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## Articles

### The impact of clinical and psychological characteristics on alexithymia in type 1 diabetes

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#### Abstract

**Background:** Alexithymia is a psychological construct characterized by inability to express emotions, poor imagination and operational thinking. It is well known its association with several chronic disease such as Diabetes type 2, little is known about diabetes type 1. We examined the association of alexithymia with clinical and psychological outcomes in subjects with type 1 diabetes.

**Methods:** The study was conducted in a single diabetes center. The patients fully completed a protocol composed of the following instruments: the Toronto Alexithymia Scale-20 (TAS-20), the State-Trait Anger Expression Inventory-2 (STAXI-2), the State-Trait Anxiety Inventory form Y (STAI-Y), and the Hamilton Rating Scale for Depression (HAM-D). TAS-20 scores were subdivided into tertiles, Correlations and two linear regression analyses, adjusted for only clinical and clinical plus psychological characteristics, were performed. Overall, 75 patients were enrolled (mean age  $41.0 \pm 11.4$  years, diabetes duration  $19.9 \pm 11.9$  years, 49.3% males, 30.7% treated with CSII).

**Results:** People with diabetes of the upper TAS-20 tertile had the greatest rate of depression (with the highest degree of severity) and the higher levels of anger and anxiety. There was a significant correlation between TAS-20 scores with BMI ( $r=0.26$ ;  $p=0.03$ ), HAM-D ( $r=0.38$ ;  $p=0.001$ ), STAXI-2 ( $r=0.34$ ;  $p=0.003$ ) and STAI-Y ( $r=0.48$ ;  $p<0.0001$ ). Further regression analysis showed TAS-20 scores were associated with BMI ( $\beta=0.29$ ;  $p=0.02$ ). The association with BMI was confirmed ( $\beta=0.28$ ;  $p=0.007$ ) when psychological variables are considered; furthermore, a strong association with STAI-2 ( $\beta=0.48$ ;  $p<0.0001$ ) was detected, while the analysis did not reveal any significant correlation between alexithymia and HbA1c levels.

**Conclusions:** Alexithymia is strongly associated both with clinical and psychological characteristics, notably with BMI and anxiety traits. People with diabetes type 1 should be assessed for alexithymia. Future studies on the current topic are therefore required in order to elucidate the role of alexithymia in diabetes type 1. We believe that patients with diabetes and alexithymia could take advantage of psychological counseling.

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## 1. Introduction

The modern concept of caring people with diabetes implies a cultural leap on the part of health care professionals. A traditional approach consisting in giving recommendations and prescriptions in a vertical way cannot be an effective solution. A considerable amount of literature shows how a patient-centered model is the key (Bodenheimer et al., 2003; Coleman et al., 2009). People with diabetes are the main actors and both their family members and health care professionals are involved in the process of care as supporting team. People with type 1 and type 2 diabetes are required to take care of themselves by making daily self-management decisions and sometimes by performing complex care activities. In doing this, the effect of psychological burden could be significant.

Comorbidity of psychiatric disorders, mainly depression and anxiety, results in lower quality of life, poorer glycemic control, increased risk of developing diabetes-related complications and higher mortality rate (Anderson et al., 2001). Moreover, evidence demonstrates that psychiatric disorders in diabetics patients are underdiagnosed (Barnard et al., 2012). Beyond full-blown psychiatric disorders, symptoms of depression, anxiety, related emotional disorders and personality traits may reflect a distinct psychological attitude. Subclinical affective symptoms and personality traits are associated with worse health outcomes and with increased susceptibility to illness. A core feature both of chronic illnesses and psychiatric disorders is alexithymia, a considerable but not deeply explored personality trait. The root of alexithymia can be found starting from psychosomatic medicine. In this context it was originally referred to intrapsychic conflict complying with psychoanalysis model. Recently, alexithymia has been enhanced as a cognitive alteration in processing of emotions (López-Muñoz & Pérez-Fernández, 2020) associated with altered cortical thickness in general population (Terock et al., 2020). Alexithymia, as a psychological construct, is characterized by inability to identify and to express emotions, poor imagination and operational thinking (Topsever et al., 2006). The alteration involves both verbal and non-verbal reduced expressivity of emotion jeopardizing the

