**DEATH REPORTS AMONGST NOACS AND WARFARIN USERS. A STRATIFIED ANALYSIS OF FAERS DATA**

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**Introduction:** Controversy surrounds mortality attributable to novel oral anticoagulants in the management of non-valvular atrial fibrillation. The goal of this study was to provide and discuss updated evidence from the FDA AERS system using a focused methodological approach.

**Methods:** An updated analysis of disproportionality towards death amongst dabigatran, rivaroxaban, apixaban and warfarin with a cut-off date of Q1 2017. Outcomes were selected as MedDRA high level term “death and sudden death” and the anatomical therapeutic chemical classification system was used to identify the drugs (B01AE07, B01AX06, B01AF02 and B01AA03, respectively). The metric used were proportional reporting ratio (PRR), which were then compared using the Yates-corrected chi-square statistic. Analyses were repeated for different time segments, age groups and genders.

**Results:**According to the criteria by Evans and colleagues, no plausible association between the considered drugs and death reporting was found. Our results suggest that the PRRs in patients receiving dabigatran (PRR=0.69 95% CI 0.66-0.73) and rivaroxaban (PRR=0.70 95% CI 0.67-0.74) are lower to those receiving warfarin (PRR=0.79 95%CI 0.77-1.82, p<0.05) while higher for apixaban users (PRR=1.05 95%CI 0.99-1.11, p<0.01). These patterns remained similar after stratification on time, age and gender.

**Conclusions:**This study confirms clinical and observational findings that NOACS are not associated with higher death reports proportions amongst all adverse events than all other drugs present in the FAERS database. Dabigatran and rivaroxaban feature lower proportional death reports ratios as compared to warfarin.

Footnotes: Evans SJ, Waller PC, Davis S. Use of proportional reporting ratios (PRRs) for signal generation from spontaneous adverse drug reaction reports. Pharmacoepidemiology and drug safety 2001; 10: 483-6