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ORIGINAL ARTICLE

Investigating Hypoglycemic Confidence in Type 1 and Type 2 Diabetes

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Abstract

Background: While research designed to understand the concerns about hypoglycemia among patients with diabetes has been primarily focused on the investigation of fear and anxiety, recent evidence suggests a potentially important and conceptually distinct element—hypoglycemic confidence. To investigate this dimension, we developed the Hypoglycemic Confidence Scale (HCS); herein, we describe the construction and validation of the HCS and examine how key patient factors are associated with hypoglycemic confidence.
Methods: Items were developed from interviews with six type 1 diabetes (T1D) adults, six insulin-using type 2 diabetes (T2D) adults, and seven diabetes healthcare professionals, resulting in nine self-report items. Separate exploratory factor analyses (EFAs) were conducted with T1D adults ($N = 326$), with T2D adults using both basal and prandial insulins (T2D-BP, $N = 145$) and with T2D adults using only basal insulin (T2D-BO, $N = 82$). Construct validity for the HCS was established with overall well-being (World Health Organization-5), diabetes distress (Diabetes Distress Scale), global anxiety (Generalized Anxiety Disorder), hypoglycemic fear (Hypoglycemic Fear Survey-II), and glycemic control (self-reported A1C). Hierarchical regression analyses examined the unique contribution of HCS scores, independent of hypoglycemic fear, on key psychosocial constructs and A1C.
Results: EFAs of the nine HCS items yielded a single factor solution for each of the three subject samples, accounting for 50.8%, 65.1%, and 73.7% of the variance for the T1D, T2D-BP, and T2D-BO groups, respectively. Construct validity was established by significant correlations with criterion variables. The HCS was associated with well-being and diabetes distress in the T1D (in both cases, $P < 0.001$) and T2D-BP groups (in both cases, $P < .05$) and for self-reported A1C in the T2D-BP group ($P < .05$) independent of hypoglycemic fear.
Conclusions: Hypoglycemic confidence is a unique dimension of patient experience, different from hypoglycemic fear, and is deserving of further study. The HCS is a reliable valid measure of hypoglycemic confidence for adults with T1D and insulin-using T2D.

Keywords: Hypoglycemia, Confidence, Type 1 diabetes, Type 2 diabetes.

Introduction

OVER THE PAST few decades, research designed to assess and understand the worries and concerns about hypoglycemia among patients with diabetes has been primarily focused on the investigation of fear and anxiety. Indeed, hypoglycemic fear has often been shown to be negatively associated with glycemic control and quality of life (QOL).[1,2] In parallel, efforts to intervene have been almost solely directed on reducing or alleviating such fear. At the heart of almost all of these studies lies the Hypoglycemic Fear Survey (HFS), a widely-used self-report scale developed by Gonder-Frederick[3] and later revised as the HFS-II.[4] The HFS and HFS-II are composed of two subscales, one focusing on hypoglycemia-related worries and the other on hypoglycemia-related avoidance behaviors. However, beyond these two well-recognized dimensions (worry/fear and behavioral avoidance), recent evidence

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suggests a potentially important (and conceptually distinct) third element—hypoglycemic confidence.[5]

The concept of hypoglycemic confidence encompasses a sense of personal strength and comfort derived from the belief that one has the necessary resources to stay safe from hypoglycemia-related problems; it can, therefore, be viewed as representing the positive side of hypoglycemic fear and avoidance.[6] Of course, the broad concept of confidence (or self-efficacy) in the healthcare setting should be a familiar one, since numerous studies, in diabetes and in other health conditions, have documented that perceived confidence in one's own knowledge and/or abilities can have a sizeable impact on self-care behavior and clinical outcomes.[7] Similarly, a recent cross-sectional study found that hypoglycemic confidence was significantly associated with better glycemic control among insulin-using patients with type 2 diabetes (T2D); of note, the link between hypoglycemic confidence and glycemic control was independent of hypoglycemia-related fear and anxiety, suggesting an independent role for hypoglycemic confidence.[5] Clinically speaking, it is evident how a focus on enhancing confidence may be of considerable value. As new medications and devices are developed that continue to lower the risk for severe hypoglycemic episodes, one key goal must be on helping the patient to feel safer and more confident, not just less anxious and less avoidant.

