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RELATIONSHIP AND INFLUENCES OF BEHAVIORAL AND PSYCHOLOGICAL FACTORS ON METABOLIC CONTROL OF PATIENTS WITH TYPE 2 DIABETES MELLITUS

POVEZANOST I UTICAJ BIJEKVIORALNIH I PSIHOLOŠKIH FAKTORA NA MENTABOLIČKU KONTROLU PACIJENATA SA DIJABETESOM TIPA 2.

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Abstract

Background/Aim. Achieving good metabolic control, which play a key role in reducing or preventing macrovascular and microvascular complication of diabetes, requires continuous patient involvement in self-management of diabetes. This continued engagement, which makes type 2 diabetes (T2DM) one of most demanding diseases, physically and emotionally, can become, at certain periods of life, too severe and lead to emotional distress (symptoms of depression and diabetes-related distress) and deterioration of metabolic control. The aim of this study was to examine association and influence of behavioral and psychological factors on the metabolic control of patients with T2DM.

Methods. The research was conducted as a descriptive-analytic cross-sectional study. The method of random sampling included 324 subjects with T2DM in research. The values of biochemical parameters of metabolic control were measured by standard laboratory methods. Blood pressure was measured in two times and the arithmetic mean was calculated. Anthropometric measurement were performed and Body Mass Index (BMI) was calculated. Attitudes toward medication adherence, adherence to dietary recommendations, level of physical activity, presence of depressive symptoms and level of diabetes-related distress were examined using standardized questionnaires.

Results. The target values of metabolic control parameters were reached by 21.6% of respondents. Multivariate analysis as predictors of poor metabolic control identified: obesity, non-adherence toward dietary recommendations, insulin therapy, low level of physical activity and clinically significant diabetes-related distress. Conclusions. Routine application of the questionnaire used in this study in initial stages or critical moments of disease can assess patient’s attitudes and knowledge about behavioral determinants of diabetes self-management and timely detect psychological conditions that affect them. It would be realistic to expect that such a comprehensive holistic approach would contribute to lower incidence of complication and better metabolic control of T2DM.

Key words:
Type 2 diabetes; metabolic control; behavioral determinants; diabetes self-management; psychological factors.

Abstrakt

Uvod/Cilj. Postizanje dobre metaboličke kontrole koja ima ključnu ulogu u redukciji ili prevećiji makrovaskularnih i mikrovaskularnih komplikacija dijabetesa zahteva
kontinuiranu angažovanost pacijenata u upravljanju svojom bolešću. Ova kontinuirana angažovanost, koja čini dijabetes tipa 2 (T2DM) jednom od najznačajnijih bolesti i fizički i emocionalno, može postati, u predređenim periodima života, preteška i dovesti do emocionalnog distresa (simptomi depresije i dijabetesni distres) i pogoršavanja metaboličke kontrole. Cilj ove studije bio je ispitivanje povezanosti i uticaja bihejvioralnih i psiholoških faktora na metaboličku kontrolu pacijenata sa T2DM. **Metode.** Istraživanje je sprovedeno kao deskriptivno-analitička studija preseka Metodom slučajnog uzorka u istraživanje je uključeno 324 pacijenta sa T2DM. Vrednosti biohemijskih parametara metaboličke kontrole merene su standardnim laboratorijskim metodama. Krvni pritisak meren je u dva vremena i računat je aritmetička sredina. Vršena su antropometrijska merenja i računat je Index telesne mase. Standardizovanim upitnicima ispitivani su stavovi prema medikamentoj adherentnosti, adherentnost prema dijetetskim preporukama, nivo fizičke aktivnosti, prisustvo simptoma depresije i nivo distresa povezanog sa dijabetesom. **Rezultati.** Ciljne vrednosti parametara metaboličke kontrole dostiglo je 21.6% ispitanika. Multivarijantnom analizom kao prediktori loše metaboličke kontrole identifikovani su: gojaznost, neadherentnost prema dijetetskim preporukama, terapija insulinom, nizak nivo fizičke aktivnosti i klinički značajan dijabetesni distres. **Zaključak.** Rutinska primena upitnika korišćenih u uvoj studiji u inicijalnom stadijumu ili kritičnim fazama pogoršanja bolesti omogućila bi procenu pacijentovih stavova i znanja o bihejvioralnim determinantama upravljanja dijabetesom i blagovremeno otkrivanje sa njima povezanih psiholoških problema. Realno bi bilo očekivati da takav sveobuhvatni, holistički pristup može doprineti boljoj metaboličkoj kontroli pacijenata sa T2DM i manjoj incidenciji komplikacija. **Ključne reči:** Dijabetes tipa 2; metabolička kontrola; bihejvioralne determinante; samostalno upravljanje dijabetesom; psihološki faktori

