Toward Defining a Cutoff Score for Elevated Fear of Hypoglycemia on the Hypoglycemia Fear Survey Worry Subscale in Patients With Type 2 Diabetes

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OBJECTIVE

To determine a cutoff score for clinically meaningful fear of hypoglycemia (FoH) on the Hypoglycemia Fear Survey Worry subscale (HFS-W).

RESEARCH DESIGN AND METHODS

Data on the HFS-W, history of hypoglycemia, emotional well-being (World Health Organization-5 well-being index), and distress about diabetes symptoms (Diabetes Symptom Checklist–Revised) were available from Dutch patients with type 2 diabetes who were treated with oral medication or insulin (n = 1,530). Four criteria were applied to define a threshold for clinically meaningful FoH: *1*) modal score distribution (MD criterion), *2*) scores 2 SDs above the mean (SD criterion), *3*) concurrent validity with severe hypoglycemia and suboptimal well-being (CV criterion), and *4*) an elevated score (≥3) on more than one HFS-W item (elevated item endorsement [EI criterion]). Associations between the outcomes of these approaches and a history of severe hypoglycemia and suboptimal well-being were studied.

RESULTS

Of the 1,530 patients, 19% had a HFS-W score of 0 (MD criterion), and 5% reported elevated FoH (HFS-W ≥ mean + 2 SD; SD criterion). Patients with severe hypoglycemia reported higher HFS-W scores than those without (25 ± 20 vs. 15 ± 17; $P < 0.001$). Patients with suboptimal well-being reported higher HFS-W scores than those with satisfactory well-being (20 ± 18 vs. 13 ± 15; $P < 0.001$, CV criterion). Elevated FoH (defined by the EI criterion) was seen in 26% of patients. The SD and EI criteria were the strongest associated with history of severe hypoglycemia. The EI criterion was the strongest associated with suboptimal well-being.

CONCLUSIONS

Although no definite cutoff score has been determined, the EI criterion may be most indicative of clinically relevant FoH in this exploratory study. Further testing of the clinical relevance of this criterion is needed.

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Hypoglycemia is a common side effect of blood glucose–lowering therapies in both type 1 and type 2 diabetes (1). Hypoglycemia can invoke dangerous situations, is feared by many patients with diabetes, and is recognized as a key factor that can lead to failure to reach and maintain good glycemic control, especially in patients treated with insulin (1,2). Annual rates of hypoglycemia are estimated to be lower for patients with type 2 diabetes than for patients with type 1 diabetes, both for mild events (10.2 vs. 35.5 episodes/person/year) and severe events (0.7 vs. 1.1 episodes/person/year) (3,4).

Fear of hypoglycemia (FoH) is recognized as a problem that may not only hamper glycemic control but also can have a negative effect on a patient's quality of life (3,5). Concerns about hypoglycemia are among the most distressing aspects of living with diabetes among patients treated with insulin (6). To assess FoH, researchers have most often used the Hypoglycemia Fear Survey (HFS) (7). The HFS is well validated (7–9), has a long tradition in diabetes research, and is increasingly used in type 2 diabetes. The HFS comprises a Worry subscale and a Behavior subscale, with many studies using only the Worry subscale (HFS-W) (10), which was done in this study. The HFS-W includes items describing fear-provoking aspects of hypoglycemia scored on a 5-point Likert scale, ranging from 0 (never) to 4 (all the time), with higher scores indicating higher levels of fear. Of note, HFS-W scores are comparable between patients with type 1 diabetes and patients with type 2 diabetes who use insulin, and scores are only moderately lower in patients with type 2 diabetes who use sulphonylureas (8,11,12).

