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Worries and concerns about hypoglycemia in adults with type 1 diabetes: An examination of the reliability and validity of the Hypoglycemic Attitudes and Behavior Scale (HABS)

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ABSTRACT

Aims: To examine the factor structure, validity and reliability of the Hypoglycemic Attitudes and Behavior Scale (HABS) in T1D adults (previously examined only in T2D adults), and to determine if it has unique value, after controlling for hypoglycemic fear.
Methods: The original 14 HABS items were submitted to a confirmatory factor analysis (CFA) with T1D participants. Construct validity criteria included diabetes distress, generalized anxiety, well-being, hypoglycemic fear, hypoglycemia history and self-reported glycemic control.
Results: A CFA yielded a similar 3-factor solution, with all items loading on the same factors as in the analyses with T2D adults: Hypoglycemia Anxiety, Avoidance and Confidence. Higher levels of Anxiety and Avoidance were significantly associated with poorer well-being and higher levels of generalized anxiety, diabetes distress and hypoglycemic fear, with correlations in the reverse direction for Confidence. After controls (including hypoglycemic fear), the HABS subscales were significantly linked to several criterion variables.
Conclusions: Though originally developed and validated with T2D adults, the HABS demonstrates sufficient validity and reliability for use with a T1D population; and it captures unique critical elements of hypoglycemic concerns. Thus, it may contribute to a greater understanding of hypoglycemia management and more targeted clinical interventions in a T1D population.

1. Introduction

Adults with type 1 diabetes (T1D) frequently experience considerable worry and concern about hypoglycemia; and the extent of this concern has been shown to have an adverse impact on self-management, medication adherence, glycemic control, and quality of life.[1,2] The most prominent method for assessing the depth and breadth of hypoglycemic concerns is the Hypoglycemic Fear Survey (HFS), a widely-used self-report scale developed by Gonder-Frederick and her colleagues several decades ago[3] and later revised as the HFS-II.[4] Recent evidence, however, suggests that, although comprehensive, the two subscales of the HFS-II, Worry and Behavior, may not fully capture all of the most critical elements regarding an individual's concern about hypoglycemia.[5–7] Furthermore, the HFS-II is relatively long (33 items), making it potentially unwieldy for clinical practice, and recent authors have noted that the phrasing of many of the HFS-II items may not necessarily represent an unhealthy or unreasonable response to hypoglycemia.[8]

Building on the HFS-II and cognizant of these issues, we developed the Hypoglycemic Attitudes and Behavior Scale (HABS) and validated it with a large sample of adults with type 2 diabetes (T2D). We found that two of the newly-developed HABS subscales, Hypoglycemia Avoidance (assessing common unhealthy actions likely to prevent or avert hypoglycemia) and Hypoglycemia Confidence (assessing the belief that hypoglycemia could be mastered), were both uniquely associated with critical psychosocial constructs and hypoglycemia experience, even after controlling for hypoglycemia-related anxiety.[7] Given these findings, we sought in the current research to develop new options for assessing some of the important nuances of hypoglycemic concerns in a T1D population. More specifically, we sought to assess the factor structure,

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concurrent validity and reliability of the HABS with a T1D sample, and to determine if the HABS subscales have value regarding diabetes outcomes independent of the HFS-II.

2. Methods

2.1. Design, setting and sample

Adults with T1D were recruited from the Taking Control of Your Diabetes (TCOYD) Research Registry. The Registry is a HIPAA-protected online platform that includes T1D and T2D adults, recruited primarily from TCOYD's one-day diabetes education events conducted in multiple cities across the United States. For the current study, participants were required to be ≥21 years old and diagnosed with T1D ≥ 1 year. Respondents were asked to complete a brief eligibility questionnaire, an informed consent and an online survey that included the original 14 HABS items, the HFS-II, several other validity scales, and items to assess key demographic and disease status characteristics. Each participant received a $10 electronic gift card for participation. Survey data were de-identified and were entered into a central database using a HIPAA-protected server. The research protocol was approved by Ethical and Independent Review Services, a community-based, institutional review board.

