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Predictors of Loss to Follow-Up among Children with Type 2 Diabetes.

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Title: Predictors of Lost to Follow-Up among Children with Type 2 Diabetes

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Running Title: Lost to Follow-up in Type 2 Diabetes

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Abstract:

Background/Aims: Youth with type 2 diabetes (T2D) have poor compliance with medical care.

This study aimed to determine which demographic and clinical factors differ between youth with T2D who receive care in a pediatric diabetes center vs. youth lost to follow-up for >18 months.

Methods: Data were analyzed from 496 subjects in the Pediatric Diabetes Consortium registry. Enrollment variables were selected a priori and analyzed with univariable and multivariable logistic regression models.

Results: After a median of 1.3 years from enrollment 55% of patients were lost to follow-up. The final model included age, race/ethnicity, parent education and estimated distance to study site. The odds ratio (99% confidence interval) of lost to follow-up was 2.87 (1.34, 6.16) for those 15 - <18 years old vs. 10 - <13 years old, and was 6.57 (2.67, 16.15) for ≥ 18 years old vs. those 10 - <13 years old. Among patients living more than 50 miles from the clinic, the odds ratio of lost to follow-up was 3.11 (1.14, 8.49) vs. those living within 5 miles of the site.

Conclusion: Older adolescents with T2D are more likely to be lost to follow-up, but other socioeconomic factors were not significant predictors of clinic follow-up.

Introduction

Type 2 diabetes (T2D) is a growing pediatric health concern, accounting for 22% of new diabetes cases among youth in the United States [1]. It is estimated that the number of youth with T2D will increase 4-fold by 2050 [2]. In addition, youth diagnosed with T2D have increased morbidity and mortality compared with youth diagnosed with type 1 diabetes (T1D) [3] or those diagnosed with T2D at greater than 30 years of age [4]. Youth diagnosed with T2D are at particularly high risk of early nephropathy. Fifteen years after diagnosis, 26% of youth with T2D have experienced at least one major complication (dialysis, blindness or amputations) [5]. The rate of major complications increases to 47.9% twenty years after diagnosis [5]. In T2D, mortality is inversely correlated with age at diagnosis and patients diagnosed with T2D at <30 years old have a 36% greater mortality risk than those diagnosed at 30-39 years old [4].

Despite differences in pathophysiology, treatment and prognosis, youth with T2D are typically offered clinical care and diabetes education based on programs developed for T1D [6]. Pediatric endocrinologists report that compliance is worse in the T2D population and 29% reported a more negative attitude toward patients with T2D compared with patients with T1D [6]. Poor compliance with medical care and inconsistent visit attendance may contribute to the increased morbidity and mortality seen in youth with T2D.

In order to improve clinical care of patients with T2D, we must first identify potentially modifiable barriers to care which may differ from the T1D population. Potential barriers include socioeconomic challenges and cultural or language barriers [6]. In this paper, we utilized the Pediatric Diabetes Consortium (PDC) T2D Registry to compare the demographic and clinical characteristics of youth with continued follow-up at a pediatric diabetes center versus youth who failed to return for follow-up within 18 months.

Methods

Patients

The PDC began enrollment in February 2012. Data were analyzed from the 496 subjects, from 7 U.S. diabetes centers who had been enrolled in the registry for a minimum of 18 months. Registry enrollment criteria included age <21 years and a diagnosis of T2D according to the American Diabetes Association criteria [7]. All patients had a physician diagnosis of T2D based on weight at diagnosis (body mass index >85th percentile for age and gender prior to diabetes associated weight loss), metabolic syndrome phenotype and negative diabetes autoantibodies, if available. The research protocol was approved by each institution's IRB and appropriate consent and assent were obtained prior to enrollment.

Data Collection

Data were collected from the medical record and participant/parent interview at time of enrollment and updated yearly. Participant reported race/ethnicity and parent education history were obtained. Age, gender, health insurance type, diabetes duration, HbA1c, self-monitoring blood glucose tests per day and medication regimen were recorded from patient report and the medical record. The distance between patient's home and the clinic site was approximated using latitude and longitude of the center of their respective zip codes. Participants were classified as lost to follow-up if they had not had a clinic follow-up visit for >18 months.