But how to understand and best assess hypoglycemic confidence? Little has been written on this topic and, while recently developed measures have included subscales that touch on this dimension, either directly (Hypoglycemic Attitudes and Behavior Scale [HABS], for T2D patients)[5] or indirectly (Type 1-Diabetes Distress Scale [T1-DDS], for patients with type 1 diabetes [T1D]),[6] no single measure has yet been developed to assess this specific dimension in a broad manner among T1D and T2D patients. The development and validation of a brief comprehensive scale to assess hypoglycemic confidence will better allow for a more comprehensive assessment of patient responses to diabetes treatments, including new medications and devices, which influence the risk for hypoglycemia. A clearer definition will also help target specific treatments and interventions. Therefore, we explored the concept of hypoglycemic confidence in qualitative interviews and, from these, developed the Hypoglycemic Confidence Scale (HCS). This report describes: (1) the construction, evaluation, and validation of the HCS; (2) the independent links between the HCS (above and beyond hypoglycemic fear) and key psychosocial and glycemic variables; and (3) how T1D and T2D patient characteristics are associated with hypoglycemic confidence.

Research Design and Methods

Following a careful review of the extant literature, we completed semistructured interviews with six T1D adults, six insulin-using T2D adults, and seven diabetes healthcare professionals. We recorded respondents' verbal descriptions of their thoughts about the concept of hypoglycemic confidence, views regarding their ability to manage diabetes, and how this was linked to their overall health and QOL. Content saturation was apparent after these sets of interviews, indicating no additional themes concerning hypoglycemic confidence. Patient descriptions were reviewed for duplication and were converted into an initial set of nine self-report items that focused on three areas: (1) broad sense of personal confidence (three items; e.g., confident that you can ''catch and respond to hypoglycemia before your blood sugars get too low''), (2) confidence in regards to staying safe from hypoglycemia during specific critical times (five items; e.g., when driving, when exercising, and when asleep), and (3) estimation of the partner's confidence (one item; i.e., ''your best guess about how confident your spouse or partner feels about your ability to avoid serious problems due to hypoglycemia''). This last item was included because many patients in the initial interviews indicated that their partner's sense of confidence heavily influenced their own, even though patient and partner were not always in complete agreement. The draft scale was formatted such that respondents could rate each item on a 4-point scale: 1 = ''not confident at all,'' 2 = ''a little confident,'' 3 = ''moderately confident,'' and 4 = ''very confident.'' The nine items were part of a larger, online assessment battery that included a set of previously validated instruments that were used to examine the construct validity of the new scale.

Separate samples of T1D adults, T2D adults using both basal and prandial insulins (T2D-BP), and T2D adults using only basal insulin (T2D-BO) were recruited from the Taking Control of Your Diabetes (TCOYD) Research Registry, an online platform of individuals recruited primarily from TCOYD's 1-day diabetes education events in the United States. Participants were required to be ≥21 years old, diagnosed with T1D or T2D ≥1 year, and taking insulin ≥1 year. Respondents were asked to complete a brief eligibility questionnaire, an informed consent, and the survey battery online. They received a $20 electronic gift card for participation. The research protocol was approved by Ethical and Independent Review Services, a community-based, institutional review board.

Measures

In addition to the nine items of the newly developed scale, the self-report battery examined demographic, psychosocial, and clinical status variables. *Demographic* measures included age, gender, ethnicity, education (years), type 1 versus type 2 diabetes, types of insulin currently being used (basal only vs. basal plus prandial), number of years since diagnosis, and body mass index (BMI, calculated from self-reported weight and height). *Psychosocial* measures included the World Health Organization-5 (WHO-5), a 5-item scale that assesses well-being ($\alpha = 0.86$)[8]; the 7-item Generalized Anxiety Disorder Assessment, a widely used measure of global anxiety ($\alpha = 0.92$)[9]; and the HFS-II, including both the behavior (HFS-B) ($\alpha = 0.88$) and worry subscales (HFS-W) ($\alpha = 0.95$).[4] In addition, T2D adults completed the Diabetes Distress Scale (DDS), ($\alpha = 0.95$),[10] while T1D adults completed the T1-DDS ($\alpha = 0.92$)[6]; both scales assess worries and concerns specifically related to diabetes and its management and have been shown to be good markers of diabetes-related QOL. *Clinical status* variables included average daily frequency of self-monitoring of blood glucose, last self-reported A1C value, and number of hypoglycemic readings (BG <70 mg/dL, with symptoms) during the past week.

