UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL

PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS MÉDICAS: ENDOCRINOLOGIA

ASPECTOS PSICOLÓGICOS E SUAS REPERCUSSÕES NO CONTROLE METABÓLICO E NAS COMPLICAÇÕES CRÔNICAS EM PACIENTES COM DIABETES MELITO TIPO 1 E TIPO 2

TESE DE DOUTORADO

CAROLINA CAMPOS GROSS

Porto Alegre, novembro 2008

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Resumo

Diabetes Melito (DM) é uma condição crônica que demanda uma série de cuidados médicos contínuos, cujos tratamentos requerem uma ação colaborativa entre o paciente, a família e a equipe de saúde.

A importância dos aspectos psicológicos no cuidado do DM vem sendo discutida em muitos estudos. Desenvolver habilidades de enfrentamento, de auto-cuidado, e de atitude frente ao tratamento são características desejadas para pacientes que desejem viver bem com o DM. Evidências recentes sugerem que pacientes com diabetes tipo 1 e tipo 2 apresentam freqüentemente alterações do comportamento psicológico que podem afetar o seu tratamento.

Problemas psicológicos e sociais podem prejudicar a habilidade individual de desempenhar as tarefas referentes ao tratamento, comprometendo o acompanhamento médico, o controle metabólico e conseqüentemente a qualidade de vida. A atenção aos aspectos psicossociais deve ser constante por parte da equipe de saúde. A avaliação da percepção do paciente a respeito do DM pode ser realizada através de questionários específicos.

Em conclusão, existe uma necessidade urgente de encontrar novas técnicas para diminuir o impacto econômico e pessoal desta doença crônica e progressiva, através de estratégias eficazes de prevenção, detecção e tratamento. A partir de uma perspectiva onde o foco seja a pessoa, e não a doença, é importante investigar as barreiras emocionais e comportamentais ao efetivo tratamento da doença e sua relação com o controle glicêmico.

Abstract

Diabetes Mellitus (DM) is a chronic condition that demands a continuous series of medical interventions, and whose treatment calls for a collaborative action between the patient, family and the health team.

The importance of the psychological aspects in the care of DM has been discussed in many studies. Developing coping skills of self-care and attitude in face of the treatment is a required aim for patients who want to live well with DM. Recent evidence suggests that type 1 and type 2 diabetic patients frequently have psychological and behavioral changes that can directly affect treatment

Psychological and social problems can impact the individual's skill in fulfilling the tasks related to the treatment, affecting the medical follow-up, metabolic control, and consequently the quality of life. The attention to the psychosocial aspects must be continuously sought by the health team. The assessment of the patient's perception of DM must be carried out through specific questionnaires.

In conclusion, there is an urgent necessity of finding new techniques to reduce the economical and personal impact of this chronic and progressive disease, through efficient strategies of prevention, detection and treatment. From a perspective where the focus is the person, and not the disease, it is important to access the emotional and behavioral barriers to the effective treatment of the disease and their relation with glycaemic control.

Saúde Mental e Diabetes Melito

O Diabetes Melito (DM) é uma condição crônica que demanda uma série de cuidados médicos contínuos. Segundo as diretrizes da *American Diabetes Association* (ADA), o diabetes é uma desordem caracterizada pelo aumento do nível de açúcar no sangue, denominado hiperglicemia, resultante de defeitos na secreção e/ou ação da insulina no organismo. A classificação do DM inclui quatro classes clínicas: diabetes tipo 1 (DM1), diabetes tipo 2 (DM2), diabetes gestacional e outros tipos específicos de diabetes (1).

Atualmente, o DM representa uma epidemia e um dos maiores problemas de saúde do mundo. De acordo com as estimativas, a previsão é de que, se as tendências se mantiverem, haverá um aumento de 246 para 380 milhões de pessoas com diabetes no mundo em 2025, sendo que o maior aumento é esperado em países em desenvolvimento (2).

O DM1 acomete indivíduos com menos de 40 anos de idade e representa 10-20% de todos os casos de DM, sendo que sua prevalência média é de 0,4% na maioria das populações brancas. No Brasil, sua incidência é estimada em 7,8 casos por 100.000 indivíduos com menos de 20 anos de idade (3). Pacientes com DM1 têm uma grave carência de produção de insulina no pâncreas e são propensos a desenvolver a cetoacidose, devendo passar toda a vida tentando equilibrar os níveis de glicose no sangue. A cetoacidose é um estado de descompensação grave em pacientes com DM1 que ocorre por uma deficiência absoluta de insulina e que, em geral, tem um fator desencadeante, por exemplo, infecção ou parada da medicação. Além disso, são dependentes de injeções subcutâneas de insulina para evitar cetoacidose e a morte prematura (1).

O DM2 corresponde a 80-90% dos casos de DM e ocorre em aproximadamente 5% da população ocidental (4). No Brasil esta prevalência foi de 7,6% em estudo multicêntrico realizado na década de 80 (5). Em um estudo populacional realizado em 2001, dos 22,1 milhões de brasileiros com mais de 40 anos rasteados com teste de glicemia capilar, 16% apresentaram glicemia alterada (6). Pacientes com DM2 têm uma capacidade de secreção de insulina residual, embora os níveis de insulina sejam inadequados para superar a resistência à insulina. A maioria destes pacientes são obesos e, em geral, não têm nenhum sintoma de diabetes no momento do diagnóstico.

Embora DM2 possa ocorrer em qualquer idade, geralmente é diagnosticado depois dos 30 anos de idade. A exata etiologia do DM2 ainda é desconhecida, entretanto sabe-se que fatores hereditários e ambientais são muito importantes, em especial a obesidade. Estudo populacional mostrou que, entre aqueles diagnosticados com a doença, pelo menos 50 a 75% não atinge o controle glicêmico adequado (7).

Mesmo que 80% dos indivíduos com diabetes tipo 2 sejam obesos, ou tenham tido história de obesidade no momento do diagnóstico, este tipo de diabetes pode ocorrer em indivíduos não obesos, especialmente em idosos. Pacientes com DM2 não são propensos a desenvolver cetoacidose, exceto em períodos de estresse, assim como aqueles causados por infecções, traumas ou cirurgias. Apesar de não serem dependentes de injeções de insulina para sobreviver, muitos necessitam utilizá-la para um controle adequado da glicemia. A prevalência do diabetes tipo 2 aumenta de acordo com a idade e grau de obesidade e sedentarismo do sujeito (1).

Os tratamentos para o DM variam de acordo com o tipo da doença, mas de modo geral incluem a aquisição de uma alimentação saudável, a prática regular de atividade física, o uso de

medicações apropriadas, o uso de insulina (para todos pacientes com DM1 e para alguns com DM2) e a auto-monitorização da taxa de glicemia (8). Independente do tipo de DM, o tratamento requer uma ação colaborativa entre o paciente, a família e a equipe de saúde. Deste modo, é fundamental que o paciente e a família estejam em constante aprendizado a respeito do auto-cuidado a fim de prevenir complicações agudas e reduzir o risco de complicações crônicas (9).

A importância dos aspectos psicológicos no cuidado do DM vem sendo discutida em larga escala nas últimas décadas (10). A saúde mental é considerada condição *sine qua non* para alcançar uma vida com qualidade, especialmente quando se convive com uma condição médica crônica como o DM. Desenvolver habilidades de enfrentamento, de auto-cuidado, e de atitude frente ao tratamento são características desejadas para pacientes que desejem viver bem com o DM (11).

Recentemente, a ADA anunciou as últimas recomendações a respeito da avaliação e da assistência psicossocial necessárias para se atingir um tratamento efetivo do DM (8). Dentre as diretrizes assistenciais, a avaliação psicossocial foi apontada como fundamental durante todas as fases do tratamento, devendo ser incluída nas rotinas, através de mensurações constantes acerca das atitudes a respeito da doença, das expectativas com relação ao tratamento e desfechos, das medidas de afeto/humor, qualidade de vida, recursos emocionais, sociais e financeiros e a história psiquiátrica. Quando a adesão ao tratamento proposto for insuficiente, recomenda-se avaliar o paciente com relação aos transtornos psiquiátricos como depressão, ansiedade, transtornos alimentares e prejuízos cognitivos (11-13).

Problemas psicológicos e sociais podem prejudicar a habilidade individual (11-16) e/ou familiar (17) de desempenhar as tarefas referentes ao tratamento, comprometendo a qualidade de vida. A atenção aos aspectos psicossociais deve ser constante por parte da equipe de saúde. A

avaliação emocional pode ser realizada por qualquer membro da equipe e deve, o mais breve possível, ser encaminhada para um profissional de saúde mental com *expertise* em diabetes. Existem inúmeras oportunidades de avaliação do *status* psicológico dos pacientes e familiares, como no diagnóstico, durante as consultas regulares ou em hospitalizações, no surgimento de complicações da doença ou quando se identificam problemas em lidar com o tratamento ou com prejuízos na qualidade de vida (18).

A vulnerabilidade psicológica dos pacientes pode manifestar-se em qualquer momento do tratamento. Entretanto, deve-se dispensar especial atenção ao período do diagnóstico ou quando o *status* médico se altera, por exemplo, no final do período conhecido com lua-de-mel em pacientes com DM1, quando se torna evidente a necessidade de intensificar o tratamento ou ainda quando surgem as primeiras complicações crônicas (19).

Questionários de Avaliação

Desde a década de 70, questionários de avaliação têm sido utilizados como uma ferramenta de mensuração da percepção do paciente sobre a doença e como forma de avaliação de novas terapêuticas (18). As escalas genéricas de avaliação de Qualidade de Vida (QV) foram desenvolvidas com o objetivo de avaliar o impacto causado por uma determinada doença, avaliando vários aspectos (capacidade funcional, aspectos físicos, dor, estado geral de saúde, vitalidade, aspectos sociais, aspectos emocionais e saúde mental).

Existem muitas ferramentas para mensurar a QV em pacientes com doenças crônicas (15). Conhecidas como *Health Related Quality of Life* (HRQV), estas medidas têm o poder de fornecer escores objetivos acerca da percepção do paciente sobre a doença e suas diversas

implicações. Questionários específicos fornecem uma maior sensibilidade às particularidades de determinada doença.

Nas últimas décadas, pesquisadores desenvolveram medidas de avaliação com o objetivo de ampliar a compreensão dos fatores que podem intervir no sucesso do tratamento do DM. Com relação aos instrumentos específicos para avaliar aspectos do bem-estar subjetivo dos pacientes com diabetes, foram desenvolvidas algumas escalas, que se diferenciam em focos de atenção e conteúdos específicos (16, 17). Entre eles estão: *Diabetes Care Profile* – DCP (18), *Diabetes Quality of Life Measure* – DQOL (19, 20), *Diabetes Impact Measurement Scale* – DIMS (21), *Appraisal of Diabetes Scale* – ADS (22), *Audit of Diabetes-Dependent Quality of Life* – ADDQoL (23), *Diabetes Health Profile* - DHP-1 e DHP-18 (24), *Questionnaire on Stress in Patients with Diabetes-Revised* - QSD-R (25,26), *Well-Being Enquiry for Diabetics* –WED (27), *Diabetes-Specific Quality-of-life Scale* – DSQOLS (28), *Diabetes 39*- D-39 (29), *Problems Areas in Diabetes* - PAID (30, 31), *Hypoglycemia Fear Survey* –HFS (32) entre outros (33).

No Brasil, atualmente existem apenas 3 questionários validados que avaliam questões específicas do diabetes. O *Diabetes Quality of Life Measure* (DQOL-Brasil) originalmente foi desenvolvido pelo renomado grupo do *Diabetes Control and Complications Complications Trial* (DCCT) para adolescentes e adultos com DM 1, mas posteriormente foi utilizado em pacientes com DM2 (19,35). Este instrumento, delineado especificamente para avaliar a qualidade de vida relacionada ao DM, foi recentemente adaptado e validado para ser utilizado no Brasil, apresentando confiabilidade e validade adequadas para ser utilizado com pacientes com DM2, apresentando um α de *Cronbach* 0,92 (34). Uma versão para crianças, *Diabetes Quality of Life for youths,* também foi desenvolvida e validada no Brasil (35).

