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Insulin Pump Use and Glycemic Control in Adolescents with Type 1 Diabetes (T1D): Predictors of Change in Method of Insulin Delivery across Two Years

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Abstract

Few studies have explored durability of insulin pump use, and none have explored the link between depression and pump discontinuation. To examine the relationship between depressive symptoms (measured by the Children's Depression Inventory, CDI), method of insulin delivery, and A1c, mixed models were used with data from 150 adolescents with T1D and visits every 6 months for 2 years. Of the 63% who used a pump, compared to multiple daily injections (MDI) at baseline, there were higher proportions who were non-minorities, had caregivers with a college degree, private insurance, and two caregivers in the home ($p < 0.01$). After adjusting for time, sex, age, T1D duration, frequency of blood glucose monitoring, ethnicity, insurance, and caregiver number and education, baseline pump use was associated with -0.79% lower mean A1c (95% CI $-1.48, -0.096$; $p=0.03$). For those using a pump at baseline, but switching to MDI during the study ($n=9$), mean A1c was 1.38% higher (95% CI $0.68, 2.08$; $p<0.001$) than that for those who did not switch method of delivery. A 10-point increase in CDI was associated with a 0.39% increase in A1c (95% CI $0.16, 0.61$; $p=0.001$), independent of pump use. Regarding the temporal relationship between CDI score and changing method of insulin delivery, prior higher CDI score was associated with switching from pump to MDI (OR=1.21; 95% CI $1.05, 1.39$ $p=0.007$). Clinicians should be aware of the associations between depressive symptoms, change in insulin delivery method, and the effect on glycemic control.

Keywords

type 1 diabetes; adolescent; depression; insulin pump; diabetes mellitus

Introduction

The use of insulin pumps in adolescents with T1D, compared to multiple daily injections (MDI), has been shown to be at least modestly beneficial in improving glycemic control (1–5) and has been associated with maintenance of, and/or improved, quality of life (6–9). Few studies have reported how often children using pumps switch back to MDI, if this change from pump to MDI is associated with a change in glycemic control, and if psychosocial factors influence this change (10,11). In one longitudinal study of the durability of pump use in children with T1D, 18% of participants switched from using pumps to MDI over an average of 3.8 years, and there were higher proportions of females and single parent families in the group that discontinued pump use (10). In addition, the average hemoglobin A1c (A1c) of those who discontinued pump use was higher than those who remained on the pump, suggesting an association between pump discontinuation and glycemic control. However, further studies identifying factors associated with pump discontinuation in adolescents, beyond demographic and socioeconomic factors, are lacking.

In addition to the physiologic changes that occur during adolescence, adolescents with T1D are at risk for suffering from the psychosocial burden of diabetes, manifested as depression, anxiety, behavioral problems, and psychological distress (12). Depression is the most common psychiatric diagnosis (13), with 14–23% of 13- to 18-year-olds with T1D affected by depressive symptoms, which have been shown to be associated with suboptimal diabetes management and glycemic control (14–17). One possible mechanism for the link between depression and glycemic control is that depressive symptoms lead to decreased engagement in diabetes tasks such as frequent blood glucose monitoring, giving insulin boluses, or using precise glucose levels and carbohydrate intake when determining insulin doses. In addition to diabetes factors, other contextual factors may contribute to depressive symptoms, including lack of family support, education, or financial resources (18). Because some of these demographic factors which predispose to depression are also associated with pump use and discontinuation of pump use, it is possible that these may be related and associated with glycemic control, though causality may be bidirectional. Depressive symptoms may set the stage for frustration with diabetes management and struggles with engagement in self-care including continued use of diabetes technology. No prior studies have shown if depressive symptoms are associated with pump discontinuation.

The identification of possible factors associated with pump discontinuation, including depressive symptoms, is important to clinical practice. For clinicians, knowledge of factors that may precede pump discontinuation would enable them to identify those in need of pump education and support. This is particularly relevant for adolescents who may be transitioning from being dependent on their caregivers for assistance with pump management, to becoming independent users of this technology. An association between depressive symptoms and pump discontinuation would provide further support for the need for diabetes practices to implement routine depression and mental health screening (19,20), in part to help at-risk adolescents understand the advantages to maintaining pump therapy.

