Distress and health-related quality of life in Indonesian type 2 diabetes mellitus outpatients

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Diabetes distress in Indonesian patients with type 2 diabetes: a comparison between primary and secondary care

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Submitted

ABSTRACT

Aims: To compare diabetes distress (DD) scores in Indonesian type 2 diabetes mellitus (T2DM) outpatients treated in primary care versus those in secondary care and to investigate whether socio-demographic characteristics and clinical conditions explain potential differences in DD score across healthcare settings.

Methods: A cross-sectional study was conducted on Java island in three primary care (n = 108) and four secondary care (n = 524) facilities. The participants completed the Bahasa Indonesia version of the Diabetes Distress Scale questionnaire (DDS17 Bahasa Indonesia). Ordinal regression analysis was conducted with the quartile of the summation of the DD score as the dependent variable to investigate how the association between the level of healthcare facilities and DD altered when adding different variables in the model.

Results: The unadjusted model showed that the level of healthcare facilities was strongly associated with DD (p<.001), with participants in primary care having a 2.91 (95% CI 1.98–4.29) higher odds of being more distressed than the participants in secondary care. This association was strongly intensified when adding the socio-demographic characteristics and clinical conditions as model confounders. In addition to the care setting, we found four factors independently related to a higher DD score: younger age, participants with dependency on caregivers, higher levels of fasting blood glucose, and experiencing two or more T2DM complications.

Conclusions: This is the first study in Indonesia to compare DD scores within different healthcare facilities. We recommend the general consideration of DD by the Indonesian government.

INTRODUCTION

The number of people living with diabetes mellitus (DM) in Indonesia has continued to increase over the last six years. In 2009, the International Diabetes Federation (IDF) estimated that there were around 7.3 million people living with type 2 DM (T2DM) and in 2017 this number increased to 10.3 million, within whom 7.3 million are undiagnosed [1,2]. The percentage of females living with T2DM was higher than that of males (7.7% vs. 5.6%), and new cases were not only found in the above-55-years age group but also in younger age groups (starting at 15 years of age). With regard to the level of education, the highest prevalence was found in community groups who had never attended school (10.4%) [3].

Health services for Indonesian T2DM outpatients are managed in a tiered system, where they will receive initial care in a primary care setting, notably, puskesmas/public healthcare centre (PHC) or family doctor/general practitioner (GP). Patients can only receive advise from a consulting resident of internal medicine in secondary care in an emergency situation or when indicated by certain clinical symptoms [4]. Indonesians living with T2DM generally visit a health facility after their health condition deteriorated due to T2DM complications [5]. The most common complications, indicated in a recent study, were neuropathy and retinopathy complications [6].

People living with T2DM require a lifetime daily self-management plan [7]. The changes in their daily lifestyle and the disease may have a negative impact on their psychological state and may contribute to diabetes distress (DD). DD refers to the fear of risk of T2DM complications, lack of accessibility to high-quality healthcare facilities, worries about self-management therapy and the perception of lacking emotional support from family and colleagues [8,9]. Previous studies found that indeed higher DD score, which was due to a higher level of distress, were associated with worse psychological outcomes, poor self-care, a higher level of haemoglobin A1C (HbA1c), lower health-related quality of life (HRQoL) and increased risk of T2DM complications [8–11]. Furthermore, periodic DD assessments are important to facilitate early detection of DD and subsequent potential prevention of more severe psychological disorders; notably, T2DM patients with higher DD scores have been found to have an increased risk of mortality [12]. Regular DD assessment has been recommended by the IDF since 2012 [13].

Studies comparing DD scores across healthcare settings are currently limited. We found two studies in the Netherlands and Greece [14,15], however, we have not found a similar study in Indonesia. Both of these studies reported that the DD scores of participants treated in secondary care were higher than those in primary care. The Dutch study reported that besides the care setting, other factors such as younger age, ethnic minority status, using insulin, higher HbA1c level, higher body mass index (BMI) and neuropathy were associated with higher DD scores. Furthermore, the Greek study reported that comorbidities, the use of insulin, and T2DM duration were associated with higher DD scores. In this study, we aimed to firstly compare DD scores in Indonesian T2DM outpatients treated in primary care versus those in secondary care. Subsequently, we investigated whether socio-demographic characteristics and clinical conditions explain potential differences in DD score across healthcare settings.