quality of their interpersonal relationships (Spitzer et al., 2005), suggesting an impairment in experience feelings. Alexithymia per se is not a disease, it is better understood as risk factor for psychosomatic symptoms, rather than as a cause. In this accepted meaning it has been successfully investigated in several medical (Baiardini et al., 2011; Martino et al., 2020; Willemsen et al., 2008) and psychiatric illnesses (Hemming et al., 2019; Leweke et al., 2012; Norman et al., 2020; Ospina et al., 2019; Westwood et al., 2017). Alexithymia has been evaluated either as a stable or state trait from different authors (Hiirola et al., 2017; Martínez-Sánchez et al., 2003). The former conceptualization led to the recognition of a continuous distribution of this trait in the general population (Taylor & Bagby, 2000); the latter might be associated to defense mechanisms in stressful situations, where it might represent the main predictor of anguish in certain situations (Merlo et al., 2021).

This cognitive and affective impairment can cause a dissociation of emotional and physical responses to life events. Few studies have examined alexithymia in type 1 diabetes.

The current study

Aim of our study is to evaluate possible relationship between TAS-20 scores and patient centered out-come. In our study, we evaluate differences in anthropometric and psychopathological variables in relation to alexithymia scores. We hypothesize that higher levels of alexithymia might be related to higher levels of clinical and psychological pathology. Furthermore, we evaluate whether clinical and psychopathological parameters might represent predictors of alexithymia levels; we focused on the different contribution of only clinical or clinical plus psychological characteristics in determining alexithymia.

## 2. Materials and methods

The study was conducted in the diabetes outpatient clinic of the Department of Internal Medicine of the "G. Martino" University Hospital, Messina, Italy. Participants were included in the study according to the following inclusion criteria: people with type 1 diabetes and at least one year of disease duration, older than 18 years, with regular attendance at the diabetes outpatient clinic. Patients were excluded by: not affected by type 1 diabetes, disease duration less of one year. Further exclusion criteria were younger than 18 years and poor compliance with outpatients setting. During a scheduled visit subjects who accepted to participate at the study, fully completed a protocol composed of the following instruments:

*Toronto Alexithymia Scale-20 item (TAS-20)*

The Toronto Alexithymia Scale (TAS-20) is a 20-item self-report scale that assesses alexithymia (Bagby et al., 1994a, 1994b). The questionnaire is made of 20 items on a 5-point Likert scale

from 1 (strongly disagree) to 5 (strongly agree), with higher scores indicating more alexithymia. Original version of the TAS-20 showed Internal consistency of 0.81 (Cronbach's alphas). There are 5 items that are negatively keyed (items 4, 5, 10, 18 and 19). The total alexithymia score is the sum of responses to all 20 items, while the score for each subscale factor is the sum of the responses to that subscale. The TAS-20 has a three factors structure accounting the 31% of the total variance, respectively: Difficulty in Identifying Feelings (0.78) Difficulty in Describing Feelings (0.75) Externally Oriented Thinking (0.66) (Caretto et al., 2011; Craparo et al., 2015). The alpha coefficient scores obtained with the non-clinic sample were 0.75 for the total scale; - 0.77, 0.67 and 0.52 first, the second and the third factors; clinical sample scores: 0.82 for the full scale; 0.79, 0.68 and 0.54 for the three factors. Total scores of 61 and above indicate an alexithymic state. We used the Italian validated version of the scale (Bressi et al., 1996).