O *Problem Areas in Diabetes Scale* (PAID) é um questionário amplamente utilizado em pesquisas e na clínica e tem mostrado utilidade clínica, tendo sido adaptado em alguns países. Estudos prévios apontam a correlação do PAID com comportamentos de auto-cuidado, com o controle-glicêmico, com o estresse percebido, com crenças a respeito do diabetes e estratégias de *coping* específicas do diabetes (36-39). Foi desenvolvido especificamente para mensurar o sofrimento que os pacientes comumente experimentam com relação ao viver com DM. Consta de 20 questões acerca da percepção do indivíduo sobre os problemas enfrentados na rotina de cuidados com a doença em uma escala Likert de 4 pontos. Apresenta 4 sub-escalas: problemas com alimentação, problemas com o apoio social, problemas com o tratamento e problemas emocionais. Num escore de 0-100 quanto maior o valor, mais problemas o sujeito percebe com relação ao DM. Este questionário pode ser uma ferramenta útil capaz de orientar os profissionais e os pacientes a priorizarem e focarem sua atenção em dificuldades específicas e individuais que possam prejudicar o sucesso do tratamento.

A versão original foi desenvolvida por Polonsky *et al* (30) e a versão brasileira foi adaptada pelo nosso grupo e mostrou condições psicométricas e validade adequadas em pacientes com DM2, com um α de *Cronbach* de 0,93 (31). Nesta amostra de pacientes sul-brasileiros, o PAID mostrou que pacientes mais jovens e menos instruídos apresentam escores mais elevados de estresse com relação ao DM e concluiu-se que estes devem ser priorizados nos atendimentos.

Estes questionários podem ser úteis tanto em pesquisa como na prática clínica. Quando utilizados de forma apropriada, podem ser uma ferramenta auxiliar para orientar os profissionais a focalizarem sua atenção em dificuldades específicas e individuais de cada paciente.

Intervenções Comportamentais

Com o crescente número de pessoas com diabetes, existe uma necessidade urgente de encontrar novas técnicas de diminuir o impacto econômico e pessoal desta doença crônica e progressiva, através de estratégias eficazes de prevenção, detecção e tratamento. DAWN (*Diabetes Attitudes, Wishes and Needs*) é um projeto internacional promovido pelo Laboratório Novo Nordisk em parceria com a *International Diabetes Federation* (IDF) que, desde 2001, objetiva identificar as dificuldades enfrentadas pelos pacientes e profissionais da saúde na luta para viver com o diabetes. A partir de uma perspectiva onde o foco é a pessoa e não a doença, visa investigar as barreiras emocionais e comportamentais ao efetivo tratamento da doença (40).

Este importante estudo incentivou o desenvolvimento de uma série de projetos de pesquisa. Os primeiros achados identificaram metas a serem alcançadas mundialmente com o objetivo de aumentar o controle do diabetes (41,42). São elas: promover o papel ativo de auto-cuidado, intensificar o cuidado psicológico dos pacientes; aumentar a comunicação entre os pacientes, família e equipe de saúde; promover comunicação e coerência entre a equipe de saúde; reduzir as barreiras ao tratamento efetivo. A partir destes achados, as ações propostas são as seguintes: aumentar a conscientização sobre a doença; educar e mobilizar pessoas com diabetes e com maior risco de serem diagnosticadas; treinar profissionais da saúde e intensificar competências; promover ferramentas e sistemas práticos; executar mudanças no sistema e políticas de saúde; desenvolver pesquisas psicossociais em diabetes.

Estudos mostram a importância de desenvolver terapêuticas psicossociais efetivas para pacientes com DM (43-45). Mudanças comportamentais compreensivas são cada vez mais necessárias à medida que o tratamento pode ficar mais intensivo com o passar do tempo (46). A assistência psicológica específica deve ajudar o paciente a efetivar estas mudanças e preservar os

esforços realizados com o objetivo de atingir e manter a qualidade de vida e um bom controle glicêmico (47).

Embora poucos ensaios clínicos tenham sido conduzidos nesta área, as intervenções psico-educativas que têm mostrado maior efeito são as baseadas em Técnicas Cognitivo-Comportamentais (TCC), individuais ou em grupo (48-50). Sabe-se que grande parte dos pacientes com DM se beneficiam de práticas psicoterapêuticas bem indicadas (44, 51).

Pacientes com DM1 e controle glicêmico inadequado (HbA1c $\geq$ 8%) foram selecionados para participar de um programa de 6 semanas de psicoterapia de grupo em TCC ou para uma intervenção para melhorar a percepção dos sintomas de hipoglicemia. Os pacientes foram avaliados quanto ao controle glicêmico e com relação às questões psicossociais (Depressão, estresse e auto-eficácia relacionados ao DM). Os resultados mostraram que nos dois grupos o controle glicêmico se manteve igual, mas os pacientes apresentaram uma melhora significativa nos sintomas psicológicos, por exemplo, na escala PAID os escores passaram de 47.0 ± 21.6 para 42.6 ± 20.8 (49).

Recente meta-análise mostrou que os tratamentos psicológicos podem melhorar o controle glicêmico em crianças e adolescentes, mas em adultos não apresenta nenhum efeito (52). Uma revisão sistemática sugere que intervenções familiares podem ser efetivas na melhora do controle glicêmico e nos conhecimentos da família sobre a doença. Este resultado foi baseado em 19 estudos com mais de 700 pacientes (53).

Recente estudo multicêntrico com 344 pacientes mostrou que terapia motivacional conduzida por enfermeiros e a terapia cognitivo-comportamental são práticas factíveis em pacientes adultos com DM1 mal-controlado. Ambas terapias combinadas resultaram em uma

modesta melhoria no controle glicêmico durante 12 meses comparado ao cuidado usual, mas a terapia motivacional sozinha não demonstrou este efeito (54).

Programas integrados educacionais e psicoterápicos melhoram significativamente comportamentos de auto-cuidado em pacientes com diabetes (55,56). Evidências de 72 estudos comprovam a efetividade, a curto-prazo, do treinamento do auto-cuidado em pacientes com DM2, na melhora do controle glicêmico (55). Programas terapêuticos são mais efetivos quando são orientados às necessidades individuais dos pacientes (57). A construção de um ambiente terapêutico colaborativo (58), a identificação das crenças a respeito da eficácia do tratamento e seriedade da doença (59), focada na perspectiva do paciente (60) e o treinamento de habilidades para solucionar problemas são terapêuticas que têm se mostrado efetivas em pacientes com DM.

Programas que incluem a Entrevista Motivacional são considerados métodos efetivos em mudanças comportamentais em adolescentes com DM1 e conseqüentemente melhoram o controle glicêmico (61,62). Em estudo com 60 pacientes, durante 12 meses, a média da hemoglobina glicada melhorou no grupo que participou da entrevista motivacional. (61).

Os sinais de que o paciente deve ser encaminhado para um serviço de saúde mental são a não-adesão ao tratamento (pelo paciente ou cuidadores), a presença de sintomas de depressão com possibilidade de auto-agressão (63, 64), de ansiedade elevada (11), de transtornos alimentares (65) e funcionamento cognitivo alterado que prejudique o julgamento do paciente (66). Portanto, é preferível incluir a avaliação psicológica na rotina do que aguardar que apareçam os transtornos propriamente ditos (67).

Tendo em vista que o DM1 e o DM2 são enfermidades diferentes, as repercussões psicológicas também tendem a ser distintas. Embora existam semelhanças no tratamento, as

intervenções devem levar em conta particularidades como: a idade de início da doença, a etapa do desenvolvimento, o *status* social e intelectual e o tipo de tratamento.

Considerações Finais

A rotina de cuidados do DM exige que os pacientes assumam um papel ativo no tratamento, sendo capazes de administrar informações complexas a respeito de sua saúde. Assim, é importante que as demandas psíquicas dos pacientes sejam assistidas constantemente.

Deste modo, torna-se necessário analisar as características das pessoas que conseguem atingir um bom controle glicêmico. Para tanto, é importante investigar não só as vulnerabilidades, como as comorbidades psiquiátricas, a adesão e a qualidade do tratamento de saúde, mas também os aspectos positivos e as potencialidades de enfrentamento da doença.

Em conclusão, é fundamental a realização de estudos que busquem investigar as barreiras psicológicas ao tratamento efetivo assim como o perfil daqueles pacientes que conseguem manter a qualidade de vida e também obtêm sucesso no cuidado. Para tanto é necessário levar em conta as diferenças existentes entre os pacientes com diagnóstico de diabetes tipo1 e aqueles com diabetes tipo 2.

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Capítulo 2

Metabolic Control and Microvascular Complications are Associated with Psychological Aspects in Patients with Type 1 Diabetes

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Abstract

AIMS: To assess psychological aspects in a cohort of type 1 diabetes patients and to analyze a possible association with the degree of metabolic control and presence of chronic complications.

RESEARCH DESIGN AND METHODS: Consecutive literate patients with type 1 diabetes attending the outpatient diabetes clinic of a university hospital were invited to complete the following questionnaires: Hospital Anxiety and Depression Scale (HADS), Eating Disorder Examination (EDE-Q), Problem Areas in Diabetes Scale (PAID), Resilience and the Perceived Coercion. The presence of micro- and macrovascular complications was obtained according to a standardized protocol. A1c was measured by a high-performance liquid chromatography system.

RESULTS: A total of 83 patients were included and 37 (45%) reported mild or moderate symptoms of anxiety and 21 (25%) of depression (≥ 8 score on HADS anxiety and depression, respectively). In a multiple regression analysis A1C was positive associated with diabetes distress assessed by PAID ($r^2 = 0.133$, B = 0.366, P = 0.003), EDE-R ($r^2 = 0.121$, B = 0.340, P = 0.005) and HADS depression ($r^2 = 0.071$, B = 0.259, P = 0.039). Patients with diabetic retinopathy had higher depression scores.

CONCLUSIONS: Patients with type 1 diabetes frequently presented symptoms of anxiety and depression and the degree of metabolic control was associated with diabetes related distress, and eating disorder aspects are associated with worsened metabolic control. Moreover, patients with diabetic retinopathy appear to have an increased depression score Patients with type 1 should undergo routine psychological assessment to identify those, who might benefit from psychological intervention.

Keywords: type 1 diabetes, psychological aspects, metabolic control

Introduction

Type 1 diabetes (T1DM) affects quality of life and requires psychological ability to cope effectively with treatment demands. Suboptimal glycaemic control and disease complications are associated with depression, anxiety eating problems and diabetes specific fears (1-7). Patients with T1DM are at higher risk for developing psychiatric illness since diabetes treatment imposes an intense and repetitive treatment routine, potentially increasing the daily level of stress and impacting significantly on the life of the individual and his family.

The most prevalent psychological problems in patients with diabetes are anxiety, depression, and disordered eating behaviours. Female patients with T1DM show increased rates of major depression (9.3% compared with 3.2% in the control group) and higher levels of anxiety than men (2, 5). Diabetes is also considered a risk factor for developing disordered eating behaviours and young females with T1DM may have twice as much Eating Disorders (ED) than those without diabetes. These comorbid conditions can interfere with self-care and glycaemic control and are associated with increased morbidity, mortality, and functional limitations as well as health care costs (8-15).

Diabetes-specific quality of life is an important domain of diabetes management. To live well with diabetes, patients need to accept the diagnosis, integrate demanding self-care into their daily routine, and learn to cope with the potential for complications. An effective medical treatment plan should consider diabetes-specific quality of life as well as glycaemic control as an important health outcome (16). Diabetes-related emotional distress is an important element of diabetes quality of life that may influence adherence to self care, glycaemic control, and risk of complications. It can be measured with the Problem Areas in Diabetes (PAID) Scale. PAID

scores are correlated with self-care behaviours, glycaemic control, perceived burden of diabetes, diabetes-related health beliefs and diabetes coping (8, 17-19).