The original HABS items were developed from structured interviews with insulin-using and non-insulin-using T2D adults and healthcare professionals (HCPs), yielding a 14-item scale.[7] The scale consists of three clinically meaningful subscales that capture key features associated with hypoglycemic experience: *Hypoglycemic Anxiety* (5 items), which assesses excessive fears and worries (e.g. "I am terrified that I might injure myself or someone else because of a low blood sugar episode"); *Hypoglycemia Avoidance* (4 items), which focuses solely on unhealthy actions that would not likely be construed as rationale responses to prevent or avert hypoglycemia (e.g., "To avoid serious problems due to low blood sugar, I eat or drink a lot more often than I really need to"); and *Hypoglycemic Confidence* (5 items), which examines an aspect of an individual's hypoglycemic experience that is rarely considered — not merely the absence of fear and worry, but a positive sense that hypoglycemic concerns can be mastered (e.g., "I am confident that I can catch and respond to low blood sugar before my blood sugars get to low"). In the current study, we examined the psychometric properties of the HABS using an exclusive T1D adult sample, following identical procedures and tests of validation undertaken with the T2D HABS. T1D respondents rated each of the 14 HABS items on a 5-point scale: 1 = "strongly disagree", 2 = "disagree", 3 = "neutral", 4 = "agree" and 5 = "strongly agree".

2.2. Measures

In addition to the initial 14-item HABS, three sets of measures were included to describe the sample and examine correlates of hypoglycemic attitudes and behaviors. First, demographic measures included age, gender, race (White vs. non-White), education (years), number of years since diagnosis, and body mass index (BMI, calculated from self-reported weight and height). Second, measures of diabetes status included self-reported A1C and estimated number of blood glucose readings <70 mg/dl during the past week. Third, psychological measures included the World Health Organization-5 (WHO-5), a 5-item scale that assesses overall well-being (Cronbach's $\alpha = 0.90$)[9]; the Diabetes Distress Scale for Adults with Type 1 Diabetes (T1-DDS), which assesses worries and concerns specifically related to diabetes and its management and has been shown to be a good marker of diabetes-related quality of life ($\alpha = 0.92$)[5]; the 7-item Generalized Anxiety Disorder Assessment (GAD-7), a widely used measure of global anxiety ($\alpha = 0.92$)[10]; and the HFS-II, including both the Behavior (HFS-B) ($\alpha = 0.87$) and Worry subscales (HFS-W) ($\alpha = 0.95$).[4]

2.3. Data analysis

Descriptive statistics were computed to review item and scale distributions. Chi-square and *t*-tests, as appropriate, were conducted to test for differences in patient characteristics and outcome variables using SPSS software (PASW Statistics, v. 19). A confirmatory factor analysis (CFA) was then conducted based upon the exploratory factor analysis (EFA) results of the original HABS.[7] The CFA was performed using R version 3.6.0.[11] HABS subscale scores were created by averaging across items in each resulting factor.

Internal consistency of the subscales and the total scale were determined by Cronbach's alpha statistic. Construct validity was examined by Pearson or Spearman correlations between HABS scores and the psychosocial variables, A1C and hypoglycemia history. Hierarchical regression analyses examined the unique contribution of each of the resulting HABS subscales on key psychosocial constructs and hypoglycemia history, over and above associations with the two HFS-II subscales.

3. Results

3.1. Clinical characteristics of the sample

Three hundred and thirty-eight T1D adults completed the informed consent and started the survey, with 326 (97%) completing the entire survey. The sample was predominantly Non-Hispanic White (85.3%), female (71.2%) and college educated (66.6% with 16 or more years of education). Mean T1D duration was 25.8 (±14.9) years. A majority of respondents reported currently using an insulin pump (72.4%) and 63.2% reported currently using a real-time continuous glucose monitor (RT-CGM). Participants reported an average of 4.5 (±2.8) hypoglycemic events (<70 mg/dl) in the past week. A full description of the sample is presented in Table 1.