Data analysis

Chi-square and analysis of variance tests with pairwise comparisons, as appropriate, were conducted to test for

differences in participant characteristics and outcome variables among all three patient groups: T1D, T2D-BP, and T2D-BO. Separate exploratory factor analyses (EFAs) with Promax rotation were conducted for each of the three samples to determine whether the HCS items could be reduced and grouped into a single coherent scale and/or meaningful subscales and to explore whether differences in response patterns might point to the need of separate instruments for each sample. Given that one HCS item, the partner perception item, was only relevant and completed by participants with a current partner, EFAs were then repeated with HCS items removing the partner item to evaluate the consistency of the factor structure. Construct validity was examined by Pearson correlations between HCS mean scores and the psychosocial variables, A1C, and number of hypoglycemic events during the past week. Hierarchical regression analyses examined the unique contribution of HCS scores, independent of hypoglycemic fear, on key psychosocial constructs and glycemic control.

Results

Clinical characteristics of the sample

Of the 579 respondents who began the survey, 553 (96%) completed the entire survey (T1Ds, $N=326$; T2D-BPs, $N=145$; T2D-BOs, $N=82$) (Table 1). As expected, compared to both T2D groups, the T1D group was significantly younger, composed of more Non-Hispanic Whites, reported a longer duration of diabetes, had lower BMI, lower A1C, reported more frequent blood glucose monitoring, and was more likely to have been using insulin pumps and/or continuous glucose monitors. Also as anticipated, the T1D group reported significantly more hypoglycemic events in the past week than either T2D group, while the T2D-BP group indicated significantly more events than the T2D-BO group.

Factor analysis of the HCS and an examination of its construct validity

EFAs of the nine HCS items yielded a single factor solution for each of the three subject samples, accounting for 50.8% of the common item variance for the T1D group, 65.1% for the T2D-BP group, and 73.7% for the T2D-BO group. Examination of the eigenvalues (≥1.0) and screen plots did not suggest the presence of additional underlying factors. All factor loadings for all three analyses were ≥0.50 and ranged from 0.55 to 0.92 (Table 2). Additional EFAs of the HCS items, after removing the item related to partner perception, resulted in the same one-dimensional factor structure with virtually identical factor loadings (not shown). The HCS demonstrated high internal consistency ($\alpha=0.87$ for T1D, 0.93 for T2D-BP, and 0.95 for T2D-BO). HCS scale scores were calculated as the sum total item score divided by the number of items completed (eight items for participants without a partner and nine for participants with a partner). Mean HCS scores for the three subject samples were: 3.06 ± 0.59 for the T1D group (62.7% scored ≥3.0), 3.09 ± 0.64 for the T2D-BP group (62.1% scored ≥3.0), and 3.05 ± 0.72 for the T2D-BO group (63.0% scored ≥3.0). There were no significant differences among the three groups.

Associations of HCS with Key Variables

Across the three subject samples, there were no consistent pattern of significant correlations between the mean HCS item score and any of the demographic variables, except for