While a minimally important difference on the HFS-W has been established, a cutoff score for elevated (problematic) fear has not yet been determined, limiting the clinical utility of the measure and the ability to quantify the prevalence of elevated FoH. In previous research, HFS cutoff scores have been set somewhat arbitrarily. In one study, for example, the authors calculated the percentage of the maximum score achievable on the HFS-W and deemed any score >50% as indicative of FoH (13). The current exploratory study sought to empirically explore which HFS-W scores are clinically meaningful, give an indication of the prevalence of elevated FoH, and explore its potential links with the type of medication used (insulin vs. oral), hypoglycemic history, and key patient-reported outcomes. Toward this end we combined two data sets derived from two large observational studies carried out among Dutch patients with type 2 diabetes in primary and secondary care. Since there is no agreed-upon method to determine clinically significant FoH scores, four alternative approaches to define such a threshold were investigated in this exploratory study. First, distribution of modal HFS-W scores was examined to assess the frequency distribution of FoH in the study population. Second, elevated fear was defined as scores 2 SDs above the mean score. Third, the related concept validity of the HFS-W was examined by investigating its relationship with severe hypoglycemia and suboptimal well-being. A fourth approach was related to content: elevated FoH was defined as having an elevated rating (i.e., a score of 3 or 4) on one or more HFS-W item.

RESEARCH DESIGN AND METHODS

Study Design

We combined two data sets derived from two large observational studies carried out among patients with type 2 diabetes who were treated in Dutch primary and secondary care settings. The first study, the Study of the Psychological Impact in Real care of Initiating insulin glargine Treatment (SPIRIT), included 1,020 primary care patients who used only oral medications at baseline. Of these patients, 72% (n = 735) were taking sulphonylureas. The second study, Effect Study on Patient-Reported outcomes in Insulin glargine Treatment (ESPRIT) included 510 patients with type 2 diabetes from secondary care who used NPH insulin (n = 275, 54%), premixed insulin (n = 143, 28%), or insulin detemir (n = 92, 18%) at baseline. Both studies aimed to assess the effects of long-acting insulin on health-related quality of life, defined as emotional well-being, distress about diabetes symptoms, and FoH. Patients were invited to participate in the SPIRIT and ESPRIT studies by their primary or secondary care treating physician if there was a clinical necessity to initiate long-acting insulin. Both studies are described in more detail elsewhere (14,15). The present analyses used only baseline data collected before insulin initiation or intensification.

Measures

A background questionnaire was used to measure self-reported demographic and clinical data (age, sex, duration of diabetes), current medication regimen, and history of hypoglycemic episodes. There is evidence to show that recall of self-reported severe hypoglycemia correlates well with actual episodes (16). In this study, hypoglycemia was defined as blood glucose concentrations <3.9 mmol/L (<70.2 mg/dL) (3), whereas a severe hypoglycemic episode was defined as one in which the patient is so impaired that he or she is in need of assistance from another person (3). All other hypoglycemic episodes were defined as "symptomatic." A nocturnal hypoglycemic episode was defined as hypoglycemia that occurred during sleep. The most recent HbA_{1c} test result (≤3 months before the questionnaire was administered) was retrieved from the patients' medical charts.

FoH was measured using the Dutch version of the 13-item HFS-W, which has been shown to be reliable and valid (7). Each item asks how often patients worry about hypoglycemia-related situations, with responses rated on a 5-point Likert scale ranging from 0 (never) to 4 (all the time). To facilitate interpretation of the data, HFS-W total scores were transformed to a 0–100 scale, with higher scores indicating higher FoH. Cronbach α for the HFS-W was 0.91 in this study, confirming high internal consistency.

Distress about diabetes-related symptoms was measured using the revised version of the Diabetes Symptom Checklist (DSC-R), which has been shown to have good psychometric properties (17). The DSC-R consists of 34 items grouped into 8 symptom subscales: hyperglycemia, hypoglycemia, cognitive distress, fatigue, cardiovascular distress,

neuropathic pain, neuropathic sensibility, and ophthalmologic function (17). Each item asks about the presence of complaints (yes/no) and, if present, requests the patient score the level of "troublesomeness" of each item on a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely). For the DSC-R total distress score and DSC-R subscale scores, higher scores indicate higher symptom burden. Cronbach α of the DSC-R was 0.88 in this study.