The goal of this study was to use a longitudinal cohort of adolescents with T1D to identify factors associated with changing insulin delivery method from pump to injections. We

examined the temporal relationship between pump use, depressive symptoms, and glycemic control, and, in an exploratory analysis, compared glycemic control and depressive symptoms before and after switching method of insulin delivery. Understanding whether depressive symptoms are linked to patient preferences in method of insulin delivery will provide guidance for clinicians in prioritizing earlier identification of psychosocial factors that might impact optimal glycemic control.

Methods

Participants

Participants included adolescents between 13–18 years diagnosed with T1D according to the American Diabetes Association (ADA) guidelines. All received multidisciplinary care at an ADA-certified tertiary pediatric diabetes center caring for approximately 1800 patients with T1D. All participants used basal-bolus insulin therapy, delivered either by MDI or an insulin pump, received similar diabetes education, and had a similar number of regular visits. Pump users participated in standard pump education classes prior to pump initiation. Exclusion criteria included inability to understand spoken and written English, or the presence of a major psychiatric, neurocognitive, or serious chronic medical condition that would interfere with participation. Adolescents with other chronic medical conditions, with the exception of well-controlled thyroid or celiac disease, were excluded. Using the electronic medical record and appointment system, eligible patients were identified prior to their clinic visit, and families were sent an introductory letter outlining the study. One hundred sixty-six eligible families were approached at regularly scheduled clinic visits by consecutive sampling, one hundred fifty families chose to enroll in the study (90%), and all in this convenience sample were included in analysis. Parents and adolescents gave written informed consent and assent, respectively, to research staff and answered questionnaires at baseline and at 4 subsequent visits, approximately 6 months apart, for a total duration of about 2 years for each participant. The protocol and procedures were approved by the Institutional Review Board at Cincinnati Children's Hospital.

Measures

At baseline and every subsequent visit, caregivers provided demographic information including the adolescent's age, gender, and ethnicity, the caregiver's marital status and highest level of education, and the type of medical insurance. A review of the medical record was also completed at each visit to obtain duration of diabetes, the method of insulin delivery (MDI or pump), and frequency of blood glucose monitoring (from meter download, reported as the average daily checks over a two-week period). A1c was obtained at every visit using the DCA 2000+ (reference range 4.3–5.7%; Bayer Inc., Tarrytown, NY, USA). At every visit, adolescents completed the Children's Depression Inventory (CDI) (21), a self-report of depressive symptoms which asks participants to rate their level of depression from 0 (no symptom) to 2 (distinct symptom) on 27 items, for a possible range of 0–54. Higher scores indicated more depressive symptoms. This widely used and psychometrically sound questionnaire has been used in prior studies with adolescents with T1D (14,15,17). A CDI score of 13 or greater suggested the need for further evaluation. Quality of life was also measured using the Pediatric Quality of Life Inventory (PedsQL) in all participants. PedsQL

scores were collinear with CDI score and were not included in this analysis since the focus of this study was depressive symptoms.

Statistical analysis

Descriptive statistics (t-tests for continuous variables and chi-square tests for dichotomous variables) were used for baseline variables. In order to investigate the question of the influence of insulin delivery method on glycemic control over time, a mixed-effects linear regression model was used. The mixed model used random intercepts and slopes for each participant, unstructured variance and covariance, and the restriction maximum likelihood option. A mixed model was chosen because of the presence of missing data; similar results were obtained using generalized estimating equations (results not shown).

In the base model (Model A), three variables for method of insulin delivery were included: (1) baseline method of insulin delivery, (2) baseline method of insulin delivery with an interaction with time (a time-varying variable), and (3) change of method of insulin delivery from baseline. The interaction of baseline method of insulin delivery with time was included in order to determine if there was a difference in change in A1c over time (regardless of baseline value of A1c) between the two methods of insulin delivery. The variable for change of method of insulin delivery from baseline was a categorical variable at the visit level, indicating if there was a change in method of insulin delivery at that visit compared to that at baseline visit 1 (0=no change in method of insulin delivery, 1=change from MDI at visit 1 to pump, 2=change from pump at visit 1 to MDI). The model was adjusted for possible confounding factors, including age, duration of diabetes diagnosis, frequency of blood glucose monitoring, sex, minority status, insurance status, the number of caregivers in the home, and highest level of caregiver education.

