Assessing fear of hypoglycemia among adults with type 1 diabetes – psychometric properties of the Norwegian version of the Hypoglycemia Fear Survey II questionnaire

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ABSTRACT

Background: Hypoglycemia is common in type 1 diabetes, but the overall frequency of both mild and severe hypoglycemia is difficult to estimate. The Hypoglycemia Fear Survey II (HFS-II) is often used to assess the fear of hypoglycemia.

Material and methods: The aim of this study was to assess the psychometric properties of the Norwegian version of the HFS-II for adults, including the behavior (HFS-B) and worry (HFS-W) subscales, among 235 adults in Norway with type 1 diabetes. We assessed associations between HFS-II scores and other rating scales and demographic and clinical variables.

Results: The Norwegian version of HFS-II had an acceptable factor structure in relation to HFS-W, whereas the structure within HFS-B was more questionable. The expected relationships between HFS-II subscales and measures of related constructs administered concurrently demonstrated adequate convergent and discriminant validity. Internal consistency and test-retest reliability were satisfactory.

Conclusion: Access to reliable and valid self-report instruments enables the early detection of psychosocial problems. HFS-W performs well, whereas HFS-B needs to be further examined and developed.

INTRODUCTION

Hypoglycemia is common in type 1 diabetes, but the overall frequency of both mild and severe hypoglycemia is difficult to estimate (1). The estimates must be considered in relation to divergences in definition and methods in various studies and individual differences related to both recall of the number of episodes and the definition of the severity of the episodes reported by people with type 1 diabetes. Previous research shows that the reported frequency of mild hypoglycemia among adults with type 1 diabetes ranges from 8 to 160 episodes per person per year (1). Hypoglycemia can place the individual at risk of threatening and unpleasant situations physically and socially and can result in loss of consciousness and/or convulsions (2,3). Severe hypoglycemia is also reported to be the cause of death in some cases, although hypoglycemia is difficult to establish post-mortem (4-6). Hypoglycemia is often unpredictable and can occur during daytime as well as in the night. One consequence of the continuous risk of these unpleasant, unpredictable and potentially severe episodes is that many people with type 1 diabetes significantly fear hypoglycemia. Wild et al. (7) indicated that fear of hypoglycemia is an important limiting factor in managing type 1 diabetes and that identifying the fear of hypoglycemia among people with diabetes may be of great clinical importance.

A growing recognition of the importance of eliciting information from people's subjective perspective on their health and well-being has provided numerous self-report measures that complement objective biomedical tools (8,9). Standardizing measures to enable cross-cultural and international research collaboration is important to better understand the individual challenges facing people with diabetes. The Hypoglycemia Fear Survey (HFS) was developed in the United States in the early 1990s to assess the levels of fear related to hypoglycemia (10). The scale has been further developed during recent years (11) and is now available for use in many languages and countries. Instruments measuring the fear of hypoglycemia among adults with type 1 diabetes have not previously been available in Norwegian. The aim of this study was to examine the

psychometric properties of the Norwegian version of the HFS-II for adults by examining its content and construct validity (exploratory and confirmatory factor analysis and convergent and discriminant validity) and reliability (internal consistency and 4-week test-retest reliability) among adults in Norway with type 1 diabetes. We hypothesized negative associations between the HFS-II behavior (HFS-B) and worry (HFS-W) subscales and well-being (measured using the World Health Organization 5-item Well-Being Index (WHO-5)) and positive associations between HFS-B and HFS-W and symptoms of anxiety and depression (measured using the Hospital Anxiety and Depression Scale: HADS-A and HADS-D) and diabetes-related emotional distress (measured using the Diabetes Distress Scale (DDS)). Further, associations between HFS-II scores and demographic (age, sex, levels of education and body mass index (BMI)) and clinical variables (duration, insulin regimen and concentration of glycated hemoglobin (HbA_{1c}), frequency of blood glucose measurements per day and late complications) were investigated.