#### *State-Trait Anger Expression Inventory-2 (STAXI-2)*

The State-Trait Anger Expression Inventory-2 (STAXI-2) is a 57-item self-report inventory that measures the intensity of anger as an emotional state (State Anger), the disposition to experience angry feelings as a personality trait experience (Trait Anger), and anger expression and control (Spielberger, 1999). State Anger scale consists of fifteen items measuring how intensely an individual experiences anger during either the testing period, or a time or situation specified by the examiner. The 4-point Likert scale for the State Anger scale ranges from 1 (Not at all) to 4 (Very much so). Trait Anger scale is made by ten items measuring an individual's proneness to experience angry feelings. The 4-point Likert scale for this measure ranges from 1 (Almost never) to 4 (Almost always). The final part of STAXI-2 measures how individuals express and control anger. These scales consist of 32 items with answers ranging from 1 (Almost never) to 4 (Almost always). Scores above 60 and below 40 are considered to fall outside the normative range. Total scores of 65 and above indicate anger. STAXI-2 demonstrated reliable internal consistency has good reliability, alpha coefficients ranging from .81 to .93 (Spielberger, 1988).

#### *State-Trait Anxiety Inventory form Y (STAI-Y)*

The State-Trait Anxiety Inventory form Y (STAI-Y) is one of the most widely used self-report scales for assessing anxiety (Spielberger, 1983a, 1983b). It is a 4-point psychological inventory and consists of 40 questions on a self-report basis. The STAI-Y measures two types of anxiety - state anxiety, or anxiety about an event, and trait anxiety, or anxiety level as a personal characteristic. Each type of anxiety has its own scale of 20 different questions that are scored. The internal consistency achieves good values in both scales as shown by a Cronbach's  $\alpha=0.90$  (Ilardi et al., 2021). Scores range from 20 to 80, with higher scores correlating with more anxiety symptoms. Total scores of 40 and above indicate anxiety.

*Hamilton Rating Scale for Depression (HAM-D)*

The Hamilton Rating Scale for Depression (HAM-D) investigates the presence of depressive symptoms (Hamilton, 1960). It consists of 21 items, each of which provides answers with a 5-, 4- or 3-point rating scale. A score  $> 7$  indicates the presence of a depressive condition. Six factors can be isolated from the HAM-D: anxiety/somatization, weight, cognitive disturbance, diurnal variation, psychomotor retardation, sleep. The scale shows a good internal consistency, the average reliability estimate is  $\alpha = .79$  (López-Pina et al., 2009).

Information on age, gender, diabetes duration, age at diagnosis, anthropometric characteristics, metabolic control (HbA1c levels), insulin treatment (daily insulin unit requirement and type of insulin infusion) and diabetes-related complications (type and number) was collected. Local Ethic Committee approved the protocol and all participating subjects gave a written informed consent. The study was conducted according to the Helsinki Declaration.

*Statistical analyses*

Descriptive statistics (mean  $\pm$  standard deviation; frequency and percentages) were used to summarize continuous and non-continuous clinical and psychometric data, as requested. Clinical characteristics and psychological measures were compared using the chi-square tests for categorical variables and the Kruskal-Wallis test for continuous variables. The overall sample was divided into three groups, according to TAS-20 scores tertiles, with higher scores indicating higher levels of alexithymia. A Pearson correlation analyses was carried out to evaluate the association between TAS-20 and clinical and patient-centered outcomes. Two separate linear regression analyses were performed in order to identify the clinical characteristics (predictors) associated with higher TAS-20 scores (dependent variable). The first model was adjusted only for clinical characteristics: age, gender, age of diagnosis, BMI, HbA1c, microangiopathy, macroangiopathy. The second model was adjusted for the same set of covariates of the first model plus HAM-D, STAXI-2 and STAI-Y scores. A third regression analysis was performed in order to explore the predictive role of alexithymic status in determining HbA1c levels. A  $p$  value  $< 0.05$  was considered for statistical significance. Analyses were performed using SPSS version 17.0 (Inc., Chicago, Illinois).

**3. Results**

From a total of 79 subjects with type 1 diabetes to whom the study was proposed 75 of them agreed to participate, accounting for a participation rate of 94.9%. Alexithymia was present in 16.0% of studied subjects. Overall patients' characteristics and according to TAS-20 tertiles are summarized in table 1. No between groups differences in terms of age, gender, diabetes

duration, age at diagnosis, anthropometric characteristics, HbA1c levels, daily insulin unit requirement, type of insulin infusion and type and number of diabetes-related complications were detectable. People with diabetes of the upper TAS-20 tertile had the highest HAMD scores, the greatest rate of depression (with the highest degree of severity) and the highest STAXI-2 and STAI-Y scores (table 1).

