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Adherence to Insulin Pump Behaviors in Young Children With Type 1 Diabetes Mellitus: Opportunities for Intervention

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Abstract

Background: Parents of young children are responsible for daily type 1 diabetes (T1DM) cares including insulin bolusing. For optimal insulin pump management, parents should enter a blood glucose result (SMBG) and a carbohydrate estimate (if food will be consumed) into the bolus advisor in their child's pump to assist in delivering the recommended insulin bolus. Previously, pump adherence behaviors were described in adolescents; we describe these behaviors in a sample of young children.

Methods: Pump data covering between 14-30 consecutive days were obtained for 116 children. Assessed adherence to essential pump adherence behaviors (eg, SMBG, carbohydrate entry, and insulin use) and adherence to 3 *Wizard/Bolus Advisor* steps: SMBG–carbohydrate entry–insulin bolus delivered.

Results: Parents completed SMBG ≥ 4 times on 99% of days, bolused insulin ≥ 3 times on 95% of days, and entered carbohydrates ≥ 3 times on 93% of days, but they corrected for hyperglycemia (≥ 250 mg/dl or 13.9 mmol/l) only 63% of the time. Parents completed *Wizard/Bolus Advisor* steps (SMBG, carbohydrate entry, insulin bolus) within 30 minutes for 43% of boluses. Inverse correlations were found between children's mean daily glucose and the percentage of days with ≥ 4 SMBG and ≥ 3 carbohydrate entries as well as the percentage of boluses where all *Wizard/Bolus Advisor* steps were completed.

Conclusions: Parents of young children adhered to individual pump behaviors, but showed some variability in their adherence to *Wizard/Bolus Advisor* steps. Parents showed low adherence to recommendations to correct for hyperglycemia. Like adolescents, targeting pump behaviors in young children may have the potential to optimize glycemic control.

Keywords

adherence, bolus calculator software, preschool-age children, insulin pumps, type 1 diabetes mellitus

Many families of young children (≤ 6 years) with type 1 diabetes mellitus (T1DM) are choosing to use a pump for insulin management.^{1,2} Specifically, registry data from the Prospective Diabetes Follow-up Registry (DPV) in Europe suggest about 74% of young children are using a pump, while in the United States, the T1 Diabetes Exchange suggests about 50% of young children are using a pump.¹ For young children in particular, insulin pumps present a number of distinct advantages to injections, including the ability to deliver very small doses of insulin, to deliver multiple doses without a need for multiple needle sticks, and if needed, to temporarily suspend insulin in the event of hypoglycemia.^{3,4}

Another advantage to insulin pumps is the bolus advisors, which several pumps contain and which can alleviate the burden associated with calculating a child's insulin bolus doses.^{5,6} These bolus calculators use algorithms that account

for a multitude of variables including the child's current "insulin-on-board" (ie, the remaining bolus insulin in the body), current blood glucose level, target blood glucose level, the amount of carbohydrates to be consumed, the child's insulin-to-carbohydrate ratio, and an approximation of the

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insulin action curve. It has been shown that using the bolus advisor can improve glycemic control.⁵⁻⁷ However, its use requires 2 essential pieces of information: the child's current blood glucose level and the number of grams of carbohydrates to be consumed, if a meal/snack is planned.⁵ Previous research in older youth with T1DM revealed some inconsistency in the percentage of days where youth inputted blood glucose values and carbohydrate amounts into their Medtronic pump and in the number of days where youth bolused at least 3 times.⁵ This study also found that youth completed all 3 Medtronic *Wizard* steps (viz, entered a glucose, entered a carbohydrate amount, and received a bolus) within 30 minutes for only 29% of boluses, which is suboptimal.⁵ However, because the study did not include children less than 7 years old, it is not known if similar challenges to insulin pump adherence behaviors exist for parents of young children. Therefore, our aim was to describe the insulin pump adherence behaviors that are required for optimal bolus advisor use in families of young children with T1DM and to relate these behaviors to children's daily glycemic control and glycated hemoglobin (HbA1c). If found to be correlated with glycemic control, our results would suggest that intervening to improve parents' pump adherence behaviors may be another pathway to better child health outcomes.