Table 1
Characteristics of the sample (N = 326).

Characteristic	Mean (SD) or n (%)
Age (years)	48.67 (14.76)
Female, n (%)	232 (71.2%)
College educated, n (%)	217 (66.6%)
Ethnicity, n (%)	
Non-Hispanic White	278 (85.3%)
African American	3 (0.9%)
Hispanic	15 (4.6%)
Asian or Pacific Islander	4 (1.2%)
Native American	7 (2.1%)
Multiple ethnic backgrounds	7 (2.1%)
Other	12 (3.7%)
Years since diagnosis (years)	25.77 (14.90)
Insulin delivery system, n (%)	
Pen	54 (16.6%)
Vial and syringe	36 (11.0%)
Pump	236 (72.4%)
Currently uses RT-CGM, n (%)	206 (63.2%)
Number of blood glucose checks per day	5.05 (2.12)
Number of insulin boluses per day	5.19 (1.90)
Number low blood glucose readings (<70 mg/dl) in past week	4.50 (2.80)
BMI	25.85 (5.54)
HbA1c	7.10 (1.08)
Well-being (WHO-5)	2.81 (1.13)
Diabetes distress (T1-DDS)	2.22 (0.74)
Generalized anxiety (GAD-7)	5.61 (5.13)
Hypoglycemic fear Survey (HFS-II)	
Behavior subscale (HFS-B)	16.86 (9.19)
Worry subscale (HFS-WB)	22.93 (14.50)

Means and standard deviations are presented for continuous variables.

Table 2
Factor loadings for confirmatory factor analysis (CFA).

HABS item	Standardized factor loading (SE)	*p* value
HABS Anxiety		
I am terrified that I might pass out in public due to a low blood sugar episode.	0.74 (0.03)	<0.0001
I am terrified that I might injure myself or someone else because of a low blood sugar episode.	0.74 (0.03)	<0.001
To avoid serious problems due to low blood sugar, I stay close to home more than I would really like to.	0.62 (0.04)	<0.001
I spend so much time worrying about the possibility of a low blood sugar episode that it makes it hard for me ever feel happy.	0.77 (0.30)	<0.001
If I don't have plenty of emergency supplies to raise my glucose with me, I won't leave my house.	0.15 (0.06)	0.01
HABS Avoidance		
Without even bothering to test, I take quick action to raise my blood sugars at the first hint of any "funny" feelings.	0.43 (0.05)	<0.001
To avoid serious problems with low blood sugar, I tend to keep my blood sugars higher than I probably should	0.68 (0.04)	<0.001
To avoid serious problems due to low blood sugar, I eat or drink a lot more often than I really need to.	0.76 (0.04)	<0.001
If I think my blood sugar is too low, I'll start eating and eating and I won't stop until I feel better.	0.73 (0.04)	<0.001
HABS Confidence		
I am confident that I can avoid serious problems due to low blood sugar when I'm alone.	0.77 (0.03)	<0.001
I am confident that I can stay safe from serious problems with low blood sugar while driving.	0.57 (0.04)	<0.001
I am confident that I can catch and respond to low blood sugar before my blood sugars get too low.	0.77 (0.03)	<0.001
I am confident that I can stay safe from serious problems with low blood sugar while exercising.	0.57 (0.04)	<0.001
I am confident that I can stay safe from serious problems with low blood sugar while out in public.	0.70 (0.04)	<0.001

3.2. Confirmatory factor analysis (CFA)

A CFA of the original 14-item HABS with the new T1D sample (Polonsky et al., 2015) yielded a similar 3-factor solution (Table 2). All 14 items significantly loaded on the same 3 factors as derived from the original EFA with T2D adults (all $p \leq .01$), providing support for the viability of the HABS for a T1D audience. The overall model fit of the CFA model was: $\chi^2(df) = 135.07(74), p < .001$; Comparative Fit Index = 0.96; Root Mean Square Error of Approximation [90% CI] = 0.05 [0.04 0.06], Standardized Root Mean Square Residual = 0.04. Internal consistency analyses using Cronbach's *alpha* demonstrated adequate reliability for each of the three subscales: Anxiety (5 items) = 0.71, Avoidance (4 items) = 0.75, and Confidence (5 items) = 0.80.

