



ORIGINAL ARTICLE

Insulin Pump Use in Young Children with Type 1 Diabetes: Sociodemographic Factors and Parent-Reported Barriers

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Abstract

Background: Managing type 1 diabetes (T1D) in young children presents challenges to families and caregivers. Pump therapy may reduce challenges and benefit glycemic control. However, pump use is not universal; parent-reported reasons for lack of uptake are not well described.

Methods: Parents of children <7, with T1D for ≥1 year, in the T1D Exchange registry completed surveys capturing demographic and clinical characteristics, as well as barriers to pump use. Data from pump users were compared to nonusers, and barriers were analyzed among parents who received pump recommendations, but decided against uptake.

Results: Young children ($N=515$) from 41 sites were identified (mean age 5.2 ± 1.2 years, diabetes duration 2.4 ± 1.0 years, 46% female, and 78% Non-Hispanic White). Overall glycemic control was suboptimal (HbA1c $8.1\% \pm 1.0\%$). The majority were pump users (64%, $n=331$; nonusers 36%, $n=184$). Pump users had longer T1D duration (2.5 ± 1.1 years vs. 2.2 ± 1.0 years, $P=0.001$), were more likely to have annual household incomes $\geq \$75,000$ (62% vs. 36%, $P<0.001$), have a parent with college education or higher (70% vs. 45%, $P<0.001$), perform more frequent blood glucose monitoring (7.5 ± 2.5 times/day vs. 6.5 ± 2.3 times/day, $P<0.001$), and use continuous glucose monitoring (CGM) (45% vs. 13%, $P<0.001$). Only income, education, frequency of blood glucose monitoring, and CGM use remained significant in a multivariate model including age, sex, ethnicity, and duration of diabetes. Barriers to pump uptake included concerns with physical interference, therapeutic effectiveness, and to a lesser extent, financial burden.

Conclusions: These findings provide an opportunity to address potentially modifiable parent-reported barriers to pump uptake through education and behavioral intervention.

Keywords: Young children, Barriers, Insulin pump use, Insulin pump adoption.

Introduction

THE MANAGEMENT OF TYPE 1 DIABETES (T1D) in young children creates unique challenges for the families and secondary caregivers of children under the age of seven. Young children may have erratic eating patterns, as well as fluctuating amounts of physical activity from day-to-day, both of which contribute to an increased risk for hypoglycemia.¹ At this young age, many children also lack the developmental

maturity to recognize, comprehend, and communicate to their adult caregivers their symptoms of hypoglycemia and hyperglycemia.^{2,3} Thus, younger children are entirely dependent on adult caregivers (e.g., parents, daycare providers, or teachers) to manage their T1D^{2,4} until old enough to develop more independent self-care behaviors.

Pump therapy has shown greater improvements in glycemic control compared to injection therapy in both adult and pediatric patients,⁵⁻⁹ although pump use in children under the

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age of seven is less well studied than in other pediatric age groups and has shown mixed results in its effectiveness at improving glycemic control.^{10,11} However, a position statement from the American Academy of Pediatrics analyzing the safety and efficacy of pump use in children under the age of seven concluded that pump therapy is a safe, effective, and viable option for select young children with T1D.¹² In particular, the pump's ability to bolus small doses for multiple frequent meals, as well as suspend insulin delivery if necessary, may be especially beneficial for youth in this age group.¹³ A recent analysis of the T1D Exchange clinic registry data showed that among children aged 1 to <6 years, children using pump therapy had significantly lower A1c than children on injections¹⁴; another analysis showed that 37% on pumps met the International Society of Pediatric and Adolescent Diabetes (ISPAD) glycemic control target of <7.5%, compared to only 17% of those on injections.⁹ In a qualitative study conducted by Sullivan-Bolyai et al., parents of young children with T1D reported that pump therapy provided better perceived glucose control and easier day-to-day management of diabetes, as well as the opportunity for more "freedom, flexibility, and spontaneity in their daily lives."¹⁵ Similarly, international studies comparing pump therapy to injection therapy in small samples of young children under the age of seven have shown that pump therapy was associated with higher parent quality of life,¹⁶ as well as less parenting stress, less overall diabetes burden, fewer hypoglycemia-related worries, and less frequent struggles and less difficulty managing eating behaviors than injection therapy.¹⁷

