, problems with interpretation of the findings have included small sample sizes, use of a retrospective study design,<sup>15,16</sup> and lack of a control group.<sup>17-21</sup> Therefore, many in the field have continued to regard insulin pumps as untested or experimental therapy in the very young child with diabetes mellitus. During the last several years, however, results from a number of prospective controlled trials of CSII in very young patients have become available.

In 2004, outcomes from an initial randomized, controlled study of insulin pumps in diabetic preschoolers were published.<sup>22</sup> Children under 5 years were assigned to CSII or multiple daily injections (MDI) for 6 months. Although hemoglobin A1C (HbA1C) declined significantly in both groups of patients, no difference between groups was apparent at the end of the 6-month period. Similarly, no differences were noted in blood sugar vari-

ability, severe hypoglycemia, or episodes of diabetic ketoacidosis (DKA). This study was followed by a second report of a randomized trial in which young subjects on insulin pump therapy again were compared with a group of patients on MDI for 1 year.<sup>23</sup> Glycemic control, quality of life (QoL), and incidence of adverse events were comparable between groups. A virtually identical study design was used in a third trial in which children aged 1 to 6 years were assigned to current MDI therapy or CSII for 6 months.<sup>24</sup> Mean HbA1C, blood glucose levels and frequency of hypoglycemia, DKA, and hospitalization were similar between groups. Reassuringly, none of these trials reported problems with manipulation of pumps or inadvertent insulin delivery on the part of young subjects. Including uncontrolled prospective studies, results from >100 preschool-aged diabetic children treated with CSII are available in the literature and are summarized in Table 1. Given the remarkably consistent findings among these clinical trials, it seems that CSII is both safe and effective in this age group. However, evidence that insulin pump therapy a priori improves diabetes control in these children is currently lacking.

#### CSII IN RELATION TO QoL AND PARENTAL STRESS

The emotional toll that having a young child with diabetes extracts from adult caregivers is daunting.<sup>25</sup> Inherent challenges related to this age group include a notorious variability in food intake and activity levels, as well as diminished ability to verbalize symptoms of hypogly-

**TABLE 1 Results From Studies of Insulin Pump Therapy in Very Young Children With Type 1 Diabetes**

Author	Design	N	Age, y	Findings
Boungneres et al <sup>1</sup> (1984)	Uncontrolled; 6-mo prospective trial of CSII	6	1.4-4.4	Decrease in HgbA1 from 192% to 152% ( $P < .02$ )
Ahern et al <sup>20</sup> (2002)	Uncontrolled; 12-mo prospective trial of CSII	26	<7	Decrease in HbA1C from 7.1% to 6.5% ( $P < .02$ )
Litton et al <sup>19</sup> (2002)	Retrospective; comparison of prepump and postpump glycemic control	9	0.8-3.3	Decrease in HbA1C from 9.5% to 7.9% ( $P < .001$ ) Decrease in hypoglycemia from 0.52 to 0.09 episodes per month
Shehadeh et al <sup>17</sup> (2004)	Retrospective; 1-y multicenter comparison of prepump and postpump glycemic control	15	1-6	Decrease in HbA1C from 8.82% to 8.18% after 1 y of CSII ( $P < .05$ ) No difference in hypoglycemia Improvements in QoL scales on CSII
DiMeglio et al <sup>22</sup> (2004)	Prospective; controlled trial of CSII vs MDIs for 6 mo	37	1.8-4.7	No difference in glycemic control or incidence of severe hypoglycemia between groups More mild hypoglycemia with CSII No episodes of DKA
Wilson et al <sup>23</sup> (2005)	Prospective; controlled trial of CSII vs MDIs for 1 y	19	1.7-6.1	No difference in glycemic control, QoL, or incidence of hypoglycemia between groups No episodes of DKA
Fox et al <sup>24</sup> (2005)	Prospective; controlled trial of CSII vs MDIs for 6 mo	22	1-6	No difference in glycemic control or incidence of severe hypoglycemia between groups More mild/moderate hypoglycemia with CSII Improved QoL in fathers
Jeha et al <sup>21</sup> (2005)	Uncontrolled; 6-mo prospective trial of CSI	10	<6	Decrease in HbA1C from 8.6% to 7.5% ( $P = .01$ ) Decrease in blood glucose variability ( $P = .02$ ) Decrease in hypoglycemia from 1.16 to 0 episodes per 24 h No difference in parental stress index