RESEARCH DESIGN AND METHODS

Study population

All 314 people with type 1 diabetes aged 18-69 years visiting an endocrinology outpatient clinic between October 2008 and February 2009 were invited to participate. A sample comprising 235 adults completed the HFS-II survey in addition to other generic and disease-specific questionnaires (response rate 75%). To examine the test-retest reliability, the patients visiting the outpatient clinic during the last 8 weeks of the data collection period received the survey for a second assessment by mail (response rate 41% (n=39)).

Demographic and clinical data

The following demographic variables were collected from the participants (Table 1): age, sex, levels of education (university, more than 4 years, up to 4 years, college/high school, primary school), height, weight, insulin regimen (1-3 injections per day, multi-injection regimen or insulin pumps) and blood glucose management (self-reported number of measurements per day). In addition, clinical information on the duration of diabetes, HbA_{1c} (using a DCA-2000 (Bayer, Elkhart, IN, USA)) and the presence of cardiovascular disease, nephropathy, retinopathy and neuropathy was collected from medical records.

Questionnaires

HFS-II has 33 items (Table 2) and two subscales: HFS-B and HFS-W (11). The items in HFS-B measure behavior to avoid hypoglycemia and its negative consequences (15 items). The items in HFS-W measure worries about hypoglycemia and its negative effects (18 items). The respondents rank the responses on a 5-point Likert scale from 0 (never) to 4 (always). Higher scores indicate increased fear of hypoglycemia. Both HFS-II subscales have demonstrated adequate psychometric properties in previous studies and have been translated into more than 20 languages (11). The scale was translated into Norwegian using a translation procedure recommended by WHO (www.who.int/substance_abuse/research_tools/translation/en) including 1) two bilingual professional forward-translators, 2) one bilingual native English-speaking translator to perform the back-translation and 3) approval of the back-translated version by the original developers at the University of Virginia. Moreover, meetings with experts in the field were conducted to agree about the final version and pilot testing among relevant people with type 1 diabetes to establish the satisfactory face validity of the scales.

We used measures of related constructs to examine construct validity (respectively the DDS, HADS and WHO-5 questionnaires). The DDS (12) assesses diabetes-related emotional distress. It is a 17-item scale comprising 4 subscales: emotional burden (EB) (5 items), physician-related distress (PD) (4 items), regimen distress (RD) (5 items) and diabetes-related interpersonal distress (ID) (3 items). The responses are

Table 1. Characteristics of 235 participants (aged 18-69 years) with type 1 diabetes.

Demographics, *n* (%)	
Women	100 (42.6)
Age, mean (SD)	39.4 (13.7)
Education, *n (%)* (*n* = 228)	
University, more than 4 years	30 (13.2)
University, up to 4 years	67 (29.4)
College/high school	104 (45.6)
Primary school, 9 years	27 (11.8)
Clinical, *n* (%)	
HbA_{1c}, % (SD)	8.1 (1.6)
Duration of diabetes, mean (SD)	18.9 (12.0)
BMI	25.8 (4.2)
Insulin regimen (*n* = 233)	
1-3 injections per day	22 (9.4)
Multi-injection treatment	149 (64.0)
Insulin pump treatment	62 (26.6)
Blood glucose management (*n* = 231)	
Less than once a week	15 (6.5)
Less than every day	39 (16.8)
1-3 times per day	81 (35.1)
4-6 times per day	72 (31.2)
7 or more times per day	24 (10.4)
Complications (*n* = 199-214)	
Cardiovascular disease	9 (4.2)
Nephropathy	25 (11.9)
Eye problems	52 (24.3)
Neuropathy	28 (13.7)
Other diseases or disabilities (*n* = 183)	38 (20.8)

Table 2. Forced 4- and 2-factor solutions for the HFS-II among 235 participants in Norway (aged 18-69 years) with type 1 diabetes.

