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Effectiveness and Safety of Non-Vitamin K Oral Anticoagulants in Non-Valvular Atrial Fibrillation Patients: Results of A Real-World Study in a Metropolitan Area of Northern Italy

Emanuele Crocetti [1], Sarah Cattaneo [2], Walter Bergamaschi [3], Stefano De Servi [4] and Antonio Giampiero Russo [1,*]

1 Epidemiology Unit, Agency for Health Protection (ATS) of Milan, C.so Italia, 19, 20122 Milan, Italy; emanuelecrocetti@yahoo.com
2 Pharmacy Department, Agency for Health Protection (ATS) of Milan, C.so Italia, 19, 20122 Milan, Italy; scattaneo@ats-milano.it
3 General Directorate, Agency for Health Protection (ATS) of Milan, C.so Italia, 19, 20122 Milan, Italy; wbergamaschi@ats-milano.it
4 Department of Molecular Medicine, University of Pavia, 27100 Pavia, Italy; stefano.deservi01@gmail.com
* Correspondence: agrusso@ats-milano.it; Tel.: +39-02-8578-211

Abstract: Background: New oral anticoagulant agents (NOACs) are valid alternatives for vitamin K antagonists (VKA) in patients with non-valvular atrial fibrillation (NVAF) for stroke prevention. In clinical practice, NOACs users may differ from patients enrolled in clinical trials in age or comorbidities, and thus it is a critical issue to evaluate the effectiveness and safety of NOACs in the real-world. Accordingly, we assessed two-year overall mortality and hospital admissions for myocardial infarction, stroke or bleeding in patients with NVAF users of NOACs compared to warfarin-treated patients. Methods: This is a population-based retrospective new user active comparator study. All atrial fibrillation patients who were naïve and not switcher users of oral anticoagulants from January 2017 to December 2019 were included (n = 8543). Data were obtained from the electronic health records of the Milan Agency for Health Protection, Italy. Two-year risks for overall mortality, myocardial infarction, stroke and bleeding were computed using Cox models. Age, sex, number of comorbidities, use of platelet aggregation inhibitors and Proton pump inhibitors and area of residence were used as confounding factors. We also controlled by indication bias-weighting NOACs and warfarin users based on the weights computed by a Kernel propensity score. Results: For all NOACs, we found a decrease in the risks compared with warfarin for mortality (from −25% to −49%), hospitalization for myocardial infarction (from −16% to −27%, statistically significant for apixaban, edoxaban and rivaroxaban) and ischemic stroke (from −23% to −41%, significant for dabigatran and apixaban). The risk of bleeding was decreased for rivaroxaban (−33%) and numerically but not significantly for the other NOACs. Conclusions: After two years of follow-up, in comparison with warfarin, NOACs users showed a significant reduction of overall mortality (all NOACs), hospital admission for myocardial infarction (apixaban and edoxaban), ischemic stroke (dabigatran) and bleeding (rivaroxaban).

Keywords: atrial fibrillation; new oral anticoagulant agents; effectiveness; safety; real-world

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