cemia compared with older children. Parents often suffer extreme anxiety related to the perceived vulnerability of their child to devastating diabetes-related problems such as seizures, neurocognitive damage, or death. Because parental well-being has a direct impact on children's QoL, it is critical to examine these factors in relation to diabetes-management regimens. Thus far, minimal formal investigation regarding the effect of CSII on QoL has been undertaken. In older children, insulin pump therapy has been associated both with improvements<sup>14</sup> and no differences<sup>26,27</sup> in QoL measures. In very young children, CSII has also been reported to improve QoL,<sup>15,17</sup> to result in no difference in parental stress,<sup>28</sup> and to particularly benefit fathers.<sup>24</sup> Given the short duration and small sample sizes involved, however, these results must be considered preliminary. Nonetheless, the observation that nearly all families of preschool-aged children choose to continue CSII after having participated in a study is compelling.<sup>22</sup> Despite this positive impression, CSII in the hands of some parents seems (anecdotally) to exacerbate diabetes-related stress. The ability to manipulate blood sugar levels in a minute-to-minute fashion seems to lead to an inordinate frequency of blood sugar testing (up to 25 times per day in some cases) and inability to "see the forest for the trees" (personal experience and communication). This observation is supported by data suggesting that more meticulous management is associated with higher degrees of perceived stress in the caregivers of very young children with type 1 diabetes.<sup>29</sup> Clearly, additional study in this area is sorely needed.

#### **COST COMPARISON OF CSII VERSUS MDIs**

An obvious disadvantage of insulin pump therapy is cost. Depending on the insurance plan and the manufacturer, it has been estimated that CSII requires an up-front expenditure of approximately \$5000, with monthly costs totaling more than \$100.<sup>30,31</sup> Pump supplies in addition to a MiniMed 508 pump (Medtronic Diabetes, Northridge, CA) amortized over 7 years have been projected to require \$3400 annually, in comparison to estimated annual costs of MDI of \$1800.<sup>4</sup> Exact out-of-pocket costs for any given family will also be impacted by the percent copayment, the contracted price, and trade-up values for previously owned pumps. Table 2 provides representative estimates of currently available pumps and pump supplies as well as a description of some associated features. CSII also results in additional expense in the form of personnel, because the intensive follow-up typically provided in the days, weeks, and months after transition to CSII in young children requires many hours on the part of diabetes-team members. In the case of young school-aged children on pumps, training of multiple caregivers often represents further drain on the resources of the diabetes program, although parents can assist with this to some extent. Because most school systems lack 24/7 school nurse

coverage, education must also be provided to school personnel so that appropriate insulin dosing and pump troubleshooting can occur when parents are not physically present. Finally, given the constant shifts in the reimbursement policies and requirements of third-party payers surrounding coverage of insulin pumps, significant effort must be devoted to ensuring that the mandatory documentation, letters of medical necessity, certification of diabetes education, and other forms are continually in place. This process is only partially facilitated by the direct contact that is often established between the pump manufacturers and insurance companies. With the complexities inherent in having to navigate multiple different insurance plans simultaneously, this paperwork alone currently consumes 30% to 40% of a "pump educator's" or secretary's time. Cumulatively, these issues place a significantly greater economic burden on both families and providers than is incurred with traditional therapy.

#### **UNANSWERED QUESTIONS AND FUTURE DIRECTIONS**

One of the most important aspects of prescribing insulin pumps in children is the ability to recognize the best candidates for this form of therapy. Thus far, however, attempts to identify factors that are predictive of success with CSII have proved elusive.<sup>32</sup> An additional gap in our knowledge revolves around the question of what happens long-term to very young children treated with CSII, particularly in the context of a clinical trial. Are safety and efficacy maintained, or do episodes of DKA and severe hypoglycemia increase? How do these children fare as they progress through childhood and enter adolescence? Are there differences in diabetes-related transition-to-adulthood milestones in the context of long-standing insulin pump therapy? Does CSII confer any advantages in this vulnerable population in terms of neurocognitive function, which has been reported to be adversely affected by early-onset diabetes?<sup>33-35</sup> In contrast, are there nutritional consequences of insulin pump therapy in childhood, such as an increased propensity for obesity?<sup>36</sup> Does the long-term intense supervision of these children by their parents put them at greater risk for conflict during adolescence than in those managed with less-intensive regimens? Because these and multiple other questions abound, it will be essential for pediatric diabetologists to perform careful, ongoing, systematic follow-up of young children treated with insulin pumps. Whether novel treatments such as pramlintide will prove to be a useful adjunctive therapy for the maintenance of good metabolic control in the setting of CSII also remains to be seen.<sup>37</sup>