HFS-II items Items 1-15 (HFS-B) Items 16-33 (HFS-W)	Forced 4-factor solution				Forced 2-factor solution	
	1	2	3	4	1	2
1. Ate large snacks	0.082	0.026	0.367	0.042	0.207	0.093
2. Tried to keep my blood sugar above 8 mmol/l (150mg/dl)	0.121	0.135	**0.595**	0.015	0.307	0.221
3. Reduced my insulin when my blood sugar was low	0.078	0.129	**0.422**	0.243	0.238	0.244
4. Measured my blood sugar six or more times a day	0.222	–0.007	0.277	0.122	0.317	0.067
5. Made sure I had someone with me when I go out	0.098	0.009	0.011	**0.572**	0.164	0.133
6. Limited my out-of-town travel	0.075	**0.663**	0.181	0.193	0.094	**0.725**
7. Limited driving (car, truck or bicycle)	0.189	**0.615**	0.128	0.244	0.193	**0.679**
8. Avoided visiting friends	0.283	**0.812**	0.135	–0.062	0.240	**0.757**
9. Stayed at home more than I liked	0.219	**0.788**	0.195	0.005	0.207	**0.779**
10. Limited my exercise/physical activity	0.251	**0.481**	0.039	0.109	0.218	**0.494**
11. Made sure there were other people around	0.104	0.252	0.013	**0.779**	0.192	0.365
12. Avoided sex	0.127	**0.401**	–0.003	0.059	0.089	0.**400**
13. Kept my blood sugar higher than usual in social situations	0.340	0.192	**0.712**	–0.035	**0.528**	0.287
14. Kept my blood sugar higher than usual when doing important tasks	0.366	0.116	**0.768**	–0.079	**0.564**	0.221
15. Had people check on me several times during the day or night	0.201	0.186	0.177	**0.452**	0.289	0.302
16. Not recognizing/realizing I was having low blood glucose	**0.536**	0.131	0.209	–0.005	**0.557**	0.159
17. Not having food, fruit or juice available	**0.436**	0.135	0.224	–0.053	**0.462**	0.154
18. Passing out in public	**0.608**	0.134	0.233	0.211	**0.661**	0.213
19. Embarrassing myself or my friends in a social situation	**0.668**	0.163	0.277	0.069	**0.710**	0.215
20. Having a hypoglycemic episode while alone	**0.559**	0.167	0.235	0.276	**0.619**	0.262
21. Appearing stupid or drunk	**0.733**	0.202	0.198	0.041	**0.734**	0.233
22. Losing control	**0.766**	0.151	0.286	0.110	**0.813**	0.213
23. No one being around to help me during a hypoglycemic episode	**0.551**	0.086	0.207	0.357	**0.616**	0.200
24. Having a hypoglycemic episode while driving	**0.657**	0.152	0.183	0.121	**0.674**	0.203
25. Making a mistake or having an accident	**0.716**	0.235	0.099	0.094	**0.685**	0.264
26. Getting a bad evaluation or being criticized	**0.677**	0.207	0.129	–0.006	**0.650**	0.217
27. Difficulty thinking clearly when responsible for others	**0.741**	0.102	0.083	0.194	**0.726**	0.157
28. Feeling lightheaded or dizzy	**0.430**	0.212	0.242	0.109	**0.480**	0.267
29. Accidentally injuring myself or others	**0.698**	0.118	0.047	0.182	**0.670**	0.164
30. Permanent injury or damage to my health or body	**0.599**	0.210	0.098	0.201	**0.593**	0.265
31. Low blood sugar interfering with important things I was doing	**0.694**	0.155	0.357	0.058	**0.761**	0.220
32. Becoming hypoglycemic during sleep	0.366	0.038	0.363	0.285	**0.495**	0.162
33. Getting emotionally upset and difficult to deal with	**0.612**	0.207	0.061	0.050	**0.573**	0.220

Bold: ≥0.4.

rated on a 6-point Likert scale from 1 (not a problem) to 6 (a serious problem). Higher scores indicate greater emotional distress. The Norwegian version of DDS has been shown to have good psychometric properties (13).