Table 1. Sample Description By Group

	T1D (N = *326*)	*T2D-BP* (N = *145*)	*T2D-BO* (N = *82*)
Age	48.7 (14.8)[a]	60.1 (12.3)[b]	59.0 (11.1)[b]
Gender (female), *n* (%)	232 (71.2)	93 (64.1)	49 (59.8)
Education level (years)	16.2 (2.6)	15.8 (2.8)	15.6 (2.5)
Ethnicity, *n* (%)			
Asian or Pacific Islander	4 (1.2)[a]	14 (9.7)[b]	6 (7.3)[b]
African American	3 (0.9)[a]	13 (9.0)[b]	6 (7.3)[b]
Hispanic	15 (4.6)	9 (6.2)	4 (4.9)
Native American	7 (2.1)	1 (0.7)	3 (3.7)
Non-Hispanic White	278 (85.3)[a]	96 (66.2)[b]	50 (73.3)[b]
Multiple ethnic background	19 (5.8)	12 (8.3)	3 (3.7)
Partnered (married or living with partner), *n* (%)	227 (69.6)[a]	93 (64.1)[a,b]	45 (54.9)[b]
BMI	25.9 (5.5)[a]	35.4 (8.6)[b]	32.1 (8.2)[c]
Years since diagnosis	25.8 (14.9)[a]	17.6 (9.3)[b]	14.4 (9.6)[b]
Current insulin delivery system, *n* (%)			
MDI	90 (27.6)[a]	116 (80.0)[b]	79 (96.3)[c]
Pump	236 (72.4)[a]	29 (20.0)[b]	3 (3.7)[c]
Blood glucose monitoring (tests/day)	5.0 (2.1)[a]	3.5 (1.7)[b]	1.9 (1.3)[c]
HbA1c, *n* (%)	7.1 (1.1)[a]	7.7 (1.5)[b]	7.6 (1.1)[b]
No. of times blood glucose <70 in past week	4.5 (2.8)[a]	1.5 (2.0)[b]	0.8 (1.9)[c]

Superscript letters denote significant pairwise group comparisons ($P<0.05$). Means or percentages sharing the same superscript are not significantly different from one another. Means or percentages that have no superscript in common are significantly different from one another (LSD, $P<0.05$).

BMI, body mass index; LSD, least significant difference; MDI, multiple daily injections; T1D, type 1 diabetes; T2D, type 2 diabetes.

Table 2. Factor Loadings for Hypoglycemic Confidence Scale Items By Group

	T1D	*T2D-BP*	*T2D-BO*
How confident are you that you can stay safe from serious problems with hypoglycemia? When you are exercising?	0.621	0.796	0.885
How confident are you that you can stay safe from serious problems with hypoglycemia? When you are sleeping?	0.709	0.690	0.850
How confident are you that you can stay safe from serious problems with hypoglycemia? When you are driving?	0.693	0.841	0.918
How confident are you that you can stay safe from serious problems with hypoglycemia? When you are in social situations?	0.693	0.875	0.905
How confident are you that you can stay safe from serious problems with hypoglycemia? When you are alone?	0.803	0.904	0.924
In general, how confident are you that you can: avoid serious problems due to hypoglycemia?	0.781	0.869	0.913
In general, how confident are you that you can: catch and respond to hypoglycemia before your blood sugars get too low?	0.764	0.796	0.844
In general, how confident are you that you can: continue to do the things you really want to do in your life, despite the risks of hypoglycemia?	0.694	0.847	0.870
What is your best guess about how confident your spouse or partner feels about your ability to avoid serious problems due to hypoglycemia?	0.633	0.591	0.554

education level—greater years of education were associated with greater hypoglycemic confidence for all three samples ($r=0.15$ for T1D, $r=0.21$ T2-BP, $r=0.30$ T2-BO; in all cases, $P<0.05$). In support of the construct validity of the new measure, HCS scores were significantly and negatively linked with diabetes distress and hypoglycemic fear for all three patient groups. In addition, HCS scores were significantly and negatively linked with global anxiety and positively associated with well-being and lower A1C, but only for the T1D and T2D-BP groups (Table 3).

The independent value of the HCS

Given the centrality of hypoglycemic fear in previous studies, we investigated the potential independent contribution of hypoglycemic confidence on diabetes-related variables. In separate multiple regression equations for each patient group, demographics (age, gender, education level, years since diagnosis, ethnicity, and partnered status) were entered in step 1, HFS-W and HFS-B scores in step 2, and HCS scores in step 3, with well-being (WHO-5), diabetes distress, or self-reported A1C as dependent variables (Table 4). Hypoglycemic confidence reached statistical significance in the third step of the equation for well-being and diabetes distress in the T1D (in both cases, $P<0.001$) and T2D-BP groups (in both cases, $P<0.05$) and for self-reported A1C in the T2D-BP group ($P<0.05$). There were no significant findings for hypoglycemic confidence for the T2D-BO group.

