

BMJ Open How to identify clinically significant diabetes distress using the Problem Areas in Diabetes (PAID) scale in adults with diabetes treated in primary or secondary care? Evidence for new cut points based on latent class analyses

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ABSTRACT

Introduction The Problem Areas of Diabetes (PAID) questionnaire is a frequently used measure to assess diabetes-distress. The aim of this study was to identify clinically meaningful levels of diabetes-distress, using latent class analyses (LCA), and to determine which groups were at increased risk of elevated diabetes-distress in terms of sex, age, type of diabetes and glycaemic control.

Methods Data were derived from four studies (total N=2966, 49% female, age range 18–95 years, 43% type 1 diabetes, diabetes duration range 0–79 years). LCAs were performed to examine possible latent groups in the distribution of answers on the individual PAID items. Demographic and diabetes-related characteristics were added to the model to estimate their effects on latent class membership and receiver operating curves to determine cut-offs.

Results Three levels of diabetes distress were distinguished with defined cut-off scores and labelled as: low, moderate and high diabetes distress. Levels of distress did not associate with distinct clusters of items. Older people were more likely to be part of the low distress class; women and people with high HbA_{1c} were more likely to be part of the high distress class. Sensitivity and specificity of the commonly used cut-off of 40 for high distress are 0.95 and 0.97, respectively. To distinguish the moderate distress group, cut-off scores of 17 and 39 are optimal with a sensitivity of 0.93 and a specificity of 0.94.

Conclusion Three levels of diabetes-distress can be distinguished: low, moderate and high diabetes distress. Younger people, women and people with poor glycaemic control are at an increased risk for high levels of distress. A cut-off of 40 is satisfactory to detect people with high levels of diabetes-distress; a score of 0–16 indicates low diabetes distress and a score of 17–39 moderate diabetes distress.

INTRODUCTION

High levels of diabetes-specific emotional distress (or diabetes-distress) are common, affecting 10%–30% of people with type 1

Strengths and limitations of this study

- Data from international samples of adults with type 1 or type 2 diabetes were pooled into a large dataset (N=2966).
- Latent class analysis was used, which is a model-based approach with the advantage that the choice of the cluster criterion is less arbitrary compared with cluster analysis and the approach includes rigorous statistical tests.
- By merging data from different studies we faced incomplete data on education level and complications in some studies, that could therefore not be included in the current analyses.

and type 2 diabetes^{1–3} and are associated with poor glycaemic control.^{3–5} The construct of diabetes distress is clearly distinct from depression, and refers to the worries and negative emotions specifically related to the experience of living with and self-managing diabetes and its complications.³ The prevalence of diabetes distress varies greatly across different populations of people with diabetes. Higher distress has been associated with female gender, younger age and shorter diabetes duration, both in people with type 1 and type 2 diabetes.^{6,7} People with a lack of a social network are more likely to experience diabetes distress.⁷ Furthermore, studies have shown an association between ethnicity and diabetes distress.⁷ In terms of self-management and diabetes outcomes, diabetes distress is consistently associated with lower levels of self-care and a modest association with higher HbA_{1c} values.⁶

The Problem Areas of Diabetes (PAID) scale is a widely used and validated self-report measure of diabetes distress, originally

developed in the USA by Polonsky *et al*⁸ and translated in at least 15 languages.^{8–11} The PAID contains 20 items asking about problem areas, such as not having clear goals for the diabetes management and worrying about complications, and is suitable for use in both clinical and research settings among individuals with type 1 or type 2 diabetes.¹² The PAID has shown to be a psychometrically valid with demonstrated sensitive to change, speaking to its clinical utility.¹³ Factor analysis confirmed its unidimensional structure,¹³ although factor analysis extracted four subdomains: emotional distress, food-related distress, social distress and treatment related distress.¹¹ Most commonly, the PAID total score is used as a continuous measure of distress with higher scores indicating higher levels of distress. Elevated diabetes distress is arbitrarily defined as a total score of ≥ 40 which roughly equates to 1 SD above the mean.^{4 14} Use of a cut-off can help identify ‘caseness’ areas,¹⁵ but persons with similar total scores may have different profiles in terms of their specific problem areas definition of severe/clinically relevant distress (with characterising symptoms or diagnostic criteria) of DD has not yet been established.⁹ Latent class analysis (LCA) can be used to identify different PAID item clusters and profiles, that is, patient groups based on their item responses.¹⁶ We sought to empirically test whether meaningful levels of diabetes distress can be identified, based on individual PAID item responses using LCA, and whether these levels of distress associate with different item profiles and patient characteristics.