METHODS

Definition of primary care and secondary care

Primary care

In our study, we defined primary care as the T2DM outpatients who were managed by a GP and every six months they have an opportunity to consult with a resident of internal medicine in a secondary care facility. Allocation of primary care facilities is organized by the Badan Penyelenggara Jaminan Sosial/BPJS (social security administrative agency) by matching the patients' home with the nearest primary care location. However, patients are given the flexibility to change the primary care location.

Secondary care

In secondary care, the T2DM outpatients are treated in a hospital and monitored by a consulting resident of internal medicine. During the monitoring process, the resident of internal medicine plans the therapy according to guidelines including the prescription of insulin to T2DM outpatients whose blood glucose remains uncontrolled with oral antidiabetic drugs (OADs) therapy. Insulin administration may continue for a certain period of time until the patient shows better clinical outcomes, for instance, his/her blood glucose is brought under control (for example, fasting blood glucose (FBG) ≤126 mg/dL) and afterwards, therapy may be reverted from insulin to OAD. Then, the consulting resident of internal medicine refers them back to a primary care facility for continuing OAD therapy. However, there are also some T2DM outpatients whose insulin therapy is not possible to be replaced with OAD, i.e. those who report OAD side effects or, based on clinical judgment, those in continued need of insulin [16]. For this group of patients, therapy continues in secondary care and they continue to be monitored by a consulting resident of internal medicine. So far, insulin is only available in hospital pharmacies and is not provided in primary care facilities in Indonesia. In the area with limited facilities of internal medicine, T2DM outpatients with insulin therapy can take routine examinations in a primary care facility and get the insulin at private pharmacies that collaborate with the BPJS. Until now, T2DM outpatients can directly visit the consulting resident of internal medicine in a private clinic without a referral from a primary care facility, but the service is not covered by health insurance.

Instrument

We used the Diabetes Distress Scale questionnaire in Bahasa Indonesia (DDS17 Bahasa Indonesia) [17] to measure the DD score. DDS17 Bahasa Indonesia consists of 17 items which are divided into four domains. First, three items are specified in the interpersonal distress domain concerning items on support from family members and colleagues of T2DM outpatients. Second, five items specify the emotional burden domain with regard to the concerns and fears of T2DM outpatients concerning complications. Third, four items in the physician distress domain describe opinions of T2DM outpatients concerning the knowledge and attitude of and the care provided by the treating physician. The last five items measure difficulties of T2DM outpatients concerning the management of T2DM therapies (inclusive motivation) and issues in self-confidence or stress, for example, caused by routine blood sugar checks. Each item consists of a scale ranging from 1 (not a problem) to 6 (a very serious problem) [9]. The resulting sum score of the 17 items would then range from 17, 'not a problem' to 102, 'a very serious problem' [9].

Participants

We included outpatients with T2DM that were older than 18 years, read and signed a statement of willingness to participate, and were comfortable with filling out the questionnaire. For participants with limited reading ability or physical limitations, informed consent was given orally by the caregiver (spouses or children).

Study design and setting

A cross-sectional study was conducted between February 2015 and April 2016. In primary care settings, participants were selected from a family doctor in Wonosari in Yogyakarta, a primary healthcare center (PHC) in Surabaya (East Java) and a T2DM outpatient' community in Surakarta (Central Java). Data collection was done every Friday and Saturday within a weekly patient education program. In secondary care settings, participants were selected from RSUD Kota Yogyakarta Hospital, PKU Muhammadiyah Hospital in Yogyakarta, Moewardi Hospital in Surakarta (Central Java) and BLUD RSUD Sekarwangi Hospital in Sukabumi (West Java). Most of the participants were interviewed in the waiting rooms of the hospitals while they were waiting for a consultation with a consulting resident of internal medicine. The remaining participants were questioned in the waiting rooms of the hospitals' pharmacies. The Medical Ethics Committee of Universitas Gadjah Mada, Yogyakarta, Indonesia approved the study with document number KE/FK/1188/EC on November 12th, 2014 (the approval was amended on March 16th, 2015).

