Master's Thesis project 2019

Example of a project in the Pharmacovigilance Research Group

The research within pharmacovigilance is focused on surveillance of adverse drug reactions. Data is analyzed using statistical software such as SAS, R, and Stata. In the following example, the student made all the coding in SAS on a local computer using simulated data. At the end of the study period, the coding and programs were conducted on data from Danish registries on Statistics Denmarks server by an authorized employee in the research group, as data access cannot be provided for students.

Title

Factors influencing the choice of direct oral anticoagulants and vitamin K antagonists in non-valvular atrial fibrillation patients and evaluation of channelling

Background

Channelling is a form of allocation bias where newly launched drugs, with the same or similar indications, are prescribed to patients with different severity of risk, which may lead to biased treatment effect.

Objectives

The study aimed to investigate factors that influence the choice between direct oral anticoagulants (DOAC) and vitamin K antagonists (VKA) and if channelling has occurred.

Methods and Materials

We conducted a retrospective, cross-sectional study in non-valvular atrial fibrillation (NVAF) patients aged 18 and over, who were naïve DOAC or VKA users between August 2011 and December 2015. We used logistic regression to investigate predictors for DOAC choice including age, sex, comorbidity, and co-medications. Propensity scores were calculated to investigate channelling.

Results

We included 41,597 patients of which 24,167 (58%) were DOAC users. Eleven thousand five hundred and thirty-tree (47%) of DOAC and 7,582 (43%) of VKA users were female. Mean age (SD) were 73.7 and 72.4 (11.49) for DOAC and VKA users, respectively. Predictors for DOAC choice were being female (OR 1.19; 95% CI 1.14-1.23), over 80 years (1.39; 1.30-1.47), history of stroke (1.28; 1.21-1.35) and intracranial hemorrhage (1.38; 1.03-1.84). VKA choice was associated with renal disease (0.49; 0.45-0.54), heart failure (0.81; 0.78-0.85), and co-medications such as aspirin (0.66; 0.61-0.71) and clopidogrel (0.73; 0.69-0.78). We identified nearly identical distribution of

propensity scores over time.

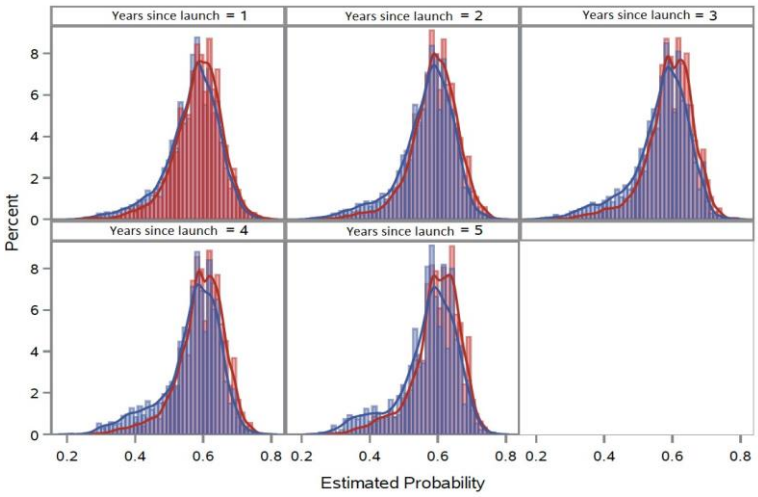

***Figure 1**: Channelling of DOAC each year since launch in 2011 illustrated as propensity scores versus percent of patients. Red is VKA, blue is VKA.*

Conclusion

We identified differences in sex, age, comorbidity, and co-medications between the choice of DOAC and VKA. However, these factors are not frequent enough to observe major channelling.

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