**Introduction**

Diabetes mellitus represents a global public health crisis of pandemic proportions due to the growing number of patients, numerous complication that lead to disability and premature mortality, as well as due high cost of treatment and prevention\(^1\,^2\). Data from International Diabetes Federation indicate that in 2019, 463 million people in the world, or
9.2% of adults aged 20-79 years had diabetes\textsuperscript{2,3}. Globally, about 90% of the total number of people with diabetes suffers from T2DM\textsuperscript{3}.

In Serbia, according to the data of the Institute of Public Health of Serbia, in 2019, 770,000 people or 12% adults suffered from diabetes. This rate ranks Serbia third in Europe in the prevalence of diabetes\textsuperscript{2}.

Metabolic control is one of key outcomes of diabetes management and involving maintaining blood glucose level, arterial blood pressure (BP) and lipid status within limits as close to normal as possible\textsuperscript{4}. The American Diabetes Association (ADA) state following parameters values as indicative of good metabolic control: glycosylated hemoglobin (HbA1c ≤ 7%), low density lipoproteins (LDL-C) ≤ 2.6 mmol/l, high density lipoproteins (HDL-C) ≥ 1.15 mmol/l, triglycerides (TG) ≤ 1.7 mmol/l and BP ≤ 140/90 mmHg\textsuperscript{5,6}. Unregulated BP and dyslipidemia are associated with insulin resistance and less likelihood of optimal blood glucose control which increases risk of macrovascular and microvascular complications of diabetes\textsuperscript{7}. Despite that, ADA state in this data for 2019 that only 33-49% patients reach target values of some of the parameters of metabolic control, while reaching the target values of all the parameters is rare and amounts 14\%\textsuperscript{8}.

Achieving good metabolic control, which play a key role in reducing or preventing complications of diabetes, requires continuous patient involvement in self-management of diabetes\textsuperscript{9}, where 90-95\% of decision about their disease are made by person independently\textsuperscript{10}. This need for continued engagement makes T2DM one of most demanding chronic diseases, physically and emotionally\textsuperscript{11}. Therefore, behavioral requirements of self-management (medication adherence, physical activity, body mass control, and adherence to dietary recommendations) they can in certain periods of life, become too difficult for patients and result in poor metabolic control\textsuperscript{12} Perception inability to meet the behavioral requirements of self-management of diabetes can result in the manifestation of emotional distress (symptoms of depression and diabetes-related distress), which may result in worsening of metabolic control\textsuperscript{12,13}.

Despite the importance of problem and attitudes about the need for holistic and multidisciplinary approach to patients with T2DM, studies that comprehensively consider metabolic control are limited. Therefore, the purpose of this study was to examine the association and influence of behavioral and psychological factors on metabolic control of patients with T2DM.
Methods

Selection method, size and construction of sample

The research was conducted as a descriptive-analytical cross-sectional study. The research population considered of 4620 patients with T2DM from electronic register of the Diabetes Dispensary of the Health Center in Zajecar, Serbia. Statistical software G*Power 3.0.1. was used to estimate the required sample size for multivariate logistic regression analyzes. By entering the assumed moderate effect size of r=0.2 for study strength of 95% and the error level α=0.05 and potential 10 predictors, the minimum required simple size of n=324 subjects was obtained. To reduction selection bias respondents were determined by random sampling method, based on scheduling examination by the Integrated Health Information System performed by their chosen physicians. Thus, difference between outpatients and inpatients were avoided and generalization to the entire sample population was provided.

Exclusion criteria for all the study participants were as follows: disease duration less than one year, subjects only on dietary therapy and subjects with comorbidities that interfere with understanding and self-completion of questionnaire.

After the approval of the Ethic Board of the Health Center in Zajecar the research was conducted in the period from September 2018 to March 2019 in the Diabetes Dispensary of the Health Center in Zajecar.

