Characteristics Associated with Uncontrolled Blood Pressure Among Portuguese Primary Care Patients with Type 2 Diabetes

Fatores Associados a Tensão Arterial Não Controlada em Pessoas com Diabetes Tipo 2 Seguidas nos Cuidados de Saúde Primários em Portugal

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ABSTRACT

Introduction: Determine whether socio-demographic, habits and risk factors are associated with a better tensional control in type 2 diabetes in primary care patients in order to identify a specific target population for compensatory interventions improving diabetes control and reducing its morbi-mortality.

Material and Methods: Cross-sectional study in primary care. Randomized type 2 diabetes patient data collection by their volunteer family doctors, proportionally stratified from the 5 Portuguese continental regions. Variables: blood pressure, age, gender, education, diabetes duration, HbA1c, smoking habits, weight, waist circumference, physical activity and adherence to medication. Bivariate and logistic regression analysis to evaluate each measured variable's independent association with uncontrolled blood pressure (≥ 140/90).

Results: 709 patients were included in the study, 60.2% men, mean age 66.12 ± 10.47 years. In logistic regression analysis, the factors independently associated to uncontrolled BP were lower education (p = 0.014), shorter diabetes duration (p = 0.002), higher waist circumference (p < 0.001), higher pulse pressure (p < 0.001), higher physical activity level (p = 0.043) and being a smoker (p < 0.001).

Discussion: The main limitations are the fact that the sample was not totaly random and included only primary care patients, a possible inter-observer bias and being a cross-sectional study, thus not providing information on temporal relation or causality.

Conclusion: The sub-group of people with diabetes identified to have worse tensional control should have a different and more intensive approach in primary care. We recommend further longitudinal and population based confirmatory research.

Keywords: Blood Pressure; Blood Pressure Determination; Diabetes Mellitus, Type 2; Portugal; Primary Health Care

RESUMO

Introdução: A hipertensão arterial está associada a maior morbimortalidade na diabetes tipo 2. É assim importante identificar quais as características socio demográficas, hábitos e fatores de risco das pessoas com diabetes tipo 2 que estão associadas a descontrolo tensional de modo a intervir de forma ajustada nesta população.

Material e Métodos: Estudo observacional transversal nos cuidados de saúde primários com recolha de dados de pessoas com diabetes tipo 2 aleatorizadas pelos seus médicos de família, estratificados proporcionalmente pelas cinco regiões de saúde de Portugal continental. Variáveis: tensão arterial, idade, sexo, formação, duração da diabetes, HbA1c, hábitos tabágicos, peso, perímetro abdominal, nível de atividade física e adesão à medicação. Análise bivariada e por regressão logística para avaliar a associação independente de cada variável com descontrolo tensional (tensão arterial ≥ 140/90).

Resultados: Estudados 709 doentes, 60,2% homens, idade média 66,12 ± 10,47 anos. Após análise de regressão logística, verificou-se que os fatores independentemente associados a não controlo da tensão arterial foram a menor formação académica (p = 0,014), a menor duração da diabetes (p = 0,002), o maior perímetro abdominal (p < 0,001), a maior pressão de pulso (p < 0,001) e o maior nível de atividade física (p = 0,043), assim como o facto de ser fumador (p < 0,001).

Discussão: As principais limitações do estudo são o facto da amostra não ser totalmente aleatória e incluir apenas frequentadores dos cuidados primários, um possível vies inter-observador e o facto de ser um estudo transversal e não poder deduzir causalidade.

Conclusão: O sub-grupo de pessoas com diabetes tipo 2 identificadas como tendo maior associação a pior controlo tensional deveriam ser alvo de uma abordagem diferente e mais intensiva nos cuidados de saúde primários em relação a este fator de risco. Recomendamos estudos longitudinais e populacionais para confirmar estes resultados.