The presence of depressive symptoms was evaluated for association with A1c by adding CDI score to Model A and performing mediation analysis. We considered CDI score to be a mediating factor between method of insulin delivery and A1c only if the coefficients for the method of insulin delivery variables were appreciably different between models. Model A (the multivariate model without CDI score) was compared to the multivariate model with CDI score but without the method of insulin delivery variables (Model B), and to the complete multivariate model including all three method of insulin delivery variables and CDI score (Model C).

Mixed-effects logistic regression with random intercepts was used to identify variables associated with switching method of insulin delivery. In these analyses, subjects who were using MDI versus pump at the baseline visit were separated into subgroups. The outcome of interest was whether or not the subject switched from one method of delivery to the other (e.g. MDI to pump, or pump to MDI) at any given visit. For this analysis, dichotomous variables were created at the visit level, which indicated whether or not the method of insulin delivery at the current visit was different than the method at the immediately prior visit; the two subgroups, based on baseline method of use, were analyzed separately. In an exploratory analysis, for those who did switch method of insulin delivery, t-tests were used to compare the mean A1c and CDI score from the visit immediately prior to the switch to the mean A1c and CDI score from the visit after which the switch occurred. All statistical

analyses were performed using Stata, version 12.1 (College Station, TX). For all statistical tests, significance was set to $\alpha=0.05$.

Results

Baseline participant characteristics

The baseline characteristics of the 150 participants in this study, which have been previously reported, are listed in Table 1 (22). Attrition was low in this 2-year longitudinal study; of the 150 participants enrolled in the study, 135 were still enrolled at the fifth and final assessment. The participants were 51.3% female, with a mean age at baseline of 15.5 ± 1.4 years old, and average duration of diabetes of 6.1 ± 3.9 years, none of which were significantly different between those using MDI or those using pump at baseline. More participants were using pumps (62.7%) rather than MDI (37.3%) at baseline. Amongst those using pumps at baseline, there were larger proportions of adolescents who were non-Hispanic white, had a caregiver with at least a college degree, had private insurance, and had two caregivers in the home, when compared with those using MDI at baseline. Those adolescents using pump at baseline had a lower baseline A1c ($8.4 \pm 1.4\%$ vs $9.5 \pm 2.4\%$, or 68 vs 80 mmol/mol; $p=0.0005$) and a greater frequency per day of blood glucose monitoring (4.6 ± 1.8 vs 3.8 ± 1.5 , $p=0.004$). There were no statistically significant differences in the adolescent CDI score at baseline (Table 1).

Effect of demographic and psychosocial factors on glycemic control

Using data for all visits over the 2-year period for each subject, a mixed-effects linear regression model was used to look for the association of demographic factors and depressive symptoms with A1c. After adjusting for trends in A1c over time, age, duration of diagnosis, frequency of blood glucose monitoring, sex, minority status, insurance status, the number of caregivers in the home, and highest level of caregiver education, the use of an insulin pump at baseline was associated with a -0.79% (95% CI $-1.48, -0.096$; $p=0.03$) difference in mean A1c compared to use of MDI (Table 2). The interaction of baseline method of insulin delivery with time was used to look for possible differences in change of A1c from baseline based on method of insulin delivery; there was no statistically significant difference in change in A1c over the two years between those who started on pumps and those who started on MDI. However, for those who started on pumps and switched to MDI, the mean A1c was 1.38% (95% CI $0.68, 2.08$; $p<0.001$) higher compared to those who did not switch method of insulin delivery. The only other factor significantly associated with lower A1c was increased frequency of blood glucose monitoring ($\beta=-0.30$, 95% CI $-0.038, -0.23$, $p<0.001$; Table 2).

When the adolescent report of CDI score was included in the multivariate mixed model, higher CDI score was associated with higher current A1c, independent of other factors including baseline use of an insulin pump; for every 10-point increase on the CDI, there was an increase in A1c of 0.39% (95% CI $0.16, 0.61$; $p=0.001$; Table 3). Mediation analysis showed that pump use did not mediate the association between CDI and A1c, and CDI did not mediate the association between pump use and A1c (data not shown).