The HADS elicits general feelings of anxiety and depression during the past week (14-16). The two subscales comprise 7 items measuring symptoms of anxiety (HADS-A) and 7 items measuring symptoms of depression (HADS-D). The responses are rated on a 4-point Likert scale from 0 (not a problem) to 3 (a serious problem). Higher scores indicate more symptoms of anxiety and depression. HADS has good psychometric properties and is widely used across various populations and countries and among people with diabetes (17,18).

We used WHO-5 (www.who-5.org) to assess general well-being during the past 2 weeks. WHO-5 comprises 5 items rated on a 6-point Likert scale graded from 0 (at no time) to 5 (all the time). Higher scores indicate better perceived well-being. WHO-5 is widely used in various populations and among people with diabetes, such as in the recently DAWN2 release (www.dawnstudy.com).

Ethical considerations

The Western Norway Regional Committee on Medical and Health Research Ethics approved the study, which was performed according to the Declaration of Helsinki (Ref. no. 19580/865). Informed consent was obtained for each participant.

Statistical analysis

We performed descriptive statistics with proportion, mean (SD) and median on continuous and categorical variables as appropriate. We investigated the factor structure of HFS-II by using exploratory factor analy-

sis using principal axis factoring and varimax rotation. We used the eigenvalue ≥1 criterion, supplemented with judgment based on inspection of the scree plot, to determine the number of factors. We did not allocate items with all loadings below 0.4 or more than one loading at least 0.4, in absolute value, to any factor. We also considered forced two-factor solutions as described by the developers (11). We conducted maximum likelihood confirmatory factor analysis to test for fit of a priori-defined models and the model from the explorative factor analysis. The model fit was based on root mean square error of approximation (RMSEA; preferably less than 0.08), comparative fit index (CFI; preferably at least 0.95 and Tucker-Lewis index (TLI; preferably at least 0.95). In case of moderately inferior model fit, we conducted exploratory post hoc investigations in complete cases, by the few most indicated model modifications. We based the sum scale computations on the mean of answered items if at least 50% of the items in a scale were answered (19).

We assessed convergent validity by Pearson correlations to examine the relationships between HFS-II scores and DDS, HADS-A, HADS-D and WHO-5. We assessed discriminant validity by using exact Mann-Whitney *U*-tests to test for the differences between women and men, between people with and without long-term diabetes complications (cardiovascular disease, nephropathy, retinopathy or neuropathy), and between people on continuous subcutaneous insulin infusion (CSII) versus insulin injections. We used Kruskal Wallis test to test for the differences between 1-3 injections per day, multi-injection regimen or insulin pumps and, the differences between levels of education. We explored the relationships between the HFS-II subscale scores and age, duration of diabetes, BMI, HbA_{1c} and self-reported frequency of blood glucose measurements per day by Pearson correlations.

We used Cronbach's alpha to determine the internal consistency for HFS-II total scores and the HFS-B and HFS-W subscales. Values ≥0.70 are regarded as satisfactory (19). We examined 4-week test-retest reliability by intraclass correlation coefficients. We used SPSS version 20.0 and AMOS for Windows (IBM SPSS, Armonk, NY, USA). We defined statistical significance as $P < 0.05$.

RESULTS

The study included 235 adults in Norway with type 1 diabetes, mean age 39.4 years (13.7) and 100 women and 135 men. The 79 nonparticipants did not differ significantly in mean age (39.4 versus 37.9 years, P=0.39), sex (female 100 vs 26 and male 135 vs 53, P=0.13) and HbA_{1c} (8.1% versus 8.4%, P=0.23).