Data collection procedure and data source

We collaborated with treating GPs and consulting residents of internal medicine to collect our data. The GPs and residents assisted us by providing participants with information about the research objectives, ethics and the importance of participating. This information helped participants to be more focused and comfortable and strengthened the feeling that the research was supported by the hospital staff. Participants were assisted by the researcher or the research assistant while filling out the questionnaire.

Socio-demographic characteristics such as age, sex, educational background, and occupation were collected using the participants' identity cards and from self-reporting. In this study, the age of participants was classified into two categories: younger/productive age (18-56 years) or retirement age (>56 years). Furthermore, those who reported not currently having a job were defined as unemployed. Those who stated their main job is to take care of the household were classified as housewives. Clinical condition such as the type of therapy, complications and comorbidities were obtained from the treating GPs and residents of internal medicine. Postprandial blood glucose, FBG and T2DM duration were collected from self-reporting. In this study, participants were defined as having comorbidities if they suffered from major diseases such as cancer or tuberculosis. Patients experiencing exclusive T2DM complications would classify as having complications.

Statistical analysis

To investigate whether socio-demographic characteristics, clinical variables, and the DD score differed between participants in primary and secondary care, we performed independent T-tests for continuous variables. χ^2 tests were conducted for categorical variables, and Kruskal-Wallis rank sum tests were performed when the continuous variables did not follow the normal distribution. Ordinal regression analysis was conducted with the quartile of the summation of the DD score as the dependent variable

to investigate how the association between the level of healthcare facilities and the DD score altered when adding different variables in the model. We assessed the existence of multicollinearity in our model by the correlation matrix of all independent variables (r > 0.80 indicates multicollinearity) and the variance inflation factor (a value > 10 indicates multicollinearity). The association between the level of healthcare facilities and DD score was firstly investigated in an unadjusted model (model 1). Subsequently, we investigated how such association altered when adjusting for sex, age, educational level, occupation, and the presence or absence of a caregiver (model 2). We then investigated the alteration by further adding the clinical variables (diabetes duration, FBG) into model 2 (model 3). Finally, complications and comorbidities were added as variables into model 4 and model 5 (in model 4 replacing the variables of clinical conditions and in model 5 a full model). The differences in odds ratios between the models (ΔOR) were calculated. In addition, we investigated in each multivariate model (model 2 to 5) how the socio-demographic characteristics and clinical variables independently related to the DD score except for the effect of the level of care. We did not include the type of therapy and postprandial glucose into any of our ordinal regression models because adding these variables would cause the resulting models deviating from the proportional odds assumption [18]. Missing values on diabetes duration and FBG were dealt with using multiple imputations [19]. Considering the high percentage of missing measurements, we obtained 50 imputed datasets for each measurement. The completed measures were then computed by taking the average values generated from each imputed dataset. Statistical analyses were performed using R (R Foundation for Statistical Computing, software version 3.4.0, Vienna, Austria). The factors were considered statistically significant coefficients in the regression analyses if the two-tailed p-value was <.05.

RESULTS

In total, 632 participants were included in the study, of whom 108 (17%) were from a primary care setting and 524 (83%) were from a secondary care setting (Table 1). Participants in the primary care setting were older and were relatively more frequently housewives. In addition, they had a longer T2DM duration and a lower percentage of suffering from two or more complications and comorbidities. The total DD score in the primary care setting was shown to be significantly higher than the score in the secondary care setting. This was also the case for the score in each domain.

Factors explaining differences in DD scores between primary and secondary care

Table 2 depicts the results of the ordinal regression models. The multicollinearity statistics indicated no significant multicollinearity between the independent variables. The unadjusted model (model 1) showed that the level of health facilities was strongly associated with DD (p<.001), with participants in primary care having a 2.91 (95% CI 1.98~4.29) higher odds of being more distressed than the participants in secondary care. Model 2 showed that after adjusting for socio-demographic characteristic variables, the association was strongly intensified (ΔOR = 0.48). In Model 3, adding the clinical condition variables further intensified the association between the level of health facilities and DD (ΔOR = 0.09). In Model 4, replacing clinical variables with complications showed a moderately

Table 1.Socio-demographic characteristics, clinical condition and scores of diabetes distress of the participants in primary care compared to those treated in secondary care