MATERIAL AND METHODS

We pooled data from four studies,^{4 17–19} where adults with type 1 or type 2 diabetes had completed the PAID, along with demographics and clinical characteristics (for details, see online supplemental table S1). A short description of each study is provided below.

Patient and public involvement

People with diabetes were not involved in the development of the research question and design of the current study. In the development of the PAID as well as in the design and conduct of the individual studies, people with diabetes were involved in several ways.^{4 8 17–19} The results of this study will not be disseminated to the participants of the original studies but the results can be translated to (inter)national guidelines as well as to clinical care, thereby reaching the people with diabetes.

Studies

DAWN MIND – Snoek *et al*

Several diabetes centres from a total of eight countries participated in the observational DAWN MIND study, which aimed at implementing computer-assisted assessment and discussion of emotional well-being as part of the annual diabetes review and evaluate its impact. Participants lived in Croatia (n=200), Denmark (n=202), Germany (n=248), Ireland (n=124), Israel (n=288),

the Netherlands (n=312), Poland (n=89) and the UK (n=104), which resulted in a total of 1567 participants.⁴ All adults (age ≥ 18 years) with type 1 or type 2 diabetes were eligible, unless they were unable to read or complete questionnaires on the computer.

Diabetergestemd - van Bastelaar *et al*

The participants in a randomised waitlist-controlled trial testing the effectiveness of a web-based depression intervention were recruited in the Netherlands via advertisement in (outpatient) clinics, patient journals and websites.¹⁷ Inclusion criteria were: a score of ≥ 16 on the Centre for Epidemiological Studies Depression scale (CES-D), having an email address and access to the internet. Exclusion criteria were a self-reported history of suicide attempt(s) or current suicidal ideation, bipolar depression or psychotic disorder, pregnancy and recent loss of a significant other (<6 months ago). In this study, baseline data from 273 participants were used.

Mental health survey - de Wit *et al*

In this cross-sectional study, the aim was to examine mental health (care) in patients with one or more complications in an online survey.¹⁸ Inclusion criteria were: age ≥ 18 years; type 1 or type 2 diabetes; having at least one diabetes-related complication; being able to read and understand Dutch. For this study, data of the baseline assessment of 213 participants were used.

Screening study – Pouwer *et al*

This study aimed to test the added value of an active depression screening in diabetes care, using a stepped, mail-based screening procedure informing both patient and the treating physician, compared with care as usual. Participants were recruited in three Dutch diabetes outpatient clinics.¹⁹ Inclusion criteria were: adult (≥ 18 years); outpatient with established diabetes (type 1 or type 2); and elevated depressive symptoms (CES-D score of 16 or more). Exclusion criteria were: not being able to read Dutch; a history of suicide attempt(s); a history of hospital admission for depression; and a history of electroconvulsive therapy for depression. In this study, baseline data from 913 participants were used.

Measure

The total PAID score is calculated by summing item scores $\times 1,25$ resulting in 0–100 score, where a score ≥ 40 has been suggested as cut-off for of high diabetes distress.¹¹ Cronbach’s alpha within the whole sample was 0.94.

Statistical analyses

Data from persons in the afore mentioned studies who had completed all 20 items on the PAID were eligible for inclusion in the current analysis. In the DAWN MIND study, diabetes duration was categorised. To be able to merge the datasets, we transformed this variable in the other datasets accordingly: diabetes duration of: <2 years, 2–5 years, 6–10 years and >10 years. To determine latent groups in the patterns of responses to the individual

PAID-items, LCAs were performed using the polytomous variable LCA package²⁰ in R, V.3.2.2.