Statistical Analysis

Enrollment variables (study site, age, gender, race/ethnicity, parent education, diabetes duration, hemoglobin A1C, health insurance, blood glucose self-monitoring, distance from site and type of diabetes treatment) were chosen a priori by the investigators based on potential impact on clinic follow-up or as markers of compliance with the clinical care plan. Continuous

data are presented as median (interquartile range: IQR). A univariable logistic regression model was used to assess the association of each risk factor with participant status (active or lost to follow-up). Then, a multivariable logistic regression model was constructed using stepwise selection methods. Only factors with p-value <0.10 during the stepwise selection procedure were included in the multivariable model to adjust for possible confounding. Due to multiple comparisons, only factors with p-values <0.01 were considered statistically significant. For continuous variables, linearity was tested, if non-linear trend was detected, either higher order polynomials were added or the variable was discretized. All reported p-values are two-sided. Analysis was conducted using SAS version 9.4 (SAS institute, Cary, NC, USA).

Results

The 496 participants had a median (IQR) age of 16.0 years (14.1-17.8) and the majority were female (65%). Participants self-identified as Hispanic (54%), African American (30%), White (9%) and other (6%). Only 30% of parents had education beyond high school and 62% of the participants had Children's Health Plan or other government health insurance. At enrollment, 85% were classified as obese (BMI \geq 95th percentile for age and gender). The median (IQR) HbA1c was 7.3% (6.0-9.4) [56 mmol/mol (42-79)] and participants tested their blood glucose 2 times per day (1-3). Median (IQR) diabetes duration was 2.1 years (0.8-4.5) at enrollment. After a median (IQR) of 1.3 years (0.5-2.3) of follow-up (from enrollment to the last visit date), 55% of patients had been lost to follow-up. The median (IQR) follow-up time was 2.3 years (1.9-2.8) among those active participants and was 0.7 years (0-1.1) among those lost to follow-up. The baseline characteristics of the active participants and the lost to follow-up group are detailed in Table 1.

The univariable and multivariable analyses are presented in Table 2. The only factor that met our criteria for significance in the final multivariable model was age. The final model also adjusted for race/ethnicity, parent education and estimated distance to study site. Diabetes duration, gender and number of blood glucose tests per day were all confounded by age, thus were not selected into the final multivariable model. The odds ratio (99% confidence interval) of lost to follow-up was 2.87 (1.34, 6.16) for those 15 - <18 years old vs. the younger participants (10 - <13 years old), and was 6.57 (2.67, 16.15) for the adult participants (\geq 18 years old) vs. those 10 - <13 years old. Since older patients may be more likely to leave a pediatric practice and seek care from a local adult provider, we also performed a post-hoc analysis excluding patients who were \geq 18 years old at enrollment and found no change in the results. Among

patients living more than 50 miles away from the clinic, the odds ratio of lost to follow-up was 3.11 (1.14, 8.49) vs. those living within 5 miles of the site. BMI and family status were not associated with lost to follow-up rate (data not shown).

Discussion

In this large, multi-center cohort of youth with T2D, 55% of patients were lost to follow-up after median of 1.3 years (from enrollment to the last visit date). This high percentage highlights the challenges of caring for this population. We found that older adolescents are more likely to be lost to follow-up than younger children. Other socioeconomic factors were not significant predictors of clinic follow-up. The rate of lost to follow-up in the PDC registry T2D cohort was much higher compared with the T1D cohort, with only 18% lost to follow-up rate after a median of 2.9 years (unpublished data).

Much of our knowledge about the demographic characteristics of T2D comes from the Treatment Options in Type 2 Diabetes in Youth trial (TODAY) and the SEARCH for Diabetes study [8, 9]. While T1D accounts for >95% of diabetes diagnoses in white youth, 25% of diabetes cases in Hispanic, black and Asian/Pacific Islander patients are T2D [9]. Patients with T2D are disproportionately from economically disadvantaged backgrounds as shown in this study and the TODAY trial. More than 40% of TODAY study participants reported a household income of <\$25,000 per year and the majority of parents reported a high school education or less [8]. The TODAY study was carefully designed to help minimize barriers to follow-up and medication compliance, utilizing a greater number of resources than typical clinical practice. In this resource intense setting, more than 90% of randomized patients completed the multi-year study (average follow-up 3.8 years) [10]. In contrast, we report more than 50% of patients are lost to follow-up in a clinical care setting. The PDC T2D cohort described in this study is 85% black or Hispanic and 70% of parents have a high school education or less. In comparison, a contemporaneous PDC T1D cohort, drawn from the same pediatric diabetes centers, has almost opposite demographics – majority white with relatively high median income and parental