Resilience and perceived coercion are other important psychological aspects that might influence adherence to the treatment and consequently metabolic control. Resilience is defined as the process of successful coping with or reintegration from life events, stressors, and adversity through the use of various protective qualities and by accessing one's innate resilience (20). Coercion is defined as the act of limiting, impeding, restraining or forcing someone to act in a certain way. A voluntary and active action, such as diabetes treatment, assumes that there is no perceived coercion.

Very few studies have analysed the aspects of depression, anxiety, eating disorders and quality of life in patients with T1DM and the possible influence in metabolic control, but only one analysed the role of resilience in psychological adjustment to type 1 diabetes (21). There are no studies analyzing patient's perceived coercion in diabetes treatment**.** Considering that mental counselling reduces the A1c level (1) we hypothesized that, by identifying the psychological aspects associated with metabolic control, one could detect the individuals who might benefit from mental health care.

Therefore, this study aimed to assess psychological aspects, specifically depression, anxiety, eating disorders, diabetes specific quality of life, resilience and perceived coercion through validated scales in a cohort of T1DM patients and to analyze a possible association with the degree of metabolic control and presence of chronic complications.

Subjects, materials and methods

This study followed a cross sectional design in a cohort of consecutive patients attending the outpatient clinic of the Endocrine Division of the Hospital de Clínicas de Porto Alegre during

the period from April 2007 to December 2007. The study protocol was approved by the Ethics Committee of the hospital, and written informed consent was obtained from all patients.

The inclusion criteria were: literacy, ages between 14 and 60 years, diagnosis of T1DM at least 1 year before the interview. Patients with severe chronic complications such as amaurosis, chronic renal failure in renal replacement therapy, major amputations, serious disease that limits life expectancy to less than 1 year, clear cognitive deficit or history of major psychiatric disease were not included.

Patient Evaluation

One hundred and sixty-five patients were invited to participate after a brief explanation about the objectives of the study. Eighty-three subjects completed all the proposed evaluation procedures and 82 did not participate due to limited time availability or did not show an interest.

Clinical Measurements

Clinical data were obtained according to a standardized protocol as previously described (22). Briefly, patients underwent an interview and clinical examination to record demographic and anthropometrical data. Physical activity level was assessed by a self-report questionnaire (23). Body mass index (BMI) was calculated [weight (kg)/height^2 (m)]. Eye fundus examination was performed by an experienced ophthalmologist after mydriasis and, for the purpose of this study, patients were grouped according to the presence or absence of any degree of diabetic retinopathy (DR). The presence of diabetic nephropathy (DN) was defined according to urinary albumin excretion rate (UAER), measured in two 24-h sterile urine collections, at 3-monthly intervals. Patients with microalbuminuria (UAER $\geq$20 and $\leq$200 μg/min) and macroalbuminuria (UAER >200 μg/min) were analyzed as a group with DN. Neurological evaluation consisted of

physical examination of the foot for deformities, callus, infection, ulceration, ankle reflexes, with the patient in the sitting position, twice (normal, reduced or absent); vibration perception threshold (normal, reduced or absent, 128 MHz tuning fork) at the dorsum of the great toe. The same trained examiners tested all participants. The diagnosis of peripheral neuropathy was established if there was a score of > 2 on Michigan Neuropathy Screening Instrument clinical portion (24).

Laboratory Measurements

UAER was measured by immunoturbidimetry (Microal; Ames-Bayer, Tarrytown, NY) (intra-and interassay coefficients variation of 4.5 and 11%, respectively). A1C test was measured by the high-performance liquid chromatography system (reference range 4.7 – 6.0%; Merck-Hitachi 9100, Merck, Darmstadt, Germany).

Psychological Assessment

Subjects were asked to complete the following self-report questionnaires: Hospital Anxiety and Depression Scale (HADS), Eating Disorder Examination (EDE), Problem Areas in Diabetes Scale (PAID), Resilience, and Perceived Coercion scales. An adequately silent environment was offered.

Hospital Anxiety and Depression Scale (HADS)

The HADS is a well-validated questionnaire that has been widely used in medical and research populations (25). It is divided into two subscales to assess symptoms of anxiety and depression separately. Each subscale consists of seven questions with a maximum score of 21. Scores are interpreted to indicate symptoms that are either mild (between 8 and 10), or moderate to severe (between 11 and 21). The Portuguese version of the scale was validated in Brazil (26)

and proved to have adequate internal consistency (*Cronbach's alpha*= 0.68 and 0.77 on anxiety and depression scales, respectively).

Eating Disorder Evaluation –Questionnaire (EDE-Q)

The EDE-Q is a 36-item self-report measure derived from the Eating Disorders Examination interview (EDE) and therefore it is based on the DSM-IV criteria (27). Items addressing eating disorders particular behaviours, attitudes or feelings are scored using a 7-point Likert scale, forced-choice, rating scheme focusing on the past 28 days. Scores ≥ 4 indicate clinically significant eating disorder symptoms. This instrument generates a global score which is the average of its four subscale scores, namely: Restraint (EDE-R), Eating Concern (EDE-E), Shape Concern (EDE-S) and Weight Concern (EDE-W). The Portuguese version show high internal consistency (*Cronbach's alpha* = 0.95) and was developed in Portugal (28) and adapted to Brazilian Portuguese (29). To address diabetes specific issues, we included 2 items about insulin omission for the purpose of weight loss.

Problem Areas in Diabetes Scale (PAID)

The PAID is a 20-item self-report measure of diabetes-related emotional distress with high internal reliability, sensitivity to change, and clinical usefulness (17-19). Questions are framed as 'From your own perspective, to what degree are the following diabetes-related issues currently a problem for you?' with a 6-point scale to rate each item (ranging from 0 = 'not a problem' to 5 = a 'serious problem'). This questionnaire has four subscale scores, namely: Emotional, Social, Treatment and Food diabetes problems. The Brazilian Portuguese version (B-PAID) was previously validated by our group in a sample of patients with Type 2 Diabetes in southern Brazil and showed high levels of internal consistency (*Cronbach's alpha* =0.93) (30).

Resilience

The Resilience Scale was originally developed by Wagnild & Young (31) to measure positive psychosocial adaptation levels during important life events. It has 25 positive descriptive items, with a 7 point Likert scale, varying from totally disagree (1) to totally agree (7). Scores vary from 25 to 175 points, higher values indicating elevated resilience status. It was validated into Portuguese in a sample of healthy students in Brazil (*Cronbach's alpha* = 0.80) (32).

Perceived Coercion

The Perceived Coercion is an adapted 4 item scale that assesses patient perceived coercion about the treatment. It includes items about the patient's perception about their role on treatment, such as "Did I have sufficient opportunity to communicate my expectations about the treatment?" Answers can vary from agree to disagree. The original version was developed by Hoge & colleagues (33) and a Portuguese version was adapted with a hospitalized patient sample (34).

Statistical Analysis

Data were expressed as mean ± standard deviation (SD), or as median (minimum-maximum). Quantitative variables without normal distribution were log transformed. Student t test or chi-square tests were used to compare clinical and laboratory data. Pearson correlations were used as appropriate. Multivariate linear regression models were constructed with A1c as dependent variable and values of the scales and diabetes duration as independent variables. Multiple logistic analyses were also performed with microvascular complications as dependent variables and Anxiety, Depression and Eating Disorders questionnaires as independent variables. P values <0.05 (two tailed) were considered to be significant.

Results

Of 165 patients invited to participate 50.3% (n=83) accepted and completed the clinical, laboratory assessment and answered the questionnaires. The mean age was 30.5 ± 11.0 years, 90% (n=75) were white and 58% (n=48) male. The mean BMI was 24.8 ± 3.8 kg/m^2 and mean waist circumference was 84.5 ± 10.8 cm. Patients had a mean duration of diabetes of 17.1 ± 8.7 years. The patients were usually normotensive with systolic and diastolic blood pressure levels of 115.8 ± 14.8 and 74.2 ± 11.2 mmHg, respectively. The mean A1c was 8.2 ± 1.7%. Regarding level of education 22.5% (n=18) had basic education, 40% (n=33) had completed high school, 20% (n=16) had completed the undergraduate level, and only 5% (n=4) had reached the level of *post* graduate education. Concerning socio-economic aspects, 56% (n=46) were not married and average family income was reported to be equivalent to US$ 850.00 per month. All patients were treated with basal (NPH or glargine) and bolus (regular or lispro) insulin regimen. The majority of the patients, 66.2% (n=55) do not receive any psychological or psychiatric assistance and only 5% (n=4) of the patients were using antidepressant medications. Finally, 42% (n=35) patients reported regular exercise.

Patients not included (n = 82) did not differ from the study group regarding mean age (33 ± 10.8 years, P=0.74), ethnicity (90% were white, P=0.83) and gender (53 % were male, P=0.24), mean BMI (24.4 ± 3.3 kg/m^2, P=0.53), waist circumference (84.5 ± 10.8 cm, P=0.38), duration of diabetes (16.2 ± 9.1 years, P=0.13) and A1c level (8.5 ± 1.9 % , P=0.15)

Concerning the prevalence of chronic complications of diabetes, 15 (18% of the patients were considered to have DN (microalbuminuria 12%, macroalbuminuria 6%) and 37 (45%) had DR, although no patient had severe visual problems affecting reading. Peripheral neuropathy was

identified in 12 (15%) of the patients. No patient had macrovascular complications characterized by coronary artery disease, stroke or peripheral vascular disease.

Regarding the psychological assessment the scores of the scales were (mean ± SD): HADS Anxiety scores 7.8 ± 4.6, HADS Depression 5.9 ± 3.9, EDE-Q 1.5 ± 1.3, PAID 44.4 ± 25.3, Resilience 129.1 ± 16.1 and Perceived Coercion 0.58 ± 0.9. Presence of mild to moderate symptoms of anxiety (HADS Anxiety score ≥ 8) was observed in 37 (45%) of the patients and 21 (25%) reported scores of 8 or more on HADS Depression scale. Of those patients that reported high levels of anxiety symptoms, 18 (48.6%; $P<0.001$) also had high level of depression scores. Only 4 (5%) patients fulfilled the criteria for the presence of clinically significant eating disorder symptoms (EDE-Q ≥ 4) and 5 (6%) patients (4 women and 1 man) mentioned insulin omission or dose reduction for the purpose of weight control. Only 1 patient who reported insulin omission showed a positive eating disorder score, but the other 4 patients had scores in the EDE subscales (shape, weight, eating and restrain) ≥ 4, suggesting the presence of some degree of eating disturbance.

The correlation coefficients of psychological scales, with BMI (kg/m^2), diabetes duration (years) and A1c (%) were described in Table 1. BMI had a positive correlation with EDE, EDE-W, EDE-S, EDE-R and a negative correlation with HAD Anxiety and Perceived Coercion. There was no correlation between BMI and insulin omission or dose reduction. Duration of diabetes presented a significant negative correlation with the HAD Anxiety ($r= -0.280$, $P < 0.05$). A1c was significantly associated with PAID, Resilience, HAD Depression and EDE subscale Restrain (EDE-R) scores.

Interestingly, the PAID scale was significantly correlated with Resilience, HADS Anxiety, HADS Depression, EDE-Q, EDE-E, EDE-S and EDE-W.

Multiple linear regressions models were performed with A1c as the dependent variable and diabetes duration and one of the following scales PAID, RES, EDE-R or HADS depression as independent variables. Only Resilience did not remain associated with A1c. PAID ($r^2 = 0.133$, B = 0.366, P = 0.003), EDE-R ($r^2 = 0.121$, B = 0.340, P = 0.005) and HADS depression ($r^2 = 0.071$, B = 0.259, P = 0.039) remained significantly associated with A1c.

