Clinical outcomes of patients with newly diagnosed atrial fibrillation who refused anticoagulation: findings from the global GARFIELD-AF registry

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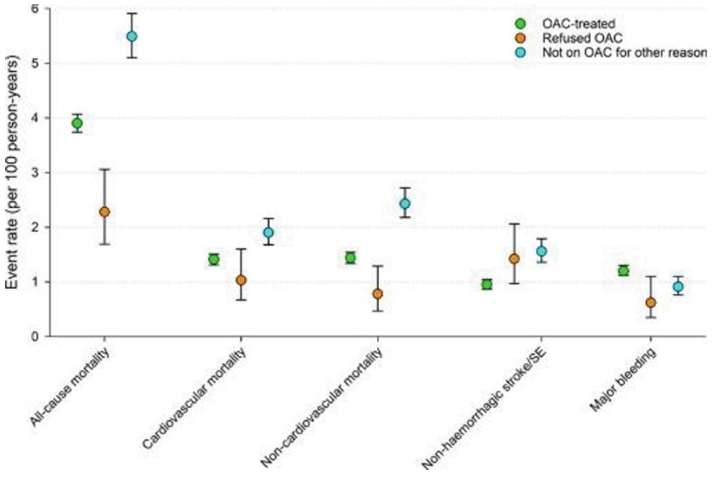
Introduction: Atrial fibrillation (AF) remains a common cause of stroke and anticoagulation (AC) treatment reduces the risk of stroke. Reasons for patients with AF not receiving anticoagulation are generally attributed to the clinician decision, however in reality a proportion of patients refuse anticoagulation. The aim of our study was to investigate the clinical outcomes of patients with AF who refused anticoagulation.

Methods: The Global Anticoagulant Registry in the FIELD (GARFIELD-AF) was an international prospective observational study of patients ≥18 years with newly diagnosed AF and ≥1 investigator determined risk factor for stroke. We analysed two-year outcomes (unadjusted) of non-haemorrhagic stroke/systemic embolism (stroke/SE), major bleeding and all-cause mortality in patients at high risk of stroke (men with CHA2DS2VASc≥2 and women with CHA2DS2VASc≥3) who did not received anticoagulation due to patient refusal, patients at high risk of stroke who received anticoagulation, and patients who were not on anticoagulation due to reasons other than patient refusal.

Results: Out of 43,154 patients, 13,283 (30.8%) are at the higher risk of stroke and did not received anticoagulation at baseline. The reason for not receiving anticoagulation was unavailable for 38.7% (5146/13283); of the patients with a known reason for not receiving anticoagulation, 12.5% (1014/8137) refused anticoagulation. Overall the study participants had a mean (SD) age of 72.2 (9.9) years and 50% were female. The median (Q1; Q3) CHA2DS2VASc score was 3.0 (3.0; 5.0) in patients who refused anticoagulation and 4.0 (3.0; 4.0) in patients who received anticoagulation. The median (Q1; Q3) HAS-BLED score was 1.0 (1.0; 2.0) in both groups. Of the patients who received anticoagulants, 59.7% received VKA and 40.3% received non-VKA oral anticoagulants. 79.4% of patients who refused anticoagulation were on antiplatelets. At two-year follow up the rate of events per 100 person-years (AC refused vs AC received) were: stroke/SE 1.42 vs 0.95 (p=0.04), major bleeding 0.62 vs 1.20 (p=0.02), and all-cause mortality 2.28 vs 3.90 (p=0.0004) (Figure). The event rates in patients who were not on anticoagulation for reasons other than patient refusal were stroke/SE 1.56, major bleeding 0.91, and all-cause mortality 5.49.

Conclusion: In this global real-world prospective study of patients with newly diagnosed AF, patients who refused anticoagulation had a higher rate of stroke/SE but lower rates of all-cause mortality and major bleeding than patients who received anticoagulation. While patient refusal of anticoagulation is an acceptable outcome of shared decision-making, clinically it is a missed opportunity to prevent AF related stroke. Patients' beliefs about AF related stroke and anticoagulation need to be explored. The difference in all-cause mortality warrants further investigation; further analysis will include adjusted results.



Event rates at two years of follow-up