education [11]. Despite the vast socioeconomic differences between T1D and T2D patients, clinical care for youth with T2D is typically provided in a T1D clinic setting. This care is provided by physicians and staff with more experience with T1D than with T2D. Less than a quarter of pediatric diabetes clinics report using diabetes education programs designed specifically for T2D and most clinics use the same staff to care for both T1D and T2D [6]. T1D education programs may fail to recognize the cultural diversity present in T2D clinic populations. In order to develop T2D specific diabetes care models, we must address cultural differences, language barriers and possible limitations of both reading level and numeracy skills in patients with T2D and their parents [12].

As clinicians have begun to recognize the unique challenges of T2D, several potential barriers to care have been hypothesized. The majority of pediatric diabetes providers have identified culture/language as a barrier to successful treatment of T2D [6]. Although we did not find that a particular race or ethnicity influenced clinic follow-up, addressing cultural barriers may improve T2D care. Other provider concerns have included the unhealthy lifestyle of family members and the lack of immediate consequences from uncontrolled T2D [6] for poor follow-up seen in T2D youth.

In this study, the main predictor of loss to follow-up was increasing patient age. Older patients may be more likely to receive care from a local adult provider but a post-hoc analysis excluding patients ≥ 18 years did not alter our results. Adolescents also report a desire to fit in with their peers which interferes with both healthy diet choices and diabetes management [13]. However, increasing age has not been associated with loss to follow-up in pediatric weight management clinics [14, 15]. Further research is needed to better understand why older adolescents are less likely to continue to receive care at pediatric diabetes centers.

Financial stress is reported as a barrier to care, impeding access to medications, clinic visits and the purchase of healthy foods [13]. We were unable to include patient reported income as a variable due to high rates of missing data. Insurance type was used as a surrogate for household income but was not associated with clinic loss to follow-up. We were unable to use zip code as a surrogate for income as there was poor correlation between our available income data and zip code based data from the 2014 5-Year American Community Survey. It does appear that distance from the clinic site may influence clinic follow-up. Longer travel distances pose a challenge to families without private transportation and longer travel time means more hours of missed work. Travel distance has also been associated with unsuccessful transition from pediatric to adult sickle cell disease centers [16]. In adults, the majority of studies have shown worse health outcomes, including follow-up non-attendance, for patients living further away from healthcare facilities [17].

Novel treatment paradigms utilizing satellite clinics, telemedicine or home health services could reduce patient burden and improve access to care. A recent meta-analysis of 55 randomized controlled trials found that telemedicine provided a larger reduction in HbA1c than traditional treatment programs and was particularly effective for T2D vs. T1D [18]. Despite the effectiveness in adult populations, none of the 55 studies included pediatric patients with T2D. Telemedicine interventions may combine online modules, videoconferencing, or motivational text messages or prompts with less frequent clinic or home health visits. Telemedicine has been effective in minority, urban and rural populations [19-21].

Our study is limited by the lack of data related to why patients stopped seeking care in the pediatric diabetes clinic. T2D youth may be receiving medical care from primary care providers. It is possible that primary care providers are more comfortable with the management

of T2D and more likely to assume care of adolescents with T2D versus T1D. The main advantage of our cohort is that it reflects routine clinical care at 7 pediatric diabetes centers, though the efforts of study staff to contact patients may mean that we have underestimated the loss to follow-up rate. While clinicians have long suspected poor clinic follow-up in patients with T2D, this study is the first to quantify the loss to follow-up rate. We believe that T2D care requires a new clinic model that is specifically designed for these adolescent patients and addresses the unique socioeconomic, cultural, and language barriers of this population. Next steps include evaluating in pediatric clinics the effectiveness of available culturally sensitive T2D diabetes education models that have been validated in adult populations [12]. We also recommend investigating telemedicine as distance from clinic was an identifiable barrier to care for these adolescent patients.