A1c levels, duration of diabetes, BMI and presence of microvascular complications were analyzed in patients grouped according to the presence of anxiety (HADS ≥8), depression (HADS ≥8) and eating disorders (EDE ≥4) (Table 2). Patients with mild to moderate symptoms of anxiety had shorter duration of diabetes than non-anxious patients. Female had more anxiety symptoms [n=21 (56.8%)], than men [n=16 (43.2%)], P=0.01. Patients with mild to moderate symptoms of depression had higher Alc values than patients with lower scores and females also had more intense symptoms of depression [n=13 (61.9%)], than men [n=8 (38.1%)], P=0.03. Finally, patients with eating disorders had higher BMI than patient without these symptoms. There were no gender differences regarding eating disorder scores.

The scores of the psychological scales according to the presence or absence of microvascular complications were described in Table 3. Patients with DN had lower levels of anxiety symptoms than patients without DN. Depression symptoms were more frequent in patients with DR and neuropathy than in patients without these complications.

To analyze a possible association between psychological measurements and microvascular complications, separate models of multiple logistic regression analysis with DN, DR and neuropathy as dependent variables, and A1c, duration of diabetes and anxiety or depression scores as independent variables were performed. DN was associated with duration of diabetes [OR: 1.12 (95% CI: 1.02 – 1.23), P = 0.013)] and anxiety [OR: 0.03 (95% CI: 0.002 –

0.88), P = 0.04]. DR was associated with duration of diabetes [OR: 1.14 (95% CI: 1.06 -1.23), P<0.001] and HAD depression had borderline significance [OR: 1.17 (95% CI: 0.98 – 1.33), P = 0.07]. Neuropathy did not show association with the variables analyzed.

Discussion

In this sample of patients with type 1 diabetes mild to moderate symptoms of anxiety and depression were frequent, and patients with anxiety had higher levels of A1c. A1c levels were also associated with diabetes distress (PAID scale), and eating restraint concerns. Microvascular complications were more frequent in patients with anxiety and depression.

Very few studies have analysed the prevalence of anxiety in patients with type 1 diabetes. The prevalence of mild to severe symptoms of anxiety observed in this sample (45%) was similar to that reported by Shaban et al. (37%) using the same method of assessment (HADS questionnaire) (5). In another study (35), the prevalence of anxiety was only 25.2%, but the authors employed the State Trait Anxiety Inventory, which was conceived for the general population and not for subjects with health problems.

Depression has been studied more often in patients with type 1 diabetes and has been reported to occur in 11 to 60% (3). This wide range of prevalence may be related to the methods used to assess depression, the settings from which patients were recruited, ethnicity, age range and other factors (3). In Shaban´s study, the prevalence of mild to severe symptoms of depression seems to be less frequent (13.5%), but it is not significantly different from our sample (25%, chi-square, P=0.44) (5).

The prevalence of eating disorders in patients with type 1 diabetes varied from 15 to 38% depending on the criteria used to define this situation, the ethnic origin and the settings where the patients were recruited (4, 14, 15, 36, 37). In the present study, only 4% of the patients fulfilled

the criteria for the presence of ED according to the questionnaire used (EDE-Q ≥ 4), and 6% reported insulin omission or dose reduction for the purpose of weight control. This lower prevalence than in the other studies might be due to the use of different diagnostic criteria (14, 15). In the study of Peveler and collaborators. the authors used the same questionnaire plus an interview taking into account the specific eating behaviours of diabetes and previous diagnosis on clinical notes (4).

Regarding diabetes related distress, assessed by the PAID questionnaire, we found higher scores (44.4 ± 25.3) than in a population based study conducted in the Netherlands (24.6 ± 18.7) and at the Joslin Clinic in USA (33.4 ± 22.2) (19). The high value of diabetes related distress in our sample might be due to the selection of patients taking place at a tertiary centre, which might indicate that the cases were more complex and may have also social economical reasons. It is interesting to note that the PAID scale was significantly correlated with anxiety and depression symptoms and also with disordered eating attitudes, suggesting that the PAID questionnaire performs a more comprehensive assessment of psychological aspects in patients with T1DM.

Furthermore, the results of the current study support the association of A1c with diabetes related distress (PAID) and restrained eating behaviour (EDE-R). Other studies have already shown an association of diabetes related distress and A1c levels (17, 18). In terms of dieting and fasting behaviour measured by the EDE-R subscale, our results indicate that patients who had attempted to cut down on the amount of food they ate to influence shape or weight, also have significantly higher A1c. This finding supports the importance of assessing disordered eating behaviour in T1DM to identify these patients, since they have an increased rate of mortality and morbidity (37).

The associations of microvascular complications with the psychological assessments performed in the present study were modest. DR had a borderline significant association with depression and, interestingly, patients with DN had lower anxiety levels. In the Takii study, duration of type 1 diabetes and insulin omission were significantly associated with DR and DN (38). A six-year longitudinal study indicated that depression is significantly associated with both poor glycaemic control and higher 6-year progression to proliferative diabetic retinopathy in African-Americans with Type 1 diabetes (39). Another study found a significant and enduring elevation of anxiety and depression in newly registered blind or visually handicapped patients (40).

An additional contribution of this study is the comprehensive psychological evaluation and the correlation between scales. Patients with depression, anxiety and eating disordered problems show a decreased rate of resilience. Resilience was negatively and significantly associated with PAID, indicating that patients with more resilience characteristics have lower levels of diabetes related distress. In the Yi study, resilience resources predicted future metabolic control, and buffered worsening A1c levels and self-care behaviours in the face of rising distress levels (21).

Interestingly, disordered eating problems are negatively associated with patient perceived coercion, suggesting that patients who have eating, shape and weight concerns appear to perceive themselves as less active participants in the diabetes treatment process. In other current studies, in different outpatients groups, we found higher values of perceived coercion (data not published yet).

The potential limitations of this study are the use of questionnaires and not an interview to establish the psychiatric diagnosis more appropriately. However the questionnaires used have

been validated and they are used for screening of psychological symptoms. Only PAID was designed specifically for diabetes patients, but this study could contribute to further validation of those scales in this particular population. Another aspect, was that patients were recruited from the outpatient clinic of a university hospital (tertiary care centre), and consequently these patients might have more unstable diabetes and/or have more advanced disease. Moreover, in order to minimize possible confounding factors, patients should ideally underwent through an evaluation of cognitive functioning, fear of hypoglycaemia and psychiatric diagnostic.

In conclusion, the data presented suggest that psychological symptoms are frequent in patients with type 1 diabetes and might influence not only the glycaemic control but also the prevalence of microvascular complications, specially the association between DR and depression. Psychological assessment should ideally be performed routinely in patients with type 1 diabetes to identify those who might benefit from psychological intervention.

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Table 1. Correlation between psychological scales, A1C level, BMI and duration of diabetes

	A1C	DURATION OF DM (Years)	BMI	PAID
PAID	0.326**	-0.213	0.006	-
RES	-0.236*	0.217	0.026	-0.417§
HAD ANX	0.076	-0.280*	-0.316**	0.584§
HAD DEP	0.274*	-0.160	-0.07	0.348**
COE	0.154	-0.006	-0.246*	-0.023
EDE-Q	0.186	-0.034	0.350**	0.326**
EDE-E	0.129	-0.238	0.171	0.353**
EDE-R	0.282*	0.028	0.336**	0.154
EDE-S	0.107	0.032	0.333**	0.306**
EDE-W	0.134	0.040	0.324**	0.283*

*P < 0.05, ** P<0.01, § P<0.001; A1C= glycohemoglobin level, BMI= Body Mass Index, PAID= Problem Areas in Diabetes Scale, RES= Resilience scale, HADS ANX= Anxiety scale, HADS DEP= Depression scale, COE=Perceived coercion, EDE-Q= Eating Disorder-Questionnaire, EDE-E= Eating concerns, EDE-R= Eating restraint, EDE-S= Shape concerns, EDE-W= Weight concerns.

Table 2. A1c, duration of diabetes, BMI and presence of microvascular complications in patients with type 1 diabetes grouped according to the presence of anxiety, depression and eating disorders

. **HADS anxiety ≥ 8**	**YES (37)**	**NO(46)**	**P**
A1c (%)	8.49 ± 1.54	7.91 ± 1.79	0.13
Duration of diabetes (years)	11.36 ± 9.49	17.27 ± 10.72	0.02
BMI (kg/m^2)	23.17 ± 3.70	25.24 ± 3.69	0.02
Gender (female/male) n %	21 (56.8) /16 (43.2)	13 (28.6) /33 (71.3)	0.01
Nephropathy n (%)	1 (2.7)	10 (21.7)	0.01
Retinopathy n (%)	17 (45.9)	19 (41.3)	0.97
Neuropathy n (%)	7 (18.9)	2 (4.3)	0.002
HADS depression ≥ 8	**YES(21)**	**NO(62)**	
A1c (%)	9.63 ± 1.99	7.87 ± 1.45	0.02
Duration of diabetes (years)	12.9 ± 10.16	15.1 ± 10.68	0.45
BMI (kg/m^2)	23.04 ± 4.14	24.72 ± 3.64	0.12
Gender (female/male) n %	13 (61.9) / 8 (38.1)	22 (35) / 40 (65)	0.03
Nephropathy n (%)	2 (9.5)	9 (14.5)	0.33
Retinopathy n (%)	14 (66.7)	22 (35.5)	0.02
Neuropathy n (%)	3 (14.3)	6 (9.7)	0.57
EDE-Q ≥ 4	**YES(4)**	**NO(79)**	
A1c (%)	8.65 ± 3.58	8.15 ± 1.46	0.80
Duration of diabetes (years)	10.25 ± 10.43	14.57 ± 10.66	0.43
BMI (kg/m^2)	26.99 ± 0.56	24.15 ± 3.93	<0.001
Gender (female/male) n %	2 (6.3) / 2 (4.5)	30 (93.8) / 42 (95.5)	0.74
Nephropathy n (%)	0	9 (100)	-
Retinopathy n (%)	1 (25)	32 (45.1)	0.43
Neuropathy n (%)	1 (100)	8 (14.8)	0.02

A1C= glycohemoglobin level, BMI= Body Mass Index, EDE-Q= Eating Disorder-Questionnaire.

Table 3. Scores of psychological scales according to the presence of microvascular complications.

	HAD DEP	**HAD ANX**	**EDE-Q**	**PAID**	**RES**	**COE**
NEPHROPATHY						
YES	4.8 ± 3.6	5.3 ± 1.8	1.3 ± 1.1	35.4 ± 13.1	130.1 ±15.7	0.89 ± 0.27
NO	6.2 ± 3.4	7.9 ± 4.5	1.5 ± 1.1	41.1 ± 21.4	127.8 ±17.6	0.63 ± 0.9
P	0.24	0.007	0.74	0.15	0.74	0.48

RETINOPATHY						
YES	6.8 ± 4.5	8.2 ± 4.8	1.1 ± 1.2	46.4 ± 21.7	127.2 ±17.0	0.53 ± 1.1
NO	5.0 ± 3.3	7.5 ± 4.3	1.6 ± 1.3	41.4 ± 28.1	130.8 ±15.5	0.60 ± 0.9
P	0.043	0.45	0.65	0.39	0.33	0.77
NEUROPATHY						
YES	8.4 ± 5.8	9.2 ± 4.3	1.9 ± 1.3	44.4 ± 24.8	126.2 ±20.3	0.22 ± 0.44
NO	5.3 ± 3.6	7.7 ± 4.8	1.3 ± 1.1	42.1 ± 25.4	130.3 ±15.1	0.56 ± 0.81
P	0.034	0.23	0.15	0.8	0.49	0.11

PAID= Problem Areas in Diabetes Scale, RES= Resilience scale, HADS ANX= Anxiety scale, HADS DEP= Depression scale, COE=Perceived coercion, EDE-Q= Eating Disorder-Questionnaire.