Palavras-chave: Cuidados de Saúde Primários; Determinação da Pressão Arterial; Diabetes Mellitus Tipo 2; Portugal; Pressão Arterial

INTRODUCTION

Diabetes mellitus (DM) is a major public health concern and has become one of the main causes of morbidity and total or partial disability through the 21st century. An estimated 415 million people affected with diabetes has been found worldwide in 2015 and is expected to rise to 642 million by 2040. Five-million diabetes-related deaths have occurred worldwide in 2015.[1]

An increasing prevalence of diabetes has been found and in Portugal, according with the 2014 Annual Report of the National Diabetes Observatory (*Relatório Anual do*

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Observatório Nacional da Diabetes), a 13.3% estimated diabetes prevalence rate has been found in people aged 20-79, showing a 1.4% increase when compared to 2009. In 2014, 4% of overall mortality was diabetes-related and in 2013 eight life-years were lost per each diabetes-related death in the population under the age of 70.[2]

DM has been responsible for a high frequency of medical appointments and emergency episodes, in addition to a great number of hospital stays. Diabetes drug spending has been increasing and corresponded to a 43.1 million euro SNS (Portuguese healthcare system) expenditure in 2014 and overall Portuguese expenditure associated with diabetes represented 0.7% - 0.9% of the GDP (gross domestic product) and 8-10% of health expenditure in 2014.[2]

Atherosclerotic cardiovascular disease is the major cause for morbidity and mortality and for direct and indirect costs in patients with diabetes. Common conditions coexisting with diabetes (such as high blood pressure and dyslipidaemia) are cardiovascular risk factors (CVR) and diabetes independently represents itself a risk.[3] In Portugal, a significant association of DM with coronary heart disease (CHD) and with stroke has also been confirmed.[4] Different studies have shown the efficacy of the individual control of each of these risk factors and great benefits have been shown when different factors are simultaneously controlled.[5] A systematic CVR factor evaluation is recommended at least annually for all the patients with diabetes: high blood pressure, dyslipidaemia, smoking, microalbuminuria and family history of early coronary heart disease.

High blood pressure (HBP) is a major risk factor for atherosclerotic cardiovascular disease and microvascular complications and is more prevalent in patients with diabetes.[6] A significant association between DM and HBP has been found in Portugal and 78.3% of the patients with diabetes have HBP.[7]

There is an evidence that adequately controlled BP is related to a reduction in mortality, risk of cardiovascular events, albuminuria and retinopathy.[8–10] A NNT (number needed to treat) of 6 to prevent one major complication of diabetes in 10 years and NNT of 15 to prevent one death in 10 years have been described[11] and BP control has been even more important than glycaemic control as no reduction has been shown in these endpoints with any intensive blood-glucose control.[12,13] This BP control intervention has also proved to be cost-effective.[14] There is a strong evidence that systolic > 140 mmHg and diastolic BP > 90 mmHg are harmful, even though no additional benefit seemed to emerge when lowering this value well below these levels.[15]

Different socio-demographic patient characteristics have been associated with adequately controlled BP, such as male gender,[16,17] younger age[17–19] and higher educational level.[19,20] As regards the variables associated with other risk factors, controlled BP levels were associated with lower LDL-cholesterol levels,[18,21] lower BMI,[18,19,21] lower physical activity levels[22] and longer diabetes duration.[18,21]

Only 37.9% of the Portuguese patients with diabetes had BP < 140/90[7] in 2006/2007 and, in 2014, this number had already reached 66.7% in primary care records.[2]

Knowledge on the characteristics of the patients with diabetes associated with poorly controlled BP allows for a differentiated intervention in these subgroups aimed at the reduction of diabetes-related morbidity and mortality. This was an innovative study aimed at understanding the influence of socio-demographic characteristics, lifestyle patterns and risk factors on BP control in Portuguese patients with diabetes.

MATERIAL AND METHODS

This was a cross-sectional and observational study involving the initial 18 patients with type-2 diabetes attending the general practice follow-up outpatient from 15 October 2014 onwards. An invitation has been made to general practitioners through social networks and volunteers were accepted until 65 physicians from mainland Portugal were obtained, distributed by the five Portuguese ARS (*Administração Regional de Saúde* – Regional Healthcare Administration) (25 from the Northern region, 11 from the Central, 23 from Lisbon and the Tagus Valley region, three from Alentejo and three from the Algarve). The number of physicians from each region has been determined with multi-stage stratified cluster sampling based on geodemographics of each region (2011 data from the INE [*Instituto Nacional de Estatística* – Statistics Portugal] and the 2009 PREVDIAB study[23] regarding the number of patients with diabetes and the population per region), producing a patient distribution which was tendentially proportional to regions (in order to obtain a total number as deemed necessary) and subsequently grouping the patients into the selected general practitioners (18 patients per physician). Patients aged under 18, pregnant mothers, bedridden and wheelchair-bound patients or diagnosed with depression in the list of clinical problems were excluded from the study.

