

Insulin Pump Therapy for 1–6 Year Old Children with Type 1 Diabetes

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Abstract

Background: The management of diabetes in preschool children poses unique difficulties for both the families and the medical team.

Objective: To test the feasibility and safety of insulin pump therapy in the 1–6 year age group in order to improve quality of life and metabolic control.

Methods: The study group comprised 15 type 1 diabetic children aged 1–6 years old (mean \pm SD, 3.8 ± 1.2 years) from three diabetes centers. Insulin pump therapy was applied for 12 months. Data, including insulin dose, hemoglobin A1c, hypoglycemic events, as well as scores on the Diabetes Quality of Life Measure Questionnaire and the Diabetes Treatment Satisfaction Questionnaire, were collected and compared with the multiple daily injection treatment prior to entry into the study.

Results: HbA1c was measured at the beginning of the study and at 2, 4, 8 and 12 months later; the respective levels (mean \pm SD) were 8.82 ± 0.98 , 8.45 ± 1.05 , 8.37 ± 0.85 , 8.32 ± 0.71 , $8.18 \pm 0.90\%$. HbA1c measurements after 12 months were significantly lower than at the beginning of the study ($P < 0.05$). There were no significant differences in insulin dose and the total number of hypoglycemic events. In both the DQOL and DTSQ scales there were significant differences in scores in favor of the insulin pump period (43.7 ± 8.0 versus 33.7 ± 7.9 , $P < 0.001$; and 10.9 ± 2.3 versus 14.5 ± 2.3 , $P < 0.001$), respectively.

Conclusions: For very young diabetic children, insulin pump therapy improves quality of life and is feasible and safe. It should be considered as an optional mode of therapy for this age group.

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The incidence of type 1 diabetes in preschool children is increasing [1] and the management of diabetes in this age group poses unique difficulties for both the families and the medical team. While the importance of intensive insulin therapy in improving long-term outcomes for patients with type 1 diabetes was demonstrated in adolescents and adults by the Diabetes Control and Complications Trial [2], the issue becomes more complicated when suggesting glycemic control "as close to normal" for younger children. The feasibility and safety of using an intensive insulin regimen for achieving near-euglycemia in this age group are not established. Lower hemoglobin A1c values were associated with a greater

likelihood of severe hypoglycemia [2], and several studies have demonstrated central nervous system damage as a result of severe hypoglycemia in young children [3,4]. Use of insulin pump therapy has increased dramatically during the last decade, and it is regarded as a good and viable alternative in adults, adolescents and school-age children. Insulin pump usage may offer some advantages over multiple daily insulin injections, such as better insulin pharmacokinetics, greater freedom in timing of meals and snacks, and decreased risk of nocturnal hypoglycemia [5,6]. However, its feasibility, safety and impact on quality of life in preschool diabetic children have not been sufficiently studied [7,8]. We undertook a 12 month study to evaluate use of the insulin pump in this age group as a means of improving quality of life and metabolic control.

Patients and Methods

The study was conducted in three pediatric diabetes clinics at the following centers: the National Center of Childhood Diabetes, Schneider Children's Medical Center of Israel, Petah Tiqva; Meyer Children's Hospital of Haifa, Israel; and the University Children's Hospital, Slovenia. Fifteen type 1 diabetic children (7 girls and 8 boys) aged 1.3–5.7 years old (mean \pm SD, 3.8 ± 1.2 years) were enrolled in the study. Initial therapy consisted of multiple daily injections (3–5 insulin injections per day), and all families received extensive diabetes education and dietary counseling. Insulin pump therapy was suggested for young children (<6 years) who had diabetes for at least 6 months. Parents and/or caretakers were given instructions regarding insulin pump usage and all were willing to participate in the study. The initial daily dose of insulin (NovoRapid[®], Novo Nordisk, Denmark) was estimated to be 80% of the previous daily dose. Insulin pump therapy, using the MiniMed 508 pump (Sylmar, CA, USA), was applied for 12 months and all families had 24 hour phone access to a diabetes staff member for consultation. Families were instructed to replace the infusion sets and insulin at intervals not exceeding 48 hours for the duration of the study. Insulin dose, HbA1c and hypoglycemic events were recorded and compared with the previous 4 months MDI treatment prior to entry into the study. Samples for HbA1c determination were assessed using the Bayer DCA 2000 instrument (Tarrytown, NY,

MDI = multiple daily insulin injections

HbA1c = hemoglobin A1c

DQOL = Diabetes Quality of Life Measure

DTSQ = Diabetes Treatment Satisfaction Questionnaire

USA). The normal reference value is 4.3–6.3%, and the inter-assay coefficient of variation is 3.6% at a normal HbA1c level (5.3%) and 2.7% at a moderately elevated level (9.2%). Samples were collected at the beginning of the study (reflecting metabolic control during the last 4 months before pump therapy), and at 2, 4, 8 and 12 months. An episode of severe hypoglycemia was defined as uncontrolled shaking, disorientation or loss of consciousness, with or without seizures.