Capitulo 3

Psychological correlates with metabolic control and assessment of health-related quality of life (HRQoL) of patients with type 2 diabetes

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Abstract

AIMS: To assess psychological aspects in a cohort of type 2 diabetes patients and to analyze a possible association with the degree of metabolic control and presence of chronic complications.

RESEARCH DESIGN AND METHODS: Consecutive literate patients with type 2 diabetes attending the outpatient diabetes clinic of a university hospital were invited to complete the following questionnaires: Hospital Anxiety and Depression Scale (HADS), Eating Disorder Examination (EDE-Q), Problem Areas in Diabetes Scale (PAID), Resilience and the Perceived

Coercion. The presence of macro- and microvascular complications was obtained according to a standardized protocol. A1c was measured by a high-performance liquid chromatography system.

RESULTS: A total of 154 patients was included and 30.6% reported mild to moderate symptoms of anxiety and 29.6% of depression (≥ 8 score on HADS anxiety and depression, respectively). A1C was negatively associated with symptoms of anxiety (r= - 0.194, P < 0.05) assessed by HADS anxiety. In a multiple regression analysis DR was associated with PAID [OR: 1.01 (95% CI: 1.00-1.03), P=0.04] and DN was also associated with PAID [OR: 0.97 (95% CI: 0.95-0.99), P=0.007].

CONCLUSIONS: Patients with type 2 diabetes frequently presented symptoms of anxiety and depression. Furthermore, patients with DR show an increased diabetes related distress and, curiously, patients with absence of DN had more diabetes related distress. Patients with mild to moderate symptoms of anxiety were more frequently female and sedentary than non-anxious. Patients with type 2 should routinely undergo psychological assessment to identify those who might benefit from psychological intervention.

Keywords: type 2 diabetes, psychological aspects, metabolic control

Introduction

There is an ongoing debate on the role of psychological issues in diabetes treatment and clinical outcomes (1). It is well known that diabetes is a chronic health condition that requires continuing medical care and patient self-management education to prevent acute complications and to reduce the risk of long-term complications (2-4). Therefore, patient mental health status is considered a key aspect to be addressed in order to make it easier to achieve success in treatment.

Patients with Type 2 Diabetes Mellitus (T2DM) need to integrate several behavioral changes into their routine (5-8). Treatments differ in terms of particular needs, but most require long-term adherence to a complex diet, physical activity, medication, in some cases including insulin injection, and self- monitoring of blood glucose and self-care regimens. Since T2DM is mostly diagnosed when patients have well established habits, it can be difficult to perform those changes in daily life (9).

Thus, emotional issues can affect the patient's ability to cope effectively with the demands of diabetes. Diabetes-related emotional distress is an important element of quality of life in diabetes that may influence adherence to self care, glycaemic control, and risk of complications (10-12).

Psychosocial screening and follow-up should include: attitudes about the illness, expectations for medical management and outcomes, affect, mood, general and diabetes- related quality of life, social and financial resources and psychiatric history (13-15). Screening for psychosocial problems such as depression, anxiety, eating disorders, and cognitive impairment should be done when adherence to the medical regimen is poor (1).

Other aspects that may influence metabolic control and diabetes complications are resilience and perceived coercion. Resilience is defined as the process of successful coping with stressful life events, such as a chronic illness, by using various protective qualities (16,17). Coercion is defined as the act of limiting, impeding, restraining or forcing someone to act in a certain way. A voluntary and active action, such as diabetes treatment, assumes that there is no perceived coercion.

Several studies have analyzed the aspects of depression, anxiety, eating disorders and quality of life in patients with T2DM and the possible influence on metabolic control. There are

no studies analyzing resilience and patient's perceived coercion in diabetes treatment in T2DM. Considering that mental health treatment reduces the A1c level (1) we hypothesized that identifying the psychological aspects associated with metabolic control could detect the individuals who might benefit from mental health therapy.

Thus, the objective of this study was to measure psychological aspects, specifically depression, anxiety, eating disorders, diabetes-specific quality of life, resilience and perceived coercion through validated questionnaires in a cohort of T2DM patients, and to analyze a possible association with the degree of metabolic control and presence of chronic complications.

Subjects, materials and methods

This study followed a cross sectional design in a cohort of consecutive patients attending the outpatient clinic of the Endocrine Division of the Hospital de Clínicas de Porto Alegre during the period from April 2007 to December 2007. The study protocol was approved by the ethics committee of the hospital, and written informed consent was obtained from all patients.

The inclusion criteria were literate patients aged between 30 to 70 years, diagnosis of T2DM since at least 1 year. Patients with severe chronic complications such as amaurosis, chronic renal failure in renal replacement therapy, major amputations, serious disease that limits life expectance to less than 1 year, evident cognitive deficit or with previous psychiatric diagnosis were not included.

Patient Evaluation

Two hundred and five patients were invited to participate after a brief explanation about the objectives of the study. One hundred and fifty-four subjects completed almost all the

evaluation procedures proposed, and 55 did not participate due to lack of time available or other personal reasons.

Clinical Measurements

The clinical data were obtained according to a standardized protocol as previously described (18). Briefly, patients underwent an interview and clinical examination to record demographic and anthropometrical data. Physical activity was measured with a 4 item self-report questionnaire (19). Body mass index (BMI) was calculated [weight (kg)/height^2 (m)]. Eye fundus examination was performed by an experienced ophthalmologist after mydriasis and for the purpose of this study, patients were grouped according to the presence or absence of any degree of diabetic retinopathy (DR). The presence of diabetic nephropathy (DN) was defined according to urinary albumin excretion rate (UAER), measured in two 24-h sterile urine collections, at 3-monthly intervals. Patients with microalbuminuria (UAER ≥20 and ≤200 μg/min) and macroalbuminuria (UAER >200 μg/min) were analyzed as a group with DN. Neurological evaluation consisted of physical examination of the foot for deformities, callus, infection, ulceration, ankle reflexes, with the patient in the sitting position, twice (normal, reduced or absent); vibration perception threshold (normal, reduced or absent, 128 MHz tuning fork) at the dorsum of great toe. The same trained examiners tested all participants. The diagnosis of peripheral neuropathy was established if there was a score of > 2 in the clinical portion of the Michigan Neuropathy Screening Instrument (20).

The presence of Cerebrovascular Disease (CVD) was established if a history of stroke and/or compatible findings (sequelae) were present. Peripheral Vascular Disease (PVD) was defined in the presence of intermittent claudication, as assessed by the WHO questionnaire for cardiovascular disease (21), and/or absence of posterior tibial pulse upon clinical examination.

The diagnosis of coronary artery disease was based on the presence of at least one of the followings: angina or possible infarct according to the WHO questionnaire for cardiovascular disease (21), resting ECG abnormalities (Minnesota Codes: Q and QS patterns [1-1 to 1-3]; S-T junction [J] and segment depression [4-1 to 4-4]; T-wave items [5-1 to 5-3], and complete left bundle branch block [7-1]) (ref), and perfusion abnormalities on myocardial scintigraphy at rest (fixed) or after dipyridamole infusion (variable).

Laboratory Measurements

UAER was measured by immunoturbidimetry (Microal; Ames-Bayer, Tarrytown, NY) (intra-and interassay coefficient variation of 4.5 and 11%, respectively). The A1C test was measured by the high-performance liquid chromatography system (reference range 4.7 – 6.0%; Merck-Hitachi 9100, Merck, Darmstadt, Germany).

Psychological Assessment

Subjects were asked to complete the following self-report questionnaires: Hospital Anxiety and Depression Scale (HADS), Eating Disorder Examination (EDE), Problem Areas in Diabetes Scale (PAID), Resilience, and Perceived Coercion scales. An adequately silent environment was offered.

Hospital Anxiety and Depression Scale (HADS)

The HADS is a well-validated questionnaire that has been widely used in medical and research populations (22). It is divided into two subscales to assess symptoms of anxiety and depression separately. Each subscale consists of seven questions with a maximum score of 21. Scores are interpreted to indicate symptoms that are either mild (between 8 and 10), or moderate to severe (between 11 and 21). The Portuguese version of the scale was validated in Brazil (23)

and proved to have adequate internal consistency (*Cronbach's alpha*= 0.68 and 0.77 on anxiety and depression scales, respectively).

Eating Disorder Evaluation – Questionnaire (EDE-Q)

The EDE-Q is a 36-item self-report measure derived from the Eating Disorders Examination interview (EDE) and therefore it focuses on on the DSM-IV criteria (24). Items addressing particular eating disorder behaviors, attitudes or feelings are scored using a 7-point, forced-choice, rating scheme focusing on the past 28 days. Scores ≥ 4 indicates clinically significant eating disorder symptoms. This instrument generates a global score which is the average of its four subscale scores, namely: Restraint (EDE-R), Eating Concern (EDE-E), Shape Concern (EDE-S) and Weight Concern (EDE-W). The Portuguese version shows high internal consistency (*Cronbach's alpha*= 0.95) and was developed in Portugal (25) and adapted to Brazilian Portuguese (26).

Problem Areas in Diabetes Scale (PAID)

The PAID is a 20-item self-report measure of diabetes-related emotional distress with high internal reliability, sensitivity to change, and clinical utility (13-15). Questions are framed as 'From your own perspective, to what degree are the following diabetes-related issues currently a problem for you?' with a 6-point scale to rate each item (ranging from 0 = 'not a problem' to 5 = a 'serious problem'). This questionnaire has four subscale scores, namely: Emotional, Social, Treatment and Food diabetes problems. The Brazilian Portuguese version (B-PAID) was

previously validated by our group in a sample of patients with Type 2 Diabetes in the south of Brazil and showed high levels of internal consistency *(Cronbach's alpha*= 0.93) (27).

Resilience

The Resilience Scale was originally developed by Wagnild & Young (28) to measure positive psychosocial adaptation levels when faced with major life events. It has 25 positive descriptive items, with a 7-point Likert scale, varying from totally disagree (1) to totally agree (7). Scores vary from 25 to 175 points, higher values indicating elevated resilience status. It was validated into Portuguese in a sample of healthy students in Brazil *(Cronbach's alpha* = 0.80) (29).

Perceived Coercion

The Perceived Coercion is an adapted 4-item scale that accesses patient perceived coercion about the treatment. It include items about patients' perception about their role in treatment, such as "Did I have sufficient opportunity to communicate my expectations about the treatment?" Answers can vary from agree to disagree. The original version was developed (30) and a Portuguese version was adapted with a psychiatric hospitalized sample (31).

Statistical Analysis

Data were expressed as mean ± standard deviation (SD), or as median (minimum-maximum). Quantitative variables without normal distribution were log transformed. Student t test or chi-square tests were used to compare clinical and laboratory data. Pearson or Spearman correlations were used as appropriate. Multivariate logistic regression models were constructed

with diabetes complications as dependent variable and values of the scales, A1c and diabetes duration as independent variables. P values <0.05 (two-tailed) were considered to be significant.

Results

Of 205 patients invited to participate 154 accepted and completed the assessment, including the questionnaires. The mean age was 60 ± 9.9 years, 73.6% were white and 57 % were male. The mean BMI was 30.9 ± 5.7 kg/m^2 and mean waist circumference was 102.7 ± 6.1 cm. Patients had a mean duration of diabetes of 12.7 ± 8.9 years. The mean systolic and diastolic blood pressures were 134.3 ± 19.4 and 74.7 ± 11.2 mmHg, respectively. The mean A1c was 7.8 ± 1.3%.