The World Health Organization-5 Well-being Index (WHO-5) (18), a validated 5-item instrument, was used to assess general emotional well-being. The WHO-5 measures positive mood (good spirits, relaxation), vitality (being active, waking up fresh and rested), and general interest (being interested in things). Each item is rated on a 6-point Likert scale ranging from 0 (at no time) to 5 (all of the time). Item scores are summed to compute a total well-being score, with higher scores indicating better well-being. The commonly used WHO-5 cutoff score of 50 or lower was used to indicate suboptimal well-being (www.who5.org, accessed 11 July 2012). Cronbach α of the WHO-5 was 0.90 in this study. All total and subscale scores from the patient-reported outcomes were transformed to a score of 0–100 for data analysis.

Statistical Analysis

Descriptive statistics were used to compute mean HFS-W scores and SDs. Spearman correlations were calculated to examine the extent to which HFS-W scores correlated with WHO-5 scores, DSC-R total score, and DSC-R hypoglycemia scores.

When no gold standard is available, a commonly used approach to determine a scale cut point is to determine concurrent validity (CV). FoH has been consistently linked with more frequent episodes of severe hypoglycemia and increased depression and trait anxiety (19–22), so we hypothesized that FoH should be associated with having experienced at least one severe hypoglycemic episode and suboptimal well-being. This hypothesis was applied to all four approaches to determine a scale cutoff score: modal distribution (MD) criterion, SD criterion, CV criterion, and elevated item endorsement (EI) criterion.

Using the MD criterion, we examined the MD of HFS-W scores as a means to ascertain the frequency distribution of FoH in our population and identify any distinctive break point that might serve as an appropriate indication of elevated FoH. The SD criterion consisted of a classic statistical approach of determining elevated fear, which was considered with any score greater than 2 SDs above the mean HFS-W score. With the CV criterion, mean HFS-W total scores were calculated for patients who had experienced at least one severe hypoglycemic episode and for those with suboptimal well-being. The underlying assumption was that FoH is closely linked to these concepts and thus they may be indicative of clinically meaningful scores. In the final approach—the EI criterion—elevated FoH was operationalized as an elevated score (scoring 3 [often] or 4 [all the time]) on at least one HFS-W item. This approach was applied to identify individuals who, aside from their total HFS-W score, feel markedly worried about at least one aspect of FoH (23). In the last three approaches, Student *t* tests were used to examine statistical significance.

Mean HFS-W scores that resulted from the SD, CV, and EI criteria were added separately as independent variables in logistic regression analyses to predict history of severe hypoglycemia and suboptimal well-being (dependent variables). Variables with a right-skewed distribution (time since diagnosis and the number of symptomatic, nocturnal, and severe hypoglycemic episodes, as well as HFS-W and DSC-R scores, were transformed with a natural logarithm for the purpose of statistical testing).

Data were missing for 25% of patients on the HFS-W, 26% on the DSC-R, and 16% on the WHO-5. Missing data were imputed using multiple imputation, as imputation is recommended over complete case analysis and multiple imputation is currently recommended as the most robust technique for imputing missing data (24,25). Multiple imputation was conducted with an imputation model based on all available baseline data both within and between patients. Questionnaire data were imputed based on item scores. Five data sets were generated this way, and results from analyses were merged using rules for multiple imputation defined by Rubin (24). Analyses were carried out using STATA, version 10.0, with *P* values of <0.05 considered statistically significant.

RESULTS

Description of the Study Sample

Patient characteristics are described in Table 1. Across oral medication and insulin groups, the mean age of the population was 61 $\pm$ 11 years, 49% were female, mean duration of diabetes was 9 $\pm$ 7 years, and mean HbA_{1c} was 8.5 $\pm$ 1.5% (69 $\pm$ 17 mmol/mol). Half of the patients (50%) reported at least one symptomatic hypoglycemic episode during the past 3 months. For nocturnal and severe hypoglycemia, these percentages were 23 and 6%, respectively. The mean emotional well-being (WHO-5) score was 56 $\pm$ 25 and the mean symptom distress (DSC-R total) score was 16 $\pm$ 14, with most pronounced scores on the subdomains of fatigue (31 $\pm$ 28), hyperglycemia (19 $\pm$ 21), and cognitive distress (18 $\pm$ 20). The mean hypoglycemia fear (HFS-W) score for the total sample was 16 $\pm$ 17.