Variables	Primary care (n = 108)	Secondary care (n = 524)	Overall (n = 632)
Socio-demographic characteristics			
Male sex	32%	44%	43%
Age [years]*	62±9	60±10	60±10
University degree	12%	26%	26%
Occupation (I/II/III)#,***	10%/40%/50%	31%/34%/35%	29%/35%/36%
Caregiver	53%	62%	61%
Clinical variables			
Diabetes duration [years]*	5 (4~14); N=31	4 (1~10); N=312	5 (1~10); N=343
Type of therapy (I/II/III/IV)$,***	11%/67%/14%/8%	2%/57%/24%/17%	5%/59%/22%/14%
Fasting blood glucose (FBG) [mg/dL]	130 (112~134); N=9	140 (115~179); N=249	140 (115~180); N=258
Postprandial glucose [mg/dL]	167 (160~184); N=9	192 (151~236); N=234	190 (153~236); N=243
Complications			
With complications	53%	67%	67%
One complication	33%	37%	36%
Two or more complications**	17%	23%	26%
Comorbidity*	3%	7%	6%
Diabetes distress			
Total score***	28 (21~41)	21 (18~30)	23 (18~35)
Emotional burden***	8 (6~11)	6 (5~9)	7 (5~10)
Physician distress***	7 (5~10)	5 (4~7)	5 (4~8)
Regimen distress***	9 (6~13)	6 (5~9)	7 (5~11)
Interpersonal distress***	4 (3~6)	3 (3~5)	3 (3~6)

*&Continuous variables are presented as mean ± standard deviation or median (interquartile range), and categorical variables are presented as percentages; #Occupation I, II, III respectively stand for active employee, unemployed, and housewife; $Type of therapy I, II, III, IV respectively stand for Diet or no drugs, OAD, Insulin, Insulin+OAD; ***P<0.001;**P<0.01;*P<0.05*

Table 2. Results of the ordinal regression models (n = 632)

Variables	Models				
	1 pseudo r-square: 0.050	2 pseudo r-square: 0.087	3 pseudo r-square: 0.102	4 pseudo r-square: 0.099	Model 5 pseudo r-square: 0.113
Primary care	2.91 (1.98~4.29)***	3.39 (2.28~5.09)***	3.48 (2.34~5.23)***	3.61 (2.42~5.44)***	3.68 (2.46~5.55)***
Socio-demographic characteristics					
Male sex		1.01 (0.68~1.49)	1.03 (0.69~1.52)	0.98 (0.66~1.45)	1.01 (0.68~1.50)
Age [years]		0.97 (0.96~0.99)***	0.98 (0.96~0.99)**	0.97 (0.96~0.99)***	0.97 (0.96~0.99)**
University degree		1.40 (0.97~2.02)	1.40 (0.97~2.02)	1.38 (0.96~2.00)	1.37 (0.95~1.99)
Occupation (IIvs. I)		1.07 (0.72~1.58)	1.13 (0.76~1.67)	1.08 (0.73~1.60)	1.13 (0.76~1.68)
Occupation (III vs. I)		0.98 (0.62~1.56)	1.01 (0.64~1.61)	0.95 (0.60~1.51)	0.98 (0.62~1.57)
Caregiver		1.58 (1.17~2.13)**	1.58 (1.17~2.14)**	1.55 (1.15~2.10)**	1.57 (1.16~2.12)**
Clinical condition					
Diabetes duration			0.98 (0.95~1.01)		0.98 (0.96~1.01)
Fasting blood glucose (FBG)			1.01 (1.00~1.01)**		1.01 (1.00~1.01)**
Complications					
One				1.24 (0.88~1.74)	1.22 (0.87~1.72)
Two or more				1.75 (1.19~2.59)**	1.73 (1.17~2.56)**
Comorbidities				1.25 (0.67~2.32)	1.11 (0.59~2.08)

*OAD: Oral Antidiabetic Drugs; Occupation I, II, III respectively stand for active employee, unemployed, and housewife; ***P<0.001;**P<0.01;*P<0.05*

intensified association compared to model 2 (ΔOR = 0.22). The higher odds of experiencing DD in primary care compared with secondary care remained significant in the fully adjusted model (OR = 3.68, 95% CI 2.46–5.55; p <.001). In addition to care setting, we found four factors independently related to a higher DD scores: younger age, participants with dependency on caregivers, higher levels of FBG, and experiencing two or more T2DM complications.