Factors associated with switching method of insulin delivery

To identify factors associated with changing methods of delivery from pump to MDI, we looked for associated factors that were present at the visit prior to the switch, to understand if any variables preceded the switch. The outcome of interest was whether or not the method of insulin delivery at the current visit was different than the method at the immediately prior visit. In baseline pump users, the only variable from the prior visit that was significantly associated with the switch was the prior CDI score, adjusted for time (OR=1.21; 95% CI 1.05, 1.39 $p=0.007$). This meant that for every 1 point increase in CDI score from the previous visit, there was 1.21 times increased odds that the participant switched from pump to MDI by the current visit, compared to staying on the pump. At the current visit, no variables were significantly associated with having switched from pump to MDI. In baseline MDI users, no demographic or clinical factors were associated with switching from MDI to pump in this cohort.

Description of the participants who switched method of insulin delivery

There were 17 adolescents who transitioned from MDI to pump during the study, and 9 who switched from pump to MDI, though three who switched from pump to MDI were using the pump again by the end of the study. Table 4 shows the characteristics of those who had switched methods of insulin delivery during the study, compared to those who used the same method of insulin delivery since baseline. For those who entered the study using MDI, there was a trend towards higher proportions of caregivers with higher education and private insurance in those who switched to pump, but neither was statistically significant. Of note, for those adolescents who started the study using the pump, there was a larger proportion of females in the group that switched from pump to MDI, compared to the group who remained on the pump (88.9% vs. 48.2%; $p=0.02$).

The mean CDI score for adolescents who switched from pump to MDI was lower after, compared to prior to, the switch (11.2 ± 8.3 prior and 6.6 ± 5.5 after; $p=0.01$). A similar trend was found in mean CDI score after adolescents switched from MDI to pump (6.6 ± 7.6 prior and 4.6 ± 5.6 after), but this difference was not statistically significant ($p=0.06$). For adolescents who switched from pump to MDI, there was a trend towards higher mean A1c after the switch ($9.0\% \pm 2.3$ vs. $10.2\% \pm 2.6$, or 75 vs 88 mmol/mol), but this was not statistically significant ($p=0.24$). There was no difference in mean A1c prior to and after the switch from MDI to pump ($9.9\% \pm 2.5$ vs. $9.6\% \pm 2.3$, or 85 vs 81 mmol/mol, $p=0.44$).

Discussion

In this longitudinal cohort of adolescents with T1D, we have shown that depressive symptoms are associated with A1c, independent of insulin pump use, and increased depressive symptoms precede a change in method of insulin delivery from pump to MDI. In a preliminary analysis, depressive symptoms decrease after pump discontinuation, in the small number of adolescents that switched. Prior work with adolescents with T1D has yielded mixed results with regard to pump use and the clinical improvements in A1c (4,23,24). Our results add support to the body of literature showing that pump use is associated with lower A1c. Those participants who started the study on a pump had lower

mean A1c values at baseline compared to those on MDI. Frequency of blood glucose monitoring was also associated with A1c, which is consistent with prior studies (22,25,26).

Another variable related to A1c, and for the first time investigated as a predictor of durability of insulin pump use, was the presence of depressive symptoms. The link between depressive symptoms and suboptimal glycemic control has been shown previously (14,15,17) and was demonstrated by our finding that higher CDI score is associated with higher A1c values. The relationship of depressive symptoms with glycemic control appears to be independent of the effect of pump use on A1c. Depression and pump use was investigated in a retrospective study of adults starting pump therapy, in which the frequency of mental health problems was higher in those who started pumps, compared to those using only MDI, though increased mental health problems were already present before the initiation of the pump (27). Our study differs, in that we explored depressive symptoms in adolescents around the time of pump discontinuation, rather than initiation. The unique finding that a higher CDI score precedes a switch from pump use to MDI provides a preliminary temporal link between depressive symptoms and changing method of insulin delivery in this small sample. The findings suggest that depressive symptoms may precede a shift in attitudes or behaviors around diabetes, such as dissatisfaction with the pump, or feeling that the pump is not working well or is too burdensome.

