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Cardiovascular risk factors and metabolic control in type 2 diabetic subjects attending outpatient clinics in Italy: The SFIDA (survey of risk factors in Italian diabetic subjects by AMD) study

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Summary *Background and aim:* To perform an observational, cross-sectional study aiming to assess multiple cardiovascular risk factors and metabolic control in a very large and representative sample of type 2 diabetic subjects attending diabetes outpatient clinics (DOCs) in Italy.
Methods and results: Two hundred and sixty-one clinics were involved, representing about one-third of the whole number of DOCs in the Country. Each clinic recruited on a random basis from 50 to 100 type 2 diabetic patients aged 35–70 years, diagnosed more than six months before the start of the study. Demographic and clinical data were collected and blood pressure, lipids, HbA_{1c}, fasting blood glucose (FBG), and microalbuminuria were measured. Overall, 12,222 type 2 diabetic patients were recruited in 253 DOCs. Female subjects showed higher FBG, HbA_{1c}, blood pressure, lipid levels, and a longer duration of disease. The proportion of patients with BMI $\geq$ 30 was 33.3% among males and 45.9% among females; 40.9% of male patients had a waist circumference greater than 102 cm, while 79% of

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female patients had a waist circumference over 88 cm. More than two-third of the patients (74.4%) had systolic blood pressure values of $\geq$130 mmHg, and one-third (33.2%) had diastolic values $\geq$ 85 mmHg. The mean value of HbA_{1c} was 7.6 $\pm$ 1.6, and 23.7% of the observed population had an HbA_{1c} level $>$ 8.5%. More than half of the study population had total cholesterol levels $\geq$ 5.2 mmol/l, 47% had LDL cholesterol values of 3.3 mmol/l or greater and 9.6% had HDL cholesterol level lower than 0.90 mmol/l. The presence of multiple lipid alterations was associated with markedly higher HbA_{1c} levels, in both subjects treated with lipid lowering drugs and untreated subjects. Finally, even moderate increases in HbA_{1c} levels (i.e. $HbA_{1c} > 7.5\%$) were associated with a statistically significant greater risk of systolic blood pressure levels $\geq$ 160 mmHg in women (OR = 1.40; 95% CI 1.09–1.80) but not in men (OR = 1.21; 95% CI 0.96–1.54).
Conclusions: The SFIDA study provides a clear indication of the need to orient diabetes care towards the control of global cardiovascular risk. Only a stricter adherence to the existing guidelines and a much stronger attention to the attainment of the desired therapeutic goals will allow a decrease in morbidity and mortality as well as in the costs related to diabetes.

Introduction

Coronary heart disease is the leading cause of morbidity and mortality in type 2 diabetic subjects, showing a risk 2–4 times higher than in the general population [1–2]. The reasons for this increased cardiovascular risk are not fully explained; a major role is probably played by the deleterious effects of hyperglycaemia on vascular function and structure [3] and this role has been confirmed by epidemiological, observational studies. In the UKPDS it has been demonstrated that each 10% reduction in mean value of HbA_{1c} was associated with a highly significant 14% reduction in the risk of myocardial infarction [4]. In addition, other well established contributing risk factors, such as hypertension, obesity and dyslipidemia, are often present in type 2 diabetes [5,6].

Achieving and maintaining an optimal control of the multiple, modifiable cardiovascular risk factors associated with type 2 diabetes, including plasma glucose, is mandatory. On the other hand, only a minority of patients achieve the target values [7] and this probably explains why, despite all the efforts, cardiovascular morbidity and mortality are still unacceptably high in this population [2]. On this background, the Italian Association of diabetes specialists (AMD) decided to perform an observational, cross-sectional study aiming to assess multiple cardiovascular risk factors and metabolic control in a very large and representative sample of type 2 diabetic subjects attending outpatient clinics. This paper reports the main characteristics of this population and some short-term outcomes of diabetes care provided in the Italian Diabetes Outpatient Clinics (DOCs).

Methods

Patients

The Steering Committee of the present survey contacted a large numbers of DOCs spread in each part of Italy, and then chose 261 clinics, about one-third of the whole number of the country, in which the best standards of quality of biochemical laboratory methods were satisfied. Each DOC had to recruit, among those attending the center for a routine visit, and using random sampling lists, from 50 to 100 type 2 diabetic patients aged 35–70 years, diagnosed more than six months before the start of the study. Patients were recruited between November 2001 and February 2002. Participating clinicians had to fill in a data sheet for each patient, containing information about medical history, diabetes micro- and macrovascular complications, clinical status, and the results of an accurate physical exam (BMI kg/m^2, waist circumference, blood pressure measured according to ISH/WHO guidelines). Lastly, blood and urine specimens were collected, in order to determine fasting blood glucose (FBG), HbA_{1c}, total and HDL cholesterol, triglycerides, serum creatinine and spot microalbuminuria. Records were carefully reviewed at the collecting site for completeness; in case of missing or evidently erroneous data, investigators were requested to provide or check/correct the entry. The sporadic absence (for whatever reason) of a single entry was considered as acceptable, and marked as ''not available''.

The accuracy of the central data entry procedure was assessed by double digitization of