Despite these reported advantages of pump use, universal uptake in young patients is lacking, with few explanations for parent-reported barriers to pump use. Overall, the published literature has not focused on potential negative perceptions or limitations of pump use in young children. The aim of this study was to examine modifiable and nonmodifiable factors associated with initiating insulin pump therapy in young children. Modifiable factors were assessed through the analysis of parent-reported barriers to pump initiation among nonusers, as well as comparisons of clinical outcomes (e.g., HbA1c, continuous glucose monitoring [CGM] use, and diabetic ketoacidosis [DKA]/severe hypoglycemia [SH] frequency) of pump users and nonusers. Nonmodifiable characteristics were assessed through comparisons of demographic characteristics of pump users and nonusers. Understanding demographic and parent-perceived barriers to pump use in young children may help to inform future interventions directed at families of young children aimed at improving the child's glycemic control and parents' quality of life through the use of new technologies.

Methods

The T1D Exchange clinic registry includes >30,000 individuals with T1D followed in a network of 74 adult and pediatric diabetes clinics across the United States. Information about informed consent, assent, and IRB processes, T1D diagnostic criteria for inclusion in the registry, and data collection methods have been previously published (see Supplementary Data online at www.liebertpub.com/dia).^{18,19} Data are collected for the clinic registry central database from participants' medical records. In addition, at the time of registry enrollment,

comprehensive questionnaires are completed by participants (or parents/guardians of participants if minors).^{18,19}

This report includes registry and parent/guardian-reported data on participants <7 years old enrolled from February 2015 through May 2, 2016. All participants had diabetes for at least 1 year. Demographic, socioeconomic, and diabetes management factors (including pump and CGM use) were obtained from parent/guardian questionnaires at enrollment. Pump and CGM use were confirmed by clinic report. The most recent hemoglobin A1c (HbA1c) measurement within 6 months before registry enrollment was obtained from the clinic medical record (mean time between HbA1c record and enrollment was 18 days). HbA1c values were measured by point-of-care device or local laboratory. Occurrences of DKA and SH during the 3 months before enrollment were reported by the parent/guardian. DKA was defined by occurrence of ketoacidosis diagnosed by a healthcare provider requiring a visit to hospital, emergency room, or other healthcare facility. SH was defined as severe hypoglycemia resulting in seizure or loss of consciousness.

Demographic and clinic characteristics of nonusers were compared based on whether they had previously received a pump recommendation from their healthcare provider. Parents/guardians who decided not to use an insulin pump despite a recommendation from their doctors or healthcare providers to do so provided survey responses for their reasons. The survey contained a list of 13 potential burdens or reasons against using an insulin pump. These burdens were derived by a multidisciplinary team of experts in pediatric diabetes care; items included focused on potential issues with physical interference, therapeutic effectiveness, and financial burden of pump use. Parents/guardians rated the importance of each burden on their decision not to use an insulin pump using a 5-point Likert scale from *Not Very Important* to *Important*. The proportion of parents who endorsed a concern as *More Than Somewhat Important* and *Important* was summed together. As the aim of this study was to compare insulin pump users versus participants who had never used a pump, children who used a pump in the past but were not currently using pump therapy at the time of registry enrollment were excluded from the study due to small sample size ($n = 11$ participants).

Statistical analyses

Demographic and diabetes-related characteristics were compared between pump users and nonusers using chi-square and *t*-tests. Wilcoxon rank-sum procedures were used to compare continuous factors among the two groups if the distributions were skewed. A multivariate logistic regression model with pump use as the outcome was performed to assess for any independently significant factors associated with pump use using the following demographic and clinical characteristics: age, duration of diabetes, youth sex, race/ethnicity, annual household income, parent education, frequency of self-monitoring of blood glucose (SMBG) per day, and CGM use. A linear regression model was performed to assess the association between pump status and HbA1c with adjustment for age, duration of diabetes, youth sex, race/ethnicity, annual household income, parent education, and SMBG. Separate logistic regression models were performed to assess the associations between pump status and the occurrence of at least one DKA and SH event, adjusting for potential

confounders. Similar models were performed to compare nonpump users who received recommendation from their doctor or healthcare provider to use an insulin pump versus those who did not report receiving a recommendation. Data analyses were performed using SAS version 9.4 (2011 SAS Institute Inc., Cary, NC). All *P*-values are two sided, and, given the multiple comparisons, only *P*-values <0.01 were considered statistically significant.