Research implementation and methodology

Biochemical parameters of metabolic control were measured by a fully automated high performance chromatographic test. Data on complications and comorbidities were taken from the electronic medical records of the subjects BP Values were obtained by measuring with a conventional mercury sphygmomanometer in a sitting position at two times, after which the mean value was calculated. Anthropometric measurements obtained the values of body mass and body height of the subjects after which BMI was calculated Ina accordance with ADA guidelines, the classification of the degree of nutrition was performed: BMI < 18.5 kg/m² - malnutrition; BMI= 18.5-24.9 kg/m² - normal body mass; BMI= 25-29.9 kg/m² - overweight; BMI ≥ 30 kg/m² - obesity

As research tools, standardized questionnaires were used in order to reduce information errors. Questionnaires that have not been used in our area so far, after obtaining permission for use by the authors, were translated according to internationally recognized methodology with cultural adaptation.
**Medication adherence**

It was assessed by Questionnaire on Attitudes toward Medication Adherence. Score 1-3 classifies subjects into a group with negative attitudes toward medication adherence, while score > 3 indicates positive attitudes\(^{15}\). Research using this questionnaire finds its high negative predictive value (76.5%-82.9%), i.e. that 76.5%-82.9% of respondents with negative attitudes toward medication adherence are really non adherent toward medication therapy\(^{15}\). The assessment of reliability of the questionnaire was based on an acceptable internal consistency (Cronbach $\alpha=0.74$).

**Adherence to dietary recommendations**

It was assessed by the Questionnaire on the Perception of Adherence to Dietary Recommendations (PDAQ). The questionnaire consist 9 questions designed to cover all guidelines of dietary recommendations for patients with T2DM. Total score is obtained by summation the answers to all question\(^{16}\). In the studies in which the questionnaire was used, the respondents were classified in the group of adherents if they ate healthy for at least 4 days a week\(^{17}\). Accordingly, in this study, the point of intersection of the scale as a whole was set at 37 with score 1-3 indicating nonadherence, while score > 37 indicate adherence according dietary recommendations. The questionnaire showed acceptable internal consistency (Cronbach $\alpha=0.78$).

**Level of physical activity**

It was assessed by the Physical Activity subscale of Personal Diabetes Questionnaire (PDQ). Physical activity was assessed with two questions: 1. The level of daily physical activity and 2. The level of program activity (exercises). The answers are coded categorically: 0-inactivity; 1-subrteshreshold activity; 2-threshold activity and 3-supratreshold activity. The score of questions 1 and 2 are summed and give the scale score as a whole (0 and 1-unsatisfactory level of physical activity; score $\geq 2$-satisfactory level of physical activity\(^{18}\).

**Symptoms of depression**

The symptoms of depression were assessed using Patient Health Questionnaire-9 (PHQ-9), which validated as a screening instrument for use in Primary Health Care in Serbia. The questionnaire consist 9 questions about symptoms and signs of depression. According to achieved scores, the subjects are classified into 4 groups: absence of symptoms of
depression (score =0-4); mild symptoms of depression (score: 5-9); moderate symptoms of
depression (score 10-14); moderate to severe symptoms (score: 15 – 27)\textsuperscript{19}.

*Diabetes-related distress*

The diabetes-related distress was assessed by Diabetes Distress Scale. The questionnaire
differentiates 3 groups of subjects: with little or no distress (score > 2); with moderate
distress (score = 2-2.9); with high, clinically significant distress (score > 3)\textsuperscript{20}. The
questionnaire showed good internal consistency (Cronbach α=0.93).

*Statistical Analyzes*

Statistical data processing was performed using the statistical program IBM SPSS 21.0.
Data processing included methods of descriptive and inferential statistics. Numerical
features are presented through mean values (arithmetic mean) and measure variability
(range of values and standard deviation), and attributive features using frequencies and
percent. A binary logistic regression model was used to examine the correlation and
prediction of dependent variable defined as dichotomous. The odds ratio (OR) was used in
interpretation of the model together with 95% confidence interval (CI). As measure of the
model’s adaptation to real data, The Hosmer-Lemeshow test was used to test the
differences between the observed and expected values. The sensitivity and specificity of the
model and the total percentage of correctly classified respondents based on the model were
used in the interpretation of the results. All test were two-sided with significance level of p
< 0.05.

