PREVALENCE OF STATIN-ASSOCIATED MUSCLE SYMPTOMS IN ITALY: THE PROSISA STUDY

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Background: Statin associated muscle symptoms (SAMS) are one of the main reasons for statin non-adherence and/or discontinuation, contributing to adverse cardiovascular (CV) outcomes. However, a definitive diagnosis of SAMS is difficult because symptoms are subjective, influenced by comorbidities, and there is no 'gold standard' diagnostic test. Furthermore, there is also no validated muscle symptom questionnaire for their evaluation.

Aim and methods: PROSISA (PROject Statin Intolerance SISA) is an observational, retrospective, and multicenter study aimed at assessing the prevalence of statin intolerance, due to muscular symptoms, in dyslipidemic patients on statin therapy, followed by Italian lipid clinics between January 2006and December 2015. Demographic and anamnestic data (clinical history and current pharmacological therapy), biochemical levels (pre- and post-statin treatment), and potential occurrence of muscular symptoms (type and regional distribution/pattern) were collected. Adjusted logistic regression was fitted to estimate odds ratio (OR) and 95% confidence intervals for the association between SAMS onset and several factors.

Results: In the first six months, the PROSISA database accounted for 6429patients (mean age 66.7±12years; 53.9% men) on statins, characterized by high percentages of comorbidities known to be associated with a higher CV risk (60.4% with hypertension, 22.4% with diabetes, 47.7% with previous CV events). During statin therapy, 787patients (12.2%) reported muscular symptoms (63.9% within the first year of treatment), mainly myalgia (74.2%), cramps (25.8%) and fatigue (18.8%). Among them, 375stopped statin treatment (dechallenge), with disappearance of muscular symptoms in 87.2% of cases. Of them, 266patients received a statin prescription (in 7% of the same statin as before) after a wash out period without treatment, while 237patients were prescribed a different statin/lower dose without stopping the therapy. Therefore, among 503patients experienced a rechallenge, muscular symptoms were reported by only 151patients (myalgia 76.2%). Risk of SAMS onset was significantly higher for patients with diabetes (OR 1.58[1.26-1.98]), using high potency statins (OR 1.32[1.09-1.59]) and treated with drugs that could increase the risk of SAMS (OR 1.65[1.14-2.39]). Women had a nonsignificant lower risk of SAMS (OR 0.89[0.76-1.03]).

Conclusions: This preliminary analysis of the PROSISA study offers a real life outlook of SAMS. The reported prevalence of SAMS was 12%, but the percentage of patients in whom intolerance has been confirmed by dechallenge/rechallenge was between 26-30%, emphasizing the need for a better management of muscle symptoms to provide a definitive diagnosis of SAMS and treatment re-evaluation.