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Original research

Differences in positive expectancy of hybrid closed loop (HCL) insulin delivery systems do not explain racial differences in HCL use

Jody B. Grundman [a], Amanda Perkins [a], Maureen Monaghan [a,b,1], Seema Meighan [c], Randi Streisand [a,b], Brynn E. Marks [c,d,*]

[a] Children's National Hospital, 111 Michigan Ave NW, Washington DC 20010, USA
[b] George Washington University School of Medicine, 3200 I St NW, Washington DC 20052, USA
[c] Children's Hospital of Philadelphia, 3501 Civic Center Boulevard, Philadelphia, PA 19104, USA
[d] Perelman School of Medicine at the University of Pennsylvania, 3400 Civic Center Boulevard, Philadelphia, PA 19104, USA

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ABSTRACT

Aims: Hybrid closed loop (HCL) insulin delivery systems improve glycemia and quality of life among youth with type 1 diabetes (T1D), however there are inequities in use. We aimed to evaluate whether differences in positive expectancy of HCL systems may explain differences in use.

Methods: Fifteen publicly-insured, non-Hispanic Black (NHB) youth with hemoglobin $A1_C$ (HbA1c) $\geq$ 10% enrolled in a study exploring changes in glycemia and person reported outcomes (PRO) during 6 months of Tandem t:slim X2 insulin pump with Control-IQ technology. At baseline youth and parents completed PROs, including Insulin Delivery Systems: Perceptions, Ideas, Reflections and Expectations (INSPIRE) survey assessing positive expectancy of HCL use, and Problem Areas in Diabetes (PAID) survey assessing diabetes-related distress. Differences between this cohort and the Tandem Control-IQ pediatric pivotal trial (DCLP5) cohort were assessed.

Results: As compared to the DCLP5 cohort (0% NHB, 10% publicly-insured), baseline glycemic indicators were suboptimal (M_{HbA1c} 11.9 $\pm$ 1.4% vs 7.6 $\pm$ 0.9%, $p < 0.0001$; continuous glucose monitor (CGM) time-above-range > 180 mg/dL 82 $\pm$ 15% vs 45 $\pm$ 18%, $p < 0.0001$). INSPIRE scores in both cohorts were equally high among youth (80 $\pm$ 10 vs 77 $\pm$ 13, $p = 0.41$) and parents (88 $\pm$ 14 vs 85 $\pm$ 11, $p = 0.37$). PAID scores were higher among parents (68 $\pm$ 19 vs 43 $\pm$ 16, $p < 0.0001$), but not youth (43 $\pm$ 16 vs 35 $\pm$ 16, $p = 0.09$) in the historically marginalized cohort as compared to the DCLP5 cohort.

Conclusions: Despite differences in glycemic control and diabetes related burden, positive expectancy of HCL systems is comparable among historically marginalized youth with T1D and the predominantly non-Hispanic White, privately insured DCLP5 cohort. These findings suggest that differences in perceptions of HCL technology may not explain inequities in use.

Introduction

Diabetes technologies, including CGMs and insulin pumps, improve glycemic control and diabetes-related quality of life (DRQL) while simultaneously decreasing the incidence of hypoglycemia and microvascular complications [1–7]. The use of diabetes technologies among people with type 1 diabetes (T1D) has increased dramatically over the last decade, but has also worsened pre-existing healthcare inequities among people of different races, ethnicities, and socioeconomic statuses [1,8,9]. Using data from 80 clinics across the United States in 2016–2018, the T1D Exchange Registry [10] demonstrated that rates of insulin pump use in the highest income group were approximately 20% lower for non-Hispanic Black (NHB) adolescents as compared to non-Hispanic White (NHW) and Hispanic/Latinx adolescents [1]. From 2017 to 2019 similar gaps in CGM use were reported with 50% of NHW, 18% of NHB, and 38% of Hispanic/Latinx youth using CGM [11].

Racial-ethnic inequities in participation in clinical trials of T1D technology have also been documented [12–15]. In the most recent T1D

* Corresponding author at: Children's Hospital of Philadelphia, 3501 Civic Center Boulevard, Philadelphia, PA 19104, USA.
E-mail addresses: jgrundman@childrensnational.org (J.B. Grundman), aperkins@childrensnational.org (A. Perkins), maureen.center@nih.gov (M. Monaghan), meighans@chop.edu (S. Meighan), rstreis@childrensnational.org (R. Streisand), marksb@chop.edu (B.E. Marks).
[1] Present address: National Institute of Diabetes and Digestive and Kidney Diseases, 10 Center Dr, Bethesda MD 20814, USA.