In contrast to variable-centred approaches that look for relationships among variables, person-oriented analyses use patterns of scores across cases to identify individuals who can be grouped together. LCA is a special case of person-centred mixture modelling that identifies latent subpopulations within a sample, based on patterns of responses to the observed variables.²¹ In contrast to cluster analysis, such as k-means, LCA is model based: (A) statistical procedure is used to identify different subgroups within populations that share certain outward characteristics. More precisely, it is assumed that a mixture of underlying probability distributions generates the data. Where K-Means clustering is limited to interval scale quantitative variables, LCA models can be estimated in situations where the variables are of different scale types (eg, continuous, ordinal, categorical).^{22 23} For the PAID, we assumed ordinal variables where higher scores indicate more distress, but the distance between the response categories is not the same.

The assumption underlying LCA is that membership in unobserved classes can cause or explain patterns of scores across survey questions, assessment indicators or scales. Based on the statistical theory, individuals' scores on a set of indicator variables are driven by their class membership.²⁴ In this study, we explored whether patterns of distress as measured by the PAID could be distinguished.

Furthermore, in K-means cluster analysis, the researcher must decide on the number of clusters where the choice of the cluster criterion is less arbitrary in LCA and statistics such as the Bayesian information criterion (BIC) and scree plots can assist in choosing a model.²²

The scientific goal of LCA-based clustering is to arrive at a solution that represented the most parsimonious and interpretable set of classes. In this study, we selected the model with the fewest number of classes while ensuring both statistical and clinical significance. The number of latent classes was identified by evaluating the Akaike information criterion, BIC, adjusted BIC, entropy for models and scree plot. Up to seven classes were examined and the model that fits the data best taken into account the improvements in fit indices and scree plot.^{25 26} To examine whether there was a difference in response patterns for people with type 1 or type 2 diabetes, LCAs were repeated in both strata separately and these results were then compared using the difference G^2 statistic.

In the next step, individuals were assigned to their most likely class. We used logistic (multi)nominal regression analyses to examine the association of sociodemographic or clinical characteristics with the likelihood for membership to a specific latent class.

We employed receiver operating curves (ROC) analyses to determine the sensitivity and specificity of the commonly used cut-off score of 40 or higher for high diabetes-distress.¹⁴

Statistical significance level was set at $p < 0.05$ for all analyses.

RESULTS

A total of 2966 adults with diabetes across the four studies had completed all 20 items on the PAID and were included in the analysis. Mean age was 53 ± 15 years, 49% women, 43% type 1 diabetes, 60% reported >10 years of diabetes duration and mean hemoglobin A1c (HbA_{1c}) was $7.8 \% \pm 1.4$ ($61.8 \text{ mmol/mol} \pm 15.7$) (table 1).

Latent class analysis

The model with three latent classes best fit the data, as evidenced by the greatest improvement scores on the indices and scree plot (figure 1). The first class resembles a group of participants we labelled 'low diabetes distress' (43%), the second class 'moderate diabetes distress' (37%), and the third class 'high diabetes distress' (21%) (figure 2). The distribution of items was similar across the three classes, with no distinct clusters of problem areas. Irrespective of their latent class membership, a large number of participants were likely to score high on item 12 ('Worrying about the future and the possibility of serious complications'). As a result of this, item 12 scores did not discriminate between individuals in the three different latent groups.

Logistic nominal regression showed that females are more likely to be part of the high distress class ($p < 0.001$). Age distribution also differed across classes: mean age for the low distress group was 56 ± 15 years, for the moderate group 52 ± 14 years and for the high distress group 50 ± 14 years ($p < 0.001$). In addition, HbA_{1c} was highest in the high distress class: HbA_{1c} for the low distress group was $7.6 \% \pm 1.3$, for the moderate group $7.8 \% \pm 1.4$ and for the high distress group $8.2 \% \pm 1.7 \%$ ($p < 0.001$) (table 1). Logistic multinomial regression showed further a significant interaction effect for age and type of diabetes when comparing the low and moderate distress classes ($\beta = 0.034$, $p = 0.039$), such that the effect of age is stronger in people with type 2 diabetes.