Regarding level of education and socio-economic aspects: 49.7% had basic education, 41.3% had high school and only 7% had completed college education, 58% were married, 91% have at least one child and 36% of patients reported family income equivalent to US$ 640.00/month. Most of the patients, 59.4% were treated with at least one oral agent, 4% were only on a diet, 10% were treated with insulin and 26.7% were receiving oral agents plus insulin regimen. Almost half of the patients, 47%, reported working out and 89.4% did not receive any psychological or psychiatric assistance. Only 3.2% of the patients were using antidepressants and only 1.3% were using sibutramine. Patients were using multiple pharmacological treatment, including: diuretics 29.2%, statins 20.7%, beta blocker 24.6%, angiotensin converting enzyme inhibitors 38%, acetyl salicylic acid 33.7%, calcium channel blocker 5.8% and isosorbide 5.8%.

Patients not included (n=55) did not differ from the study group regarding mean age (61 ± 9.9 years, P=0.82), ethnicity (75% were white, P=0.97) and gender (53 % were male, P=0.35), mean BMI (31.0 ± 4.3 kg/m^2, P=0.53), waist circumference (99.0 ± 10.8 cm, P=0.56), duration of diabetes (11.2 ± 9.1 years, P=0.15) and A1c level (7.4 ± 2.3 % , P=0.15)

Concerning the complications of diabetes, 46% were considered to have DN (38.4% microalbuminuric and 8% macroalbuminuric) and 45.3% had DR. If patients (n=4) had a severe visual problem which affected reading, the survey questions were asked by a trained researcher. researcher. Peripheral neuropathy was identified in 37.7% of the patients. Macrovascular complications were observed in 46.8% of the patients of whom 36.7% had coronary artery disease, 7.6% had stroke and 16.5% had peripheral vascular disease.

The results of the questionnaires used to assess the psychological assessment were: (mean ± SD): HADS Anxiety scores 6.0 ± 4.6, HADS Depression 5.6 ± 4.2, EDE-Q 1.5 ± 1.3, EDE-E 0.9 ± 1.3, EDE-R 1.4 ± 1.5, EDE-S 2.0 ± 1.9, EDE-W 1.9 ± 1.7, PAID 29.4 ± 26.6, Resilience 139.7 ± 26.9 and Perceived Coercion 0.5 ± 0.9.

The correlation indices of psychological scales with A1c (%), BMI (kg/m^2), age and diabetes duration (years) were described in Table 1. A1c was only significantly and negatively associated with the HADS anxiety score. Diabetes duration was significantly and negatively associated with EDE-S (subscale about shape concerns). BMI was significantly associated with EDE-Q and its subscales regarding eating, shape and weight concerns. Age was significantly and negatively associated with PAID, EDE-Q and its subscales regarding eating, shape and weight problems. Analyzing the correlation of PAID with the other psychological questionnaires it was observed that PAID was significantly and positively associated with anxiety, depression, perceived coercion and eating disorders and negatively associated with resilience.

A total of 30.6% of the patients reported scores of 8 or more on HADS Anxiety and 29.6% reported scores of 8 or more on HADS Depression. Of those patients, who reported high levels of anxiety symptoms (HADS Anxiety ≥ 8), 81.2% (P=0.0001) also had high depression scores (HADS Depression ≥ 8). Regarding eating disorders, only 2.3% fulfilled the criteria for

the presence of clinically significant eating disorder symptoms (EDE-Q ≥4). Regarding the EDE-Q subscales, it was found that 6% of patients reported scores ≥ 4 on eating, 6.6% on restraint, 24.3% on shape and 3.6% on weight concerns.

The presence of macro and microvascular complications, A1c levels, duration of diabetes, BMI, gender and physical inactivity was analyzed according to the presence of anxiety (HADS≥ 8) and depression (HADS≥ 8) and reported in Table 2. Patients with mild to moderate symptoms of anxiety were more frequently female and sedentary than non-anxious patients, and there were no significant differences regarding A1c level, BMI, duration of diabetes and macro- and microvascular complications. Patients with mild to moderate symptoms of depression were more frequently female and sedentary, and more frequently had DR. There were no differences regarding A1c, BMI, duration of diabetes and other diabetes complications. Logistic regression models were performed to analyze the associated factors with anxiety or depression scores (dependent variables). Anxiety remained associated with being sedentary [OR: 4.15 (95% CI: 1.56-11.04), P=0.004], but gender and BMI were excluded from the model. Depression only remained significantly associated with female [OR: 3.23 (95% CI: 1.24-8.44), P=0.02] and DR and being sedentary did not remain associated.

The scores of the psychological scales according to the presence or not of macro-microvascular complications were described in Table 3. Patients with DN had lower levels of diabetes-related emotional distress (PAID) than patients without this condition. Patients with DR had higher levels of diabetes-related emotional distress (PAID) than patients without DR.

To analyze a possible association between psychological questionnaires and micro-macrovascular complications, separate models of multiple logistic regressions analysis with DN, DR, neuropathy and CVD as dependent variables and A1c, duration of diabetes and one of the

following psychological measures: PAID, HAD Anxiety or HAD Depression were performed. DR remained associated with PAID [OR: 1.01 (95% CI: 1.00-1.03), P=0.04] and duration of diabetes [OR: 1.05 (95% CI: 1.00-1.11), P=0.04]. There were no associations between DR and HAD Anxiety or Depression. DN remained associated with PAID [OR: 0.97 (95% CI: 0.95-0.99), P=0.007], but there were no associations between DN and HAD Anxiety or Depression. Neuropathy remained associated with HAD Anxiety [OR: 1.11 (95% CI: 1.00-1.23), P=0.04] and duration of diabetes [OR: 1.06 (95% CI: 1.01-1.12), P=0.02]. Neuropathy was not associated with HAD Depression or PAID. CVD was only associated with duration of diabetes [OR: 1.06 (95% CI: 1.00-1.13), P=0.04] and with A1c [OR:1.73 (95% CI: 1.11-2.70) P=0.01].

Discussion

In this sample of patients with T2DM it was observed that BMI was associated with eating disorder score (EDE-Q) and age was inversely associated with PAID and EDE-Q. Known duration of diabetes was not significantly associated with psychological questionnaires, except with EDE-S (shape concerns). The degree of metabolic control, evaluated by A1c levels, was also not associated with psychological questionnaires in general but it presented a negative correlation with anxiety score. Interestingly, PAID showed a significant correlation with all the psychological questionnaires used. Microvascular complications were more frequent in patients with mild to moderate symptoms of anxiety (HAD Anxiety) and diabetes related emotional distress (PAID).

Several studies presented the association of IMC and eating disorders (6, 25) and associations with age and diabetes related distress (PAID) and eating disorders had already been shown (15, 25).

Some studies analyzed the prevalence of anxiety in patients with diabetes. The prevalence of mild to severe symptoms of anxiety observed in this sample (30.6%) was similar to that reported by Hermanns et al. (25.2%) using a different method of assessment (State Trait Anxiety Inventory) (32). In another study (33) the prevalence of anxiety was only 10%, but the authors employed the DIS-IV (Diagnostic Interview Schedule for Diagnostic and Statistical Manual of Mental Disorders- DSM-IV).

Concerning depression symptoms, the prevalence observed in this sample (29.6%) was similar to that reported by Hermanns et al. (31.4%), using another using other assessment tools [Centre of Epidemiological Studies—Depression Scale (CES-D)] and Beck Depression Inventory (32). In another recent study using CES-D the prevalence of depression was 22% (34).

Few studies analyzed the prevalence of eating disorders in patients with type 2 diabetes. The prevalence of eating disorders observed in this sample (2.3%) was lower than other studies. In the study of Herpertz et al. (35) the prevalence of eating disorders was reported to occur in 6.5-9.0% of type 2 diabetic patients, but authors used different kinds of measures (Eating Disorder Inventory and Body Shape Questionnaire).

Regarding diabetes-related distress assessed by PAID questionnaire, we found higher values (29.4 ± 26.6) than in a community-based study conducted in Revere Health Center in the USA (18.7 ± 10.3) (36). In another study (37) conducted in the Netherlands (22.5 ± 19.8) and at Joslin Diabetes Center in USA (27.8 ± 23.2) more similar scores were found with this sample. Those data suggest that sources of diabetes-related emotional distress are different in type 2 diabetes depending on treatment modality and provide specific direction to guide patients and providers towards a more focused assessment and intervention to improve diabetes specific quality of life.

It is interesting that the PAID was highly and significantly correlated with all others questionnaires such as anxiety, depression, eating disorders, resilience and perceived coercion, confirming that it can perform a comprehensive assessment of the psychological status of patients with T2DM (38).

Additionally, the results of the current study support the association of diabetes-related distress (PAID) with DR and DN. Curiously, patients with absence of DN had more diabetes-related distress. Other studies have already shown associations with metabolic control (14, 39, 40) but not with diabetes complications. In this sample of T2DM, neuropathy was associated with anxiety. One study, using the same method (HADS), found support for the association of neuropathy with depression but anxiety was not measured (41).

Furthermore the results of the current study sustain a negatively weak correlation between A1c and anxiety symptoms. Interestingly, it suggests that patients who are more anxious have lower levels of A1c. Other studies have already shown correlations between anxiety and A1c levels in patients with T2DM, but they were in positive way (39).

Moreover, the results of the present study support the association of anxiety level and the physical activity level. Patients who were sedentary showed clinically significant anxiety symptoms (HADS Anxiety $\geq$ 8). Other studies showed an association of anxiety and level of physical activity (42).

A supplementary contribution of this study is the comprehensive psychological evaluation and the correlation between scales. Patients with high scores on PAID, HADS Depression and Anxiety and EDE-Q demonstrate decreased rates of resilience. Interestingly, PAID are associated with patient perceived coercion, suggesting that patients who have high scores on diabetes-related distress perceive themselves as less active participants in the diabetes

treatment. In other current studies, in different outpatients groups, we found higher values of perceived coercion (data not published yet).

Our study has some limitations. The data are cross-sectional, so causal associations between diabetes characteristics and psychological scores cannot be ascribed. Our sample is representative of the racial/ethnic distribution of the population in southern Brazil, but may be impossible to generalize to other populations. An additional assessment of cognitive impairment and psychiatric diagnostic interview would clarify possible bias.

Another limitation is the unexpected associations between A1c levels and HADS Anxiety, and between DN and PAID. DR presents obviously threatening symptoms that cause expected emotional concerns. On the other hand, there is no plausible explanation for the lower level of concern about DN. Although DN is an asymptomatic condition and the full comprehension of the patient's understanding about the meaning of the disease is unknown, it is difficult to understand why PAID scores were lower in patients with DN.

Furthermore, other possible limitation is the use of multiple comparisons which might give significant associations only by chance. However, most of the significant associations described are coherent. Probably, the negative associations between anxiety and A1c and PAID and DN might be an example of fortuitous associations.

Finally, the data presented suggest that psychological symptoms, especially anxiety and depression, are frequent in patients with type 2 diabetes and might influence microvascular complications, in particular the association between diabetes-related distress (PAID) and DR and HADS Anxiety and Neuropathy. Patients with mild to moderate symptoms of anxiety were more frequently female and sedentary than non-anxious patients. Therefore, PAID might be a comprehensive assessment tool and probably should be used as a screening test.

Acknowledgments

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Table 1. Correlation between psychological scales, A1C level, BMI, age and duration of diabetes

	A1C	DURATION OF DM (Years)	BMI	PAID	AGE
PAID	0.038	-0.061	0.006	-	-0.307§
RES	0.031	-0.026	0.069	-0.330**	0.133
HAD ANX	-0.194*	-0.032	0.109	0.477 §	-0.155
HAD DEP	-0.106	0.014	0.121	0.400 §	0.022
COE	-0.020	0.140	-0.196	0.215*	0.077
EDE-Q	0.042	-0.168	0.475 §	0.519 §	-0.262**
EDE-E	-0.015	-0.154	0.271**	0.655 §	-0.338§

EDE-R	0.044	-0.039	0.107	0.234**	-0.026
EDE-S	-0.020	-0.247*	0.565 §	0.448§	-0.298§
EDE-W	0.021	-0.176	0.510 §	0.420 §	-0.232**

*P < 0.05, ** P<0.01, § P<0.001; A1C= glycohemoglobin level, BMI= Body Mass Index, PAID= Problem Areas in Diabetes Scale, RES= Resilience scale, HADS ANX= Anxiety scale, HADS DEP= Depression scale, COE=Perceived coercion, EDE-Q= Eating Disorder-Questionnaire, EDE-E= Eating concerns, EDE-R= Eating restrain, EDE-S= Shape concerns, EDE-W= Weight concerns.