The following variables were analysed: patient's gender, age, education, duration of diabetes (years), HbA1c level (obtained as an outpatient and brought by the patient to the clinic or determined at the outpatient clinic on the day of the medical appointment) and insulin therapy. Patient's body weight and body mass index (BMI), waist circumference (WC) (measured at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest, as recommended)[24] and blood pressure (BP) (measured with the patient seated and based on the average value of two readings, as recommended) have been obtained.[25] Patients presenting with BP <140/90 at this examination were considered with adequately controlled BP. Smoking (daily cigarette consumption), physical activity (PACE instrument in Portuguese)[26] and medication adherence (Morisky Medication Adherence Scale in Portuguese) were assessed.[27] Prescribed oral anti-diabetic and anti-hypertensive drugs were recorded.

Qualitative values are presented in descriptive statistics as *n* and *%* and quantitative as mean ± standard deviation.

Chi-square and Mann Whitney's U-test were used in inferential statistics to compare qualitative and quantitative variables, respectively, in patients with adequately and poorly controlled BP. Multivariate analysis was also obtained using logistic regression (backward method including factors with a level of significance < 0.5 in bivariate analysis) in order to study the influence of each factor, using intention to treat analysis and odds ratio were calculated. A 0.05 level of significance has been used in all the calculations and association tests between variables or groups of patients.

RESULTS

A group of 709 patients recruited nationwide by 41 general practitioners (63% of those initially recruited) has been involved in this study (60.2% male patients, mean age 66.12 ± 10.47 years and with 6.26 ± 3.90 years of education, including 1.7% illiterate patients and 9.3% with over-12-year education, mean diabetes duration of 9.25 ± 7.83 years and 13% of the patients were on insulin therapy).

Mean systolic was 137.02 ± 16.45 mm Hg and diastolic BP was 76.48 ± 10.65 mm Hg (Table 1) and 57.1% of the patients presented with controlled systolic and 88.3% with controlled diastolic BP. Mean pulse pressure was 60.54 ± 15.34 mmHg. A percentage of 54.6% of our patients had BP < 140/90 and 83.1% of the patients were on at least one anti-hypertensive drug; 9.9% of the patients with adequately controlled BP were not on any anti-hypertensive drug.

Mean BMI in our group of patients was 29.39 ± 4.87 and 45.1% were overweight, 26.2% were mildly obese and 11.8% were severely obese. Mean BP was 102.57 ± 11.58 and 88.3% of female and 72.1% of male patients presented with HBP and 81.2% of female and 48.7% of male patients with extremely HBP.

As regards blood pressure control (BP < 140/90) and other variables, an association was found in bivariate analysis (Table 2) with higher educational level ($p < 0.001$), lower BMI ($p = 0.001$), lower WC ($p < 0.001$) and lower pulse pressure ($p < 0.001$). Even though a tendency to more adequately controlled BP has been found in female patients, non-smokers, patients with adequately controlled

Table 1 – Social and demographic characteristics, HbA1c level and risk factors in our group of patients with diabetes

Variable	Mean ± standard deviation	Minimum	Maximum	n
Age	66 ±10	30	91	707
Education	6 ± 4	0	22	689
Diabetes duration	9 ± 8	0	47	708
HbA1c level	6,8 ± 1.0	4.4	12.1	690
Systolic blood pressure	137 ± 17	90.00	195.00	709
Diastolic blood pressure	77 ± 11	40.00	120.00	709
Body mass index	29.4 ± 4.9	17.62	50.95	709
Pulse pressure	61 ± 15	23	113	709
Waist circumference	102.6 ± 11.6	60	149	630

n = Number of patients with a recorded value for the variable

Table 2 – Social and demographic factors, lifestyle patterns and risk factors and association with blood pressure (BP) control

Variable		Patients with adequately controlled BP	Patients with poorly controlled BP	n	*p*
Region*	Northern Central	51.6	48.4	709	0.055
	Lisbon and Tagus Valley/ Alentejo/ Algarve	58.8	41.2		
Gender*	Female	55.3	44.7	709	0.749
	Male	54.1	45.9		
Education**		6.88 ± 4.18	5.52 ± 3.39	689	**< 0.001**
Physical activity*	Active	53.4	46.6	709	0.310
	Inactivity	57.6	42.4		
Smoking*	Yes	50.7	49.3	709	0.471
	No	55	45		
Body mass index**		28.85 ± 4.74	30.03 ± 4.95	708	**0.001**
Waist circumference**		101.08 ± 11.43	104.40 ± 11.52	630	**< 0.001**
Pulse pressure**		53.25 ± 10.32	69.29 ± 15.81	709	**< 0.001**
HbA1c level*	Adequately controlled (< 7%)	55.2	44.8	709	0.675
	Poorly controlled	53.5	46.5		
Diabetes duration**		9.53 ± 7.97	8.91 ± 7.65	709	0.273

n = Number of patients with a recorded value for the variable
* Percentage. Chi-square test; ** Mean ± standard deviation. Mann-Whitney U-test.