Construct validity

Exploratory factor analysis for HFS-II yielded a 7-factor solution. However, the scree-plot rather indicated a 4-factor solution. These results are presented in Table 2 together with the 2-factor solution as originally demonstrated by the developers (11,20). HFS-W was generally reproduced in both the 2-factor and 4-factor solutions (Table 2). No one-dimensional behavior scale was reproduced. The structure of the behavior items was more interpretable in the 4-factor solution with only two items unclassified. The remaining behavior items were split into three factors: one factor related to "blood glucose-regulating behavior" (items 2, 3, 13 and 14), one "avoidance behavior" factor (items 6, 7, 8, 9, 10 and 12) and one "seeking support from others" factor (items 5, 11 and 15). All factor loadings in confirmatory factor analysis were significant and positive (HFS-B, 0.94-2.40, HFS-W 0.83-1.65). The fit indices were CFI = 0.75, TLI = 0.72 and RMSEA = 0.088, whereas the 4-factor solution found in our exploratory factor analysis had somewhat better fit (CFI = 0.87, TLI = 0.85 and RMSEA = 0.066).

Most respondents answered the questions in the HFS-II well. One respondent answered no HFS-II items and was excluded from all HFS-II analysis. One further respondent answered only behavior items, and thus two respondents were excluded from analysis of HFS-W. All others (99.1%) completed at least half the items in both subscales.

Convergent validity

The HFS-B and HFS-W were moderately positively correlated with DDS total scale, DDS EB subscale and HADS-A (r = 0.51 to 0.59) and less positively related to other DDS subscales (PD and RD) (r = 0.30 to 0.38) (Table 3). The HFS-II subscales were significant but weakly positively associated with HADS-D (r = 0.24 to 0.27). We found a negative relationship with WHO-5 (r = 0.24 to 0.30) such that higher levels of perceived well-being were related to less behavior to avoid hypoglycemia and less worrying.

Discriminant validity

Women scored higher than men on both HFS-B ($P < 0.001$) and HFS-W ($P < 0.001$), people with nephropathy scored higher than people without nephropathy on both HFS-B ($P = 0.01$) and HFS-W ($P = 0.04$), and people with neuropathy scored higher on HFS-B than people without neuropathy ($P = 0.001$). We identified no significant differences between people on CSII versus insulin injections, however, mean HFS-W scores among people using 1-3 injections (n=22) were significantly lower compared to people on CSII or multi-injection regimen ($P = 0.023$). HFS-B and HFS-W were statistically significantly but weakly correlated with the self-reported frequency of blood glucose management (r = 0.16 and 0.26, respectively). We identified no significant correlations for age, metabolic control (HbA_{1c}), duration of diabetes or BMI (Table 3), nor significant associations with levels of education.

Reliability

Cronbach's alpha was 0.90 for HFS-II total score, 0.92 for HFS-B and 0.87 for HFS-W. Test-retest reliability

Table 3. Pearson correlation coefficients for HFS-II subscales with demographic and clinical variables and other self-report questionnaires measuring similar constructs for 235 participants (aged 18-69 years) with type 1 diabetes.

	HFS-II	
	HFS-W	HFS-B
Age	–0.04	0.06
HbA_{1c}	–0.02	0.00
Duration	–0.01	–0.004
BMI	–0.13	–0.04
Blood glucose management	0.16*	0.26**
WHO–5[a]	–0.30**	–0.24**
DDS[b,c]		
EB	0.55**	0.55**
PD	0.34**	0.35**
RD	0.34**	0.30**
ID	0.44**	0.40**
HADS scales[a]		
HADS-A	0.43**	0.42**
HADS-D	0.26**	0.24**

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

[a] Higher scores indicate greater greater anxiety and depression and better general well-being.

[b] Higher scores indicate more emotional distress.

[c] DDS subdimensions: emotional burden (EB), physician-related distress (PD), regimen distress (RD) and diabetes-related interpersonal distress (ID).

was high. The intraclass correlation coefficients were 0.77 for HFS-B, 0.84 for HFS-W and 0.82 for HFS-II total score.

DISCUSSION

The Norwegian version of HFS-II had an acceptable factor structure in relation to HFS-W, whereas the structure within HFS-B was more questionable. The expected relationships between HFS-II subscales and other measures of related constructs administered concurrently demonstrated adequate validity. Internal consistency and test-retest reliability were satisfactory.