Each of the three subscale scores was calculated as the mean of the contributing items, ranging from 1.0 to 5.0. Mean subscale scores were: HABS Anxiety, 2.18 (0.79); HABS Avoidance, 2.67 (0.93); and HABS Confidence, 3.65 (0.77). Inter-correlations among subscales were low to moderate (r = ±0.24 to r = ±0.45), suggesting related, but distinct dimensions. Higher levels of HABS Avoidance were associated with younger age ($r = -0.20$, $p < .001$), poorer glycemic control (self-reported A1C; $r = 0.34$, $p < .001$) and higher BMI ($r = 0.20$, $p < .001$), while greater HABS Anxiety was associated only with higher A1C ($r = 0.15$, $p < .01$). Greater HABS Confidence was linked to more years of education ($r = 0.12$, $p < .05$), lower likelihood of pump use ($r = -0.12$, $p < .05$) and being male ($r = -0.11$, $p < .05$). Of note, there were no significant associations between the likelihood of RT-CGM use and any of the three HABS subscales.

3.3. Construct validity of the HABS for T1D

HABS subscales were significantly related to key psychosocial and clinical criterion variables (Table 3). Higher levels of HABS Anxiety and Avoidance were each associated with: poorer well-being (WHO-5), more symptoms of general anxiety (GAD-7), higher levels of diabetes distress (T1-DDS) and greater hypoglycemic fear (HFS-B and HFS-W) ($p < .05$ in all cases). Conversely, greater HABS Confidence was associated with: better well-being (WHO-5), fewer general anxiety symptoms (GAD-7), lower levels of diabetes distress (T1-DDS) and less hypoglycemic fear (HFS-B and HFS-W) ($p < .05$ in all cases). Finally, fewer hypoglycemic episodes (BG values <70 mg/dl) was linked to greater HABS Avoidance ($p < .001$) and greater HABS Confidence ($p < .05$), but was unrelated to HABS Anxiety. In total, these analyses suggest that the three factors originally established with a T2D population demonstrated sufficient concurrent validity and reliability for use with a T1D population.

3.4. The unique value of the three HABS subscales

Since the HFS-II has been a key measure in a majority of studies examining hypoglycemic fear over the decades, we examined whether the T1D HABS subscales might provide additional, unique utility. Using hierarchical multiple linear regression, demographics were entered in Level 1, the Worry and Behavior subscales of the HFS-II were entered in Level 2, and the three HABS subscales were entered in Level 3, with psychosocial variables, glycemic control and hypoglycemic events included as dependent variables in separate models.

After controlling for demographics and HFS-II, all three HABS subscales were significantly associated with one or more of the key outcome measures (Table 4). Furthermore, using similar controls, HFS-II, HABS Avoidance and Anxiety were each significantly linked to greater diabetes distress (T1-DDS, $p < .01$), but only HABS Anxiety was associated with more symptoms of general anxiety (GAD-7; $p < .01$). Furthermore, only HABS Confidence was significantly associated with greater well-being (WHO-5; $p < .05$). Regarding behaviorally relevant outcomes, both HABS Avoidance and HABS Confidence were

Table 3
Construct validity associations.

	WHO-5[a]	T1-DDS[b]	GAD-7[c]	HFS-B[d]	HFS-W[e]	BG < 70 past week
HABS Anxiety	−0.28***	0.52***	0.43***	0.60***	0.60***	−0.01**
HABS Confidence	0.28***	−0.41***	−0.28***	−0.42***	−0.52***	−0.13*
HABS Avoidance	−0.22***	0.45***	0.36***	0.44***	0.40***	−0.23***

[a] World Health Organization-5, assessing overall well-being.
[b] Diabetes Distress Scale for Adults with Type 1 Diabetes (T1-DDS).
[c] Generalized Anxiety Disorder Assessment.
[d] Hypoglycemic Fear Survey, Behavior subscale.
[e] Hypoglycemic Fear Survey, Worry subscale.
* $p < .05$.
** $p < .01$.
*** $p < .001$.

