Potential eligibility for low dose rivaroxaban treatment in a "real world" population of Spanish patients with stable coronary artery disease: a subanalysis of the CICCOR registry

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Funding Acknowledgement: Type of funding source: None

Background: In the COMPASS trial, low dose rivaroxaban (2.5 mg/12h) on top of aspirin showed a 26% reduction in major cardiovascular events in patients with stable coronary artery disease (sCAD). However, information about external applicability of these results is limited. Our objective was to assess potential eligibility for this treatment in a "real world" cohort of Spanish patients with sCAD and to evaluate the incidence of major events in the long-term follow up in this population.

Methods: The CICCOR registry ("Chronic ischemic heart disease in Cordoba", in Spanish "Cardiopatía isquémica crónica en Cordoba") is a prospective, monocentric study. From February 1, 2000 to January 31, 2004, all consecutive patients with sCAD attended at two outpatient cardiology clinics in a city of the south of Spain were included in the study and prospectively followed. The COMPASS inclusion and exclusion criteria were applied to this cohort, and the proportion of patients potentially eligible for this trial was described. The rate of the main COMPASS endpoint (the composite of acute myocardial infarction, stroke, or cardiovascular death), as well as mortality rates, were investigated in this subset of patients, and compared with those of sCAD patients included in the aspirin alone group of the COMPASS trial.

Results: From a total population of 1268 patients, 1246 subjects presented enough data to assess eligibility. Among these, 575 patients (46%) had exclusion criteria, and another 229 (18%) did not fulfill the inclusion criteria and were not eligible. The main reasons for exclusion were requirement for dual antiplatelet therapy within 1 year of an acute coronary syndrome or coronary stent implantation (70%), high-bleeding risk (33%), other non-aspirin antiplatelet therapy (13%), atrial fibrillation (12%), anticoagulant use (11%), history of ischemic stroke (5%) and heart failure with severe left ventricular dysfunction (4%). The reason for not fulfilling inclusion criteria was the absence of additional high risk factors in patients younger than 65 years. The potentially eligible population included 442 patients (35% of evaluable patients), with up to 17 years of follow-up (median 9 years, IQR 4–15 years, only 1 patient lost in follow-up, 4174 patients-years of observation). These patients experienced higher primary outcome event rates than coronary patients actually enrolled in the aspirin alone arm of COMPASS (5.1% versus 2.9% per year), and higher rates of cardiovascular (4.0% versus 1.1%) and all-cause mortality (6.3 versus 2.1%, $p<0.00005$ for all comparisons).

Conclusion: More than one third of "real world" patients with sCAD of this prospective Spanish registry could be potentially eligible for low dose rivaroxaban therapy, according to COMPASS inclusion and exclusion criteria. This population had a higher risk of cardiovascular events and mortality than COMPASS participants with sCAD in the reference aspirin group.