#### **RECOMMENDATIONS**

In consideration of the present state of knowledge regarding the use of insulin pumps in very young diabetic children, we propose the following:

**TABLE 2 Representative Cost Estimates of Insulin Pumps as of January 2006**

Manufacturer	Pump	Insulin Capacity, U	Pump Cost, \$	Pump Supplies	Supplies Cost (Box of 10–12), \$	Software and Special Features
Medtronic MiniMed	Paradigm 515 or 715	180 and 300	6195.00	Paradigm reservoir	31.00	Free software downloads pump data using radio frequency technology. This information can also be downloaded into a personal computer using Paradigm Pals software. Pump can also communicate with BD Logic via infrared technology. Patients can trade in an older-model MiniMed pump for up to \$500.00 credit.
				Quick-set 6 mm Sof-set infusion set	110.00–135.00	
				Silhouette infusion set	150	
Deltac	Cozmo (comes with CoZmonitor blood glucose module and CoZmanager PC communications software)	300	5595.00	Comfort	\$110.00	The glucose meter communicates with the pump through infrared technology. Software included with the pump provides 2-way communication, allowing the patient to program the pump and review insulin and blood glucose level history.
Animas	Animus IR1250	200	5975.00	USB adapter package Cleo infusion set Pump cartridges	\$49.00 (each) \$128.50 \$36.00	The EZ manager software allows connections with personal computers and access to an individualized sick-day quick-reference guide. A database with carbohydrate content of foods can be customized for individual patients.
Nipro	Amigo	300	5495.00	Inset infusion set Insertion sets Reservoirs Tape and adhesive removers	\$135 \$120.00 \$40.00 \$25.00	

1. All children with diabetes, regardless of age, should be considered to be potentially eligible candidates for insulin pump therapy.
2. The decision to implement CSII in a young patient should rest solely with that child's physician and parents or legal guardians rather than with third-party payers.
3. Every effort must be made to ensure that parents have realistic expectations of what CSII can and cannot do, as well as what will be required to safely manage their child's diabetes with this modality. All too often, media and cyberspace hype regarding insulin pumps gives parents the mistaken impression that these devices ameliorate diabetes simply by being worn or render it exceedingly easy to manage. In fact, the need for increased frequency of blood sugar testing (6–9 times per day initially) and scrupulous attention to precise carbohydrate counting and infusion-set function actually increases the diabetes-related workload after transition to CSII.
4. Baseline eligibility criteria for insulin pump therapy in this age group should include having motivated parents with excellent to good compliance with diabetes care and demonstrated mastery of carbohydrate counting. Many pediatric diabetes programs also offer preparatory pump classes and require that children be on MDI and insulin/carbohydrate ratios before starting pump therapy. Introducing CSII using a saline pump can be a useful tool for familiarizing children and caregivers with the hands-on aspects of wearing an insulin pump. In the absence of clear predictors of optimal pump candidates, selecting against pump therapy is perhaps as reasonable as selecting CSII for an individual patient. CSII may be implemented on a "probationary" basis in some cases.
5. Research must be directed toward elucidating the immediate and long-term consequences of CSII in young children in terms of metabolic control, long-term complications, psychosocial function, nutritional status, neurocognitive outcomes, and family stress.

## CONCLUSIONS

Compared with older children and adolescents, very young children with diabetes represent a unique population.<sup>38</sup> Not only do they have an inherent need for a therapeutic regimen that confers maximum flexibility, but the burden of day-to-day diabetes management rests entirely on their parents and other adult caregivers. Although the immediate costs of insulin pump therapy are arguably greater, it is impossible to assign a monetary value to the improvements in QoL that the majority of parents report for their children and themselves after experiencing treatment of diabetes with CSII as com-

pared with conventional insulin therapy.<sup>39</sup> The available evidence indicates that CSII is safe and effective in this age group. Adding to this the considerable experience of numerous seasoned pediatric endocrinologists, sufficient information has been amassed to establish CSII as a viable option for select pediatric patients regardless of age. Prospective controlled studies will enhance our understanding of the risk-to-cost/benefit ratio of insulin pump therapy in young children with type 1 diabetes.

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