Results

A total of 515 children from 41 sites were included in the analysis; average age was 5.2 ± 1.2 years and duration of T1D was 2.4 ± 1.0 years (Table 1). The sample was 46% female and 78% Non-Hispanic White. HbA1c results extracted from the medical record ranged from 5.7% to 11.8%, with a mean of $8.1\% \pm 1.0\%$. Thirty-six percent ($n=184$) never used a pump and 64% ($n=331$) were pump users (mean duration of pump use 2 years, range <1 to 6 years).

As shown in Table 1, pump users had significantly longer diabetes duration (2.5 ± 1.1 years vs. 2.2 ± 1.0 years, $P=0.001$),

were more likely to live in homes with annual household incomes of or greater than \$75,000 (62% vs. 36%, $P<0.001$), and were more likely to have a parent with college education or higher (70% vs. 45%, $P<0.001$). Pump users also were more likely to use CGM (45% vs. 13%, $P<0.001$) and reported measuring blood glucose levels more frequently (7.5 ± 2.5 times/day vs. 6.5 ± 2.3 times/day, $P<0.001$) than nonusers (Table 1).

Pump users were more likely to have lower HbA1c than nonusers ($8.0\% \pm 0.9\%$ vs. $8.3\% \pm 1.1\%$, unadjusted $P<0.001$), but this difference was not sustained after adjustment for confounders, including race/ethnicity and socioeconomic status (adjusted $P=0.61$, Table 1). The frequency of SH events was not significantly different between the two groups. Nonusers were more likely to have experienced a DKA event in the past 3 months than pump users (8% vs. 3%, unadjusted $P=0.01$), but this difference was not sustained after adjustment for confounders (adjusted $P=0.08$).

Multivariate logistic regression was used to identify variables independently associated with pump use. In a model, including age, sex, ethnicity, income, parent education, duration of

TABLE 1. DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE ANALYSIS COHORT

	Overall (N=515)	Never used pump (N=184)	Current pump users (N=331)	P-value never vs. current
Age in years				
Mean \pm SD	5.2 ± 1.2	5.3 ± 1.2	5.2 ± 1.2	0.26
1 to <4 years old, %	19	15	21	
4 to <7 years old, %	81	85	79	
Female, %	46	41	49	0.09
Race/ethnicity, %				
White Non-Hispanic	78	71	82	0.04
Black Non-Hispanic	6	7	5	
Hispanic or Latino	11	14	8	
Other	6	8	5	
Annual household income \geq \$75,000, %	53	36	62	<0.001
Highest level of parent education, %				
High school/GED or less	39	55	30	<0.001
Associate or bachelor degree	35	25	40	
Master, professional, or doctorate degree	26	20	30	
Duration of diabetes in years				
Mean \pm SD	2.4 ± 1.0	2.2 ± 1.0	2.5 ± 1.1	0.001
1 to <3 years, %	74	78	72	
3 to <7 years, %	26	22	28	
Frequency of SMBG				
Mean \pm SD	7.1 ± 2.4	6.5 ± 2.3	7.5 ± 2.5	<0.001
≥ 6 times per day, %	75	62	82	
CGM user, %	33	13	45	<0.001
Most recent HbA1c ^{a,b}				
Mean \pm SD	8.1 ± 1.0	8.3 ± 1.1	8.0 ± 0.9	0.61
<7.5%	25%	22%	27%	
Occurrence of at least one SH event in the past 3 months ^a , %	7	8	6	0.64
Occurrence of at least one DKA event in the past 3 months ^a , %	4	8	3	0.08

^aAdjusted for age, duration of diabetes, sex, race/ethnicity, income, education, and frequency of SMBG. Models with occurrence of SH and DKA event as outcome were not adjusted for income due to missing data.

^bOne participant had an available HbA1c that was deemed inaccurate and therefore was omitted from analyses involving HbA1c.

CGM, continuous glucose monitoring; DKA, diabetic ketoacidosis; SD, standard deviation; SH, severe hypoglycemia; SMBG, self-monitoring blood glucose.

diabetes, frequency of self-monitoring blood glucose, and CGM use, only household income ($P=0.003$), parent education ($P=0.007$), frequency of SMBG ($P<0.001$), and CGM use ($P<0.001$) significantly increased the likelihood of pump use.

Among the 184 parents of youth who were pump nonusers, 87 (47%) reported that their healthcare provider or doctor had never recommended insulin pump therapy for their child while 97 (53%) reported that a healthcare provider had recommended insulin pump therapy for their child. Demographic and clinical characteristics of these two groups are shown in Table 2.