**Table 1.** Overall and according to TAS-20 tertiles patients' characteristics.

	Overall	I tertile (n=25)	II tertile (n=26)	III tertile (n=24)	<i>p</i>
TAS-20	49.6±12.8	35.4±6.0	49.9±3.7	63.8±6.7	<0.0001
Gender (%):					0.67
Male	49.3	52.0	42.3	54.2	
Female	50.7	48.0	57.7	45.8	
Age (years)	41.0±11.4	39.2±10.1	42.6±13.2	40.9±10.7	0.59
Age of diagnosis (years)	21.1±11.8	20.1±12.2	20.2±8.5	23.0±14.5	0.63
Diabetes duration (years)	19.9±11.9	19.3±8.5	22.4±15.5	17.8±10.4	0.39
Classes of diabetes duration (%):					0.66
1-10 years	22.7	12.0	23.1	33.3	
11-20 years	29.3	36.0	30.8	20.8	
21-30 years	32.0	44.0	26.2	33.3	
>30 years	16.0	8.0	19.9	12.5	
BMI (Kg/m <sup>2</sup> )	25.5±4.0	24.6±3.4	25.1±3.7	26.8±4.5	0.13
Classes of BMI (%):					0.16
<25	47.2	54.2	56.0	30.4	
25-29	40.3	37.5	32.0	52.2	
≥30	12.5	8.3	12.0	17.4	
HbA1c mmol/mol (%)	63±10 (7.9±1.2)	63±9 (7.9±1.3)	62±10 (7.8±1.2)	65±11 (8.1±1.1)	0.69
Insulin units/die	40.4±24.5	35.2±18.3	37.4±25.4	49.4±27.5	0.10
Type of insulin infusion (%):					0.67
MDI	65.3	68.0	61.5	72.7	
CSII	30.7	28.0	38.5	27.3	
Diabetes complications (%):					
Microangiopathy	52.7	54.2	61.5	41.7	0.37
Non proliferative retinopathy	50.7	54.2	57.7	41.7	0.50
Proliferative retinopathy	6.7	8.3	0.0	12.5	0.20
Maculopathy	4.1	4.2	3.8	4.2	0.99
Microalbuminuria	6.7	8.4	7.7	4.2	0.84
Macroangiopathy	31.1	25.0	26.9	41.7	0.40
Cardiopathy	5.4	4.2	0.0	12.5	0.15
Peripheral artery disease	28.4	20.8	26.9	37.5	0.44
Feet	5.4	4.2	11.5	0.0	0.19
Neuropathy	14.9	16.7	19.2	8.3	0.54
Number of diabetes complications (%)					0.80
0	27.0	25.0	26.9	29.2	
1	41.9	41.7	50.0	33.3	
≥2	31.1	33.3	23.1	37.5	
HAMD	10.7±7.9	7.9±7.0	9.0±6.1	15.5±8.6	0.001
Depression [(HAMD >7) (%)]	56.0	40.0	50.0	79.2	0.02
Level of depression (%):					0.006
slight (HAMD 8-13)	25.3	16.0	30.8	29.2	
moderate (HAMD 14-18)	13.3	16.0	7.7	16.7	
severe (HAMD 19-22)	5.3	0.0	11.5	4.2	
very severe (HAMD ≥23)	12.0	8.0	0.0	29.2	
STAI2	52.4±11.6	44.9±10.0	54.0±7.4	58.4±13.0	<0.0001
Anxiety [(STAI >40) (%)]	85.3	64.0	100.0	91.7	0.001
STAXI-2	50.2±10.8	46.3±9.8	49.2±11.7	55.2±9.1	0.01
Anger [(STAXI-2 >65) (%)]	10.7	4.0	15.4	12.5	0.40

Moreover, TAS-20 was significantly correlated with BMI ( $r=0.26$ ;  $p=0.03$ ), HAMD ( $r=0.38$ ;  $p=0.001$ ), STAXI-2 ( $r=0.34$ ;  $p=0.003$ ) and STAI-Y ( $r=0.48$ ;  $p<0.0001$ ), showing that alexithymia is correlated both to clinical and patient-centered outcomes. Results of all the performed correlation analyses are reported in table 2.