Table 2: A1c, duration of diabetes, BMI and presence of diabetes complications in patients with type 2 diabetes grouped according the presence of anxiety, depression and eating disorders.

HADS anxiety ≥ 8	**YES (n=33)**	**NO (n=75)**	**P**
A1c (%)	7.6 ± 1.3	8.0 ± 1.4	0.08
Duration of diabetes (years)	11.0 ± 8.2	13.6 ± 9.7	0.18
BMI (kg/m^2)	32.1 ± 5.4	30.0 ± 5.8	0.08
Male n (%)	15 (45.5)	49 (65.3)	0.05
Sedentary n (%)	26 (78.8)	33 (44.6)	0.001
Nephropathy n (%)	13 (39)	37 (49)	0.40
Retinopathy n (%)	17 (51.7)	32 (43.5)	0.45
Neuropathy n (%)	16 (50)	26 (35.4)	0.17
CVD n (%)	16 (50)	40 (53.2)	0.78
HADS depression ≥ 8	**YES (n=32)**	**NO (n=76)**	**P**
A1c (%)	7.8 ± 1.3	7.9 ± 1.4	0.59
Duration of diabetes (years)	12.5 ± 11.2	12.7 ± 8.2	0.89
BMI (kg/m^2)	31.3 ± 5.5	30.6 ± 5.8	0.57
Male n (%)	13 (40.6)	51 (67.1)	0.01
Sedentary n (%)	23 (71.9)	35 (46.7)	0.017
Nephropathy n (%)	12 (37)	36 (48)	0.35

Retinopathy n (%)	20 (63)	29 (39)	0.04
Neuropathy n (%)	14 (44.8)	28 (36.9)	0.47
CVD n (%)	16 (50)	39 (52.1)	0.86

A1C= glycohemoglobin level, BMI= Body Mass Index and CVD= Cardiovascular Disease.

Table 3: Scores of psychological scales according to the presence of microvascular complications.

	HAD DEP	HAD ANX	EDE-Q	PAID	RES	COE
CVD						
YES	6.6 ± 5.1	6.4 ± 4.5	1.4 ± 1.1	30.8 ± 25.9	141.4 ± 29.5	0.5 ± 0.7
NO	6.3 ± 3.8	7.2 ± 4.3	1.3 ± 1.2	29.1 ± 28.6	136.2 ± 24.1	0.5 ± 0.9
P	0.80	0.50	0.82	0.78	0.44	0.89
Neuropathy						
YES	6.3 ± 4.8	7.0 ± 4.5	1.6 ± 1.2	33.2 ± 25.2	137.7 ± 29.7	0.4 ± 0.7
NO	5.5 ± 3.9	5.4 ± 4.3	1.2 ± 1.1	26.2 ± 26.9	141.5 ± 22.7	0.5 ± 0.9
P	0.35	0.09	0.10	0.17	0.50	0.50
Nephropathy						
YES	5.5 ± 4.3	5.8 ± 4.4	1.2 ± 1.1	22.3 ± 23.4	140.0 ± 26.7	0.6 ± 0.8
NO	6.3 ± 4.3	6.9 ± 4.4	1.5 ± 1.2	35.5 ± 29.3	138.8 ± 26.4	0.5 ± 0.8
P	0.39	0.26	0.26	0.01	0.85	0.43
Retinopathy						
YES	6.1 ± 4.3	6.4 ± 4.5	1.6 ± 1.3	34.8 ± 29.3	141.4 ± 24.9	0.6 ± 1.0
NO	4.8 ± 4.0	5.5 ± 4.5	1.3 ± 1.0	25.4 ± 22.9	139.6 ± 25.9	0.4 ± 0.7
P	0.13	0.31	0.21	0.04	0.74	0.17

Anexo 1- Termo de Consentimento do Estudo

TERMO DE CONSENTIMENTO INFORMADO

Eu,……..…….declaro, sob a responsabilidade do pesquisador que assina este documento, que concordo em participar do projeto de pesquisa: ***ASPECTOS PSICOLÓGICOS E SUAS REPERCUSSÕES NO CONTROLE METABÓLICO E NAS COMPLICAÇÕES CRÔNICAS EM PACIENTES COM DIABETES MELITO TIPO 1 E TIPO.***

Recebi explicação clara e detalhada sobre a pesquisa acima mencionada, a qual submeto-me de livre e espontânea vontade, reconhecendo que:

1) Foi explicado que o objetivo do estudo é possibilitar uma melhor compreensão dos fatores associados ao diabetes. Incluindo fatores clínicos, psicológicos e socio-econômicos.

2) Minha participação envolve uma visita inicial, composta de entrevista, exame físico, preenchimento de questionários (sobre aspectos psicológicos relacionados com o diabetes e sobre características da minha vida pessoal).

3) Me foi dada a liberdade de retirar meu consentimento a qualquer momento e deixar de participar do estudo, sem que isso traga prejuízo à minha pessoa.

4) Foi dada a garantia de receber resposta a qualquer pergunta ou dúvida acerca dos benefícios e riscos da pesquisa. Os dados referentes a este estudo poderão ser acessados por mim, pelos pesquisadores envolvidos.

5) Foi dada a garantia de não ser identificado e de ser mantido o caráter confidencial da informação em relação à minha privacidade.

6) Foi explicado que os resultados e conclusões desta pesquisa serão publicados em uma revista cientifica de medicina e que o sigilo da minha identidade será mantido.

7) Foi explicado que não receberei medicação e foi garantido que não terei gastos por participar desse estudo.

8) Foi explicado que os pesquisadores envolvidos nesta pesquisa não receberam compensação financeira dependente dos resultados.

9) Para qualquer dúvida poderei entrar em contato com o pesquisador responsável por este projeto. Carolina Campos Gross pelo telefone 33111923 - 96499202.

……

assinatura do paciente Data: ____ / ____ / ____

.....

assinatura do pesquisador responsável Data: ____ / ____ / ____

Anexo 2- Hospital Anxiety and Depression Scale (HADS)

Este questionário ajudará seu médico a saber como você está se sentindo. Leia todas as frases. Marque com um "X" a resposta que melhor corresponder a como você tem se sentido na **última semana**. Não é preciso ficar pensando muito em cada questão. Aqui as respostas espontâneas têm mais valor do que aquelas em que se pensa muito. Marque apenas uma resposta para cada pergunta.

A **Eu me sinto tenso ou contraído**

3 ( ) A maior parte do tempo
2 ( ) Boa parte do tempo
1 ( ) De vez em quando
0 ( ) Nunca

D **Eu ainda sinto gosto pelas mesmas coisas de antes**

0 ( ) Sim, do mesmo jeito que antes
1 ( ) Não tanto quanto antes
2 ( ) Só um pouco
3 ( ) Já não sinto mais prazer em nada

A **Eu sinto uma espécie de medo, como se alguma coisa ruim fosse acontecer**

3 ( ) Sim, de um jeito muito forte
2 ( ) Sim, mas não tão forte
1 ( ) Um pouco, mas isso não me preocupa
0 ( ) Não sinto nada disso

D **Dou risada e me divirto quando vejo coisas engraçadas**

0 ( ) Do mesmo jeito que antes
1 ( ) Atualmente um pouco menos
2 ( ) Atualmente bem menos
3 ( ) Não consigo mais

A **Estou com a cabeça cheia de preocupações**

3 ( ) A maior parte do tempo
2 ( ) Boa parte do tempo
1 ( ) De vez em quando
0 ( ) Raramente

D **Eu me sinto alegre**

3 ( ) Nunca
2 ( ) Poucas vezes
1 ( ) Muitas vezes
0 ( ) A maior parte do tempo

A **Consigo ficar sentado à vontade e me sentir relaxado**

0 ( ) Sim, quase sempre
1 ( ) Muitas vezes
2 ( ) Poucas vezes

3 | ( ) Nunca

D **Estou lento para pensar e fazer as coisas**

3 | ( ) Quase sempre
2 | ( ) Muitas vezes
1 | ( ) De vez em quando
0 | ( ) Nunca

A **Eu tenho uma sensação ruim de medo, como um frio na espinha ou um aperto no estômago**

0 | ( ) Nunca
1 | ( ) De vez em quando
2 | ( ) Muitas vezes
3 | ( ) Quase sempre

D **Eu perdi o interesse em cuidar da minha aparência**

3 | ( ) Completamente
2 | ( ) Não estou mais me cuidando como eu deveria
1 | ( ) Talvez não tanto quanto antes
0 | ( ) Me cuido do mesmo jeito que antes

A **Eu me sinto inquieto, como se eu não pudesse ficar parado em lugar nenhum**

3 | ( ) Sim, demais
2 | ( ) Bastante
1 | ( ) Um pouco
0 | ( ) Não me sinto assim

D **Fico esperando animado as coisas boas que estão por vir**

0 | ( ) Do mesmo jeito que antes
1 | ( ) Um pouco menos do que antes
2 | ( ) Bem menos do que antes
3 | ( ) Quase nunca

A **De repente, tenho a sensação de entrar em pânico**

3 | ( ) A quase todo momento
2 | ( ) Várias vezes
1 | ( ) De vez em quando
0 | ( ) Não sinto isso

D **Consigo sentir prazer ao assistir um bom programa de TV, de rádio, ou quando leio alguma coisa**

0 | ( ) Quase sempre
1 | ( ) Várias vezes
2 | ( ) Poucas vezes
3 | ( ) Quase nunca

Anexo 3- Eating Disorder Evaluation - Questionnaire (EDE-Q)

As questões que seguem dizem respeito APENAS às últimas quatro semanas (28 dias).

QUANTOS DIAS NOS ÚLTIMOS 28 DIAS	Nenhum	1-5 dias	6-12 dias	13-15 dias	16-22 dias	23-27 dias	Todos dias
1 Tentou diminuir a quantidade de comida para mudar seu peso e forma corporal?	0	1	2	3	4	5	6
2 Passou longos períodos de tempo (8 horas ou mais) sem comer para mudar seu peso e forma corporal?	0	1	2	3	4	5	6
3 Tentou evitar comer alimentos preferidos para mudar seu peso e forma corporal?	0	1	2	3	4	5	6
4 Tentou seguir regras rígidas na sua alimentação para modificar seu peso e forma corporal como, por exemplo, um limite de calorias, quantidade exata de comida, aquilo que devia ou não comer ou mesmo quando devia comer?	0	1	2	3	4	5	6
5 Desejou experimentar a sensação de ter o estômago vazio?	0	1	2	3	4	5	6
6 Pensou sobre comida ou quantidade de calorias a ponto de atrapalhar em sua capacidade de se concentrar em outras atividades como, por exemplo, ler, ver televisão, ou escutar uma conversa?	0	1	2	3	4	5	6
7 Teve medo de perder o controle sobre o quanto você comia?	0	1	2	3	4	5	6

	QUANTOS DIAS NOS ÚLTIMOS 28 DIAS	Nenhum	1-5 dias	6-12 dias	13-15 dias	16-22 dias	23-27 dias	Todos os dias
8	Teve episódios de ingestão alimentar compulsiva, ou seja, comer grandes quantidades de comida, num curto período de tempo, com a sensação de não ter controle sobre o quanto comia?	0	1	2	3	4	5	6
9	Comeu em segredo (não contar as vezes que comeu grande quantidade de comida, rapidamente, com a sensação de não ter controle sobre o quanto comia)?	0	1	2	3	4	5	6
10	Desejou não ter barriga?	0	1	2	3	4	5	6
11	Pensou sobre seu peso e forma corporal e quantidade dos alimentos a ponto de atrapalhar em sua capacidade de prestar atenção em outras atividades como, por exemplo, ler, ver televisão, ou escutar uma conversa?	0	1	2	3	4	5	6
12	Sentiu medo de ganhar peso ou ficar gordo(a)?	0	1	2	3	4	5	6
13	Sentiu-se gordo(a)?	0	1	2	3	4	5	6
14	Teve um grande desejo de perder peso?	0	1	2	3	4	5	6

NAS ÚLTIMAS QUATRO SEMANAS (28 DIAS)

15 Quantas vezes se sentiu culpado(a) depois de comer, por causa do efeito que isso teria no peso e forma corporal (não conte as situações de ingestão alimentar compulsiva)
(faça um círculo à volta do número que se aplica a sua resposta)

0 -Nenhuma vez
1 -Raramente
2 -Às vezes
3 - Metade dos dias
4 - Muitas vezes
5 - Quase sempre
6 - Sempre

16 Nas últimas quatro semanas (28 dias), houve situações em que sentiu que comeu o que as pessoas considera na mesma situação? (Por favor, coloque o número adequado nos colchetes)

0 - Não[ ]**ir para 19**
1 - Sim

17 Quantas vezes teve este episódio nas últimas quatro semanas?

18 Quantos destes episódios de ingestão alimentar exagerada, você sentiu como não tendo controle?

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19 Houve outras situações em que sentiu não ter controle e comeu muito, mas <u>não</u> comeu grande quantidade dadas as circunstâncias?