Methods

This study used deidentified data extracted from the *MERCY on TO_DP* database, a health outcomes repository containing data on over 5900 patients receiving care at Children's Mercy Hospital-Kansas City from 1993-present, including insulin pump downloads from 2007-present. The inclusion criteria were (1) children between the ages of 0 and 6.99 years old, (2) a minimum of 14 consecutive days of insulin pump data, and (3) a corresponding HbA1c level matched to their insulin pump data. These criteria yielded a sample of 116 young children, all of whom had a confirmed diagnosis of T1DM for at least 3 months prior to the date of data extraction. We obtained institutional approval for this study before any data were retrieved. The Institutional Review Board granted a waiver of written informed consent for the present study in accordance with 45 CFR 164.512(i)(1)(i).

Procedure

The specific data extracted included demographics (ie, child age, sex, race/ethnicity, and duration of diabetes), between 14-30 consecutive days of insulin pump/glucometer data randomly selected for each participant, and an HbA1c level collected within 15 days following the available pump data. These data were imported into a spreadsheet to calculate the percentage of days with ≥ 4 SMBG checks, the percentage of days with ≥ 3 carbohydrate inputs, the percentage of days with ≥ 3 insulin boluses administered, and the percentage of times insulin was administered for a blood glucose level

≥ 250 mg/dl, based on methodology established by Driscoll et al.⁵ In addition, we determined the percentage of time pumps recorded a combination of optimal pump behaviors using modified software developed by Driscoll and colleagues. Children's HbA1c values were originally obtained for clinical management using the Tosoh G8 HPLC Analyzer (Tosoh Bioscience Inc, San Francisco, CA, USA). We calculated children's mean daily blood glucose values using the SMBG data collected directly from children's glucometers. Finally, we calculated a mealtime insulin *BOLUS* score for children,⁸ which is a valid measure of adherence to mealtime insulin use, to compare with the other pump measures developed by Driscoll et al.⁵

Analyses

We used means, standard deviations, and frequency counts to evaluate children's demographics, HbA1c, mean daily blood glucose, and their pump behaviors. We ran simple correlations to associate children's adherence scores and pump behaviors with their HbA1c and mean daily blood glucose levels.

Results

Young children had a mean age of 5.2 ± 1.4 years (range: 0.27-6.94 years), a mean HbA1c of $8.2 \pm 1.4\%$ (6.20-13.30) and a mean daily blood glucose level of 208 ± 49 mg/dl (range: 132-381). There were 65 boys. Of children, 85% were identified by their parents as White and 4% were identified as Hispanic/Latino. Children had a mean time since diabetes diagnosis of 1.62 ± 1.77 years. The majority of children included in the sample used a Medtronic insulin pump (83%).

Individual Pump Adherence Behaviors

We used all available data to evaluate young children's pump behaviors and *BOLUS* scores. Children had a mean of 24 ± 6 days of data captured. Overall, parents showed greater than or equal to 90% adherence to the percentage of days with ≥ 4 SMBG checks, the percentage of days with ≥ 3 carbohydrate inputs, and the percentage of days with ≥ 3 insulin boluses administered. In contrast, parents corrected for glucose levels ≥ 250 mg/dl only 63% of the time. Children's *BOLUS* score suggests that they may either miss a meal, consume a meal outside of typical mealtimes, or miss bolusing for a meal approximately 1 time every 3 days.

Table 1 reports the correlations between children's HbA1c and mean daily blood glucose levels with their general pump behaviors and *BOLUS* scores. Children's mean daily blood glucose level was significantly inversely related to their *BOLUS* score ($r = -.293$, $P = .01$), the percentage of days with ≥ 4 SMBG checks ($r = -.220$, $P = .05$), and the percentage of days with ≥ 3 carbohydrate inputs ($r = -.274$, $P = .01$). However, their HbA1c level was significantly inversely

Table 1. Correlations Between Measures of Children's Glycemic Control and Pump Adherence Behaviors.

	1	2	3	4	5	6	7	8
1. Mean daily glucose level	1	.498**	-.029	-.293**	-.220*	-.274**	.054	.073
2. HbA1c		1	-.168	-.389**	-.177	-.366**	.018	-.060
3. Age			1	-.053	-.062	.059	.324**	.252*
4. <i>BOLUS</i> score				1	.079	.565**	.285**	.058
5. % days BG \geq 4					1	.513**	.094	-.153
6. % days CHO \geq 3						1	.484**	.080
7. % days insulin \geq 3							1	.055
8. % bolus \geq 250 mg/dl (13.9 mmol/l)								1

* $P < .05$. ** $P < .01$.

Table 2. Correlations Between Children's Glycemic Control and Combined Wizard/Bolus Advisor Adherence Behaviors.