While the number of subjects who switched from pump to MDI in this cohort is small, our results provide a preliminary look at characteristics of those adolescents who switch from pump to MDI. The number of subjects who switched from pump to MDI (9 of 150, or 6%) is similar to the frequency of pump discontinuation in other studies of adolescents (10,11,28). The higher proportion of females in the group that switched from pump to MDI is similar to previous findings (10,11,28). The trend towards higher mean A1c after switching from pump to MDI is notable, suggesting that either the switch itself, or the factors that influenced the switch (including prior depressive symptoms) or are associated with the switch (decreased compliance and/or motivation) may be linked to worsening glycemic control, though larger, more highly powered studies are needed to more definitively address this hypothesis. It is also of interest that the adolescent CDI score was significantly lower after the switch from pump to MDI, providing evidence to support the notion that switching back to MDI may be an adolescent's attempt to alleviate depressive symptoms. The trend in decreased CDI score after switching from MDI to pump suggests that perhaps regardless of the direction of the change in method of insulin delivery, adolescence is stressful and changing methods may impact mood. Other work has shown that adolescents stop using pumps for a variety of reasons, including diabetes burnout, concerns with body image, interference with sports and physical activity, and not wanting to be connected to a foreign body (10,29). Our findings that increased depressive symptoms precede or coincide with stopping pump use, and symptoms decrease after the switch, support the idea that social and psychological factors influence the decision to stop pump therapy.

The limitations of this study include the relatively small number of subjects who switched method of insulin delivery, which prevented adjustment for demographic factors in the analysis of predictors of switchers from pump to MDI. For example, among the switchers,

there was only one male, one participant who was an ethnic minority, and one participant who had public insurance, which made adjustment for sex, ethnicity, and insurance status impossible. Because of this, we acknowledge that our findings may be due to confounding; further studies with larger sample sizes are necessary to perform a more complete adjusted analysis. In addition, data regarding incidence of severe hypoglycemia and diabetic ketoacidosis, weight gain, and technical problems with the insulin pump, which might impact compliance, was not available, and may be explored in future studies.

Our findings add to the body of evidence showing that insulin pump use is associated with better glycemic control, and, for the first time, show that depressive symptoms precede the switching from pumps to MDI. From a clinical perspective, given the relationship between continued pump use and more optimal glycemic control, providers should provide additional support and educational resources for adolescents on pumps, who may be transitioning from relying on caregivers for their pump care and diabetes management to taking full responsibility on their own for the first time. Providers should be aware of the common complaints about pumps amongst adolescents, and begin to anticipate, recognize, and address these concerns before the decision is made to discontinue use. Our results also highlight the need for careful screening for depressive symptoms in adolescents with T1D, which can aid in counseling and providing support as they make decisions about method of insulin delivery and other aspects of their diabetes management. Clinic-based depression prevention strategies, such as education about early signs of depression and diabetes burnout, as well as interventions focusing on coping and problem solving skills (30–33) may help with fluctuations in depressive symptoms and, ultimately, more optimal diabetes care.

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Table 1

Baseline participant characteristics

	Total n=150	MDI at baseline n=56	pump at baseline n=94	p[*]
Age (in years)	15.5 ± 1.4	15.6 ± 1.4	15.4 ± 1.4	0.51
Sex (% female)	51.3%	50.0%	52.1%	0.80
Ethnicity (% minority status)	14.0%	23.2%	8.5%	0.012
White, not of Hispanic origin (%)	86.0%	76.8%	91.5%	0.015
Black/African-American (%)	11.3%	21.4%	5.3%	
Hispanic/Latino	1.3%	0.0%	2.1%	
Asian/Pacific Islander (%)	0.7%	0.0%	1.1%	
Education level of primary caregiver (% with at least college degree)	58.7%	42.9%	68.1%	0.002
Insurance status (% with private insurance)	85.3%	67.9%	95.7%	<0.001
Family status (% with 2 caregivers in the home)	76.7%	62.5%	85.1%	0.002
Duration of T1D (in years)	6.1 ± 3.9	6.0 ± 4.2	6.1 ± 3.8	0.94
HbA1c (%)	8.8 ± 1.9	9.5 ± 2.4	8.4 ± 1.4	0.0005
Frequency of blood glucose monitoring (per day)	4.3 ± 1.8	3.8 ± 1.5	4.6 ± 1.8	0.0038
CDI score	7.9 ± 7.1	7.9 ± 6.4	8.0 ± 7.5	0.98

Means ± SD for continuous variables, and frequencies for dichotomous variables

* p-values based on t-test for continuous variables and chi-square tests for dichotomous variables