0 - Não[ ] **Ir para 21**
1 - Sim[ ]

20 Quantas vezes nas últimas quatro semanas?

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21 Nas últimas quatro semanas provocou vômito como um meio de controlar o seu peso e a forma corporal?

0 - Não[ ]
Ir para 23
1 - Sim[ ]

22 Quantas vezes nas últimas quatro semanas?

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23 Tomou laxante (remédio para ir aos pés) como um meio de controlar seu peso e forma corporal?

0 - Não[ ]
Ir para 25
1 - Sim[ ]

24 Quantas vezes nas últimas quatro semanas?

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25 Tomou diuréticos (remédios para perder água) como um meio de controlar o seu peso e forma corporal?

0 - Não[ ]
Ir para 27
1 - Sim[ ]

26 Quantas vezes nas últimas quatro semanas?

27 Fez exercício físico excessivo como um meio de controlar o seu peso e forma corporal?

0 - Não[ ]

Ir para 29

1 - Sim[ ]

28 Quantas vezes nas últimas quatro semanas?

NAS ÚLTIMAS QUATRO SEMANAS (28 DIAS) (Por favor faça um círculo à volta do número que descreve melhor o seu comportamento)	NADA		UM POUCO		MODERADAMENTE		MUITO
29 Seu peso modificou a forma como pensa sobre si?	0	1	2	3	4	5	6
30 Sua aparência modificou a forma como pensa sobre si?	0	1	2	3	4	5	6
31 Até que ponto se aborreceria se lhe tivessem pedido para se pesar uma vez por semana durante as quatro semanas seguintes?	0	1	2	3	4	5	6
32 Até que ponto se sentiu insatisfeito(a) com seu peso?	0	1	2	3	4	5	6
33 Até que ponto se sentiu insatisfeito(a) com sua aparência?	0	1	2	3	4	5	6
34 Até que ponto esteve preocupado(a) com o fato de as outras pessoas a verem comer?	0	1	2	3	4	5	6

35 Até que ponto se sentiu desconfortável ao ver seu corpo, por exemplo, em um espelho, no reflexo de uma vitrine, enquanto se vestia ou enquanto tomava banho?	0	1	2	3	4	5	6
36 Até que ponto se sentiu mal pelo fato de os outros verem seu corpo; por exemplo, na praia, ou quando usava roupas que mostravam suas formas?	0	1	2	3	4	5	6

Por favor, responda as seguintes perguntas somente se você UTILIZA insulina

QUANTOS DIAS NOS ÚLTIMOS 28 DIAS	**Nenhum**	**1-5 dias**	**6-12 dias**	**13-15 dias**	**16-22 dias**	**23-27 dias**	**Todos dias**
37 Tentou alterar a dose de insulina com o objetivo de diminuir seu peso e forma corporal?	0	1	2	3	4	5	6
38 Não aplicou (omitiu) insulina com o objetivo de diminuir seu peso e forma corporal?	0	1	2	3	4	5	6

Anexo 4- Problem Areas in Diabetes (PAID)

PAID - Questionário de avaliação dos problemas relacionados ao diabetes

Instruções: Qual das seguintes questões relacionadas ao diabetes são um problema comum para você? Circule o número que indicar a melhor resposta para você. Por favor, dê uma resposta para cada questão.

	Não é um problema	Pequeno problema	Problema moderado	Problema quase sério	Problema sério
1. A falta de metas claras e concretas no cuidado do seu diabetes	0	1	2	3	4
2. Sentir-se desencorajado com o seu tratamento do diabetes	0	1	2	3	4
3. Sentir medo quando pensa em viver com diabetes	0	1	2	3	4
4. Enfrentar situações sociais desconfortáveis relacionadas aos cuidados com seu diabetes (por exemplo: pessoas falando para você o que você deve comer)	0	1	2	3	4
5. Ter sentimentos de privação a respeito da comida e refeições	0	1	2	3	4
6. Ficar deprimido quando pensa em viver com diabetes	0	1	2	3	4
7. Não saber se seu humor ou sentimentos estão relacionados com o seu diabetes	0	1	2	3	4
8. Sentir que o seu diabetes é um peso para você	0	1	2	3	4
9. Preocupar-se com episódios de glicose baixa	0	1	2	3	4
10. Ficar brabo/ irritado quando pensa em viver com diabetes	0	1	2	3	4
11. Preocupar-se com a comida e o que comer	0	1	2	3	4
12. Preocupar-se com o futuro e com a possibilidade de sérias complicações	0	1	2	3	4
13. Sentir-se culpado(a) ou ansioso(a) quando você deixa de cuidar do seu diabetes	0	1	2	3	4
14. Não aceitar seu diabetes	0	1	2	3	4
15. Sentir-se insatisfeito com o médico que cuida o seu diabetes	0	1	2	3	4
16. Sentir que o diabetes está tomando muito de sua energia mental e física diariamente	0	1	2	3	4
17. Sentir-se sozinho com seu diabetes	0	1	2	3	4
18. Sentir que seus amigos e familiares não apoiam seus esforços em lidar com o seu diabetes	0	1	2	3	4
19. Lidar com as complicações do diabetes	0	1	2	3	4
20. Sentir-se esgotado com o esforço constante que é necessário para cuidar do seu diabetes	0	1	2	3	4

Anexo 5 - Resiliência

	DISCORDO			NEM CONCORDO NEM DISCORDO	CONCORDO		
	Totalmente	Muito	Pouco		Pouco	Muito	Totalmente
1. Quando eu faço planos, eu levo eles até o fim.	1	2	3	4	5	6	7
2. Eu costumo lidar com os problemas de uma forma ou de outra	1	2	3	4	5	6	7
3. Eu sou capaz de depender de mim mais do que qualquer outra pessoa.	1	2	3	4	5	6	7
4. Manter interesse nas coisas é importante para mim.	1	2	3	4	5	6	7
5. Eu posso estar por minha conta se eu precisar.	1	2	3	4	5	6	7
6. Eu sinto orgulho de ter realizado coisas em minha vida.	1	2	3	4	5	6	7
7. Eu costumo aceitar as coisas sem muita preocupação.	1	2	3	4	5	6	7
8. Eu sou amigo de mim mesmo.	1	2	3	4	5	6	7
9. Eu sinto que posso lidar com várias coisas ao mesmo tempo.	1	2	3	4	5	6	7
10. Eu sou determinado	1	2	3	4	5	6	7
11. Eu raramente penso sobre o objetivo das coisas.	1	2	3	4	5	6	7
12. Eu faço as coisas um dia de cada vez.	1	2	3	4	5	6	7
13. Eu posso enfrentar tempos difíceis porque já experimentei dificuldades antes.	1	2	3	4	5	6	7
14. Eu sou disciplinado.	1	2	3	4	5	6	7
15. Eu mantenho interesse nas coisas.	1	2	3	4	5	6	7
16. Eu normalmente posso achar motivo para rir.	1	2	3	4	5	6	7
17. Minha crença em mim mesmo me leva a atravessar tempos difíceis.	1	2	3	4	5	6	7
18. Em uma emergência, eu sou uma pessoa em quem as pessoas podem contar.	1	2	3	4	5	6	7
19. Eu posso geralmente olhar uma situação de diversas maneiras.	1	2	3	4	5	6	7
20. Às vezes eu me obrigo a fazer coisas querendo ou não.	1	2	3	4	5	6	7
21. Minha vida tem sentido.	1	2	3	4	5	6	7
22. Eu não insisto em coisas as quais eu não posso fazer nada sobre elas.	1	2	3	4	5	6	7
23. Quando eu estou numa situação difícil, eu normalmente acho uma saída.	1	2	3	4	5	6	7
24. Eu tenho energia suficiente para fazer o que eu tenho que fazer.	1	2	3	4	5	6	7
25. Tudo bem se há pessoas que não gostam de mim.	1	2	3	4	5	6	7

Anexo 6 - Coerção Percebida

ESCALA DE COERÇÃO PERCEBIDA (adaptada)

Com relação ao seu atual tratamento do diabetes: Leia as seguintes frases e assinale se concorda ou discorda com a afirmação:

	Concordo	Discordo
Tive oportunidade suficiente de dizer para a equipe de saúde se queria me tratar.		
Tive oportunidade de dizer para a equipe de saúde o que queria a respeito do tratamento.		
Ninguém parecia interessado em saber se eu queria me tratar.		
Minha opinião sobre o tratamento não interessou à equipe de saúde.		

Considerações Finais e Perspectivas Futuras

Os resultados destes estudos reforçam a importância dos aspectos psicológicos no cuidado de pacientes com DM. Sintomas de ansiedade e depressão são frequentes tanto em pacientes com DM1 quanto em pacientes com DM2 e repercurtem de diversas maneiras no controle metabólico, nas complicações crônicas e na qualidade de vida dos pacientes.

Em pacientes com DM1, os aspectos psicológicos mostraram influenciar não só o controle gligêmico, mas também a prevalência de complicações microvasculares, em especial a associação da Retinopatia Diabética (RD) com a depressão (HAD Depression ≥ 8). Além disso, encontrou-se associação significativa entre os *scores* de resiliência e as medidas de depressão, ansiedade, transtornos alimentares e problemas emocionais relacionados ao diabetes (PAID).

Neste estudo, pacientes com DM2 também apresentaram sintomas de ansiedade e depressão frequentes, o que pode repercurtir nas complicações microvasculares, em especial no que se refere as associações entre o sofrimento emocional relacionado ao diabetes (PAID) e a RD e Nefropatia Diabética.

Tendo em vista que o DM1 e o DM2 são doenças de etiologia e tratamento diferentes, as repercussões psicológicas também tendem a ser distintas. Embora existam algumas semelhanças, as avaliações e as intervenções devem levar em conta a idade de início da doença, a etapa do desenvolvimento, o *status* social e intelectual e o tipo de tratamento.

Deste modo, torna-se necessário realizar pesquisas que analisem as características dos pacientes que conseguem atingir um bom controle glicêmico. Para tanto, é importante investigar não só as vulnerabilidades, como as comorbidades psiquiátricas, a adesão e a qualidade do tratamento de saúde, mas também os aspectos positivos e as potencialidades de enfrentamento da

doença. Além disso, o desenvolvimento deste trabalho possibilitou uma abertura para o desenvolvimento de uma linha de pesquisa em psicologia do diabetes.