ROC analyses

ROC analyses demonstrated that the sensitivity and specificity of the commonly used cut-off of 40 is 0.95 and 0.97 respectively to identify the high distress group. To distinguish the moderate distress group from the low distress group, a cut-off score of ≥ 17 turned out to be optimal with a sensitivity of 0.93 and a specificity of 0.94.

DISCUSSION

Based on a large pooled dataset, this study shows that three levels of distress can be distinguished with corresponding cut-off scores: low (0–16), moderate (17–39) and high (40–100) diabetes distress. No distinct clusters of specific items (symptoms) were found, confirming a unidimensional structure over the three identified classes. Sex, age and HbA_{1c} values were significantly associated with the likelihood to be part of a certain level of distress. Being female and high HbA_{1c} values were associated with higher diabetes-distress, while low distress was

**Table 1** Participants' characteristics by diabetes distress class

Characteristics	All		Low diabetes distress		Moderate diabetes distress		High diabetes distress		P value
	n/mean	%/SD	n/mean	%/SD	%/mean	%/SD	n/mean	%/SD	
N (%)	2966	100	1258	42	1102	37	606	20	
Women n (%)	1440	49	540	44	547	51	353	60	<0.001
Age, mean±SD	53.4	14.9	55.7	15.3	52.4	14.4	50.2	14.0	<0.001
Type of diabetes n (%)									
Type 1 diabetes	1253	42	527	42	481	38	245	20	0.412
Type 2 diabetes	1679	57	727	43	605	36	347	21	
Unknown	34	1							
Insulin treatment, n (%)	2307	80	958	79	873	80	476	80	0.153
Diabetes duration (years), n (%)									
<2 years	160	6	67	6	54	5	39	7	0.390
2–5 years	422	15	179	15	146	14	97	17	
6–10 years	542	19	226	19	197	19	119	21	
>10 years	1663	60	712	60	633	62	318	55	
HbA _{1c} , mean±SD									
mmol/mol	61.8	15.7	59.5	14.7	61.9	14.8	66.5	18.5	<0.001
%	7.8	1.4	7.6	1.3	7.8	1.4	8.2	1.7	

Note: Participants are assigned to the class for which the probability of membership is the highest.

Bold values indicate significant differences

HbA_{1c}, Haemoglobin A1c.

associated with older age. Women were more likely to be represented in the higher distress class, in line with previous literature showing that women tend to report higher diabetes distress compared with men.^{7 27} Previous studies have shown that higher diabetes distress is associated with less optimal HbA_{1c} levels.^{3 28} People with low HbA_{1c} values, on the other hand, are more likely to report low levels of distress. The likelihood that someone is part of the low distress class increases with older age, particularly for people with type 2 diabetes. This concurs with other studies that found that younger people with either type 1 or 2 diabetes are more likely to report elevated diabetes distress.^{7 29 30} The moderate distress group did

not have a clear profile—the likelihood of belonging to the moderate distress class was similar across age ranges and levels of HbA_{1c}.

We found no differences between people with type 1 or type 2 diabetes. This might be due to the sample characteristics of our selected studies. In previous research, Stoop *et al* have shown a difference in level of diabetes distress between people with type 2 diabetes treated in primary vs those treated in a secondary diabetes care setting.²⁹ Most persons with type 2 diabetes in our sample were treated in secondary care and/or had one or more comorbidities. In samples where more people with type 2 diabetes are treated in primary care, the number of people might be somewhat larger for the low distress class.

A closer examination of the responses to the two items that pertain to distress related to (lack of) perceived support (15 and 18; support from physician or family), reveals that they are similar across the three levels of distress. Interestingly, in our samples, people in the high distress group tend to score low on both items, indicating that lack of support is not a common source of distress. This contrasts with other studies showing that lack of social support and 'miscarried helping' are prevalent in diabetes and a major source of stress.^{31–33} Future research should replicate our analyses in other, more diverse samples, including persons with lower education.

