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IS ATORVASTATIN SAFE TO PATIENTS WITH SYSTEMIC AUTOIMMUNE MYOPATHIES? A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

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BACKGROUND

The use of lipid-lowering drugs, such as statins, to treat dyslipidemia in patients with systemic autoimmune myopathies (MAS) is hampered by the low quality of evidence of case reports and one retrospective study. We therefore assessed in a prospective, randomized double-blinded placebo controlled study design the impact of atorvastatin in MAS patients on myalgia and other side-effect, lipid profile and disease status.

MATERIALS AND METHODS

A prospective, double-blinded, randomized, controlled study in which 25 patients with MAS and dyslipidemia were evaluated between 2017 and 2019. All patients were evaluated at baseline and 12 weeks for the following parameters: International Myositis Assessment & Clinical Studies Groups (IMACS) set scores.

RESULTS

The mean age of the patients was 49.0 ± 10.0, being 75% female, with a median disease time in years of 5.5 (3.3-11.8). All patients presented IMACS values close to normal. At baseline, demographic data, disease status, treatment, cardiovascular comorbidities, and risk factors were comparable between the atorvastatin and placebo groups (P> 0.05). After 12 weeks of follow-up, when comparing the atorvastatin group with placebo, we observed a reduction in LDL-cholesterol levels 95.5 (79.3-134.5) vs 135.0 (123.0-174.6) (P> 0.011). In relation to the other variables evaluated, there was no statistical difference (P> 0.05).

CONCLUSION

The use of atorvastatin was safe and effective in patients stable with MAS and with dyslipidemia. Additional studies, with a larger sample and patients with different levels of disease activity, are necessary to corroborate with the data of the present study. ClinicalTrials.gov identifier: NCT03092154.

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