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Exchange data, 65% of those in the registry identify as NHW, and among the participants enrolled in studies of T1D technology use, 85% identified as NHW [11,16]. Studies of youth from historically minoritized backgrounds and those of lower socioeconomic status have demonstrated that clinicians can serve as barriers to accessing diabetes technologies [17–19]. While clinicians play a role in accessing diabetes technologies, individual perceptions of anticipated benefits of diabetes technology, or positive expectancy, also influence uptake and sustained use of diabetes technologies [20,21]. Little is known about whether differences in positive expectancy of HCL technology among youth and parents of diverse racial, ethnic, socioeconomic backgrounds may also contribute to known inequities.

To determine whether differences in positive expectancy of HCL system may be contributing to inequities in use among youth with T1D, we compared baseline positive expectancy of HCL systems between our cohort of historically marginalized youth with T1D and their parents with the youth and parents from the intervention arm of the randomized, controlled trial of the t:slim X2 insulin pump with Control-IQ technology developed by Tandem Diabetes Care (DCLP5) [13,22]. Data reported reflect baseline survey measures collected from a 6-month non-randomized prospective pilot study assessing changes in glycemic control and person reported outcomes (PROs) in a cohort of historically marginalized youth. Although positive expectancy of many HCL systems has been assessed in pediatric pivotal trials [14,23], recognizing the nuances of HCL systems currently available and the potential affect on positive expectancy, we chose to focus our comparison to youth using the same HCL system.

Materials and Methods

We conducted a single-center, non-randomized, prospective cohort pilot study with fifteen publicly insured, NHB youth ages 6–21 years with T1D managed with insulin $\geq$ 1 year, two HbA1c values $\geq$ 10% in the preceding year, and a total daily insulin dose of $\geq$ 10 units/day. Inclusion criteria were chosen in order to specifically assess the effects of HCL use among the subset of youth with the lowest rates of diabetes technology use [1,14,23]. We confirmed that all youth enrolled had insurance coverage for the HCL system to ensure continued access to the technology after study completion. The parent primarily involved in T1D management was also enrolled in the trial. Exclusion criteria included: concurrent use of any non-insulin diabetes medication, $\geq$3 episodes of DKA in the year prior to enrollment, major illnesses other than T1D, significant cognitive limitations, and major psychiatric disorders. This study was approved by the Institutional Review Board of Children's National Hospital (Protocol Number Pro00013963). Written informed consent was obtained from all participants $\geq$ 18 years, with parental consent for youth $<$ 18 years and written assent for youth 14–17 years. Demographic characteristics and a battery of validated PRO measures were completed by youth and their parent at study enrollment.

In this report, we present a subanalysis of baseline data from our larger study (NCT04807374) focusing on baseline positive expectancy of HCL systems and if this may be contributing to inequities in the use of this technology. Our cohort was compared with the parent-youth dyads enrolled in the intervention arm of the pivotal trial of the t:slim X2 insulin pump with Control-IQ technology in children ages 6–13 (DCLP5) [13,22]. In the DCLP5 trial just 10% of participants were publicly insured, none identified as NHB, and all youth had baseline hemoglobin A1c (HbA1c) values $\leq$ 10.1% [13].

PRO measures

Insulin Delivery Systems: Perceptions, Ideas, Reflections and Expectations (INSPIRE) measures positive expectations related to HCL system use. The 17 questions on the youth version, 22 on the adult version, and the 21 items on the parent version are answered using a five-point Likert scale, and scores range from 0 to 100 with higher scores reflecting greater positive expectancy [24]. Problem Areas in Diabetes (PAID) measures diabetes-related burden over the past month using a six-point Likert scale [25]. PAID scores were scaled from 0 to 100 to account for different numbers of items in the age-appropriate youth and parent versions of the surveys administered to our cohort and to allow for comparison with the scaled scores reported in the DCLP5 study [22]. Higher PAID scores indicate a greater burden of distress related to having diabetes [25]. T1D and Life (T1DAL) assesses diabetes-specific health-related quality of life using a five-point Likert scale. T1DAL scores range from 1 to 100, with higher scores reflecting better quality of life [26]. In addition to INSPIRE and PAID, the DCLP5 study used the Pediatric Quality of Life Inventory 3.2 Diabetes Module for Children, Adolescents, and Youth Adults with T1D survey (PEDsQL), rather than T1DAL, to assess diabetes-specific health-related quality of life. PEDsQL uses a five-point Likert scale and total scores range from 0 to 100 with higher scores reflecting better quality of life [27]. We chose to use the more recent 2020 T1DAL PRO rather than the 2018 PedsQL 3.2 Diabetes Module, as the T1DAL does not inquire about self-monitored blood glucose or insulin injections.