	1	2	3	4	5
1. Mean daily glucose level	1	.498**	-.227*	.451**	.039
2. HbA1c		1	-.041	.218*	-.049
3. All 3 steps (SMBG+ carbohydrate entry + insulin bolus)			1	-.232*	-.909**
4. SMBG + insulin bolus (no carbohydrate entry)				1	-.194*
5. Carbohydrate entry + insulin bolus (no SMBG)					1

* $P < .05$. ** $P < .01$.

correlated only with their *BOLUS* score ($r = -.389$, $P = .01$) and their percentage of days with ≥ 3 carbohydrate inputs ($r = -.366$, $P = .01$). Other general pump behaviors did not correlate with children's mean daily blood glucose or HbA1c levels. Overall, older child age was associated with an increase in the frequency of days with ≥ 3 insulin boluses administered ($r = .324$, $P = .01$) and an increase in the number of times parents corrected for glucose levels ≥ 250 mg/dl ($r = .252$, $P = .05$).

Combined Wizard/Bolus Advisor Steps (ie, Combined Pump Adherence Behaviors)

We calculated the mean percentages of the events when all combinations of Wizard/Bolus Advisor steps were performed within 30 minutes. Families entered an SMBG check and carbohydrate units and completed an insulin bolus within 30 minutes for $43 \pm 28\%$ of boluses, they entered an SMBG check and completed a bolus (no carbohydrate units entered) within 30 minutes for $14 \pm 12\%$ of boluses, and they entered carbohydrate units and completed a bolus (no SMBG entered) within 30 minutes for $42 \pm 27\%$ of boluses. Notably, there were no recorded episodes where families administered an insulin bolus without either entering an SMBG or carbohydrate units. There was recorded a very low frequency of episodes where parents entered only an SMBG into their child's insulin pump ($0.2 \pm 1\%$), recorded only carbohydrate units into their child's insulin pump ($0.04 \pm 0.02\%$), or recorded an SMBG and carbohydrate units into their child's insulin pump, with no insulin administered ($0.01 \pm 0.01\%$).

We found an inverse relation between the percentage of boluses with all 3 bolus advisor steps (viz, SMBG and carbohydrate entries, insulin administered) completed and children's mean blood glucose levels ($r = -.227$, $P < .05$; Table 2). There was a direct relation between the percentage of boluses with only an SMBG entry ($r = .451$, $P < .001$) and children's mean daily blood glucose. We further found that the percentage of boluses with only an SMBG entry was directly associated with children's HbA1c ($r = .218$, $P < .05$). Other combinations of wizard steps did not correlate with either children's mean daily blood glucose or HbA1c levels.

Discussion

This study extends the existing literature because it focuses on young children, who were previously left out of studies examining youth's pump adherence behaviors.^{5,6} Overall, families of young children showed higher rates of adherence to checking SMBG, insulin use, and inputting carbohydrates into the pump than older children and adolescents.⁵ However, families of young children showed a relatively low rate of correcting for glucose levels >250 mg/dl (63%) and this variable correlated with children's age, suggesting that parents of the youngest children may be even less likely to correct for glucose values >250 mg/dl. In young children, the percentage of days with ≥ 4 SMBG checks and the percentage of days with ≥ 3 carbohydrate entries correlated with lower mean daily blood glucose levels. There was also an inverse correlation between the percentage of days with ≥ 3 carbohydrate entries and children's HbA1c levels. But these results

are inconsistent with previous findings in older children and adolescents, which found inverse correlations between youth's HbA1c levels and all of the pump adherence behaviors.⁵ It is possible that we found different results for young children because of their greater susceptibility to glycemic variation than older children and adolescents.^{4,9,10} Specifically, we predict that we might not have seen associations between young children's HbA1c levels and the percentage of days with ≥ 4 SMBG checks and percentage of days with ≥ 3 bolus doses delivered because some of these were entered to treat high blood glucose events, therefore confounding any relation with children's HbA1c levels. Although not reported previously,⁵ in the present study we also calculated a mealtime *BOLUS* score (ie, indicator of adherence to mealtime insulin use).⁸ Young children's *BOLUS* scores inversely correlated with both their mean daily blood glucose levels and their HbA1c levels, suggesting that dosing for insulin for meals is an important component of better glycemic control.