Table 4
Hierarchical regression analyses.

	WHO5[a]	T1-DDS[b]	GAD-7[c]	BG < 70 past week	HbA1c	BMI
	β	β	β	β	β	β
Level 2						
HFS-B[d]	−0.11	0.17**	0.13*	−0.07	0.11	−0.01
HFS-W[e]	−0.23***	0.54***	0.38***	0.11	0.12	0.09
Level 3						
HFS-B[d]	−0.05	0.06	0.01	0.00	0.05	−0.03
HFS-W[e]	−0.13	0.42***	0.27***	0.11	0.11	0.10
HABS Confidence	0.15*	−0.08	−0.04	−0.14*	0.07	0.03
HABS Avoidance	−0.00	0.14**	0.09	−0.30***	0.34***	0.22***
HABS Anxiety	−0.11	0.15**	0.20**	0.00	−0.07	−0.09
R^2 change Level 3	0.02*	0.04***	0.04***	0.08***	0.09***	0.03*
Total R^2 at Level 3	0.22	0.54	0.36	0.11	0.14	0.06

Note: Hierarchical multiple regressions included the following levels: Level 1 (not pictured) age, years since diagnosis, gender, and ethnicity (NHW vs. non-NHW); Level 2 HFS-B, HFS-W; Level 3 HABS Anxiety, HABS Confidence, and HABS Avoidance. Standardized beta coefficients are presented for continuous outcomes.

[a] World Health Organization-5, assessing overall well-being.
[b] Diabetes Distress Scale for Adults with Type 1 Diabetes (T1-DDS).
[c] Generalized Anxiety Disorder Assessment.
[d] Hypoglycemic Fear Survey, Behavior subscale.
[e] Hypoglycemic Fear Survey, Worry subscale.
* $p < .05$.
** $p < .01$.
*** $p < .001$.

significantly associated with fewer hypoglycemic episodes (BG values <70 mg/dl) ($p < .001$ and $p < .05$, respectively), but HABS Avoidance alone was linked to poorer glycemic control (self-reported A1C, $p < .001$) and higher BMI ($p < .01$). In sum, these findings point to the selective and clinically relevant utility of each of three subscales, independently from the broader assessment of hypoglycemic fear provided by the HFS-II.

4. Discussion

Originally developed for use with T2D adults, the current study suggests that the 14-item HABS demonstrates sufficient concurrent validity and reliability to be utilized with a T1D adult population. Confirmatory factor analysis substantiated that the HABS consists of the same three subscales in the T1D sample as were found in the original T2D study — HABS Anxiety, which targets common fears regarding hypoglycemia, HABS Avoidance, which focuses on common, typically unhealthy behaviors taken to avert the possibility of hypoglycemia, and HABS Confidence, which represents the individual's belief that they can stay safe from serious hypoglycemic problems. Although these three constructs most likely do not capture all of the nuances of hypoglycemic experience among T1D adults (because in part the items were originally based on data from a T2D population), they do capture additional meaningful elements of hypoglycemia experience that are relevant for a T1D population.