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Table 1. Participants Characteristics at Enrollment (N=496^a)

	Overall N=496	Lost to Follow- up N=275	Active N=221
Site^b			
001	77 (16%)	43 (16%)	34 (15%)
002	109 (22%)	67 (24%)	42 (19%)
003	47 (9%)	24 (9%)	23 (10%)
004	90 (18%)	46 (17%)	44 (20%)
005	25 (5%)	12 (4%)	13 (6%)
006	67 (14%)	36 (13%)	31 (14%)
008	81 (16%)	47 (17%)	34 (15%)
Age (years)			
<13	75 (15%)	28 (10%)	47 (21%)
13–<15	106 (21%)	35 (13%)	71 (32%)
15–<18	205 (41%)	128 (47%)	77 (35%)
18–<21	110 (22%)	84 (31%)	26 (12%)
<i>median (25th,75th percentiles)</i>	16.0 (14.1-17.8)	17.0 (15.3-18.5)	14.8 (13.4-16.6)

Gender			
Female	320 (65%)	165 (60%)	155 (70%)
Male	176 (35%)	110 (40%)	66 (30%)
Race/Ethnicity			
White	44 (9%)	33 (12%)	11 (5%)
Hispanic or Latino	268 (54%)	150 (55%)	118 (54%)
Black/African American	149 (30%)	71 (26%)	78 (36%)
Other/multiracial	31 (6%)	20 (7%)	11 (5%)
Parent Education			
High School or Less	322 (70%)	176 (69%)	146 (72%)
Associate	62 (14%)	31 (12%)	31 (15%)
Bachelor	50 (11%)	32 (13%)	18 (9%)
Master/Professional Degree	23 (5%)	16 (6%)	7 (3%)
Health Insurance			
Private	141 (28%)	85 (31%)	56 (25%)
Children's Health Plan or Other			
Government	307 (62%)	160 (58%)	147 (67%)

Military	3 (<1%)	3 (1%)	0
None	45 (9%)	27 (10%)	18 (8%)
Diabetes Duration (years)			
<1	144 (29%)	73 (27%)	71 (32%)
1-<2	91 (18%)	45 (16%)	46 (21%)
2-<4	116 (23%)	56 (20%)	60 (27%)
≥4	145 (29%)	101 (37%)	44 (20%)
<i>median (25th, 75th percentiles)</i>	2.1 (0.8-4.5)	2.6 (0.9-4.8)	1.8 (0.6-3.5)
HbA1c % (mmol/mol)			
<6.0 (<42)	108 (24%)	56 (23%)	52 (25%)
6.0—<7.0 (42—<53)	99 (22%)	55 (22%)	44 (21%)
7.0—<8.0 (53—<64)	58 (13%)	27 (11%)	31 (15%)
8.0—<9.0 (64—<75)	51 (11%)	31 (13%)	20 (10%)
≥9.0 (≥75)	134 (30%)	76 (31%)	58 (28%)
<i>median (25th, 75th percentiles)</i>	7.3 (6.0-9.4)	7.3 (6.0-9.4)	7.2 (5.9-9.4)
	[56 (42-79)]	[56 (42-79)]	[55 (41-79)]

Self-Monitoring Blood Glucose (# tests/day)^c			
0	69 (14%)	44 (16%)	25 (11%)
1	104 (21%)	62 (23%)	42 (19%)
2-3	232 (47%)	131 (48%)	101 (46%)
≥4	91 (18%)	38 (14%)	53 (24%)
<i>median (25th, 75th percentiles)</i>	2 (1-3)	2 (1-3)	2 (1-3)
Diabetes Treatment			
Life-style alone	95 (19%)	55 (20%)	40 (18%)
Metformin alone	145 (29%)	80 (29%)	65 (29%)
Insulin alone	106 (21%)	52 (19%)	54 (24%)
Metformin + Insulin	136 (27%)	77 (28%)	59 (27%)
Other Med ± Insulin / Metformin	14 (3%)	11 (4%)	3 (1%)

- a. Number of participants with missing or “Unknown” data (lost to follow-up/active): race/ethnicity (1/3), parent education (20/19), BMI (26/11), HbA1c (30/16).
- b. Site 007 dropped out of the registry and patient follow up data was unavailable.
- c. Self-reported values.