**Table 2.** Correlations between TAS-20 and clinical and patient-centered outcomes.

	Spearman	<i>p</i>
Age	0.06	0.63
Gender	0.05	0.70
Age of diagnosis	0.10	0.39
Diabetes duration	- 0.10	0.38
BMI	0.26	<b>0.03</b>
HbA1c levels	0.06	0.62
Type of insulin infusion	- 0.09	0.46
Microangiopathy	- 0.06	0.60
Macroangiopathy	0.20	0.09
Number of diabetes complications	0.04	0.75
HAMD	0.38	<b>0.001</b>
STAXI-2	0.34	<b>0.003</b>
STAI	0.48	<b>&lt;0.0001</b>

At first linear regression model, including only clinical characteristics, high TAS-20 scores were associated with BMI (beta=0.29;  $p=0.02$ ), with age at diagnosis close to being statistically significant (beta=0.28;  $p=0.06$ ) (table 3). In the second model, including both clinical characteristics and patient-centered outcomes, the association between high TAS-20 scores and BMI (beta=0.28;  $p=0.007$ ) and the tendency to statistical significance for age at diagnosis (beta=0.23;  $p=0.07$ ) were confirmed; furthermore, a strong association with STAI-2 (beta=0.48;  $p<0.0001$ ) was detected (table 3). It is interesting to note that these results highlight that there are anthropometric variables with complex relationship with alexithymia not only mediated from psychological factors.

**Table 3.** Correlates of alexithymia from linear regression models.

	Model 1				Model 2			
	Beta	Lower limit CI 95%	Upper limit CI 95%	<i>p</i>	Beta	Lower limit CI 95%	Upper limit CI 95%	<i>p</i>
Age	- 0.14	-0.52	0.20	0.38	-0.11	-0.44	0.19	0.43
Gender	0.07	-4.50	7.90	0.59	0.08	-3.19	7.23	0.44
Age of diagnosis	0.28	-0.01	0.61	<i>0.06</i>	0.23	-0.02	0.51	<i>0.07</i>
BMI	0.29	0.16	1.71	<b>0.02</b>	0.28	0.26	1.57	<b>0.007</b>
HbA1c	0.08	-1.65	3.38	0.49	0.02	-1.98	2.38	0.85
Microangiopathy	-	-6.71	6.45	0.97	0.007	-5.38	5.71	0.95
Macroangiopathy	0.17	-2.58	12.0	0.20	0.13	-2.69	9.79	0.26
HAMD	-	-	-	-	0.09	-0.25	0.53	0.48
STAXI-2	-	-	-	-	0.006	-0.27	0.28	0.96
STAI	-	-	-	-	0.48	0.24	0.81	<b>&lt;0.0001</b>

Linear Regression Model 1 (Dependent variable: TAS. Predictors: age, gender, age of diagnosis, BMI, HbA1c, microangiopathy, macroangiopathy)

Linear Regression Model 2 (Dependent variable: TAS. Predictors: age, gender, age of diagnosis, BMI, HbA1c, microangiopathy, macroangiopathy, HAMD, STAXI-2, STAI).

Finally, alexithymia was not associated with HbA1c levels ( $\beta = -0.06$ ;  $p = 0.59$ ). HbA1c is a common tool in diabetes management which indicate the average blood sugar level. This result might confirm that the relationship between alexithymia and diabetes is indirect and mediated by multiple factors.

## 4. Discussion

### 4.1 Main findings

Our study represents a specific investigation of clinical and psychological correlates of alexithymia in a selected category of subjects represented by people with type 1 diabetes. The study foresaw the use of validated and standardized instruments. It permitted to assess the extent to which the association between alexithymia and clinical characteristics is mediated by psychological variables. High levels of alexithymia were particularly common among people with depression, anger and anxiety. Only one clinical characteristic, which was BMI, was associated with alexithymia. Subjects with high BMI could feel their weight as a negative factor capable of influencing their body picture. High BMI is also independently associated with high level of depression and psychological disadvantages (de Wit et al., 2010). Our finding is in line with previous results, which describes alexithymia as an important factor in emotional eating and BMI (Pink et al., 2019). An interesting result from Shank et al. (2019) also describes a significant relationship for alexithymia with eating in the absence of hunger, but not other disinhibited eating behaviors.