DISCUSSION

Our study shows that participants treated in primary care settings indicated more distress on the DDS17 than those who were treated in secondary care. In addition to the care setting, we found four factors independently related to higher DD scores: younger age, participants with dependency on caregivers, higher levels of FBG, and experiencing two or more T2DM complications. These results need to be interpreted with caution as our data was collected when the Indonesian government initiated a transformation in the health insurance system. Previously, T2DM outpatients were free to choose secondary and tertiary services (including choosing a resident of internal medicine). However, the new health insurance system has been further strengthened and referral to health facilities and these changes could very well have an impact on DD.

The association between care setting and DD score was substantially intensified after adjustment for the sociodemographic characteristics (ΔOR = 0.48). This finding is not only attributable to the profound confounding effect of the included factors on the association between the level of health care and the DD score, it is also attributable to the highly significant effect of age and dependency on caregivers on the DD score itself. Specifically, we found that younger age is correlated with higher DD scores even when controlling for the full set of variables (in model 5). This finding is in line with the evidence from several other studies. A comparable study in San Diego stated that the higher DD score in the younger age group may be caused by their family responsibilities, the financial challenges and their daily work [20]. In addition, a study in Malaysia stated that higher DD scores in younger participants were not associated with a higher educational level, but stemmed from the feeling that T2DM disrupted their daily activities due to the therapy and self-management [19]. Furthermore, compared with the elderly, the younger age group has less experience in managing T2DM, specifically, in dealing with the unexpected T2DM diagnosis, therapy and (fear of) complications [22].

We also found that participants with dependency on caregivers had a higher DD score compared to those who were unaccompanied. This finding is obvious to some extent, as the participants dependent on a caregiver were those with poorer health conditions and in need of assistance in activities, such as the elderly or participants with complications or comorbidities. In addition, most participants with low education stated that they need a caregiver to assist them during the hospital administration process. In Indonesia, it takes at least 7 hours for the patient care process in the hospital starting from registration, laboratory examination and doctor's consultation until the time they receive their medication from the pharmacist [17]. A caregiver plays a role to help the patients during their treatment in a healthcare facility. Some elderly participants in our study stated that they always forget the physician's explanation during the consultation after they get back home, but with a caregiver besides them during the consultation, they felt more secure. On the other

hand, the caregiver can help them to remember the physician's explanation and can assist in picking up drugs in the pharmacy. Yet, this seems not enough to offset the increased DD scores in this group.

The association between care setting and DD score was slightly intensified after additional adjustment for the factors with regard to the clinical condition (ΔOR = 0.09). This may be partly caused by the limited amount of factors included in this group (i.e., only diabetes duration and FBG level) and the weak but significant effect of the FBG level (OR=1.01) on DD score. Two more factors regarding clinical condition (type of therapy and postprandial glucose) were initially included in our regression model. However, these two factors were not included in the final models because with these variables included the models no longer met the proportional odds assumption, an important prerequisite to conduct the ordinal regression analysis in a more direct manner [18]. The finding of the association between an elevated FBG level and a higher DD score is in line with other studies. A clinical trial in the U.S. reported that higher levels of blood glucose were associated with higher DD scores. Furthermore, in this U.S. study, it was reported that controlled blood glucose had a positive impact on mood, DD scores and HRQoL [23]. Besides, another study conducted on Hispanic and non-Hispanic patients reported that lower DD scores were associated with reductions in blood glucose levels [24]. From an analytical perspective, care has to be taken in this study that due to the high percentage of missing data on the FBG level (258 available evidence out of 632 participants), we used the multiple imputation approach to capture the FBG levels of the total sample. The significant conclusion was then generated based on the total sample instead of the 258 participants who had full evidence of their FBG levels.