Parents who chose not to initiate pump therapy for their child despite healthcare provider recommendation were asked to rate the importance of various factors associated with their decision not to use an insulin pump (Table 3). Physical interference was the most commonly endorsed theme, with concerns of physical discomfort for the child (71%), interference with sports and activities (59%), using insertion sets and tubing (53%), concern of skin reactions from insertion sites (51%), child discomfort with the idea of having a device on the body (46%), and concern that the pump would be too big (45%). Concerns with therapeutic effectiveness of the pump focused on fears of low blood

sugars (53%) more so than high blood sugars (38%). Some parents further expressed concerns of the pump being too complicated for their family (27%) or other care providers (24%) to use, although only 12% reported not having enough guidance from their child's healthcare providers on how to use the pump. Finally, parents reported concerns of financial burden through their endorsement of the pump being too expensive (43%) and a lack of insurance coverage (25%).

Discussion

The current study highlighted three major parent-reported barriers to pump use despite provider recommendations: the physical burden on the child, the therapeutic effectiveness of the pump, and perceived financial barriers. It is noteworthy that parents' perceptions of the physical burdens of using a pump outweighed concerns about the effectiveness of these devices and lack of reimbursement for the costs of pump therapy, even when encouraged to use a pump by their healthcare providers. In young children, the physical discomfort, potentially due to fewer options of areas for device placement, and device interference in daily activities are real concerns that need to be addressed. Many parents also cited additional physical disturbances associated with tubing and

TABLE 2. DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF NONPUMP USERS BASED ON PUMP RECOMMENDATION FROM HEALTHCARE PROVIDER

	<i>Pump recommended by healthcare provider (N=97)</i>	<i>No recommendation by healthcare provider (N=87)</i>	<i>P</i>
Age in years			
Mean \pm SD	5.3 \pm 1.1	5.3 \pm 1.2	0.65
1 to <4 years old, <i>n</i> (%)	13 (13)	15 (17)	
4 to <7 years old, <i>n</i> (%)	84 (87)	72 (83)	
Female, <i>n</i> (%)	43 (44)	32 (37)	0.30
Race/ethnicity, <i>n</i> (%)			
White Non-Hispanic	65 (68)	64 (74)	0.75
Black Non-Hispanic	7 (7)	6 (7)	
Hispanic or Latino	16 (17)	10 (12)	
Other	8 (8)	6 (7)	
Annual household income \geq \$75,000, <i>n</i> (%)	36 (44)	17 (25)	0.02
Highest level of parent education, <i>n</i> (%)			
High school/GED or less	47 (49)	54 (63)	0.17
Associate or bachelor degree	27 (28)	18 (21)	
Master, professional, or doctorate degree	22 (23)	14 (16)	
Frequency of SMBG			
Mean \pm SD	6.6 \pm 2.3	6.3 \pm 2.2	0.17
\geq 6 times per day, <i>n</i> (%)	66 (68)	48 (55)	
Duration of diabetes in years			
Mean \pm SD	2.4 \pm 1.0	2.0 \pm 0.9	0.02
1 to <3 years, <i>n</i> (%)	70 (72)	74 (85)	
3 to <7 years, <i>n</i> (%)	27 (28)	13 (15)	
Most recent HbA1c ^a			
Mean \pm SD	8.3 \pm 1.0	8.4 \pm 1.2	0.32
<7.5%, <i>n</i> (%)	23 (25)	16 (19)	
Occurrence of at least one SH event in the past 3 months, <i>n</i> (%)	6 (6)	9 (10)	0.30
Occurrence of at least one DKA event in the past 3 months, <i>n</i> (%)	5 (5)	9 (10)	0.18

Only 24 participants who have never used pump are currently using CGM, so the difference between the two groups was not assessed.

^aOne participant had an available HbA1c that was deemed inaccurate and therefore was omitted from analyses involving HbA1c.

TABLE 3. PARENT REPORTED BARRIERS TO PUMP USE

<i>Concern</i>		<i>Percentage endorsing “More than Somewhat Important” or “Important” (N = 96^a)</i>
Physical interference	Uncomfortable to wear	71%
	Interference with sports and activities	59%
	Using the insertion sets/tubing	53%
	Skin reactions from the insertion site/adhesive	51%
	Having a device on body	46%
	Pump would be too big	45%
Therapeutic effectiveness	Low blood sugars when using pump	53%
	High blood sugars when using pump	38%
	Pump too complicated for family to use	27%
	Pump too complicated for other care providers to use	24%
	Not enough advice/guidance from HCP on how to use pump	12%
Financial burden	Pump too expensive	43%
	Insurance does not cover pump	25%