Statistical analysis

Summary statistics are reported for the baseline characteristics. Demographic characteristics were compared with the DCLP5 cohort using Fisher's exact tests, two-sample t-tests and Wilcoxon signed-rank tests. Pearson correlation coefficients were calculated to evaluate the linear relationship between PRO scores and HbA1c.

Results

Demographics and glycemic control

Demographic characteristics, glycemic control, and PRO responses for the two cohorts are reported in Table 1. The DCLP5 cohort differed significantly from our cohort with respect to age, race, type of insurance, household income, and duration of T1D [13]. Baseline glycemic control in our cohort was suboptimal compared to the DCLP5 cohort, with significantly higher mean HbA1c ($p < 0.0001$) and time-above-range $>$ 180 mg/dL ($p < 0.0001$) and significantly lower percent time-in-range (TIR) ($p < 0.0001$).

PRO measures

INSPIRE scores were equally high among parents (88 $\pm$ 14 vs DCLP5 study 85 $\pm$ 11, $p = 0.37$) and youth (80 $\pm$ 10 vs DCLP5 study 77 $\pm$ 13, $p = 0.41$) in the two cohorts. In the DCLP5 cohort positive expectancy was higher among parents than youth ($p < 0.0001$), but did not differ between parents and youth in our study cohort ($p = 0.10$). PAID scores were higher in our cohort than in the DCLP5 study for parents (68 $\pm$ 19 vs DCLP5 study 43 $\pm$ 16, $p < 0.0001$) but not for youth (43 $\pm$ 16 vs DCLP5 study 35 $\pm$ 16, $p = 0.09$). PAID scores were higher among parents than among youth in our cohort ($p = 0.002$) and in the DCLP5 study cohort ($p = 0.002$). Different measures were used to assess DRQL in the two studies. T1DAL scores in our cohort were as follows: parent-T1DAL 59 $\pm$ 11, child-T1DAL 59 (57,68). PEDsQL scores in the Tandem cohort were: parent-PEDsQL 72 $\pm$ 12, child-PEDsQL 74 $\pm$ 12. Missing PRO data in our cohort was due to either youth being too young to complete a validated questionnaire ($n = 2$) or parent not accompanying a young-adult study participant to the visit ($n = 2$). One child received a version of the T1DAL survey intended for an older youth and those results are not reported.

Correlations among PROs and HbA1c

Baseline HbA1c and INSPIRE scores for both parents and youth were

Table 1
Baseline characteristics, glycemic control, and PROs of Historically Marginalized T1D Cohort and the pivotal trial of the t:slim X2 insulin pump with Control-IQ technology in children ages 6–13 (DCLP5).

	Historically Marginalized T1D Cohort (n = 15)	DCLP5 Trial Cohort (n = 78)	p-value
Age (years) ± SD	14.6 ± 3.7	11.3 ± 2.0	**<0.0001**
Duration T1D (years) ± SD	8.5 ± 4.8	5.0 ± 2.8	**0.0002**
Race (%)			**<0.0001**
Non-Hispanic White	0	64 (82)	
Non-Hispanic Black	15 (100)	0	
Hispanic/ Latinx	0	6 (8)	
Insurance (%)			**<0.0001**
Public	15 (100)	8 (10)	
Private	0	70 (90)	
Household Income (%)			**<0.0001**
<$75,000	13 (87)	8 (10)	
≥ $ 75,000	1 (7)	66 (85)	
Declined to Answer	1 (7)	4 (5)	
Mean HbA1c (%) ± SD	11.9 ± 1.3	7.6 ± 1.0	**<0.0001**
Mean % Time in Range (70–180 mg/dL) ± SD[a]	18 ± 15	53 ± 17	**<0.0001**
Mean % Time Above Range > 180 mg/dL ± SD[a]	82 ± 15	45 ± 18	**<0.0001**
Mean % Time Above Range > 250 mg/dL ± SD[a]	65 ± 25	17.2 (8.6, 27.6)*	NA
INSPIRE Scores[b]			
Youth	80 ± 10	77 ± 13	0.41
Parent	88 ± 14	85 ± 11	0.37
PAID Scores[c]			
Youth	43 ± 16	35 ± 16	0.09
Parent	68 ± 19	43 ± 16	**<0.0001**
DRQL Survey Scores[d]	T1DAL	PedsQL	
Youth	59 (57,68)	74 ± 12	NA
Parent	59 ± 11	72 ± 12	NA

