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Dabigatran versus vitamin K antagonists in patients with atrial fibrillation and valvular heart disease

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Background: Atrial fibrillation (AF) and valvular heart disease (VHD) are both associated with an increased risk of stroke. Outside post-hoc analyses of randomized controlled trials, knowledge on the effectiveness and safety of dabigatran in patients with AF and VHD is scarce.
Objectives: To compare the risk of all-cause mortality, stroke, and bleeding in patients with AF and VHD treated with dabigatran or a vitamin K antagonist (VKA).
Methods: All Danish residents are provided a unique personal identification number enabling cross-linking of data from Danish nationwide registries. We identified all patients with AF and VHD initiating treatment with dabigatran or VKA between the 22nd of August 2011 and the 31st of December 2014. We defined VHD as aortic stenosis/regurgitation, mitral regurgitation, bioprosthetic heart valves, mitral-, and aortic valve repair. Outcomes were all-cause mortality, stroke, and bleeding. 2-year standardized absolute risks were calculated from cause-specific Cox regression models with death as competing risk.
Results: In total, 599 (27.3%) and 1,596 (72.7%) patients initiated treatment with dabigatran and VKA. The 2-year standardized absolute risk of all-cause mortality (95% CI) for VKA was 27.6% (25.1% to 30.1%) and 25.4% (21.8% to 29.0%) for dabigatran with a corresponding absolute risk difference of –2.2% (–6.3% to 1.9%) (Figure 1). The 2-year standardized absolute risk of stroke for VKA was 3.4% (2.3% to 4.5%) and 3.9% (2.2% to 5.5%) for dabigatran with a corresponding absolute risk difference of 0.5% (–1.6% to 2.5%). Lastly, the 2-year standardized absolute risk of bleeding for VKA was 8.2% (6.6% to 9.7%) and 7.6% (5.1% to 10.1%) for dabigatran with a corresponding absolute risk difference of –0.5% (–3.4% to 2.4%).
Conclusions: In this nationwide cohort study, we found no significant difference in the risk of all-cause mortality, stroke, or bleeding in patients with AF and VHD when comparing VKA to dabigatran.

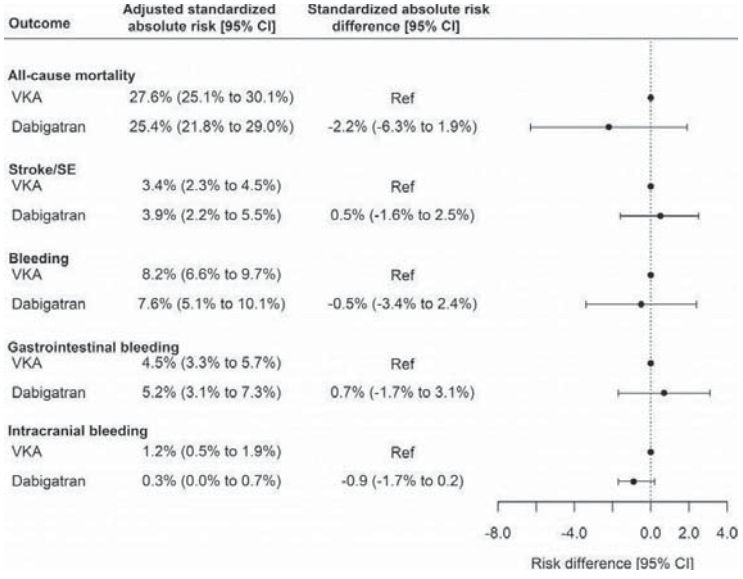

Figure 1