Even if with a borderline statistical significance, age at diagnosis was associated with high levels of alexithymia. It can be hypothesized that, given the impact of alexithymia on disease evolution, people with a younger age at diagnosis are more prone to cope with the disease management compared to people older at the time of diabetes diagnosis. This could more heavily affect subjects' psychological attitude to consider diabetes as an integral part of their own life and consequently to live with it.

When we took into account also psychological measures, a strong association between high levels of alexithymia and anxiety was revealed. Most studies have focused on anxiety-related syndromes associated with type 1 diabetes including fear of hypoglycemia, specific phobia of needles, and anxiety related to uptake of new and complicated diabetes technology (Majidi et



al., 2015). Interestingly, neither depression nor anger were significant independent predictors of alexithymia, their psychological dimensions being caught by anxiety. The association between alexithymia and anxiety appear to be well substantiated by previous research, an interesting model from Palser et al. (2018) propose that higher interoceptive sensibility in combination with alexithymia predisposes to anxiety. It can thus be conceivably hypothesized that interoceptive accuracy, which is altered in diabetes patients (Kiken et al., 2018), might in part explain this association in this group of patients. Notably, in no cases HbA1c levels resulted associated with alexithymia. It would be interesting to compare perceived blood glucose levels with anxiety levels.

#### **4.2 Comparison with existing knowledge**

The majority of existing literature on alexithymia and diabetes consists of case-control studies (Mnif et al., 2014).

Chatzi and colleagues assessed alexithymia and depressive symptoms of a sample of subjects with type 1 diabetes without any DSM-IV Axis I diagnosis comparing with healthy controls. They showed that alexithymia was higher in psychiatrically uncomplicated type 1 diabetes than in healthy controls, even after adjustment for confounding depressive symptoms (Chatzi et al., 2009). However, the selection of the sample they studied do not allow to generalize their findings because of the well-known interplay between psychiatric co-morbidity, psychopathological factors and type 1 diabetes. For this reason, it is likely that in real life condition people with type 1 diabetes could be affected also from depression or other disorders. Our study was conducted without excluding these subjects, this giving the opportunity also to detect depressive status or others psychological impairments. Anyway, none of the subjects to whom our study was proposed had a pre-existing diagnosed psychiatric co-morbidity or took drugs for this reason.

The attempt of some studies was to link alexithymia to diabetes-related clinical parameters. Alexithymia was positively associated with poor postprandial glycemic control, female gender, combination therapy, longer diabetes duration but not with worse outcomes in terms of glycemic control or diabetes-related complications (López-Muñoz & Pérez-Fernández, 2020). However, this study has two main limitations: first, it included a mixed population of subjects with both type 1 and type 2 diabetes; second, authors used only the instrument for the detection of alexithymia and did not considered others psychological measures. We wanted to explore several psychological aspects, particularly those reported to be mainly linked to type 1 diabetes and capable of influencing metabolic and more generally clinical parameters. With this regard

we included instruments capable of detecting anxiety, anger and depression, that could be strong mediators of alexithymia.

In an observational prospective pilot study involving 64 people with type 1 diabetes, the contribution of psychological measures such as depression, anxiety and alexithymia in determining good metabolic control during a fixed time was tested (Luminet et al., 2006). Results of the study were interesting: alexithymia predicted HbA1c levels over and above the predictive power of demographic information, health conditions, anxiety, and depression. Additionally, higher decrease in HbA1c was predicted by higher scores of alexithymia at baseline. Despite these attractive results, implications of the study on clinical practice should be taken with caution. The study was conducted in an inpatient setting, this limiting its generalization. Studied subjects were hospitalized and the psychological evaluation was performed at the start and at the end of the hospitalization period, this impairing not only the power of the questionnaire in catching the alexithimic dimension but also the capability in detecting score changes.