[a] 10 or 14 days of CGM data was available for 14 of 15 youth in our cohort and for 77 of 78 youth in the DCLP5 Trial Cohort.
[b] INSPIRE surveys were completed by 14 youth and 13 parents in our cohort.
[c] PAID surveys were completed by 14 youth and 13 parents in our cohort.
[d] DRQL was assessed using T1DAL in our cohort and with PedsQL in the DCLP5 trial cohort. 13 youth and 13 parents in our cohort completed T1DAL surveys. 77 youth in the DCLP5 trial completed the PedsQL.
* Data are reported as mean and IQR due to non-normally distributed data.

not significantly correlated (parent-INSPIRE r = 0.07, p = 0.82; youth-INSPIRE r = -0.21, p = 0.47). There was no significant correlation between youth and parent INSPIRE scores (r = 0.17, p = 0.60). Neither parent nor youth INSPIRE scores were correlated with other PROs.

Discussion

We intentionally enrolled and explored the perceptions of youth with suboptimal glycemic control who have historically been least likely to access HCL technologies but may stand to benefit the most. By intention, the DCLP5 cohort differed significantly from our cohort with respect to race, household income, type of healthcare insurance, and baseline glycemic control. Despite suboptimal glycemic control, high diabetes-related distress, and low diabetes-specific quality of life, positive expectancy of HCL systems in our cohort of historically marginalized youth with T1D was comparable to that of youth and parents enrolling in the DCLP5 pivotal trial. These preliminary findings suggest that differences in positive expectancy of HCL insulin delivery systems may not explain inequities in HCL use.

Inequities in T1D care and outcomes in the United States are rooted in systemic racism [28]. Differences in HCL technology use have been attributed to barriers at both the patient and clinician level. Patients of historically marginalized racial and ethnic backgrounds and those of lower socioeconomic statuses commonly report seeking access to diabetes technologies only to be dissuaded by their clinician due to poor glycemic control [17] or biased assessment readiness and ability to initiate insulin pump therapy [18,19]. Despite facing provider barriers in accessing diabetes technologies, our findings indicate that historically marginalized youth and their parents have positive views of HCL.

Racial-ethnic inequities in participation in clinical trials of T1D technology have also been documented [12]. To date pivotal trials of HCL technology have enrolled populations that are distinctly different from the T1D population in the United States. Between 2018 and 2020 in the T1D Exchange 65.8% of youth < 19 identified as NHW, 8.3% as NHB, 13.0% as Hispanic/Latinx, and 12.8% as "Other" [16]. Among 1354 participants enrolled in studies of T1D technology use, 84.5% identified as NHW, 2.2% as NHB, and 6% as Hispanic/Latinx [12]. Similarly, rates of HCL use in studies exploring real-world efficacy have not enrolled a representative population. Real-world Medtronic 670G data did not report on race and ethnicity of users [29], while a study of nearly 1,500 early adaptors of Control-IQ technology included 90% NHW, 2% NHB, and 4% Hispanic/Latinx users [30]. Focused efforts and comprehensive strategies sensitive to the unique needs of historically marginalized communities are needed to increase the inclusion of youth from racial and ethnic minority groups in diabetes technology research and to promote equity in T1D care.

Furthermore, although there are several studies that describe the impact of HCL on adults with suboptimal glycemic control [31,32], the glycemic control of youths participating in clinical trials is not representative of the population living with T1D in the United States. From 2018 to 2020 mean HbA1c according to racial/ethnic groups was: 8.3% NHW, 9.2% Hispanic/Latinx, and 10.3% NHB [33]. The multi-center Omnipod 5 pivotal trial enrolled youth with an HbA1c of 7.7 ± 1.0% [14], while the Bionic Pancreas group enrolled participants with baseline HbA1c of 7.9 ± 1.2% [23]. These differences between the overall population living with T1D and research participants limit the generalizability of study findings. Limited data have shown greater glycemic benefits among youth with the highest baseline HbA1c values, however research studies have not yet specifically focused on enrolling underrepresented youth with the highest HbA1c values [34,35].