^aParents who chose not to initiate pump therapy for their child despite healthcare provider recommendations were asked the following question: “How important was each of the following factors in the decision not to use an insulin pump for your child?”

skin reactions to adhesives. Parent perceptions of bodily discomfort and interference with the pump could be supplemented by children’s perceptions of both wearing and using the device in future research. For example, some children may consider the tasks associated with pump use as acceptable because adults manage their insulin pump therapy, while other children may prefer the pump in an effort to avoid the possible disruptions and pain associated with injection-based therapy. The perception of discomfort and difficulties in pump use from the child’s perspective needs to be explored further, particularly in verbal youth in the older half of this age range.

Concerns regarding therapeutic effectiveness may relate to parental familiarity and comfort with insulin injections. Many parents endorsed concerns with low blood glucose levels as a result of pump use, suggesting either inadequate provision of potential benefits of pump use or parental beliefs about the negative effects of pump use, given that past research has suggested potential reductions in severe hypoglycemic events and/or improvements in glycemic control.^{16,20–22} Given the fact that only 12% of parents surveyed reported not enough guidance from their child’s healthcare provider, the doubts surrounding the pump’s effectiveness may be the result of personal beliefs about pump use. For example, some parents may feel discomfort with using technology for diabetes care and prefer injections because they are more accustomed to this mode of insulin delivery.

Finally, parents reported financial barriers to pump initiation related to cost of the pump and limited insurance coverage with high co-pays and deductibles. This finding is particularly notable given the statistical differences in income between current pump users and nonusers and the association between household income and likelihood of pump use.

In an analysis of demographic and diabetes management related factors, results showed that pump use in young children was independently associated with both diabetes-specific characteristics, as well as parent characteristics. From a dia-

betes management perspective, pump use was found to be associated with more frequent blood glucose checks and CGM use. It is possible that greater familiarity with diabetes management, as a result of length of experience or greater daily engagement with diabetes care (e.g., SMBG), could be associated with greater comfort, confidence, or desire to utilize advanced diabetes technologies such as a pump or CGM. It is also possible that more frequent blood glucose monitoring or CGM use influences healthcare provider recommendations for pump therapy, as families with greater self-care may appear more likely to utilize and benefit from pump use.

Our results further indicate that children from low income families or parents with less education are less likely to be pump users. This observation may suggest that lower income and education level might limit opportunities to utilize current diabetes technologies, which may result from greater parent financial constraints. Similarly, the large multicenter SEARCH for Diabetes in Youth group also found that pump use was more likely in children from families with higher income and higher education levels.²³ Higher household income may provide certain advantages for children and families that may not be easily accessible to those of lower socioeconomic status, such as greater disposable income for diabetes supplies and subscription to private insurance. Monetary advantages may allow for greater exposure and encouragement of technology use. Similarly, greater household income may influence healthcare provider bias toward pump recommendation, as it is possible that providers may be more likely to recommend pump use to families with fewer financial constraints.

Limitations to the current study should be noted. The current analyses were cross-sectional in nature so causality cannot be determined. In addition, the use of self-report data may potentially bias results. Future research might include surveying parents who elected pump therapy for their young child to gain a better understanding of their reasons for pump initiation, as well as assessing those who previously used pump therapy but decided to transition back to multiple daily

injections. Healthcare providers could also be surveyed to ascertain their determinants and potential biases in recommending pump use to young children. Finally, given that the majority of endorsements for burdens were under 50%, it is possible that the items created in the survey may have inadvertently omitted other potential barriers to pump uptake for families.

In conclusion, the results of the current study provide an opportunity for healthcare providers, payers, and industry to address parent-reported barriers to pump uptake in young children. Further research is needed to address and manage parental concerns around physical burden and therapeutic effectiveness of devices in their young children. Parent-reported worries that the pump would be a physically uncomfortable interference on their child and would cause more frequent hypoglycemia are beliefs that may be best modified through clinical intervention and education from the family's medical team and/or mental health providers. Furthermore, reducing out-of-pocket expenses associated with pump use and providing tailored comprehensive pump education to all families may increase pump use in potentially vulnerable families with less parent education and financial means. Understanding the perceived barriers and fears surrounding pump use among parents of young children may inform future interventions aimed to increase pump uptake, as healthcare providers seek to optimize health outcomes in this young at-risk patient population.

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Authors' Contributions

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