Compared with patients taking only oral medication, a considerably larger proportion of patients who used insulin reported at least one symptomatic (74 vs. 38%; $P < 0.001$), nocturnal (39 vs. 15%; $P < 0.001$), or severe hypoglycemic episode (11 vs. 4%; $P < 0.001$). Patients treated with insulin also had higher DSC-R ($P = 0.008$) and HFS-W scores ($P < 0.001$). There were no statistically significant differences in any study variables between patients who used sulphonylureas, which are associated with more frequent hypoglycemia, and those who used other oral blood glucose–lowering medications not associated with higher rates of hypoglycemia.

Patients who reported no hypoglycemic events during the past 3 months (48%) had lower HFS-W scores (12 $\pm$ 15 vs. 19 $\pm$ 18; $P < 0.001$) than those who had experienced at least one episode (52%).

Table 1—Characteristics of the study sample

	Total sample (n = 1,530)	Patients receiving insulin (n = 510)	Patients taking oral medication (n = 1,020)	P value
Age (years)	61 ± 11	59 ± 11	62 ± 11	<0.001
Female, %	49	50	49	0.588
Less education,%*	54	51	55	0.187
Time since diagnosis (years)	9 ± 7	12 ± 8	7 ± 5	<0.001
HbA_{1c} (%)	8.5 ± 1.5	8.5 ± 1.5	8.5 ± 1.6	0.646
HbA_{1c} (mmol/mol)	69 ± 17	69 ± 17	69 ± 18	0.646
Experience with hypoglycemia,%†				
Symptomatic	50	74	38	<0.001
Nocturnal	23	39	15	<0.001
Severe	6	11	4	<0.001
Patient-reported outcomes‡				
HFS-W score	16 ± 17	19 ± 18	14 ± 17	<0.001
WHO-5 score	56 ± 25	56 ± 23	57 ± 25	0.835
Suboptimal well-being (WHO-5 <50), %	37	38	36	0.520
DSC-R total score	16 ± 14	18 ± 15	16 ± 14	0.008

Data are mean ± SD unless otherwise indicated. *Primary education or lower general secondary education. †One or more self-reported episode during the past 3 months. ‡Scores range from 0 to 100.

HFS-W scores correlated significantly ($P < 0.001$) with WHO-5 ($r = -0.279$), DSC-R total ($r = 0.330$), and DSC-R hypoglycemia subscale scores ($r = 0.277$), all in the expected direction.

Evaluation of Four Approaches to Assess Elevated FoH

MD Criterion

Table 2 summarizes the comparisons across demographic, clinical, and patient-reported variables for each of the criterion scores. Examination of the MD of HFS-W scores revealed a noticeable distinction between those who scored 0 (19% of patients), suggesting no worries at all about hypoglycemia, and those who scored >0. There were, however, no other apparent breaks in the distribution beyond >0. As seen in Table 2, there were significant differences in age, sex, insulin use, hypoglycemic experiences (symptomatic, nocturnal, and severe), and patient-reported outcomes (DSC-R and WHO-5) between patients with and without elevated fear as derived by the MD criterion (HFS-W = 0 vs. HFS-W >0).

SD Criterion

The SD criterion (HFS-W ≥ mean + 2 SD; Table 2) identified 5% of patients as experiencing elevated FoH. There were significant differences in hypoglycemic experiences (symptomatic, nocturnal, and severe) and patient-reported outcomes (DSC-R and WHO-5) between those who met this criterion and those who did not. Demographic differences were not observed (Table 2).

