ivabradine: more precautions to protect patients with coronary artery disease because of its cardiac harms

In 2015, the only action taken after the European review of ivabradine was the adoption of some restrictions on its use and some precautionary measures, despite the fact that this drug offers no advantages over other options and is known to have sometimes fatal cardiovascular adverse effects.

ivabradine (Procoralan®, Servier), an inhibitor of the cardiac IF current, offers no tangible advantages over alternative treatments in either angina or heart failure (1). Yet it can provoke adverse effects such as visual disturbances and sometimes fatal cardiovascular disorders, including severe bradycardia, atrial fibrillation (in about 5% of patients in clinical trials), prolongation of QT interval, torsades de points and myocardial infarction (1,2,3).

In mid-2014, a review by the European Pharmacovigilance Risk Assessment Committee (PRAC) was initiated in light of the preliminary results of a trial showing that ivabradine increased the combined risk of cardiovascular death and nonfatal myocardial infarction in patients with symptomatic stable angina (3,4). In early 2015, the European Commission implemented the PRAC’s recommendations: it revised the European Summaries of Product Characteristics (SPCs) of drugs containing ivabradine, in particular adding warnings about their use in patients with coronary artery disease (see below) (3,4,5).

In practice, ivabradine has more harms than benefits in both angina and heart failure. Since European health authorities have not yet decided to withdraw this drug from the market, it is advisable to simply avoid it. Other options better serve patients’ interests: beta-blockers, amlodipine or verapamil in angina; while in heart failure, it is better to refrain from adding another drug to an optimised treatment regimen, or to use a beta-blocker with a proven impact on mortality (1).

Selected from Prescrire’s literature search.

5- ANSM “Point d’information - Procoralan (ivabradine): renforcement des précautions d’emploi pour minimiser le risque d’effets indésirables cardiovasculaires” 23 December 2014: 3 pages.

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