Table 3 – Factors associated with poorly controlled BP upon logistic regression analysis, with relative risk [odds ratio and confidence interval (CI)]

Variable	*Odds ratio*	95% CI	*p*
Education	0.933	0.883 - 0.986	**0.014**
Smoking	2.128	1.133 - 3.996	**0.019**
Physical activity	1.136	1.004 - 1.285	**0.043**
Waist circumference	1.043	1.024 - 1.063	**< 0.001**
Pulse pressure	1.114	1.093 - 1.126	**< 0.001**
Diabetes duration	0.960	0.936 - 0.986	**0.002**

diabetes, with higher diabetes duration, in patients living in the southern region and in physically more active patients, no statistical differences between these variables were found.

Upon logistic regression (Table 3 and Fig. 1), lower educational level, diabetes duration, higher WC, higher pulse pressure and physically more active patients, as well smoking were independently associated with poorly controlled BP and these explained 43.9% of variance.

DISCUSSION

A percentage of 54.6% of the patients presented with adequately controlled BP (BP < 140/90), lower than the percentage of 72.1% found in patients with diabetes attending primary healthcare in 2014.[2] The difference may be due to the fact that only 80.1% of the patients were recorded into the national records of the study of the Portuguese Observatory,[2] in contrast with 100% of our patients, as data were directly collected by physicians and not retrospectively collected from the files. In Europe, only 19.7 and 19.3% of the patients presented with adequately controlled BP in PANORAMA and GUIDANCE studies, respectively[28,29] and in the USA a 52.8% BP control rate has been found in 2009/2010 (Wong *et al.*, 2013), even though BP values <130/80 mmHg were considered as adequately controlled BP in these studies. In more recent studies, using BP < 140/90 as a reference, a 36.4% of patients with diabetes and adequately controlled BP has been found in a German,[31] 51.2 – 65.4% of patients in a French[22] and 45.3% in an Australian study,[32] closer to what was found in our study. Poorer controlled systolic when compared to diastolic BP has been found in this study, in line with other studies. The effect of the risk factors associated with the limited response to anti-hypertensive drugs has been considered as the major impediment to an adequately controlled BP in patients with diabetes compared to general population, particularly as regards systolic BP.

In our group, 83.1% of the patients were at least on one anti-hypertensive drug, above the percentage found in the VALSIM study (71.3%) carried out in Portuguese primary heathcare.[7] The percentage found in this study is also above the one found in a German population study (69.7%)[31] although below what has been found in a Spanish study in which 94.7% of the patients with diabetes were on a medication, even though the study has been carried out in tertiary healthcare.[21] In this study, 9.9% of the patients with diabetes and poorly controlled BP were not on a medication, suggesting that a reinforced therapy and not a therapy onset was needed, which is consistent with other studies showing a poor intensification of therapy in this area.[33,34]

This study aimed at the identification of the characteristics associated with poorly controlled BP in patients with diabetes. Logistic regression showed that lower educational level, lower diabetes duration, higher WC,