CV Criterion

Using the CV criterion, we expected to find higher HFS-W total scores for patients who had experienced at least one severe hypoglycemic episode and those with suboptimal well-being. Indeed, patients who had experienced at least one severe hypoglycemic episode (6% of the sample) reported higher HFS-W scores than patients who had not (mean HFS-W score 25 ± 20 vs. 15 ± 17; $P < 0.001$). In addition, patients with suboptimal well-being (WHO-5 score <50) reported higher HFS-W scores than patients with satisfactory well-being (mean HFS-W score 21 ± 19 vs. 13 ± 15; $P < 0.001$). Using either of the two CV criteria, patients with and without CV-derived elevated fear differed significantly in age, sex, insulin use, hypoglycemic experiences (symptomatic, nocturnal, and severe), and patient-reported outcomes (DSC-R and WHO-5; Table 2)

EI Criterion

Using the EI criterion, 26% of patients scored 3 or 4 on at least one item of the HFS-W, indicating elevated FoH. Item analyses showed that there were no specific items that patients tended to rate high. Rather, high item endorsement was broadly distributed across the scale (data not shown). As seen in Table 2, age, sex, hypoglycemic experiences (symptomatic, nocturnal, and severe), and patient-reported outcomes (DSC-R and WHO-5) differed significantly between patients who met the EI criterion for elevated fear and those who did not.

Comparing the Four Criteria Approaches: Logistic Regression Analyses

Plausible cutoff scores on the HFS-W for FoH, derived from the SD, CV, and EI criteria, were separately added as independent variables in logistic regression analyses, with severe hypoglycemia and suboptimal well-being as dependent variables (Table 3). Mean HFS-W scores found in the CV criterion (HFS-W scores of 20 for those with suboptimal well-being and 25 for those who had experienced severe hypoglycemia) were the least strongly associated with severe hypoglycemia. HFS-W cut points derived from the SD (HFS ≥ mean + 2 SD) and EI (scoring ≥3 on one or more HFS-W item) criteria were the most strongly associated with having experienced severe hypoglycemia. In analyses with suboptimal well-being as a dependent variable, the discrepancy between HFS-W cut points was smaller, with the cut point derived from the EI criterion showing the strongest association.

CONCLUSIONS

The HFS-W is the most widely used tool for assessing FoH, but clinicians may find it difficult to make good use of the scale since a cutoff score has never been determined. Therefore, to enhance the clinical utility of the HFS-W, we sought to explore empirically what HFS-W scores might be clinically meaningful with the goal of providing an indication of the actual prevalence of FoH, and to explore how FoH is linked with the type of medication used (insulin vs. oral), hypoglycemic history, and key psychosocial attributes. To this end, four different criteria were examined to determine an acceptable cutoff value. For all criteria, patients who reported elevated levels of FoH more frequently

Table 2—Characteristics for patients meeting the four criteria* for clinically meaningful FoH