Discussion

Hypoglycemic confidence represents the degree to which T1D and T2D patients feel able, secure, and comfortable regarding their ability to stay safe from hypoglycemic-related problems. It points to the importance of considering the potential influence of the positive aspects of patients' affective experience vis-a-vis hypoglycemia (e.g., confidence), not just the negative (e.g., fear). To investigate this concept, we developed the 9-item HCS, a unidimensional self-report tool, and herein documented its reliability and validity. Our results indicate that greater hypoglycemic confidence (higher HCS scores) is significantly associated with measures indicative of better diabetes-related QOL, including lower levels of diabetes distress and hypoglycemic fear (for all three patient groups), higher well-being, and lower levels of global anxiety (for the T1D and T2D-BP groups only). Higher HCS scores are also linked to lower self-reported A1C levels (again, for the T1D and T2D-BP groups only).

Overall, hypoglycemic confidence is relatively high across the three groups, with more than 50% of each group reporting a mean score ≥3, suggesting at least moderate confidence. Few significant demographic differences are apparent, indicating that the degree of hypoglycemic confidence is independent of age, gender, duration of diabetes, and diabetes type. The one exception is education level, with higher education significantly associated with higher HCS scores. It is possible, we surmise, that higher education level allows more easily for gathering the necessary

Table 3. Construct Validity Associations

	T1D	*T2D-BP*	*T2D-BO*
Well-being (WHO-5)	0.37***	0.35***	0.11
Diabetes distress[a]	–0.52***	–0.48***	–0.24*
Anxiety (GAD)	–0.34***	–0.33**	–0.08
Hypoglycemia behavior (HFS-B)	–0.45***	–0.53***	–0.41***
Hypoglycemia worry (HFS-W)	–0.59***	–0.52***	–0.31**
Self-reported HbA1c	–0.15**	–0.26**	0.04
Number of times blood glucose <70 in past week	–0.10	–0.01	–0.01

[a]For the T1D group, diabetes distress was assessed with the T1-DDS (6); for the T2D-BP and T2D-BO groups, diabetes distress was assessed with the DDS (10).

*$P<0.05$, **$P<0.01$, ***$P<0.001$.

DDS, Diabetes Distress Scale; GAD, Generalized Anxiety Disorder; HFS, Hypoglycemic Fear Survey, WHO, World Health Organization.

Table 4. Hierarchical Regression Analyses

	Well-being (WHO-5)			*Diabetes distress*[a]			*HbA1c*		
	T1D	*T2D-BP*	*T2D-BO*	*T1D*	*T2D-BP*	*T2D-BO*	*T1D*	*T2D-BP*	*T2D-BO*
	β	*β*	*β*	*β*	*β*	*β*	*β*	*β*	*β*
Step 2									
HFS-B	–0.09	–0.06	–0.16	0.15**	0.22*	0.38**	0.10	0.13	–0.05
HFS-W	–0.24***	–0.33**	–0.26	0.54***	0.45***	0.31*	0.11	0.10	0.17
Step 3									
HFS-B	–0.06	–0.02	–0.16	0.13*	0.17*	0.38**	0.09	0.06	0.00
HFS-W	–0.10	–0.28**	–0.26	0.44***	0.40***	0.31*	0.11	0.04	0.18
HCS	**0.26*** **	**0.16***	0.01	**–0.19*** **	**–0.16***	–0.01	–0.02	**–0.21***	0.13
R^2 change step 2	0.08***	0.12***	0.11**	0.39***	0.33***	0.29***	0.04**	0.04**	0.01
R^2 change step 3	0.04***	0.02*	0.00	0.02***	0.02*	0.00	0.00	0.03*	0.01
Total R^2 at step 3	0.26	0.27	0.29	0.53	0.48	0.51	0.07	0.10	0.10

Covariates entered at step 1 included: age, gender, education level, years since diagnosis, ethnicity (non-Hispanic White vs. other), and partnered status. At step 2, the two HFS scales were added. At step 3, the HCS was added to examine the unique contribution of the HCS above and beyond the HFS scales. HCS, Hypoglycemic Confidence Scale.