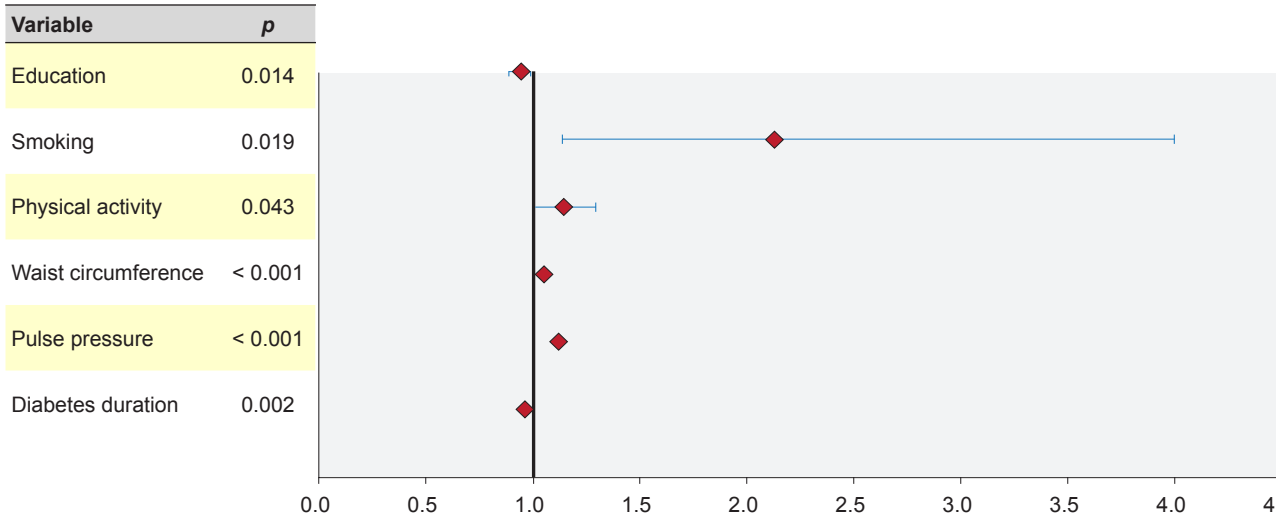

Figure 1 – Chart with odds ratio (red) and confidence interval (blue) of the factors associated with poorly controlled BP, upon logistic regression analysis

higher pulse pressure, physically more active and smokers were independently associated with poorly controlled BP.

In our study, female patients showed higher even though not significant BP control, in line with some other studies.[35,36] This may be explained by the fact that male patients show a lower use of healthcare and place less emphasis on healthcare issues, as well as less emphasis on healthy lifestyles.[37,38]

Higher educational level has been associated with more adequately controlled BP, in line with other studies[19,20] carried out in regions with overall low educational, social and economic levels. This is in line with other studies that have described an overall low level of literacy in Portugal.[39,40] Different studies have also shown an association between patient's educational level and a higher control of the level of HbA1c,[41,42] suggesting that health literacy probably has an influence on diabetes outcomes.[43]

Diabetes duration was independently associated with more adequately controlled BP, in line with other studies,[18,21] which may be explained by the fact that these patients show greater awareness towards risk factor management. The opposite happens with glycaemic control,[28,29,44–50] probably due to the progressive nature of diabetes, leading to a poorer glycaemic control as diabetes progresses.

Obesity was associated with poorly controlled BP in bivariate analysis, probably due to its close relationship with BP levels, even though not independently associated with adequately controlled BP upon the effect of confounding factors had been removed. Other studies found contradicting results, with an association between adequately controlled BP and higher[35] *vs.* lower BMI.[18,21] In fact, the patients with more than one cardiovascular risk factor apart from BP (obese patients with diabetes) seemed more aware of high blood pressure and subsequently taking more medication although, at the same time, making good outcomes with medication harder to obtain, which may have led to these contradicting results.[35] An independent and inverse association has been found between waist circumference and BP control ($p < 0.001$). This variable is probably the most predictive of metabolic syndrome in Portuguese diabetic patients, even with the absence of obesity based on BMI[4] and corresponding to an increased risk of associated cardiovascular mortality, particularly in men.[51,52] A stronger association seems to exist between an increased WC (abdominal obesity) and cardiovascular diseases when compared to obesity based on BMI.[53] The fact that BMI was associated with more adequately controlled BP in our study showed the higher cardiovascular risk in this sub-population and reinforced the relevance of abdominal obesity in patients with diabetes.

Pulse pressure was also independently associated with more adequately controlled BP levels and seemed associated with more micro and macrovascular complications in patients with diabetes,[54] reinforcing the relevance of pressure pulse in patients with diabetes.