The item pertaining to worries about complications (item 12) is commonly scored highest of all items and was previously suggested as PAID-1 short-form item for screening purposes, based on factor analysis.³⁴ However,

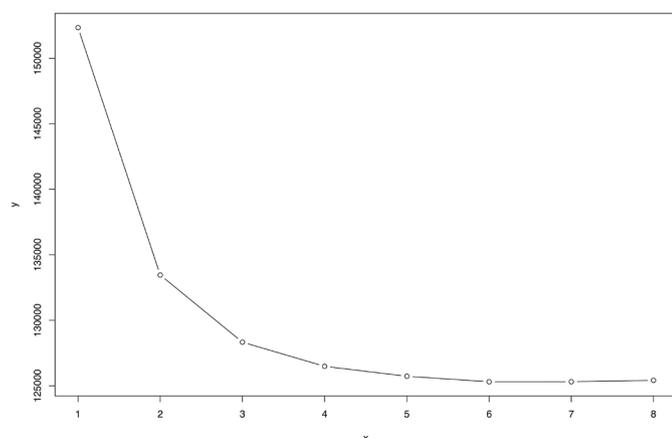


Figure 1 Scree plot fit of classes by AIC. AIC, Akaike information criterion.

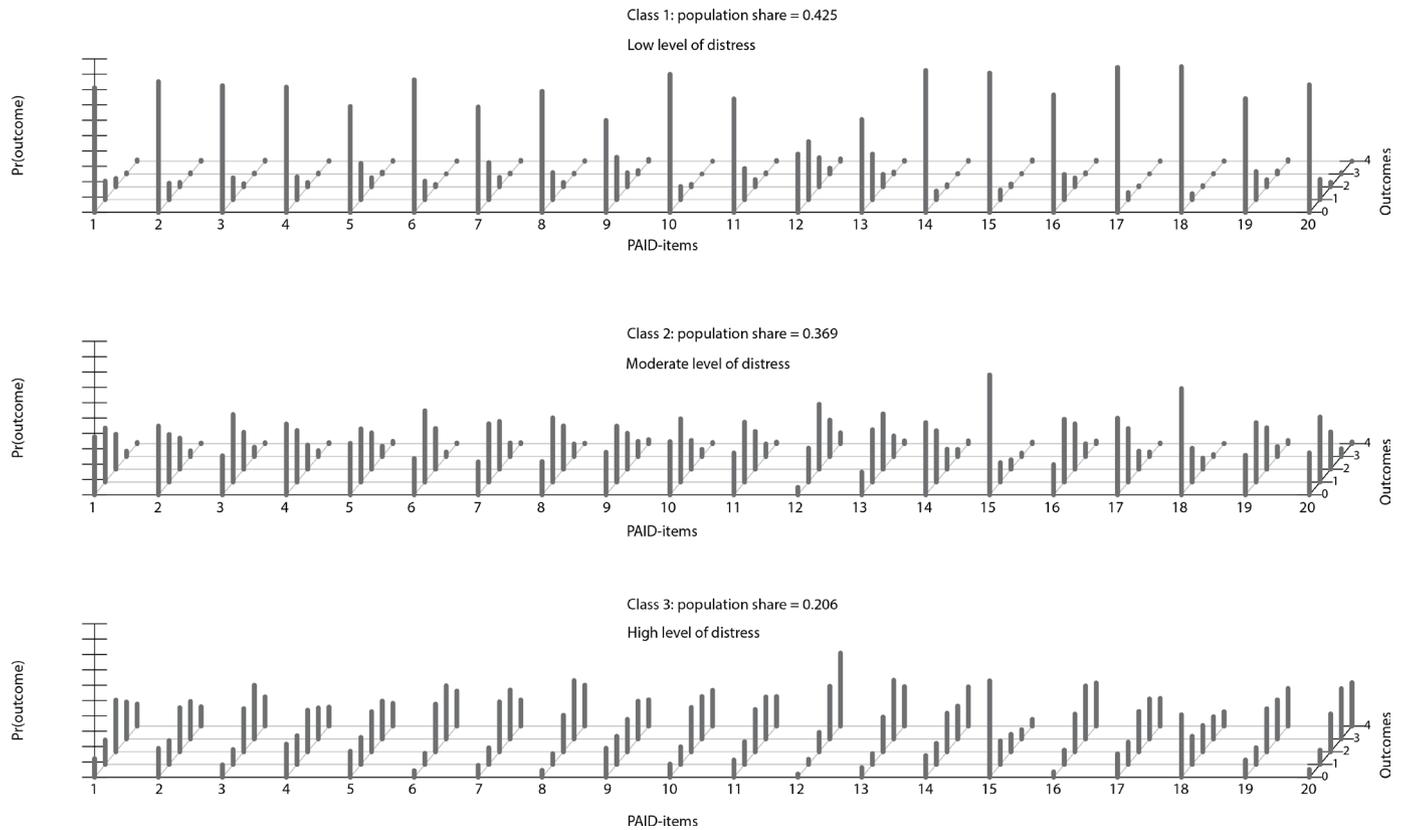


Figure 2 Probability distribution of scores on paid items by latent class. PAID, Problem Areas in Diabetes.

the likelihood that persons with overall moderate distress will score high on this item is greater than any other PAID item. So, when using this item as a screener,³⁴ there is a high risk of false positives.

Our findings have clinical implications. Rather than only screening for high diabetes distress, we should recognise that there is a significant subgroup of people with diabetes (37%) that express moderate levels of diabetes distress that could be at risk of increasing over time and may profit from early detection and preventative measures. Longitudinal studies underscore the importance of risk stratification and monitoring of different trajectories of diabetes distress and opportunities of timely interventions.^{35 36} Once high levels of diabetes distress have been developed, they tend to persist.^{35 37} Studies that examined the incidence of high diabetes-distress have found rates from 7% to 20%.^{35 37} However, these studies used only the dichotomy of elevated vs not elevated diabetes distress and did not take moderate distress into account. Future research should examine diabetes-distress trajectories across the three classes to further our understanding of the best timing and intensity of distress-reducing interventions and possibly prevention. The PAID scale is a practical and useful tool to administer in routine practice to monitor the level of diabetes distress at regular intervals, as recommended by the American Diabetes Association.¹⁵

Strengths and limitations

For this study, we were able to use data from large, international samples of adults with type 1 or type 2 diabetes,

with well validated measures. However, by merging data from different studies we faced incomplete data on education level, ethnicity and complications in some studies, that could, therefore, not be included in the current analyses. In addition, we lack information on socioeconomic status and family dynamics. Future research should take these factors into account as we know that complications and lack of social support are related to higher levels of diabetes distress.