*Results*

*Demographic and clinical characteristics*

The mean age of subjects in the research sample was 63.8±9.3 years. The largest number of
respondents belonged to age group 45-65 years (n=155; 47.8%). Demographic
characteristics of respondents stratified by gender are shown in Table 1.
The largest number of subjects in sample (n=207; 63.9%) had diabetes 1-10 years, and
average duration of disease in the sample as whole was 11.0±8.3 years. The average BMI
subjects in sample (BMI=31.3±5.7 kg/m\textsuperscript{2}) indicated obesity. Without complications or
comorbidities in the sample of our study there were only N=38 (11,1%) of respondents.
Clinical characteristics of respondents stratified by gender are shown in Table 2.

*Research variables*

*Medication adherence*
Slightly more than half of respondents (N=169; 55.2) had positive attitudes toward medication adherence, while 155 (47.8%) had negative attitude. The results of univariate analysis showed that female sex (p=0.001), respondents with <65 years (p=0.009), level of education elementary of lower (p<0.001), poor financial status (p=0.009), obesity (p<0.001), insulin therapy with load (p<0.001) and ≥ 3 therapeutic doses daily (p<0.001) were statistically significantly related to negative attitudes toward therapeutic adherence.

Adherence to dietary recommendations

By dichotomizing the total value of PDAQ score (cut off=37), almost two thirds of the respondents (n=211; 65.1) rated themselves as not adherent toward dietary recommendations. Not adherence were more common in persons >65 years compared to group > 65 years (71.5% vs 57.9%) and in obese persons compared to those with normal body mass (74.7% vs 36.4%). The duration of diabetes (p=0.772) were not statistically associated with adherence to dietary recommendations.

Physical activity

The results obtained using the subscale of Physical activity PDQ indicate that more than half of respondents (n=211; 65.1%) had unsatisfactory level of physical activity. The results of univariate analysis showed that female sex (p=0.027), level of education elementary of lower (p=0.001), obesity (p<0.001) and the presence of complications (p<0.001) were statistically significantly related to unsatisfactory level of physical activity.

Symptoms of depression

In our study population, every second respondent had mild to moderate depression (n=154; 50.6%), every tenth (n=33; 10.2) had moderate to severe depression, while two-fifths had no symptoms of depression. The results of univariate analysis showed that female sex (p<0.001), level of education elementary of lower (p=0.003), insulin therapy with load (p=0.001) and the presence of complications (p=0.002) were statistically significantly related to symptoms of depression.

Diabetes related distress

By dichotomizing the value of total scores and scored associated subscales into categories of clinically significant distress (score ≥ 3) and no distress or moderate distress without clinical significance (score < 3) we obtained that clinically significant distress was present in 114 (35.2%) of respondents. The results of univariate analysis showed that female sex (p=0.006), higher levels of education (p=0.029), insulin therapy with load (p<0.001), three
and more therapeutic doses daily (p=0.031) and the presence of complication (p=0.005) were statistically significantly related to clinically significant distress.

**Relationship and predictive influence of examined variables on the metabolic control of subjects with T2DM**

Slightly less than quarter of respondents in research sample met all three goals of good metabolic control (n=70; 21.6%). Data on the values of metabolic control parameters of the subjects in our study sample are shown in Table 3.

In order to determine correlation and prediction of good metabolic control defined by achieving the target values of all three metabolic parameters, binary logistic model was analyzed. The first step was the application of univariate analysis with a dichotomized dependent variable metabolic control (good-met all three goals and bed-not met all three goals). Some socio-demographic and clinical characteristics of respondents, behavioral determinants of diabetes self-management and psychological characteristics of the respondents (symptoms of depression and diabetes-related distress) were applied as dependent variables in the model. Detailed data are shown in Table 4.

As a results of univariate analysis showed that the metabolic control of subjects can be associated with a number of variables between which there may be an independent relationship, using multivariate analysis evaluated variables which can be independent predictors, unlike others that affect metabolic control only as cofactors. The results are shown in Table 5.