Physical activity was independently related to poorer BP control. This factor has been scarcely studied as predictive of adequately controlled BP, although its benefits are already known to reduce BP in patients with diabetes.[22,55–57] Nevertheless, different studies have described an insufficient non-pharmacologic therapy including physical activity in patients with diabetes, showing a great improvement potential for BP control.[36] A direct relationship with BP control would therefore be expected in patients with diabetes. A possible explanation for this contradicting result may be related to the fact that motivation to increase physical activity, apart from the level of physical activity, has also been evaluated with the instrument used in this study, leading to some degree of therapeutic inertia, which is specific to patients with more motivation and patients wait more time before increasing anti-hypertensive therapy. In fact, physically more active patients have shown adequately controlled BP with less medication[22] and self-described physical activity and motivation may not be equivalent to an effective higher level of activity. Further research is needed on this subject, namely in Portugal and reinforces the relevance of a Portuguese scale of physical activity.

Smoking was independently associated with poorly controlled BP in this study, in line with a German study, even though losing its statistical significance upon adjustment to confounding variables.[35] A contradicting result was found in a Portuguese study, in which the frequency of the metabolic syndrome was higher among non-smokers and ex-smokers than in smokers.[4] An important cardiovascular risk factor[58] was again related to HBP in this study.

Different demographic factors, lifestyle patterns and risk factors seem to have an influence and to be predictive of adequately controlled BP in patients with diabetes followed in Portuguese primary healthcare, explaining for 43.7% of BP variance. Therefore, these results can help doctors selecting patients in need for more attention to cardiovascular risk due to more predictably poorly controlled BP, leading to a more careful and more aggressive control of these parameters (smokers, active patients, presence of abdominal obesity, higher pulse pressure, lower educational level and longer diabetes duration). In addition, these sub-groups may show an increased BP due to some specific mechanism and its study is really relevant in order to reduce diabetes-related cardiovascular and total morbidity and mortality.

The fact that sampling was not entirely random, as collecting physicians were volunteer and selected through social networks, leading to a selection bias, is one of the limitations of this study. Nevertheless, patients with diabetes were randomly selected and this nationwide sample showed a similar distribution to the distribution of patients with diabetes in Portugal.[23] Patients in our group were frequent users of outpatient primary healthcare and patients diagnosed with depression were not included, preventing from any generalization of the results to the entire Portuguese diabetic population. In our group, 60.2% of the patients were male and these represent around 58% of Portuguese patients with diabetes. Patients were aged 66.12 ± 10.47 years and diabetes prevalence in Portugal is higher in 60-79 age group.[23] Therefore, despite these

limitations, we may consider that this is a representative sample of the Portuguese patients with diabetes.

In addition, 65 researchers were involved in this study, 41 from which have been recruited, which may have led to a heterogeneous measurement of certain variables such as BP and WC (inter-observer bias); this has been minimized with face-to-face meetings and the use of written detailed instructions sent to physicians. Researchers voluntarily collaborate to the study and did not receive any compensation, therefore limiting the collected variables and no other sociodemographic factors have been included, including patient's occupational and civil status, risk factors such as dyslipidaemia, alcohol consumption and nutritional pattern, HBP characteristics and duration, complications, polymedication and comorbidities, which may have had an impact on therapy and BP control.

The fact that it was a cross-sectional study, with no information regarding time relationship nor causality was another limitation of the study. Nevertheless, this study described one reality of diabetes-related BP control in Portuguese patients attending primary healthcare.

CONCLUSION

Variables showing an independent influence on poorly controlled BP in patients with diabetes included lower educational level, higher waist circumference, higher pulse pressure, higher level of physical activity, smoking and lower diabetes duration. Therefore, these were the subgroups of patients with diabetes in whom a more intensive action is crucial. This will involve a special attention to newly diagnosed patients with diabetes, in whom an earlier action focused on BP control is very relevant despite the tendency for an action focused on glycaemic control. These conclusions reinforce the importance of BP control in patients with diabetes and associated cardiovascular risk factors, particularly higher waist circumference and smoking as well as the relevance of pulse pressure as an associated risk factor. High BP levels should not be undervalued, despite a good adherence to physical activity and a more intensive action is recommended in this population. Knowing the awareness of the cardiovascular risk by patients with lower education is also very relevant, in addition to the importance given to therapy adherence and to the difficult BP control in this population, allowing for the selection of the best way to manage this issue.

Further longitudinal and comprehensive studies are recommended in order to confirm these results and to identify the target population for a more intensive action on cardiovascular risk factors aimed at the reduction of diabetes-related morbidity and mortality with an increasing impact worldwide.

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HUMAN AND ANIMAL PROTECTION

The authors declare that the followed procedures were according to regulations established by the Ethics and Clinical Research Committee and according to the Helsinki Declaration of the World Medical Association.

DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

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