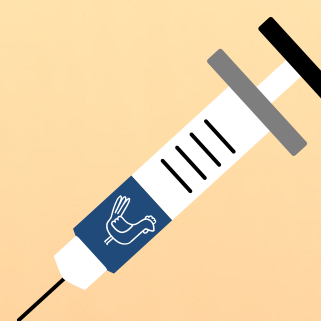


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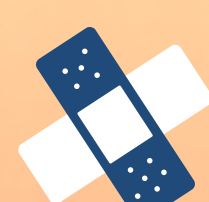
MARCH 2021

Low-Dose Edoxaban Effective for Stroke Prevention in Older Patients with Atrial Fibrillation



PRESENTING QUESTION

Is low-dose edoxaban (Savaysa) safe and effective for stroke prevention in older patients with atrial fibrillation?



INTERVENTION

In this Japanese study, investigators enrolled patients 80 years and older with nonvalvular atrial fibrillation and a CHADS2 score of 2 or more for whom standard doses of oral anticoagulants were considered inappropriate. A total of 984 patients were randomized to receive edoxaban, 15 mg daily (standard dose is 60 mg or 30 mg daily), or a matched placebo.



COMPARATOR

Placebo

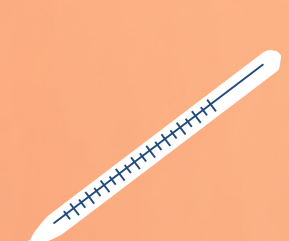
OUTCOMES

The two groups had similar baseline characteristics: mean age of 86.6 years, mean body weight of 111.5 lb (50.6 kg), and a mean CHADS2 score of 3. The annualized rate of stroke or systemic embolism was lower in the edoxaban group than in the placebo group.



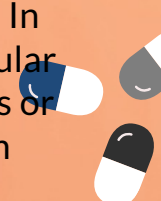
TIMEFRAME

Study Design: Randomized controlled trial (double-blinded)



SYNOPSIS

Many older patients with atrial fibrillation may not be prescribed standard doses of anticoagulation for stroke prevention because of a perceived higher risk of bleeding. In this Japanese study, investigators enrolled patients 80 years and older with nonvalvular atrial fibrillation and a CHADS2 (congestive heart failure; hypertension; age 75 years or older; diabetes mellitus; prior stroke, transient ischemic attack, or thromboembolism [doubled]) score of 2 or more for whom standard doses of oral anticoagulants were considered inappropriate (e.g., those with a history of critical bleeding, severe renal impairment, low body weight, continuous nonsteroidal anti-inflammatory drug use, or antiplatelet drug use). A total of 984 patients were randomized to receive edoxaban, 15 mg daily (standard dose is 60 mg or 30 mg daily), or a matched placebo. The two groups had similar baseline characteristics: mean age of 86.6 years, mean body weight of 111.5 lb (50.6 kg), and a mean CHADS2 score of 3. The annualized rate of stroke or systemic embolism was lower in the edoxaban group than in the placebo group (2.3% vs. 6.7%; hazard ratio [HR] = 0.34; 95% CI, 0.19 to 0.61; $P < .001$). The incidence of major bleeding was higher in the edoxaban group, although this difference did not reach significance (3.3% for edoxaban vs. 1.8% for placebo; $P = .09$). The edoxaban group had statistically significant higher rates of gastrointestinal bleeding (2.3% vs. 0.8%; HR = 2.85; 95% CI, 1.03 to 7.88) and clinically relevant nonmajor bleeding (14.5% vs. 8.9%; HR = 1.62; 95% CI, 1.14 to 2.30).



KEY TAKEAWAY

- A lower dose of edoxaban is effective in decreasing stroke and systemic embolism in older patients with atrial fibrillation compared with placebo.
- Although the difference in major bleeding rates with edoxaban vs. placebo did not reach statistical significance, edoxaban use led to higher rates of gastrointestinal bleeding and clinically significant non-major bleeding.
- This study was completed in Japan, and the mean body mass index of participants was 22 kg per m², which may not generalize to the population in the United States.



Designed by Faith Nwokorie, 2020-2021 IAFP Public Health Extern
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