**Discussion**

In the conducted research, all three goals of metabolic control are met by 21.6% of respondents, which is significantly better than the results of studies conducted in Japan (11,2%)\textsuperscript{21} and Poland (8%)\textsuperscript{22}. Females in this study have poorer metabolic control than males, which us consistent with results others published research\textsuperscript{23} The higher prevalence of psychological distress (symptoms of depression, and diabetes-related distress), negative attitudes toward medication adherence, as well as lower level of physical activity caused by traditional social roles of this gender group may be explanation for this finding.

An interesting finding is that older people ( > 65 years) have better metabolic control than people < 65 years of age. The same age distribution of metabolic control is indicated by others research research\textsuperscript{4,21}. The finding can be interpreted as a higher life load of
younger people, less tendency to change ingrained life habits and greater sensitivity to the stigma of the disease.

Results of the conducted research indicate the negative relationship between attitudes toward medication adherence and metabolic control patients with T2DM. Subjects with lower Attitude Scale scores (poorer medication adherence) also show poorer metabolic control of T2DM. Researches in the available literature published results consistent with ours\textsuperscript{24}. As T2DM medication therapy is often complex (higher number of drugs and higher daily doses), and in this study 37.7% of respondents have low level of education, while 44.8% of them assess their financial situation as bad, lack knowledge about disease and importance of therapy, as well as poor availability of drug therapy may explain the negative association of metabolic control and attitudes toward medication adherence.

In our study, complex therapeutic regimens (42.5% of respondents) showed a statistically significant association with negative attitudes toward drug adherence. This, as well as the fact that complex therapeutic regimens can create difficulties in integrating determinants in the management of diabetes into daily life routines\textsuperscript{25} can be explained by this finding.

Data from the literature on the relationship between depressive symptoms and metabolic control parameters are inconsistent. Some authors, consistent with our results find positive correlation between depressive symptoms and metabolic control parameters\textsuperscript{26}, while others do not find a correlation between depressive symptoms and metabolic control parameters values\textsuperscript{27}. The differences observed may be methodological in nature and depend on questionnaires for assessing the symptoms of depression used in the research.

The study finding of the negative predictive effect overweight (OR=2.80; CI=1.20-6.55) and obesity (OR=5.61; CI=2.36-13.35) on metabolic control is consistent with findings other studies\textsuperscript{28}. In contrast other studies have not found an association of obesity with any metabolic control parameters\textsuperscript{4}. Obesity increases insulin resistance and glucose intolerance, as well as sympathetic activity\textsuperscript{29}, worsening all metabolic control parameters of individuals with T2DM, which explain this finding.

The study finding of the negative predictive effect insulin therapy on metabolic control (OR=3.68-no load; OR=3.73-with load) is consistent with findings of other studies\textsuperscript{23}. This interesting finding can be explained by understanding of people with T2DM that the introduction of insulin into therapy means that the disease is in a phase that is difficult to control, which leads to clinically significant distress with negative impact on metabolic
control. Furthermore, fear of hypoglycemia is present in 29.4% of our subjects on insulin therapy, which leads them to take larger amounts of food and reduce physical activity in order to avoid hypoglycemia. One explanation for this finding that should be considered in future research, is that diabetes-related distress is a major barrier to initiating insulin therapy, and that clinical inertia in the introduction of insulin into T2DM therapy is one of the reasons for poorer metabolic control in this group of patients. The results of the analysis of multivariate logistic regression conducted in this study indicate the predictive effect unsatisfactory level of physical activity (OR=2.73; CI=1.39-5.35) on poor metabolic control of subjects with T2DM, which is consistent with the finding of other studies. The results of Look AHEAD study indicate this indirectly, with their finding that weight loss reduces the need for drugs that regulate glycemic status, blood pressure and lipid status.

In this study, clinically significant diabetes-related distress stands out as a significant predictor of poor metabolic control (OR=2.26; CI=1.29-5.35). Diabetes-related distress can affect metabolic control directly through pathophysiological processes (hypothalamic-pituitary axis activation, increased sympathetic activity and insulin resistance), and indirectly through diabetes self-management, which may explain this findings.

Conclusion

The study was conducted as a cross-sectional study on a representative sample. The advantage of studies of this type is that they enable good control of measurements and assessment of the prevalence of research determinants. However, the key disadvantage of these studies is impossibility of gaining insight of time sequence of the examined phenomena, i.e. it is not possible to determine the direction of causality for which longitudinal studies are necessary.