^{6 7} As we know that people with higher education and socioeconomic status are more likely to participate in research, further research should investigate how our findings generalise to populations with a lower socioeconomic status. In addition, in our data set, people with type 2 diabetes were more likely to be treated in secondary care, which may have affected the level of diabetes distress and its associations.²⁹ The cross-sectional nature of the data makes it difficult to determine the direction of the association between diabetes distress and glycaemic control. Future longitudinal studies will be able to examine directionality in addition to trajectories.

CONCLUSION

Our findings call for a three-level classification for which we determined cut-off scores of 0–16 for lower diabetes-distress, 17 till 39 for moderate diabetes-distress and 40–100 for high diabetes-distress. The profile of symptoms is more or less stable across these three levels. Sex, age and HbA_{1c} values were significantly associated levels

of distress. Being female and high HbA_{1c} values were associated with higher diabetes-distress, while low distress was associated with older age, more strongly in people with type 2 diabetes. In clinical practice, we should be aware that there is a significant subgroup of people with diabetes that express moderate levels of diabetes distress that could be at risk of increasing over time. This group may profit from early detection by routine monitoring and preventative (self-help) interventions, while those with high levels of distress could be referred to mental health specialists.

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Contributors MdW researched data and wrote the manuscript and is responsible for the overall content as guarantor. FP and FJS contributed to the discussion and reviewed/edited the manuscript.

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Patient consent for publication Consent obtained directly from patient(s)

Ethics approval All studies involved human participants and were reviewed by the VUmc Ethics Committee: Study 1: This study involves human participants but the VUmc Ethics Committee exempted this study. Study 2: METC-VUmc 2005/195. Study 3: METC-VUmc 2011/008. Study 4: METC-VUmc 2002/47. Participants gave informed consent to participate in the study before taking part.

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