

Impact on Renal Function of Rosuvastatin Preload Prior to Elective Percutaneous Coronary Intervention in Chronic Statin Users

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ABSTRACT

Background: Contrast-induced nephropathy (CIN) is a potential complication after percutaneous coronary intervention (PCI). The pathogenesis is associated to inflammatory mechanisms, endothelial dysfunction and oxidative stress and the use of statins, due to their pleiotropic effects, has been investigated in this setting. We assessed whether a preload dose of rosuvastatin prior to elective PCI in patients on chronic statin reduces the incidence of CIN. **Methods:** Prospective, randomized, open label, single-center study. Patients were divided according to the use (group 1) or not (group 2) of rosuvastatin 40 mg, 2-6 hours prior to PCI. The frequency of CIN was compared between the two groups as well as in the diabetic and renal dysfunction subgroups. **Results:** We included 135 patients, with 60.7 ± 9.3 years of age, randomized to group 1 (n = 67) or group 2 (n = 68). The prevalence of diabetes was 31.1% and the prevalence of creatinine clearance < 60 ml/min was 13.3%. The incidence of CIN was 8.1% and there was no difference between groups (9% vs. 7.4%; P = 0.89). The incidence of CIN in diabetic patients was 15% vs. 13.6% (P = 0.75) and in those with renal dysfunction it was 12.5% vs. 0 (P = 0.93). **Conclusions:** The use of a preload dose of rosuvastatin at its maximum

RESUMO

Impacto na Função Renal de uma Dose de Reforço de Rosuvastatina Prévia a Intervenção Coronária Percutânea Eletiva nos Pacientes em Uso Crônico de Estatina

Introdução: A nefropatia induzida pelo contraste (NIC) é uma complicação potencial após a intervenção coronária percutânea (ICP). A patogênese está associada a mecanismos inflamatórios, disfunção endotelial e estresse oxidativo, e as estatinas, por seus efeitos pleiotrópicos, vêm sendo analisadas nesse cenário. Avaliamos se uma dose de reforço de rosuvastatina pré-ICP eletiva, em pacientes em uso crônico de estatina, reduz a ocorrência de NIC. **Métodos:** Estudo prospectivo, randomizado, aberto, realizado em único centro. Os pacientes foram divididos de acordo com a utilização (grupo 1) ou não (grupo 2) de 40 mg de rosuvastatina, 2 a 6 horas pré-ICP. A frequência de NIC foi comparada entre os dois grupos e nos subgrupos de diabéticos e com disfunção renal prévia. **Resultados:** Foram incluídos 135 pacientes, com idade de 60,7 ± 9,3 anos, randomizados para o grupo 1 (n = 67) ou para o grupo 2 (n = 68). A prevalência de diabetes foi de 31,1% e de *clearance* de creatinina < 60 ml/min, de 13,3%. A incidência de NIC

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dosage did not exert a protective effect in renal function of chronic statin users undergoing elective PCI.

DESCRIPTORS: Angioplasty. Contrast media. Statins. Creatinine. Kidney diseases.

Contrast-induced nephropathy (CIN) is a potential complication of percutaneous coronary intervention (PCI). CIN is the third leading cause of in-hospital acute renal failure, occurring in approximately 7% of patients exposed to iodinated contrast agents, and usually presents spontaneous resolution.^{1,2} However, CIN may be associated with a longer hospital stay, increased morbidity and mortality, and higher hospitalisation costs, especially in those patients who require renal replacement therapy.³

The pathogenesis of CIN is not well understood but has been linked to inflammation, endothelial dysfunction, and oxidative stress.⁴ Pre-existing kidney disease, diabetes mellitus, left ventricular dysfunction, advanced age, and the use of large amounts of iodinated contrast are all major risk factors for CIN.^{5,6}

Statins are widely used in clinical practice for their cholesterol-lowering effects, especially in patients with atherosclerotic disease. The effects of statins, however, extend beyond cholesterol reduction and include improved endothelial function and potential anti-inflammatory and anti-oxidative effects.⁷

Short-term pre-treatment with statins is associated with favorable outcomes in various clinical scenarios, such as the prevention of peri-PCI myocardial injury or atrial fibrillation after cardiac surgery. Recent studies have suggested that the pre-PCI administration of statins can also prevent the occurrence of CIN.⁸

The present study sought to evaluate the effects of a preload dose of rosuvastatin prior to elective PCI in patients receiving chronic statin treatment.

METHODS

This prospective, randomized, open, single-center study included patients with coronary artery disease who were referred for the elective percutaneous implantation of at least one stent.

Those patients diagnosed with acute coronary syndrome for < 30 days, restenotic lesions, or lesions in venous or arterial grafts were excluded.

foi de 8,1% e não mostrou diferença entre os grupos (9% vs. 7,4%; $P = 0,89$). A incidência de NIC nos diabéticos foi de 15% vs. 13,6% ($P = 0,75$) e nos portadores de disfunção renal prévia foi de 12,5% vs. 0 ($P = 0,93$). **Conclusões:** O uso de uma dose de reforço de rosuvastatina em sua posologia máxima não exerceu efeito protetor renal nos pacientes em uso crônico de estatina submetidos a ICP eletiva.

DESCRITORES: Angioplastia. Meios de contraste. Estatinas. Creatinina. Nefropatias.

All patients included in this analysis had been receiving statin treatment for at least 30 days. After signing the informed consent, the patients were divided into two groups: those patients who would (group 1) and those who would not (group 2) receive a maximal dose of rosuvastatin (40 mg) two to six hours before the PCI.

Blood samples were collected from both groups to analyse serum creatinine levels before and 24 hours after the procedure. Creatinine clearance was also evaluated before and after the procedure using the formula developed by Cockcroft & Gault. Those with a pre-PCI creatinine clearance < 60 mL/min received intravenous hydration (0.9% saline, 1 mL/kg/hour in the case of normal left ventricular function or 0.5 mL/kg/hour in the case of left ventricular dysfunction) for at least six hours before and 12 hours after PCI, according to the institution's protocol.

Study objectives and definitions

The CIN frequency, variations in creatinine levels (pre-and post-Cr) and creatinine clearance rates (pre-and post-CrCl), and percentage variation in creatinine clearance of the two groups were compared. The subgroups containing diabetic patients with renal dysfunction were also evaluated.

CIN was defined as an absolute increase in the serum creatinine level to ≥ 0.5 mg/dL or a $\geq 25\%$ increase in the creatinine level in 24 hours.^{5,9}

Statistical analysis

The categorical data are shown as absolute numbers and percentages, and the continuous data are shown as the means \pm standard deviation. The categorical variables were compared using the chi-squared test or Fisher's exact test. The continuous variables were compared with the Student's *t*-test (paired and non-paired). The Mann-Whitney U test was used for the non-parametric variables. A two-tailed *P*-value of < 0.05 was considered to be statistically significant. The Statistical Package for Social Sciences (SPSS – Chicago, USA), release 13, was used for all analyses.

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