[a]For the T1D group, diabetes distress was assessed with the T1-DDS (6); for the T2D-BP and T2D-BO groups, diabetes distress was assessed with the DDS (10).

*$P<0.05$, **$P<0.01$, ***$P<0.001$.

Models in which HCS predicted additional significant variance appear in bold.

knowledge and skills to effectively utilize the available resources to manage hypoglycemia, thereby contributing to greater hypoglycemic confidence.

Although hypoglycemic confidence is significantly associated with hypoglycemic fear, our findings indicate that it also captures something unique. Feeling safe and confident is more than merely the absence of fear and worry; it conveys a sense that hypoglycemia can be, at least to some degree, tamed and managed. Indeed, we find that hypoglycemic confidence is independent of hypoglycemic fear in its association with well-being, diabetes distress (for the T1D and T2D-BP groups), and A1C (for the T2D-BP group only). Although there are no significant differences in the level of hypoglycemic confidence among the three patient groups, it is intriguing that the majority of the significant associations occur solely in the two groups using fast-acting insulin (T1D and T2D-BP). We suspect that the T2D-BO group stands apart because the risk and occurrence of severe hypoglycemia are substantially lower than for the two prandial-using groups[11] and the day-to-day concerns about hypoglycemia for this group are likely to be less prominent.

In total, these findings may have important implications regarding the study of patients' concerns and experiences with hypoglycemia and how treatment changes may affect those experiences. An effective change in treatment (e.g., a new medication or a real-time continuous glucose monitor) may help patients to gain, or regain, a sense of mastery and confidence over hypoglycemia (potentially leading to a broader impact on QOL), even though there may be little or no impact on reducing hypoglycemic fear—especially since some ongoing level of hypoglycemic fear may be typically warranted.[12] Furthermore, we find that hypoglycemic confidence, and not hypoglycemic fear, is linked to glycemic control (for the T2D-BP group), suggesting that intervening when hypoglycemic confidence is problematic may be key in helping patients to feel more willing and able to follow treatment recommendations. Of note, hypoglycemic confidence is also captured in one of the subscales of the HABS,[5] although that instrument has only been validated for T2D patients. We suggest that the HCS may be a better choice than the HABS in those cases where hypoglycemic confidence is the central focus of the intervention, where the investigators are interested in a more comprehensive overview of the elements contributing to hypoglycemic confidence, where a sample of T1Ds or a mixed sample of T1Ds and T2Ds are to be assessed, and/or where concerns about item response burden are critical (9 items in the HCS vs. 14 items in the HABS).

Several study limitations must be acknowledged. Although the study samples were large and diverse in many ways, the majority in each group was highly educated and mostly Non-Hispanic White, which may restrict generalizability. In addition, A1C and recent hypoglycemic history were assessed through self-report, and all data were cross-sectional; thus, any conclusions regarding causation must remain speculative. Of note, mean A1C's in our study samples (7.1%–7.7%) were not too dissimilar from the A1C mean value observed in the most recent National Health and Nutrition Examination Survey (NHANES) data (7.2%).[13] Indeed, we have found in our previous studies with T1D adults that there was close agreement between self-reported and laboratory assessed A1C ($r=0.84$).[14]

In summary, hypoglycemic confidence is a unique and important dimension of patient experience, different from hypoglycemic fear and worry, that is, deserving of further study. The newly developed HCS is a valid and reliable measure that may allow for greater understanding of this dimension and contribute to more potent clinical interventions.

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Authors' Contributions

Study conception/protocol: W.P. and L.F. Statistical analysis: D.H. Article development: W.P., L.F., D.H., and S.E. All authors read and approved the final article.

Author Disclosure Statement

Relevant competing interests: W.P. has worked as a consultant for Dexcom, Intarcia, Novo Nordisk, Lilly Diabetes, Astra Zeneca, Sanofi Diabetes, Roche Diabetes, Abbott Diabetes, and Johnson & Johnson. L.F. has worked as a consultant for Lilly Diabetes, Novo Nordisk, Dexcom, Sanofi Diabetes, and Abbott Diabetes. D.H. reports no competing interest. S.E. has worked as a consultant for Lilly, Sanofi, Dexcom, Abbott, Astra Zeneca, Johnson & Johnson, and Intarcia.

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