Criteria	Values		*P* value
MD criterion	HFS = 0	HFS >0	
Study sample, %	19	81	
Age (years)	63 ± 11	61 ± 11	0.011
Female, %	40	51	0.002
Time since diagnosis (years)	8 ± 7	9 ± 7	0.516
HbA_{1c} (%)	8.4 ± 1.6	8.5 ± 1.5	0.488
HbA_{1c} (mmol/mol)	68 ± 18	69 ± 17	0.488
Insulin use, %	24	36	<0.001
Experience with hypoglycemia, %†			
Symptomatic	31	55	<0.001
Nocturnal	14	25	<0.001
Severe	2	7	0.011
Episodes (symptomatic, nocturnal, and/or severe)	33	56	<0.001
Patient-reported outcomes‡			
HFS-W score	0	19 ± 17	<0.001
WHO-5 score	64 ± 25	55 ± 24	<0.001
DSC-R total score	12 ± 12	17 ± 15	<0.001
SD criterion	HFS-W < M+2SD	HFS ≥ M+2SD	
Study sample, %	95	5	
Age (years)	62 ± 11	58 ± 11	0.061
Female, %	49	56	0.258
Time since diagnosis (years)	9 ± 7	9 ± 7	0.774
HbA_{1c} (%)	8.5 ± 1.6	8.5 ± 1.4	0.781
HbA_{1c} (mmol/mol)	69 ± 17	69 ± 15	0.781
Insulin use, %	33	44	0.059
Experience with hypoglycemia, %†			
Symptomatic	49	63	0.055
Nocturnal	22	37	0.008
Severe	6	17	0.001
Episodes (symptomatic, nocturnal, and/or severe)	51	64	0.038
Patient-reported outcomes‡			
HFS-W score	13 ± 13	65 ± 11	<0.001
WHO-5 score	57 ± 24	45 ± 25	0.003
DSC-R total score	16 ± 14	29 ± 19	<0.001
CV criterion: suboptimal well-being	HFS-W <20	HFS-W ≥20	
Study sample, %	69	31	
Age (years)	62 ± 11	59 ± 11	<0.001
Female, %	46	56	<0.001
Time since diagnosis (years)	9 ± 7	9 ± 7	0.230
HbA_{1c} (%)	8.5 ± 1.5	8.5 ± 1.5	0.325
HbA_{1c} (mmol/mol)	69 ± 17	69 ± 17	0.325
Insulin use, %	30	40	<0.001
Experience with hypoglycemia, %†			
Symptomatic	43	66	<0.001
Nocturnal	18	34	<0.001
Severe	4	10	<0.001
Episodes (symptomatic, nocturnal, and/or severe)	45	67	<0.001
Patient-reported outcomes‡			
HFS-W score	6 ± 6	36 ± 16	<0.001
WHO-5 score	60 ± 24	48 ± 24	<0.001
DSC-R total score	13 ± 13	22 ± 16	<0.001
CV criterion: severe hypoglycemia	HFS-W <25	HFS-W ≥25	
Study sample, %	79	21	
Age (years)	62 ± 11	59 ± 11	<0.001
Female, %	47	57	<0.001
Time since diagnosis (years)	9 ± 7	8 ± 7	0.001

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used insulin, reported more hypoglycemic episodes, reported more distress about diabetes symptoms, and had lower emotional well-being.

The SD and EI criteria were most strongly associated with previous experience with severe hypoglycemia, suggesting superiority over the other two criteria given that severe hypoglycemia has been found to be one of the strongest predictors of FoH (19,21,26). Associations of the criteria with suboptimal well-being were less differentiated, yet the strongest association was found with the EI criterion. Of note, and perhaps unsurprisingly, the EI criterion classified more patients as having clinically meaningful FoH than the SD criterion (26 vs. 5%), even though both criteria showed similar associations with severe hypoglycemia. These observations may indicate that the SD criterion is too strict and may exclude patients who have clinically relevant FoH. From the point of sensitivity, this would favor the EI criterion, but further research is needed to explore the diagnostic utility (sensitivity and specificity) of both thresholds.

Adoption of the EI criterion means that an elevated score on a single HFS-W item could be enough to classify someone as having clinically relevant FoH. This parallels what occurs in many clinical practices: a patient indicating a significant worry about any aspect of hypoglycemia would (or at least should) signal that attention to this matter is likely to be of clinical importance.

The findings of this study should be interpreted as exploratory because these data are by no means ideal for establishing a definite cutoff score. A cutoff score for elevated or clinically meaningful FoH would preferably be determined by assessment of the HFS (both the Behavior and Worry subscales) in combination with a gold standard of some sort (although one does not yet exist, this might point to the need for a structured psychological interview approach). In addition, this would ideally be accompanied by detailed assessment of state and trait anxiety as well as patient behaviors to avoid and/or cope with hypoglycemia. It