Table 2

Adjusted model of associations of demographic and clinical factors with HbA1c

Effect	Coefficient (β)	SE	p	95%CI
Method of insulin delivery at baseline (pump=1)	-0.788	0.353	0.026	-1.482, -0.096
Method of insulin delivery at baseline x time	0.059	0.095	0.531	-0.126, 0.245
Change from baseline method (ref = no change)				
From MDI to pump	-0.112	0.361	0.756	-0.82, -0.596
From pump to MDI	1.380	0.357	<0.001	0.685, 2.084
Sex (male = 1)	0.036	0.08	0.649	-0.121, -0.193
Age	0.058	0.085	0.497	-0.109, 0.224
Duration of diabetes	0.047	0.027	0.075	-0.005, 0.100
Frequency of BGM	-0.302	0.039	<0.001	-0.0378, -0.226
Ethnicity (minority = 1)	-0.094	0.129	0.464	-0.346, 0.158
Baseline insurance (non-private insurance = 1)	-0.245	0.142	0.084	-0.522, -0.033
Baseline caregiver marital status (2 caregivers = 1)	-0.058	0.110	0.599	-0.274, 0.158
Baseline caregiver education (at least college = 1)	-0.033	0.085	0.699	-0.200, 0.134

Table 3

Adjusted model associations of demographic and clinical factors, including CDI score, with HbA1c

Effect	Coefficient (β)	SE	p	95%CI
CDI score	0.039	0.012	0.001	0.016, 0.062
Method of insulin delivery at baseline (pump=1)	-0.825	0.035	0.017	-1.503, -0.148
Method of insulin delivery at baseline x time	0.056	0.094	0.553	-0.128, 0.240
Change from baseline method (ref = no change)				
From MDI to pump	-0.107	0.361	0.766	-0.815, 0.600
From pump to MDI	1.460	0.362	<0.001	0.750, 2.170
Sex (male = 1)	0.014	0.080	0.859	-0.142, 0.171
Age	0.061	0.084	0.466	-0.103, 0.226
Duration of diabetes	0.050	0.026	0.059	-0.002, 0.101
Frequency of BGM	-0.287	0.040	<0.001	-0.365, -0.209
Ethnicity (minority = 1)	-0.128	0.128	0.319	-0.379, 0.123
Baseline insurance (non-private insurance = 1)	-0.237	0.140	0.090	-0.512, 0.037
Baseline caregiver marital status (2 caregivers = 1)	-0.075	0.110	0.494	-0.290, 0.140
Baseline caregiver education (at least college = 1)	-0.052	0.085	0.539	-0.218, 0.114

Table 4 Characteristics of those participants who ever switched method of insulin delivery

Baseline characteristics	MDI only n=42	MDI to pump n=14	p*	pump only n=85	pump to MDI n=9	p*
Age (in years)	15.5 ± 1.4	15.8 ± 1.5	0.52	15.5 ± 1.4	14.9 ± 1.0	0.22
Sex (% female)	50.0%	50.0%	1	48.2%	88.9%	0.02
Ethnicity (% minority status)	23.8%	21.4%	0.86	8.2%	11.1%	0.77
Education level of primary caregiver (% with at least college degree)	38.1%	57.1%	0.21	67.1%	77.8%	0.51
Insurance status (% with private insurance)	61.9%	85.7%	0.10	95.3%	100.0%	0.51
Family status (% with 2 caregivers in the home)	64.3%	57.1%	0.63	84.7%	88.9%	0.74
Duration of T1D (in years)	6.1 ± 4.2	5.8 ± 4.5	0.80	6.2 ± 3.9	4.7 ± 2.5	0.24
HbA1c (%)	9.4 ± 2.3	9.9 ± 2.8	0.50	8.3 ± 1.3	8.9 ± 2.4	0.25
Frequency of blood glucose monitoring (per day)	3.7 ± 1.6	4.0 ± 1.0	0.54	4.6 ± 1.9	4.8 ± 1.7	0.81
CDI score	8.0 ± 6.4	7.8 ± 6.7	0.92	7.9 ± 7.4	8.7 ± 9.1	0.77

means ± SD, or %

* 2-sided t-test for continuous variables, chi-square for dichotomous variables