HFS-W has also previously demonstrated a stable structure and has been frequently used alone in previous research (7). The factor structure of HFS-B was not consistent with that of the original version of the developers (11), and caution is needed in interpreting the results. A similar finding was shown in a study in Sweden, which yielded a 3-factor solution for HFS in a population of 324 adults with type 1 diabetes (21). Similarly, two distinct aspects of behavior; actions to reduce hypoglycemic risk by keeping blood glucose levels high, and actions to prevent hypoglycemia have been demonstrated in a large study with respondents from a total of nine studies in five countries (22). These findings suggest further studies in larger populations and across settings to examine the theoretical underpinning of HFS-B. It might be questioned whether some HFS-B items instead describe appropriate behavior to avoid hypoglycemia and not inappropriate behavior related to fear. For example, individuals performing numerous blood glucose measurements (item 4, Table 2) might instead be motivated by an appropriate interest maintaining "near normal" blood glucose level than experiences of fear. Frequent blood glucose measurements have been associated with improved glycemic control (7) and may enable more flexible daily living and greater freedom in choice of food and other activities. Accordingly, further investigation into the behavioral subscale of the HFS-II is needed. An initiative to pool data from several studies from different populations has been taken in order to use aggregated samples of data in further analysis (22). The developers might consider both adjusting some items and shortening of the scale.

As anticipated, we demonstrated the convergent validity of HFS-II by a stronger positive relationship between HFS-II subscale scores and the DDS EB subscale and ID subscale and with symptoms of anxiety measured by HADS-A. Further, the weaker positive relationship between HFS-II subscales and HADS-D scores is consistent with the purpose of HFS-II in assessing levels of fear related to hypoglycemia. The significant negative relationship with general well-being (WHO-5) also strengthens the anticipated validity of HFS-II. Living with diabetes often confronts people with stressors and demands interfering with daily life. Poor diabetes self-management and lack of treatment can lead to serious complications and lower quality of life (23,24).

We found no significant associations between HFS-II subscales and HbA_{1c}, suggesting that HFS-II subscales may not differentiate between levels of glycemic control. Further, previous research has demonstrated inconsistency related to the association between fear of hypoglycemia and glycemic control (7). The mental mechanisms associated with barriers to diabetes management and the role of fear of hypoglycemia need to be better understood. The behavior contributing to poor glycemic control needs to be recognized to develop adequate strategies and support programs for people with type 1 diabetes. Numerous studies have demonstrated less favorable levels of emotional and psychosocial problems among women than among men using various self-report questionnaires (11,21), as this study also found.

Strengths and limitations

The participants in this study were people in Norway scheduled for outpatient consultations, and not a population-based sample which should be taken into account when interpreting the results. Furthermore, the sample might not be representative for individuals in other cultures and settings of care. Nevertheless, our intent was to investigate whether the factors displayed from the factor analysis supported the construct of the scale, and to analyze relationships between the fear of hypoglycemia and related constructs, demographic and clinical variables and not to estimate population values per se. Further, we could not investigate the relation-

ships between the fear of hypoglycemia and the frequency of previous hypoglycemic episodes since we did not collect such data. Finally, our estimate of test-retest stability is based on a rather small group of people (39 respondents). Another limitation is the cross-sectional design of this study, which did not enable testing for responsiveness to changes. To get the most out of self-reported data, more evidence is needed to demonstrate that such data have sufficient sensitivity to detect change when change is present.

CONCLUSION

Access to reliable and valid self-report instruments enables the early detection of psychosocial problems. Identifying people with type 1 diabetes with high levels of fear of hypoglycemia seems essential to avoid emotional problems and the negative effects of hypoglycemia on self-management behavior. HFS-W performs well, whereas HFS-B needs to be further examined and developed. The scales might best be reported separately (HFS-B and HFS-W) and not as a common HFS-II total score.

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Author contributions

MG designed the study, carried out the data collection and data analysis and drafted the manuscript. BR, AH and MMI contributed to designing the study and drafting the manuscript. TWL assisted in the statistical analysis and contributed to the final manuscript. All authors read and approved the final manuscript.

Competing interests

We declare no competing interests.

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