In this T1D sample, the HABS subscales were found to display significant and clinically relevant associations with critical psychosocial and disease outcomes even after adjusting for associations with participant demographics and the HFS-II, which suggests that the HABS subscales represent independent constructs that provide additional nuanced assessment of a patient's glycemic management. For example, both HABS Avoidance and Anxiety were associated with greater diabetes distress, even after adjustment for HFS-B and HFS-W, while HABS Confidence was linked to greater well-being. HABS Avoidance was the sole HABS subscale linked to greater BMI and poorer glycemic control, as might be expected from a group of items representing common unhealthy behavioral actions to avert hypoglycemia (e.g. overeating, running one's glucose levels higher than necessary). HABS Anxiety was the subscale independently associated with, higher levels of general anxiety, which also supports much older findings that high levels of trait anxiety contribute to hypoglycemic fear.[12] Finally, both HABS Avoidance and HABS Confidence, but not HABS Anxiety, were linked to fewer hypoglycemic episodes (BG values <70 mg/dl) during the past week. These findings suggest that interventions to reduce hypoglycemic risk might potentially enhance confidence (i.e., contributing to a greater sense of safety) and reduce avoidance behaviors, while not necessarily alleviating anxiety.[13,14]

Building on the work of Gonder-Frederick and her colleagues in the development of the HFS and HFS-II,[3,4] the first subscale of the HABS (Anxiety) was originally developed to capture significant fears and worries that would be obviously *unreasonable* (e.g., note the use of the word "terrified" in each item). This was seen as an important contrast with the HFS-II, where elevated scores on many of the HFS-II Worry subscale items (e.g., "worried about having a hypoglycemic episode while alone") might be construed as an understandable response that would not necessarily indicate fearfulness. The second subscale (Avoidance) focuses on unhealthy actions to avoid hypoglycemia that would not typically be interpreted as reasonable or appropriate responses. Again, this was designed to serve as a contrast with the HFS-II Behavior subscale, where elevated scores on many of the items (e.g., "reduced my insulin when my blood sugar was low") could be potentially seen as a quite sensible way of coping. Finally, the third scale (Confidence) describes a positive sense that hypoglycemia can be mastered (HABS Confidence). In the current study, each of the HABS subscales was found to be significantly linked to key outcomes in T1D adults, independent of the HFS-II scores. Given these findings, we see the HABS subscales as providing unique, nuanced information about hypoglycemic concerns, which may round out the broader perspective as assessed by the HFS-II. Consequently, we recommend examining the three HABS subscales separately, rather than focusing on the total HABS score.

Several study limitations need to be considered. First, the sample was highly educated and mostly Non-Hispanic White; and participants were heavy users of diabetes technology (72.4% were pump users, 63.2% were RT-CGM users); all of these factors may restrict generalizability. Second, height, weight, A1C, and glycemic control were all self-reported and the observed linkages between variables were cross-sectional, so these data should be viewed with some caution. It is noteworthy, however, that we have found close agreement between self-reported and laboratory assessed A1C ($r = 0.84$) in our previous studies with T1D adults.[15] Third, one item in the HABS anxiety subscale ("If I don't have plenty of emergency supplies with me, I won't leave my house") displayed significant but marginal factor linkages. We elected to maintain this item to enhance compatibility with the T2D HABS.

5. Conclusions

Our findings indicate that the HABS, though originally developed and validated in T2D adults, demonstrates sufficient concurrent validity and reliability for use with a T1D population. Furthermore, the HABS captures additional, important and unique elements of hypoglycemic worries and concerns among adults with T1D not reflected in the HFS-II, thus reflecting a more comprehensive picture or patient concerns and worries. The HABS is comprised of three subscales that can help to identify and target specific hypoglycemic concerns, thus potentially contributing to greater understanding and more targeted clinical interventions.

Declaration of competing interest

No author reported a conflict of interest. William Polonsky: consultant for Eli Lilly, Sanofi Diabetes Care, Dexcom, Roche Diabetes Care, Abbott Diabetes Care and Johnson & Johnson; Lawrence Fisher: consultant for Eli Lilly, Abbott Diabetes Care and Sanofi Diabetes Care; Danielle Hessler: consultant for Eli Lilly and Dexcom. Ludi Fan: employee and stockholder of Eli Lilly and Company.

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Author statement

WH Polonsky: Conceptualization, methodology, data analysis, writing.
L Fisher: Conceptualization, methodology, data analysis, writing.
D. Hessler: Conceptualization, methodology, data analysis, writing.
L Fan: Review and editing.
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