The association between care setting and DD score was moderately intensified after additional adjustment for the factors with regard to the complications and comorbidities (ΔOR = 0.22) within which having two or more complications strongly increased the DD score. This finding is in line with the Dutch study [14] which reported a positive correlation with having different kinds of complications and the increased Problem Areas in Diabetes (PAID) scale. Furthermore, a study in Indian patients also reported that T2DM complications were a major predictor for high DD scores [25]. In our study, 6% of the participants reported comorbidities (cancer, tuberculosis, gastritis, hepatitis and tumor), resulting in higher DD scores. Research in Greece also reported this positive association between comorbidities and higher DD scores [15].

One limitation of this study was that we were not able to measure the HbA1c of the participants. This is because not all health facilities are equipped with HbA1c examination facilities. For some T2DM outpatients with good economic circumstances, HbA1c examinations were conducted in private laboratories. Also, there is a difference in policies on HbA1c examinations between different health facilities. As an illustration, one particular PHC recommends only one HbA1c examination per year and on the condition that the T2DM outpatient is participating in activities organized by that particular PHC, whereas Health Minister regulation No.52 of 2016 [26] states that HbA1c examinations should be performed every 3 or 6 months. In addition, we also had difficulties in collecting T2DM duration and FBG levels, with only 40-50% of participants having the full evidence. Furthermore, the number of participants in secondary care was nearly five times higher than in primary care, as primary healthcare facilities seemed reluctant to participate in

the study. More research in primary care facilities is therefore warranted.

This is the first study to present DD scores in Indonesian T2DM outpatients in primary and secondary care settings. Participants from our study were recruited from various healthcare providers such as family doctors, T2DM outpatient' community PHCs and hospitals so that we assume that the results of the study may provide an overall understanding of the state of DD in Indonesia. Moreover, although the Indonesian population is very heterogeneous, the Java population can be regarded as quite representative as 57% of all Indonesians reside in Java [27].

We recommend that besides improving access to good health services for those with T2DM, primary care should be comprehensively strengthened in terms of the management of T2DM therapy. Further, we recommend that the Indonesian government should provide psychological help in every healthcare facility to help the T2DM patients with DD. These psychologists could be involved in a number of DM club activities (for example Prolanis BPJS). Prolanis is a chronic diseases management program managed by the BPJS that facilitates monthly visits between patients and a physician or a consulting resident of internal medicine. In these visits, the patient's blood glucose will be examined, followed by exercise and education about T2DM. In Prolanis activities, doctors could play a role in providing T2DM education, while psychologists could provide psychological education to reduce DD. Another recommendation is that T2DM education should also be aimed at caregivers or family members because they are the ones who are able to monitor the developments of the therapies given to the T2DM patients. It is likely that increasing awareness and educating Indonesians with T2DM not only about DM care but also about the reforms in the health insurance system and healthcare provision may be beneficial in reducing DD. Currently, DD screening has not become a priority in Indonesia even under the recommendation of the IDF [28] and American Diabetes Association [29] as being a global guideline for T2DM. If screening for DM is undertaken, DD should be one of the concerns of the Indonesian government. Lastly, we recommend that similar studies should be conducted in Eastern Indonesia, which has limited facilities and health personnel.

CONCLUSIONS

In this study, we found a higher DD score in Indonesian T2DM outpatients from primary care compared to the patients managed in secondary care. In addition to the care settings, the following variables were found to be positively related to a higher DD score: younger age, participants with dependency on caregivers, higher levels of FBG, and experiencing two or more T2DM complications. This is the first study in Indonesia to compare DD scores within different healthcare facilities. We recommend the general consideration of DD by the government and over various patients characteristics. Our DD-estimates can fruitfully be used in Indonesian healthcare policy making for T2DM patients.

DECLARATIONS

Ethics approval and consent to participate

This study was approved by the Medical Ethics Committee of Universitas Gadjah Mada Yogyakarta, Indonesia (document number KE/FK/1188/EC, 12 November 2014, amended 16 March 2015).

Consent for publication
Not applicable for that section.

Availability of data and material
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests
Prof Maarten J Postma reports grants and honoraria from various pharmaceutical companies, all fully unrelated to this project. The other authors declare that they have no conflicts of interest.

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Authors contributions
BA, DS, JA, MJP and QC were involved in the conceptualization and the design of this study. BA carried out the data collection. QC conducted the analysis, MJP and TvA verified the findings. BA drafted the manuscript with support from TvA, MJP and QC. All authors discussed the results and approved the final manuscript.

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