At enrollment and after 4 months of insulin pump therapy, parents were asked to complete two questionnaires, the Diabetes Treatment Satisfaction Questionnaire [9] and a modification of the Diabetes Quality of Life Measure [10] for parents. The DTSQ was specifically designed to measure satisfaction with the diabetes treatment regimen in people with diabetes. The scale includes eight items of which only six are used to calculate the final score. Each question is scored from 0 (very unsatisfied) to 6 (very satisfied). The total satisfaction score can range from 0 to 36. The modified DQOL has two scores using 19 questions of the original DQOL questionnaire. The 19 questions were divided into two scores. The first score, "Impact of diabetes on the child," was derived from five questions from the original "impact scale" (questions 1, 4, 6, 9, 18). Each question is scored from 1 ("never") to 5 ("all the time"); thus, the total score can range from 5 to 25. The second score, "Impact of diabetes on the parent," was derived from 14 questions: 5 from the original "impact scale" (2, 5, 7, 13, 15) and another 9 from the "worry scale" (1, 2, 3, 5, 6, 7, 8, 10, 12). All questions were phrased in a way that would reflect the impact of the child's diabetes on the parent.

Results

Fourteen participants completed the study. Their mean age at diagnosis of diabetes was 2.16 ± 1.0 years (mean \pm SD).

- **Pump-related side effects.** During the 12 month study period, there were no episodes of pump failure, and only one case of pump site infection was reported.
- **Effects of insulin pump therapy on metabolic control:** HbA1c was measured at the beginning of the study, and after 2, 4, 8, 12 months of enrollment. Mean \pm SD levels were 8.82 ± 0.98 , 8.45 ± 1.05 , 8.37 ± 0.85 , 8.32 ± 0.71 , $8.18 \pm 0.90\%$ respectively [Table 1]. Using repeated measure ANOVA, there was a significant difference between HbA1c measures at enrollment and after 12 months ($P < 0.05$). There was a minor non-significant decrease in the number of severe hypoglycemic episodes; before initiation of pump therapy, patients had a mean of 0.36 episodes per patient year compared with 0.29 episodes recorded under pump therapy. No episodes of diabetic ketoacidosis were reported during the 12 month pump therapy.
- **Effects of pump therapy on treatment satisfaction and quality of life:** As summarized in Table 1, there was a significant difference in the DTSQ score in favor of the insulin pump period (30.67 ± 3.73 vs. 19.8 ± 4.89 , $P < 0.001$). The same patterns of significant difference were found in both DQOL scales, "Impact" and "Worry," in favor of the insulin

pump period (10.9 ± 2.3 vs. 14.5 ± 2.3 , $P < 0.001$, and 43.7 ± 8.0 vs. 33.7 ± 7.9 , $P < 0.001$), respectively.

Discussion

Advances in insulin pump technology have made these devices much easier to use, and consequently they are an attractive alternative to MDI. However, management of preschool children with diabetes poses unique difficulties due to several factors, such as unpredictable food intake and physical activities, the need for several blood glucose measurements and MDI, the increased sensitivity to short-acting insulin preparations, and the inability to convey the symptoms of fluctuations in blood glucose levels (hypoglycemia and hyperglycemia) [11,12]. It was demonstrated that diabetic children in this age group have increased frequency of severe hypoglycemia [13–15]. Several studies have suggested the possibility of negative effects of hypoglycemia on brain development, particularly in children under 5 years of age when myelin lipid development is still occurring [16]. Due to this highly important possibility, some diabetes centers have suggested different target HbA1c levels for different aged children, with higher levels for younger children to decrease the likelihood of severe hypoglycemic events [17]. However, it has been demonstrated that strict glycemic control can be achieved with less severe hypoglycemic events by using insulin pump therapy in adolescents with type 1 diabetes [5].

The purpose of our study was to test the feasibility and safety of insulin pump therapy in a young age group in order to improve quality of life and metabolic control. The fact that each diabetic participant served as his or her own control is of particular advantage because of the several factors that can affect metabolic control.

Although all participants were treated intensively with 3–5 insulin injections, and 3–8 blood glucose measurements per day were performed, their metabolic control was not satisfactory, i.e., a mean HbA1c of 8.82%. In contrast to recent publications [7,19], no improvement in HbA1c measures was observed during the first 8 months of insulin pump use. A significant improvement in HbA1c measures was observed only after 12 months of insulin pump therapy. This could be related to two factors: first, a longer time to practice is needed for optimal use of this instrument, and second, the fact that the participants were 1 year older could make diabetes management easier.

A follow-up study [19] confirmed a reduction in the risk of hypoglycemia in patients with type 1 diabetes using an insulin pump. In our study, we could not demonstrate a significant decrease in the frequency of severe hypoglycemic events after initiation of pump therapy. During the 12 month study there were

Table 1. Summary of the HbA1c, DTSQ and a modification of the DQOL questionnaire results

	Start	2 months	4 months	8 months	12 months
HbA1c (%)	8.82 ± 0.98	8.45 ± 1.05	8.37 ± 0.85	8.27 ± 0.90	$8.18 \pm 0.90^*$
DQOL	43.7 ± 8.0		$33.7 \pm 7.9^{**}$		
DTSQ	10.9 ± 2.3		$14.5 \pm 2.3^{**}$		

* $P < 0.05$ compared with measures at the start of the study.

** $P < 0.01$.

no episodes of pump failure, and no episodes of diabetic ketoacidosis were reported.

All of the participants except for one family preferred the pump to MDI and refused to consider a return to the previous mode of insulin administration.

We conclude that, for very young diabetic children, insulin pump therapy improves quality of life, is feasible and is safe. It should be considered as an optional mode of therapy for this age group, especially in highly motivated families. Newer pump designs with remote-control features and computer programs to help analyze data may facilitate and improve metabolic control and treatment satisfaction of diabetic children in all age groups.

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