As self-completing questionnaires used as research instruments, recall bias and giving socially desirable answers could not be completely avoided. The construction of individual questionnaires enabled bias of the central tendency, i.e. giving answers that were in middle of the scale of offered answers.

Despite existence of these limitations, the representativeness of the sample, random sampling methods, and the use of internationally recognized standardized research instruments give significant strength to conducted study.
This study provides insight and understanding of a wide range of issues in the context of self-management of diabetes, which is key to achieving a much more effective approach to patients with T2DM. The available therapeutic modalities are less likely to be effective in individuals who have difficulty adhering to behavioral determinants of diabetes self-management, because these problems are often beyond the reach and influence of physicians, dealing with medical treatment of persons with T2DM.

The application of questionnaires used in this study in the care of patients with T2DM, at all levels of health care, in initial stages or critical moments of disease, provides insight into their knowledge and attitudes about behavioral determinants of diabetes self-management and timely detection of psychological conditions that affect them. This is the basis of the necessary multidisciplinary approach to patients with T2DM, which, by including other specialties (psychologists, nutritionists, physiotherapists), provide support to patients through education, motivation, behavior modification and psychological support. The results of conducted research indicate that is reasonable to expect that such a comprehensive approach contribute to better metabolic control of patients with T2DM.

The study results indicate that longitudinal research is needed in order better understand the impact of research determinants and evaluate the effectiveness of a multidisciplinary approach in achieving better metabolic control of patients with T2DM. This is basic recommendation for future research.

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### Demographic characteristics of respondents stratified by gender (Table 1)

|                        | Male |          | Female |          | Total |          |
|------------------------|------|----------|--------|----------|-------|----------|
|                        | n    | %        | n      | %        | n     | %        |
| Number of respondents  | 141  | 43.5     | 183    | 56.5     | 324   | 100.0    |
| Age categories         |      |          |        |          |       |          |
| 30-45                  | 11   | 7.8      | 6      | 3.3      | 17    | 5.2      |
| 46-65                  | 69   | 48.9     | 86     | 47.0     | 155   | 47.8     |
| >65                    | 61   | 43.3     | 91     | 49.7     | 152   | 46.9     |
| Average age, years     | 62.6±9 |          | 64.7±9.2 |          | 63.8±9.3 |          |
| Marital status         |      |          |        |          |       |          |
| live alone             | 111  | 78.7     | 115    | 62.8     | 226   | 69.8     |
| community life         | 30   | 21.3     | 68     | 37.2     | 98    | 30.2     |
| Education              |      |          |        |          |       |          |
| elementary/ lower       | 29   | 20.6     | 93     | 50.8     | 122   | 37.7     |
| High school            | 86   | 61.0     | 73     | 39.9     | 159   | 49.1     |
| College/ University    | 26   | 18.4     | 17     | 9.3      | 43    | 13.3     |
| Financial status       |      |          |        |          |       |          |
| poor                   | 45   | 31.9     | 100    | 54.6     | 145   | 44.8     |
| satisfactory           | 74   | 52.5     | 68     | 37.2     | 142   | 43.8     |
| good                   | 22   | 15.6     | 15     | 8.2      | 37    | 11.4     |
| \( \bar{x} \) - mean value; SD-standard deviation |