Table 2—Continued

Criteria	Values		*P* value
HbA_{1c} (%)	8.5 ± 1.6	8.5 ± 1.5	0.405
HbA_{1c} (mmol/mol)	69 ± 18	69 ± 17	0.405
Insulin use, %	32	39	<0.001
Experience with hypoglycemia, %†			
Symptomatic	45	67	<0.001
Nocturnal	20	36	<0.001
Severe	5	11	<0.001
Episodes (symptomatic, nocturnal, and/or severe)	47	68	<0.001
Patient-reported outcomes‡			
HFS-W score	8 ± 8	43 ± 15	<0.001
WHO-5 score	60 ± 24	45 ± 24	<0.001
DSC-R total score	14 ± 13	25 ± 16	<0.001
EI endorsement criterion	0 items	≥1 items	
Study sample, %	74	26	
Age (years)	62 ± 11	60 ± 12	0.003
Female, %	47	55	0.010
Time since diagnosis (years)	9 ± 7	9 ± 7	0.852
HbA_{1c} (%)	8.5 ± 1.6	8.6 ± 1.6	0.035
HbA_{1c} (mmol/mol)	69 ± 17	70 ± 18	0.035
Insulin use, %	30	42	<0.001
Experience with hypoglycemia, %†			
Symptomatic	44	65	<0.001
Nocturnal	19	34	<0.001
Severe	4	12	<0.001
Episodes (symptomatic, nocturnal, and/or severe)	46	67	<0.001
Patient-reported outcomes‡			
HFS-W score	13 ± 13	35 ± 19	<0.001
WHO-5 score	57 ± 24	46 ± 25	<0.001
DSC-R total score	15 ± 14	23 ± 16	<0.001

Data are mean ± SD unless otherwise indicated. *These include the MD criterion (HFS-W >0), SD criterion (HFS-W ≥ mean + 2 SD[M+2SD]), CV criteria of suboptimal well-being (HFS-W ≥20) and severe hypoglycemia (HFS-W ≥25), and EI criterion (an elevated score on ≥1 HFS-W item (3 or 4 on the 5-point Likert scale). †One or more self-reported episode during the past 3 months. ‡Scores range from 0 to 100.

is also noteworthy that our sample was limited to patients with type 2 diabetes. Of those who were not using insulin, all were preparing to do so; thus it seems possible that patients taking oral medications and who have elevated FoH (and, perhaps, are unwilling to initiate insulin therapy) may have been underrepresented. However, a large sample of patients who used different treatment regimens in a naturalistic real-care setting was included in this analysis, and differences in terms of psychological variables were prominent between patients on different regimens. Furthermore, the proportion of patients with suboptimal well-being was not dissimilar from what has been reported earlier in patients with type 2 diabetes (27), indicating that our sample may not be unrepresentative of patients with type 2 diabetes in primary and secondary care in the Netherlands. The approaches we used could be applied to compare patients taking oral medications with patients who use insulin. We deemed this approach to be beyond the scope of this study and recommend it for future research.

Finally, it should be noted that data were missing in our study. However, participants with missing data did not differ from those without missing data on any of the studied variables, indicating that missing data were not selective. Furthermore, multiple imputation is a robust technique used to address this problem. Therefore, missing data are not expected to have a substantial influence on the overall results and conclusions in the study.

In summary, our findings suggest that an elevated score (≥3) on at least one HFS-W item may be a viable approach for determining elevated FoH in patients with type 2 diabetes. Using this criterion, at least one-quarter of patients with type 2 diabetes are experiencing significant FoH. Future research should help to corroborate our results in more diverse populations and using more comprehensive psychological evaluation approaches.

Table 3—Logistic regression analyses showing the association of SD, CV, and EI criteria with having experienced severe hypoglycemia and suboptimal well-being

Approach	Severe hypoglycemia	Suboptimal well-being (WHO-5 <50)
SD criterion (HFS-W cutoff of 50)	3.3 (1.6–6.9)	2.7 (1.6 – 4.6)
CV criteria		
Suboptimal well-being (HFS-W cut-off 20)	2.4 (1.6–3.8)	2.6 (2.0–3.3)
One or more episodes of severe hypoglycemia (HFS-W cutoff of 25)	2.5 (1.6–3.9)	2.8 (2.1–3.7)
EI criterion (scoring ≥3 on one or more HFS-W item)	3.2 (2.0–5.1)	3.0 (2.3–3.8)

Data are odds ratio (95% CI).

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