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\mathcal{W} Arrhythmias and Clinical EP

APIXABAN COMPARED WITH WARFARIN IN PATIENTS WITH DIABETES AND NONVALVULAR ATRIAL FIBRILLATION IN THE ARISTOTLE TRIAL

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Background: Diabetes mellitus (DM) is a risk factor for stroke and systemic embolism (SSE) in patients with atrial fibrillation.

Methods: We evaluated baseline characteristics and clinical outcomes of patients with or without DM in ARISTOTLE. The main efficacy endpoints were SSE and mortality; safety endpoints were ISTH major and major/clinically relevant non-major (CRNM) bleeding.

Results: A total of 4547/18,201 (24.9%) had DM. Those with DM were younger (69 vs. 70 yrs), more had CAD (39 vs. 31%), renal dysfunction (52 vs. 60%), and higher mean CHADS2 (2.9 vs. 1.9) and HAS-BLED scores (1.9 vs. 1.7) (all p<0.0001). Patients with DM receiving apixaban had lower rates of SSE (HR 0.75, 95% CI 0.52-1.05), all-cause mortality (HR 0.83, 95% CI 0.67-1.02), cardiovascular mortality (HR 0.89, 95% CI 0.66-1.20), and a similar rate of MI (HR 1.02, 95% CI 0.62-1.67). An interaction between DM and apixaban vs. warfarin was seen for major (interaction p=0.003) and major/CRNM bleeding (interaction p=0.0009) but not total bleeding (interaction p=0.71). Patients with DM receiving apixaban had similar rates of major (HR 0.96) and major/CRNM bleeding (HR 0.91) and a lower rate of any bleeding (HR 0.73). For patients without DM, rates of bleeding were lower with apixaban (major HR=0.60, major/CRNM HR=0.61, any HR=0.71).

Conclusions: Our findings are consistent with the main trial results. The observation that apixaban results in lower rates of bleeding in those without DM is unexpected and deserves further investigation.