### Clinical characteristics of respondents stratified by gender (Table 2)

|                        | Male |          | Female |          | Total |          |
|------------------------|------|----------|--------|----------|-------|----------|
|                        | N    | %        | n      | %        | n     | %        |
| Number of respondents  | 141  | 43.5     | 183    | 56.5     | 324   | 100.0    |
| Duration of diabetes   |      |          |        |          |       |          |
| 1-10 years             | 90   | 63.8     | 117    | 63.9     | 207   | 63.9     |
| 11-20 years            | 34   | 24.1     | 42     | 23.0     | 76    | 23.5     |
| >20 years              | 17   | 12.1     | 24     | 13.1     | 41    | 12.7     |
| Average duration, \( \bar{x}±SD \) | 10.7±8.1 |          | 11.1±8.5 |          | 11.0±8.3 |          |
| The presence of other diseases (n=286) |      |          |        |          |       |          |
| only comorbidities     | 52   | 44.1     | 75     | 44.6     | 127   | 44.4     |
| comorbidities and complication | 57   | 48.3     | 85     | 50.6     | 142   | 49.6     |
| only complication      | 9    | 7.6      | 8      | 4.7      | 17    | 5.9      |
| BMI \( \bar{x}±SD \)   | 29.9±4.7 |          | 32.3±6.2 |          | 31.3±5.7 |          |
| Therapeutic modality   |      |          |        |          |       |          |
| tablets                | 78   | 55.3     | 100    | 54.5     | 178   | 54.9     |
| insulin                | 29   | 20.6     | 43     | 23.4     | 72    | 22.2     |
| tablets+ insulin       | 34   | 24.1     | 40     | 22.1     | 74    | 22.8     |
| Dose regimens          |      |          |        |          |       |          |
| 1 dose                 | 14   | 9.9      | 21     | 11.5     | 35    | 10.8     |
| 2 dose                 | 65   | 46.1     | 86     | 47.0     | 151   | 46.7     |
| ≥ 3 dose               | 62   | 43.9     | 76     | 41.5     | 138   | 42.5     |
Is insulin additional burden (n=146)?

|       | yes   |  | no   |  |
|-------|-------|---|------|---|
|       | 33    | 52.4 | 69   | 83.1 | 102 | 69.4 |

How insulin therapy burden you (n=102)?

|                          | yes |  | no |  |
|--------------------------|-----|---|----|---|
| Fear of hypoglycemia     | 6   | 18.2 | 24 | 34.8 | 30 | 29.4 |
| Limiting the activity of everyday life | 19 | 57.6 | 25 | 36.2 | 44 | 43.1 |
| Frequent checking of blood glucose levels | 8  | 24.2 | 20 | 29.0 | 28 | 27.5 |

\[\text{\text{- mean value; SD- standard deviation}\]

### Metabolic control parameters

(\text{Table 3})

| Metabolic control parameters                  | n   | %  |
|-----------------------------------------------|-----|----|
| Regulation of blood pressure                  |     |    |
| normal blood pressure                         | 195 | 60.2 |
| arterial hypertension                         | 129 | 39.8 |
| A1C % (Mean±SD)                               | 7.5±1.5 |
| Regulation of blood glucose                  |     |    |
| good                                          | 126 | 38.9 |
| bad                                           | 198 | 61.1 |
| HDL (Mean±SD)                                 | 1.3±0.3 |
| LDL (Mean±SD)                                 | 3.2±1.1 |
| Triglycerides (Mean±SD)                       | 2.2±1.5 |
| Lipid status                                  |     |    |
| normolipidemia                                | 113 | 34.9 |
| dyslipidemia                                  | 211 | 65.1 |

SD- standard deviation

Univariate analysis. Metabolic control in relation to demographic an clinical characteristics, behavioral determinants of diabetes management and psychological characteristics of respondents. (\text{Table 4})

| Metabolic control | good | % | | bad | % | p   |
|-------------------|------|---|---|-----|---|-----|
| Number of respondents | 70  | 21.6 | 254 | 75.4 |
| Gender            |      |    |    |     |    |     |
| male              | 40   | 28.4 | 101 | 71.6 |  \chi^2=6.743 | p=0.009 |
| female            | 30   | 16.4 | 153 | 83.6 |
| Age categories    |      |    |    |     |    |     |
| 30-65             | 31   | 18.0 | 141 | 82.0 |  \chi^2=2.777 | p=0.008 |
| >65               | 39   | 25.7 | 113 | 74.3 |
| Body mass level   |      |    |    |     |    |     |
| normal            | 22   | 50.0 | 22  | 50.0 |  \chi^2=32.986 | p<0.001 |
| overweight        | 28   | 26.4 | 78  | 73.6 |
| obesity           | 20   | 11.5 | 154 | 88.5 |
| Duration of diabetes |    |    |    |     |    |     |
| 1-20 years        | 46   | 22.2 | 161 | 77.8 |  \chi^2=0.129 | p=0.720 |
| >20 years         | 24   | 20.5 | 93  | 79.5 |
Insulin therapy

|                      | No | Yes, no load | Yes, with load | \( \chi^2 \) | p \( <0.001 \) |
|----------------------|----|--------------|----------------|-------------|----------------|
|                      | 54 | 30.3         | 124            | 69.7        |                |
|                       | 8  | 17.4         | 38             | 82.6        |                |
|                       | 8  | 8.0          | 92             | 92.0        |                |

