Get Real

Real-Life Data in Drug Development

Research Briefing

Channelling of anticoagulants after launch and implication for comparative effectiveness studies

Ali Sanni M, van den Ham R, Groenwold RHH; Ankarfeldt MZ; Bortnichak EA, Girman CJ; Klungel OH

Full article DOI:

Key points

-
-

Background

Potential bias due to channelling of patients to newly approved medications due to patient, physician, and system-related factors as well as rapid changes in the characteristics of the user population during the early phase after launch pose major methodological challenges. We aimed to compare characteristics of patients starting on different oral anticoagulant (OAC) medications and the risk of ischaemic stroke (IS), acute myocardial infarction (AMI) as well as major bleeds (MB) over time since launch.

Methods

Using the US MarketScan commercial claims and the UK CPRD databases, we included atrial fibrillation/flutter patients who started OAC if they were enrolled at least 6 months and not using oral OAC medications during the six months prior to start of OAC (index date), were 18 years or older. Hazard ratios (HR) for IS, AMI, and MB were estimated in users of new oral anticoagulants (NOACs, dabigatran and rivaroxaban) versus warfarin at different time periods after launch using multivariable Cox regression and propensity scores (PS) methods. Confounder distributions among the groups were summarized as PS and time trends since launch were assessed.

Results

In general, the US MarketScan population was at lower risk for stroke compared to the UK population (younger and has lower mean CHA_2DS_2-VASc score) although the trend over time is similar between different OAC medications. There was substantial overlap in PS distributions between the treatment groups in both datasets. The risk of IS for NOACs was lower in MarketScan [HR 0.74, 95%CI: 0.61; 0.90] but higher in CPRD [HR: 1.31, 95%CI: 1.04; 1.65]. The risk for AMI was similar for NOACs and warfarin whereas the risk of MB was

higher in NOACs, as compared to warfarin [HR: 1.34, 95%CI: 1.11; 1.62 in MarketScan and 1.41, 95%CI: 1.06; 1.87 in CPRD]. HRs were similar across different PS methods.

Conclusion

Differences between characteristics for NOAC users compared to warfarin users were small with no noticeable change over the years suggesting minimal channelling bias after launch. The benefit-risk balance for treatment with NOACs seems to be better for US patients compared to UK patients.