Table 2. Factors at Enrollment Associated with Participants Dropout (N=496)

	N	Lost to Follow-up # (%)	Univariable P-value	Multivariable	
				Odds Ratio (99% CI)	P- value
Overall	496	275 (55%)			
Site			0.74		NA ^a
001	77	43 (56%)			
002	109	67 (61%)			
003	47	24 (51%)			
004	90	46 (51%)			
005	25	12 (48%)			
006	67	36 (54%)			
008	81	47 (58%)			
Age (years)			<0.001 ^b		<0.001 ^b
10-<13	75	28 (37%)		Reference	
13-<15	106	35 (33%)		0.74 (0.31, 1.74)	
15-<18	205	128 (62%)		2.87 (1.34, 6.16)	
≥18	110	84 (76%)		6.57 (2.67, 16.15)	

Gender			0.02	NA ^{a,c}
Female	320	165 (52%)		
Male	176	110 (63%)		
Race/Ethnicity^d			0.01	0.06
White	44	33 (75%)		Reference
Hispanic or Latino	268	150 (56%)		0.43 (0.15, 1.24)
Black/African American	149	71 (48%)		0.36 (0.12, 1.11)
Other/ multiracial	31	20 (65%)		0.66 (0.16, 2.82)
Parent Education^d			0.13	0.07
High School or less	322	176 (55%)		Reference
AA	62	31 (50%)		0.94 (0.42, 2.09)
BS/BA	50	32 (64%)		1.36 (0.54, 3.45)
MS/MA/Professional	23	16 (70%)		1.89 (0.51, 6.96)
Health Insurance			0.26	NA ^a
Private	141	85 (60%)		
Children's Health Plan or Other Government	307	160 (52%)		

Military	3	3 (100%)		
None	45	27 (60%)		
Diabetes Duration (years)			<0.001 ^b	NA ^{a,c}
<1	144	73 (51%)		
1–<2	91	45 (49%)		
2–<4	116	56 (48%)		
≥4	145	101 (70%)		
HbA1c^d % (mmol/mol)			0.94 ^b	NA ^a
<6.0 (<42)	108	56 (52%)		
6.0–<7.0 (42–<53)	99	55 (56%)		
7.0–<8.0 (53–<64)	58	27 (47%)		
8.0–<9.0 (64–<75)	51	31 (61%)		
≥9.0 (≥75)	134	76 (57%)		
Self-Monitoring Blood Glucose (# tests/day)^e			0.003 ^b	NA ^{a,c}
0	69	44 (64%)		
1	104	62 (60%)		

2-3	232	131 (56%)		
≥4	91	38 (42%)		
Diabetes Treatment			0.31	NA ^a
Life-style alone	95	55 (58%)		
Metformin alone	145	80 (55%)		
Insulin alone	106	52 (49%)		
Metformin + Insulin	136	77 (57%)		
Other Med ± Insulin / Metformin	14	11 (79%)		
Estimated Distance to Site^f (miles)			0.10 ^b	0.06 ^b
<5	106	49 (46%)		Reference
5-<10	81	40 (49%)		1.19 (0.50, 2.83)
10-<20	161	93 (58%)		2.27 (1.04, 4.95)
20-<50	91	55 (60%)		1.78 (0.75, 4.21)
≥50	57	38 (67%)		3.11 (1.14, 8.49)

a. Factors with P-value ≥ 0.10 were not included in the multivariate model

b. Variable was analyzed as continuous.

c. Main confounding factor is age.

- d. Missing data: race/ethnicity (4), parent education (39), HbA1c (46).
- e. Self-reported values.
- f. Approximation based on latitude and longitude of the patient's and site's zip codes.

Table Legends

Table 1. Participants Characteristics at Enrollment (N=496^a)

- a. Number of participants with missing or “Unknown” data (lost to follow-up/active): race/ethnicity (1/3), parent education (20/19), BMI (26/11), HbA1c (30/16).
- b. Site 007 dropped out of the registry and patient follow up data was unavailable.
- c. Self-reported values.

Table 2. Factors at Enrollment Associated with Participants Dropout (N=496)

- a. Factors with P-value>0.10 were not included in the multivariate model
- b. Variable was analyzed as continuous.
- c. Main confounding factor is age.
- d. Missing data: race/ethnicity (4), parent education (39), HbA1c (46).
- e. Self-reported values.
- f. Approximation based on latitude and longitude of the patient’s and site’s zip codes.