Introduction

Two-year benefit-risk of standard and reduced doses of rivaroxaban versus vitamin-K antagonists in non-valvular atrial fibrillation: a cohort study in the French nationwide claims database

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Objective

To compare the two-year risk of major events in new users of rivaroxaban 20mg and rivaroxaban 15mg versus VKA for NVAF in real-life setting.

Methods

Study design

Cohorts study in the SNDS (Système National des Données de Santé) nationwide French claims database including all new users of dabigatran, rivaroxaban or VKA for NVAF, with three-year history and two-year follow-up or until death in the database.

Data source

The SNDS database contains individual pseudonymised information from 66 million persons on: Gender, date of birth, area of residence, date of death; Chronic disease registration (asthma, diabetes, AVB, CAD); Associated ICD-10 codes for full insurance coverage (with start and end dates); Outpatient reimbursed healthcare expenditures; visits, medical procedures, lab-tests, drugs; Hospital discharge summaries with ICD-10 codes for diagnosis (primary, linked and associated diagnoses) for all private and public medical, clinical and surgery hospitalisations, with the date and duration of hospitalisation, medical procedures.

Patients with chronic disease registration, hospitalisation or procedure for atrial fibrillation without rheumatic valve disease or valve replacement, and no other probable indication using three-year database history.

Direct oral anticoagulants (DOAC), rivaroxaban, dabigatran, and apixaban had better benefit-risk than vitamin-K antagonists (VKA) for non-valvular atrial fibrillation (NVAF) in clinical trials, but real-life benefits and risks remain uncertain.

Rivaroxaban 20mg is the standard dose and rivaroxaban 15mg, the recommended dose for patients with moderate or severe renal impairment but not if renal clearance is below 15 ml/min.

This nationwide cohort study of new anticoagulant users for NVAF shows a significantly overall better long-term benefit-risk in real-life of rivaroxaban 20mg versus VKA and rivaroxaban 15mg versus VKA, respectively.

Results

Table 1: Main patient characteristics of matched NVAF populations

Conclusions

Different rivaroxaban 20mg or 15mg and VKA prescription patterns, but similar population characteristics after hdPS matching.

This nationwide cohort study of new anticoagulant users for NVAF shows a significantly overall better long-term benefit-risk in real-life of rivaroxaban 20mg or 15mg compared to VKA.

2-year cumulative incidence of outcomes for matched patients are presented in Table 2.

Benefit-risk of rivaroxaban 20mg versus VKA

The risk of all outcome was significantly lower with rivaroxaban 20mg, except for SSE for which there was no difference.

There was a significant lesser risk with rivaroxaban 15mg for major bleeding, death, composite, clinically relevant bleeding, and no difference for ACS and for SSE (Figure 3).

Table 2: Matched populations characteristics, outcomes during the drug exposure period for matched NVAF populations

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