Consistent with the previous literature,⁵ our study examined families' adherence to combined *Wizard*/Bolus Advisor actions. In general, parents of young children showed better adherence to completing all 3 of the Medtronic *Wizard* steps within 30 minutes than older children and adolescents (43% versus 29%, respectively).⁵ Interestingly, there was some similarity across the 2 samples when examining for other combinations of Medtronic *Wizard* steps. Specifically, older children and adolescents entered a SMBG value and delivered insulin within 30 minutes (no carbohydrate unit entered) for 18% of boluses,⁵ while families of young children did this for 14% of boluses. Older children and adolescents entered a carbohydrate unit and delivered insulin within 30 minutes (no SMBG entered) for 31% of boluses,⁵ while families of young children did this for 42% of boluses. This is a troubling finding because if 30 minutes or more have elapsed between the previous SMBG and the meal, the bolus calculator is likely using less accurate SMBG data to calculate an insulin dose which could lead to more or less insulin administered than is needed. Across both samples, there were very low rates of other suboptimal categories of combined *Wizard*/Bolus Advisor actions, including a low percentage of boluses where insulin only was administered (2.5% and 0% for older children/adolescents and young children, respectively⁵), which is reassuring because administering insulin without entering a SMBG level or carbohydrate amount represents a potentially dangerous self-care behavior.

Not surprising, we found that young children's mean daily blood glucose levels correlated inversely with the percentage of boluses where all 3 *Wizard*/Bolus Advisor steps were completed within 30 minutes. Completing all 3 *Wizard*/Bolus Advisor steps represents an optimal level of adherence for food-related boluses and should be closely related to children's daily glycemic variability and control. Direct correlations were found for the percentage of boluses with a SMBG entry and children's mean daily glycemic control and HbA1c

levels, which could relate to how parents are correcting for high glucose values.

Our findings suggest that families of young children with T1DM also could benefit from user-friendly reports that provide detailed statistics on their adherence to individual and combined insulin pump behaviors (ie, *Wizard*/Bolus Advisor actions), which might help families and providers to identify new targets for intervention.⁵ In addition, these updated reports might offer new insights into adherence behaviors that predict children's glycemic patterns. For example, in cases where a young child shows a high percentage of boluses delivered with a SMBG only, the diabetes team may be able to show the family how they are spending a great percentage of their effort reacting to their child's blood glucose levels versus adequately dosing for insulin across the day. In addition, highlighting the patterns associated with the percentage of time that high blood glucoses are not followed by an insulin bolus (in the absence of physical activity) may lead to discovering a family's fear of hypoglycemia, which may also be treatable.

Our study limitations include an inability to generalize our findings to families of young children who come from racial or ethnic backgrounds other than non-Hispanic white. In addition, our clinic has a rate of insulin pump use that exceeds the national average (83% versus 62%).² Therefore, our results may not generalize to samples from clinics with lower rates of pump use. By updating the software code, we were not limited to young children on a Medtronic insulin pump as in the previous study.⁵ However, our data were still vulnerable to problems created by a frequent lack of wireless communication between children's glucometers and pumps (ie, "linked meters"), problems with incorrect dates programmed into devices, and variation in the number of days with available device data prior to an HbA1c measurement. To prevent these problems, future studies should synchronize the times and dates of children's glucometers and insulin pumps ahead of data collection and clearly specify the duration of data collection to ensure that a consistent number of days are included. Finally, we used cross-sectional data collected 14-30 days before children's regularly scheduled clinic appointment. Previous research has shown a "white-coat adherence" effect for SMBG frequency¹¹ and pump adherence behaviors¹² for children immediately preceding a diabetes clinic appointment, suggesting the possibility that our data might actually overestimate adherence for some families. Future research should consider a longitudinal approach or collect data further out from children's clinic appointments to minimize this problem. In addition, it might be helpful to examine children's pump behaviors in relation to continuous and/or flash glucose monitoring data as an objective measure of glycemic control.

Conclusion

Similar to older children and adolescents, families of young children do not always adhere to insulin pump behaviors,

especially combined behaviors related to optimal *Wizard/Bolus Advisor* use. Interventions that target families' adherence to pump adherence behaviors may help young children achieve optimal glycemic control and should be the focus of future research. Likewise, we need to develop new clinical reports that make it easier for families and providers to analyze pump adherence behaviors and engage in problem solving related to improving these behaviors.

Abbreviations

DPV, Prospective Diabetes Follow-up Registry; HbA1c, glycated hemoglobin; SMBG, self-monitoring blood glucose; T1DM, type 1 diabetes mellitus.

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Declaration of Conflicting Interests

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