To the best of our knowledge there is no study planned with the aim to explore the different contribution of only clinical or clinical plus psychological characteristics in determining alexithymia. Our study is unique because it considered separately the effect of clinical and psychological factors in predicting alexithymia. Among the first we showed for the first time that an individual parameter such as BMI resulted a strong predictor of alexithymia, even when others psychological dimensions were taken into account. Furthermore, our findings showed how the presence of anxiety is able to minimize the effect of other dimensions such as anger and depression per se independently and strongly linked to alexithymia and in general to emotional problems (Hemming et al., 2019; Li et al., 2015).

### **4.3 Implications for clinical practice**

Several conditions capable of influencing progress and outcomes of the self-care process are referred to personality traits rather than psychiatric illnesses. Alexithymia might interfere with the level of communication between patient with diabetes and health care professional, this impairing the capacity of achieving good metabolic control and adherence to treatments. Results of the recent DAWN2 study depict a worrying situation (Nicolucci et al., 2016). The study assessed health-related quality of life, self-management, attitudes/beliefs, social support and priorities of people with diabetes with the aim to fully recognize the impact of the psychosocial burden of diabetes. Authors conclude that assessing and improving psychosocial outcomes of people with diabetes should be a priority. In this view a deep assessment of psychological status of subjects with diabetes in a standard clinical practice context is needed. Our study shows that

a direct association between alexithymia and anxiety exists. This finding calls for an organization of diabetes care strongly based on the centrality of patients (Lumley et al., 2007). Therefore, a challenge for healthcare systems is to extend the care of people with diabetes in order to detect and carefully consider those dimensions and factors related to psychological aspects. People with type 1 diabetes should have a periodic and comprehensive assessment of their psychological status.

#### **4.4 Strengths and limitations**

Our study has some limitations. First, because of its cross-sectional design, no inferences about a causal effect between alexithymia and anxiety can be drawn. We do not know whether the association between alexithymia and anxiety is a direct causal relationship, nor which direction a causal relationship might take, nor whether there might be underlying mechanisms that influence both alexithymia and anxiety other than those controlled for in this study. Longitudinal studies of the relationship between these two psychological dimensions in type 1 diabetes are warranted. A second limitation is that we do not included instruments specifically measuring self-care activities and empowerment. However, we included a series of questionnaires investigating the most common psychological dimensions typically impaired in type 1 diabetes. Depression and anxiety may be umbrella syndromes for other more complex psychopathological states that we have not investigated. Third the sample comes from a single hospital, a multicentric study is needed. These limitations are evidence of the difficulty of collecting real world evidence.

#### **5. Conclusions**

People with type 1 diabetes require a careful evaluation of their psychological status. Alexithymia is a psychological dimension not commonly investigated that deserves a systematic assessment. It is important to screen patients for anxiety which is common in type 1 diabetes and might worsen alexithymia status. In conclusion the findings of our research have considerable managerial implications, we believe that patients with Diabetes and Alexithymia could take advantage of psychological counseling. Future studies on the current topic are therefore required in order to elucidate the role of alexithymia in diabetes type 1, particularly the role of possible mediating factor between Alexithymia and BMI should be investigated.

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The work described has not been published previously, it is not under consideration for publication elsewhere, its publication is approved by all authors. If accepted, it will not be

published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

A first version of the data reported in this manuscript was presented at the American Diabetes Association (ADA) conference in 2015 and it is reported in the 2015 ADA Posters book (910-P).

### **Contributors**

All authors have materially participated in the research and/or article preparation. All authors have approved the final article.

B.P., G.D.V., A.N., A.B., M.M., C.C., R.Z. and A.D.B. contributed to the study design and acquisition of data, as well as the interpretation of data. B.P. and A.D.B. had the main responsibility for analyzing data and writing the first draft of the paper. G.G., B.P., G.D.V., A.N., A.B., M.M., C.C., R.Z. and A.D.B. critically revised the manuscript. B.P. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

### **Conflict of Interest Statement**

The authors declare that the research was conducted in the absence of any potential conflict of interest.

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