The baseline PROs of youth and parents in our cohort also differ from those described in prior HCL studies. Parent diabetes-related distress as measured by PAID scores, in our cohort is higher than what has previously been captured in HCL pivotal and real-world studies [13,15]. In assessing diabetes-specific quality of life, we used the T1DAL survey while the DCLP5 trial used the PEDsQL [27]. We cannot directly compare scores across these two PROs, however these validated measures compare the same construct and scores are strongly positively correlated [36]. Higher levels of diabetes distress and lower levels of diabetes-specific quality of life have been shown to be associated with higher HbA1c [37]. Although there is data to support lower rates of diabetes distress among technology-users compared to non-users [38], there are also studies that have failed to demonstrate significant improvements in distress among youth initiating HCL technology [15,22,39].

Despite differences in other PROs, INSPIRE scores among our cohort and across several HCL studies have been high [22,40,41]. Similar positive expectancy of HCL technology suggests that differences in rates of HCL use cannot be explained by differences in HCL attitudes and expectations. We did not find any correlations between baseline HbA1c and parent or youth INSPIRE scores. This contrasts with findings from a larger cohort of youth with a mean HbA1c of 8.5 ± 1.5% published by Weissberg-Benchell et al. describing a weak correlation between positive expectancy of HCLs and higher HbA1c (r = 0.19, p < 0.05) [24]. Better understanding of perceptions and attitudes about diabetes technology among youth with higher levels of diabetes distress and lower quality of life is an essential step in determining strategies to improve glycemic control and health outcomes.

There are several limitations to the current study, including a relatively small sample size and the study inclusion criteria. Although it is known that HbA1c tends to increase with age [42,43] and our cohort included participants with a broader age range, we specifically sought to enroll participants with an HbA1c > 10%. Given that survey responses were obtained from those agreeing to participate in a study initiating HCL technology, it is possible that positive expectancy is greater in this self-selected group than in other individuals who have been historically underrepresented in research. However, in post-intervention interviews 8 of 15 (53%) parent-youth dyads reported no interest in using HCL technology prior to enrolling in the study. Additionally, differences in parent PAID scores between the two cohorts may have been influenced by the younger age of the DCLP5 cohort. Larger randomized controlled trials are needed to confirm that these findings are in fact generalizable to the greater pediatric population living with T1D that may be less interested in HCL use. Strengths include our ability to capture person reported outcome measures from a historically marginalized population with poor representation in research and limited use of HCL technology. Gathering additional data from underrepresented groups may yield new insights into the benefits of HCL and also suggests that provider bias, rather than patient disinterest, is likely contributing to the existing inequities in diabetes technology use.

Conclusions

Advances in diabetes technologies, if not equally distributed among all members of the community living with T1D, have the potential risk of widening the already existing inequities in pediatric T1D care and outcomes. We found high positive expectancy of HCL systems in this historically marginalized population despite sub-optimal glycemic control, high levels of diabetes distress, and low overall diabetes-specific quality of life. Greater efforts are needed to understand barriers to technology access in this group so that we can equitably distribute HCL technology and opportunities to optimize glycemic control and quality of life among all interested youth with T1D.

Previously presented

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Author contribution

B.E.M. formulated the clinical question and designed the study. J.B.G. wrote the manuscript with contributions from A.P, S.M., and B.E.M. B.E.M. completed the statistical analysis. M.M. and R.S. contributed to study design and made critical contributions to the manuscript. All authors edited, reviewed, and approved the manuscript.

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CRediT authorship contribution statement

Jody B. Grundman: Investigation, Visualization, Writing – original draft, Writing – review & editing. **Amanda Perkins:** Investigation, Writing – review & editing. **Maureen Monaghan:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Seema Meighan:** Investigation, Writing – review & editing. **Randi Streisand:** Conceptualization, Methodology, Writing – review & editing. **Brynn E. Marks:** Conceptualization, Methodology, Data curation, Formal analysis, Visualization, Writing – original draft, Writing – review & editing, Supervision, Funding acquisition.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: J.B.G. has research support from the American Diabetes Association (7–21-PDFHD-09) and research supplies from Dexcom. A.P. has received investigator-initiated research support from Tandem Diabetes Care, Inc. (TDC20210226), and research supplies from Dexcom. MM is currently employed at the National Institutes of Health (NIH); all work on this trial was completed prior to her employment at NIH. B.E.M. is supported by the National Institutes of Health (PI: Marks, NIH: K23DK129827), and has received investigator-initiated research support from Tandem Diabetes Care, Inc, and research supplies from Dexcom. The other authors have no conflicts of interest to disclose.

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