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Persistent lipid abnormalities in statin-treated patients: Portuguese diabetic subpopulation of the Dyslipidaemia International Study (DYSIS)



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ABSTRACT

Aims: To assess the treatment patterns and prevalence of persistent lipid abnormalities in Portuguese statin-treated patients with diabetes.

Methods: DYSIS was an epidemiological, cross-sectional and multicentre international study. Outpatients ≥ 45 years old seen at primary and secondary care centres and treated with statins for at least three months were enrolled. This study presents the results for the Portuguese subpopulation, focusing on lipid control of the diabetic patients.

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Results: Of the 916 patients recruited, 348 (38%) had diabetes mellitus (DM). The majority of the diabetic patients (58%) failed to attain an LDL-C < 2.5 mmol/L, and 77% did not reach the optional goal of LDL-C < 2.0 mmol/L set by the 2007 recommendations of the European Society of Cardiology. The most frequently used statin was simvastatin, both in patients with and without diabetes (55.7% vs. 57.1%, $p = 0.68$). The mean (SD) statin dose in simvastatin-equivalent units was 26.1 (9.2) mg in diabetics and 25.3 (8.8 mg) in non-diabetics ($p = 0.19$).

Conclusions: The majority of Portuguese diabetic patients treated with statins failed to attain the recommended LDL cholesterol goals. Relatively low doses of medium potency statins were the prevailing therapy. There seems to be considerable room for improvement through the use of more potent statins, dose up-titration and/or the addition of other lipid-modifying therapies.

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1. Introduction

Recent studies have quantified the growing public health burden of diabetes across the world [1,2]. According to the International Diabetes Federation, in 2011 there were 366 million people with diabetes, and this number is expected to rise to 552 million by 2030 [3]. In Portugal, as in other countries, the prevalence of diabetes mellitus (DM) is steadily increasing, and the adjusted figure for 2012, based on the imputation of the 2009 prevalence data [4], which includes the actual sex and age distribution (age 20–79), is 12.9%, with 5.6% being previously undiagnosed [5]. Type 2 diabetes is associated with an increased risk of cardiovascular death and a higher incidence of cardiovascular diseases including coronary artery disease [6,7]. Dyslipidaemia is very common in diabetic patients and is responsible for a large proportion of their cardiovascular risk [8,9].

On the other hand, there is extensive evidence of the benefits of lipid-lowering treatment, particularly statins, for reducing cardiovascular disease and mortality in patients with diabetes as well as in those without diabetes [10–13]. However, suboptimal use of lipid-modifying therapies has been consistently documented in practice. It has been estimated that 33.5% of US adults aged ≥ 20 years fail to meet the LDL cholesterol (LDL-C) goals recommended by the National Cholesterol Education Programme Adult Treatment Panel III (NCEP-ATP III). Moreover, of the 48.1% of those who were treated, LDL-C goals were attained by only 33.2% [14]. In Europe, the proportion of patients whose lipids are not at target is 46.2% [15]. In the Dyslipidaemia International Study (DYSIS) [16], more than one third of patients with diabetes and existing cardiovascular disease were not at their LDL-C goal.

The purpose of this study was to assess the treatment patterns and prevalence of persistent lipid abnormalities in Portuguese statin-treated patients with and without diabetes mellitus.

2. Methods

2.1. Study design

The design and characteristics of the DYSIS study have been reported elsewhere [16,17]. Briefly, DYSIS was an

epidemiological, cross-sectional and multicentre international study of the lipid profiles of outpatients treated with statins that were recruited from both primary and secondary care centres. The investigators were general practitioners, internists, cardiologists and endocrinologists. In Portugal, 125 primary and secondary health care centres participated in the DYSIS project, with a selection of patients based on convenience sampling. The study protocol was approved by the Portuguese National Data Protection Commission. Written informed consent was obtained from all participants.

2.2. Study population

Outpatients ≥ 45 years old were eligible for inclusion in the study if they had been on statin therapy for \geq three months and had at least one lipid profile measurement performed within the previous 6–12 months while on lipid-lowering treatment. Patients were sequentially enrolled at consultations during the recruitment period from April 2008 to February 2009, irrespective of the reason for the appointment. Active participation in another clinical study was an exclusion criterion.

2.3. Data collection

Data were collected from medical records and clinical examination at the time of the clinic visit. For each patient, the following variables were recorded: demographics (age, gender), anthropometric data (weight, height, body mass index [BMI], waist circumference), lipid profile (total cholesterol, triglycerides, LDL-C and HDL-C), classification of cardiovascular risk and information on whether the patients were at goal/optimal levels according to the 2007 European Society of Cardiology (ESC) recommendations [18]. Collected data also comprised cardiovascular risk factors, including diabetes (previous diagnosis of diabetes or serum glucose ≥ 7.0 mmol/L or patients currently on diabetes therapy), fasting plasma glucose and HbA_{1c}, metabolic syndrome (defined according to the ATP III criteria) [18], hypertension (treatment of previously diagnosed hypertension or blood pressure [BP] values $>140/90$ mmHg), smoking, first-degree relatives with premature cardiovascular disease, and history of cardiovascular disease (ischaemic heart disease, cerebrovascular disease, peripheral arterial disease, symptomatic heart failure [New

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