ENVISAGE-TAVI AF

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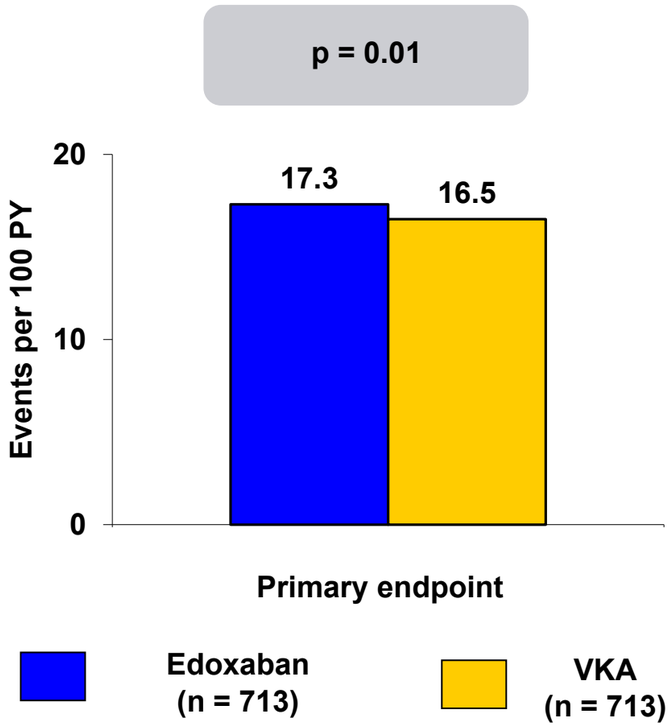
AMERICAN COLLEGE of CARDIOLOGY

Trial Description: Patients undergoing TAVR with incident or prevalent AF were randomized in an open-label 1:1 fashion to edoxaban 60 mg daily or VKA with an INR goal of 2-3. Patients were followed a median of 540 days.



RESULTS

- Primary endpoint, all-cause mortality, MI, ischemic stroke, systemic thromboembolic event, valve thrombosis, or major bleeding, for edoxaban vs. VKA: 17.3/100 PY vs. 16.5/100 PY (p = 0.01 for noninferiority)
- Major bleeding: 9.7/100 PY vs. 7/100 PY (p = 0.93 for noninferiority)
- All-cause mortality: 7.8/100 PY vs. 9.1/100 PY
- Ischemic stroke: 2.1/100 PY vs. 2.8/100 PY; intracranial hemorrhage: 1.5/100 PY vs. 2.1/100 PY

CONCLUSIONS

- Edoxaban is noninferior to VKA for efficacy but did not meet criteria for noninferiority for bleeding among patients undergoing TAVR with AF
- There were no observed clinical valve thrombosis events

Van Mieghem NM, et al. *N Engl J Med*;Aug 28:[Epub ahead of print].