\( \chi^2 = 19.424 \)

Number of therapeutic doses

|                      | 1  | 2 or more   | \( \chi^2 \) | p \( <0.001 \) |
|----------------------|----|-------------|--------------|----------------|
|                      | 55 | 29.3        | 133          | 70.7           |
|                       | 15 | 11.0        | 121          | 89.0           |

\( \chi^2 = 15.477 \)

Complications

|                      | No depression/minimal | Yes           | \( \chi^2 \) | p \( <0.001 \) |
|----------------------|-----------------------|---------------|--------------|----------------|
|                      | 40                    | 24.2          | 125          | 75.8           |
|                      | 30                    | 18.9          | 129          | 81.1           |

\( \chi^2 = 1.381 \)

Dietary adherence

|                      | Yes | No | \( \chi^2 \) | p \( <0.001 \) |
|----------------------|-----|----|--------------|----------------|
|                      | 48  | 42.5 | 65          | 57.5           |
|                      | 22  | 10.4 | 189         | 89.6           |

\( \chi^2 = 44.643 \)

Depression

|                      | No depression/minimal | Yes          | \( \chi^2 \) | p \( <0.001 \) |
|----------------------|-----------------------|--------------|--------------|----------------|
|                      | 36                    | 28.3         | 91           | 71.7           |
|                      | 34                    | 17.3         | 163          | 82.7           |

\( \chi^2 = 5.605 \)

Dietary related distress

|                      | No distress/moderate no clinical significance | Clinically significant | \( \chi^2 \) | p \( <0.001 \) |
|----------------------|-----------------------------------------------|------------------------|--------------|----------------|
|                      | 58                                             | 27.6                   | 152          | 72.4           |
|                      | 12                                             | 10.5                   | 102          | 89.5           |

\( \chi^2 = 12.746 \)

Level of physical activity

|                      | Satisfactory | Unsatisfactory | \( \chi^2 \) | p \( <0.001 \) |
|----------------------|--------------|----------------|--------------|----------------|
|                      | 51           | 35.7           | 92           | 64.3           |
|                      | 19           | 10.5           | 162          | 89.5           |

\( \chi^2 = 29.874 \)

Medication adherence

|                      | Adherent | Not adherent | \( \chi^2 \) | p \( <0.001 \) |
|----------------------|----------|--------------|--------------|----------------|
|                      | 70        | 0            | 41.4         | 58.6           |
|                      | 155       | 100.0        |              |                |

\( \chi^2 = 81.849 \)

\( \chi^2 \)-hi square test (relationship test); p-level of significance

Logistic regression model with dependent variable poor metabolic control

| Independent variables | p \( ^1 \) | OR \( ^2 \) (95% CI \( ^3 \)) |
|-----------------------|-----------|-----------------------------|
| Body mass level       |           |                             |
| Normal                | <0.001    | 1.00                        |
| Overweight            | 0.018     | 2.80 (1.20, 6.55)           |
| Obesity               | <0.001    | 5.61 (2.36, 13.35)          |
| Insulin therapy       | 0.001     |                             |
| No                    | 1.00      |                             |
| Yes/no load           | 0.008     | 3.68 (1.41, 9.60)           |
| Yes/with load         | 0.004     | 3.73 (1.54, 9.04)           |
| Dietary adherence     |           |                             |
| Good                  | <0.001    | 3.73 (1.95, 7.15)           |
| Bad                   |           |                             |
| Diabetes related distress |       |                             |
| No distress/moderate no clinical significance | 0.040 | 2.26 (1.04, 4.93) |
| Clinically significant distress |         | 1.00                        |
| Level of physical activity |       |                             |
| Satisfactory         |           | 1.00                        |
| Unsatisfactory       | 0.004     | 2.73 (1.39, 5.35)           |

1 significance level for the Wald test; 2 odds ratio; 3 confidence interval; The value of Hosmer-Lemeshow (C=8.318, p=0.403) indicates the agreement of the model with the data. The sensitivity of the model shown in table is 93.3%, the specificity is 37.1% and the overall accurate prediction is 81.2%.
