

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Connolly SJ, Ezekowitz MD, Yusuf S, et al. Dabigatran versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2009;361. DOI: 10.1056/NEJMoa0905561.

(PDF last updated on November 29, 2010.)

Dabigatran Compared to Warfarin in Patients with Atrial Fibrillation

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Online Supplementary Appendix Table 1: RE-LY Inclusion Criteria

1. Atrial fibrillation documented as follows:
 - a. There is atrial fibrillation documented by electrocardiogram on the day of screening or randomization
 - b. The patient has had a symptomatic episode of paroxysmal or persistent atrial fibrillation documented by 12-lead electrocardiogram within 6 months before randomization
 - c. There is documentation of symptomatic or asymptomatic paroxysmal or persistent atrial fibrillation on 2 separate occasions, at least 1 day apart, one of which is within 6 months before randomization. In this case, atrial fibrillation may be documented by 12-lead electrocardiogram, rhythm strip, pacemaker/ICD electrogram, or Holter electrocardiogram. The duration of atrial fibrillation should be at least 30 seconds. Electrograms (not marker channels or mode switch episodes) from pacemakers and defibrillators can be used to document only 1 episode of paroxysmal or persistent atrial fibrillation.
2. In addition to documented atrial fibrillation, patients must have one of the following:
 - a. History of previous stroke, transient ischemic attack, or systemic embolism
 - b. Ejection fraction less than 40% documented by echocardiogram, radionuclide or contrast angiogram in the last 6 months
 - c. Symptomatic heart failure, New York Heart Association class 2 or higher in the last 6 months
 - d. Age at least 75 years
 - e. Age at least 65 years and one of the following:
 - i. Diabetes mellitus on treatment
 - ii. Documented coronary artery disease (any of: prior myocardial infarction, positive stress test, positive nuclear perfusion study, prior CABG surgery or PCI, angiogram showing at least 75% stenosis in a major coronary artery)
 - iii. Hypertension requiring medical treatment
3. Age at least 18 years at study entry
4. Written, informed consent

Online Supplementary Appendix Table 2: RE-LY Exclusion Criteria

1. History of heart valve disorder (i.e., prosthetic valve or hemodynamically relevant valve disease)
2. Severe, disabling stroke within the previous 6 months, or any stroke within the previous 14 days
3. Conditions associated with an increased risk of bleeding
 - a. Major surgery within the previous month
 - b. Planned surgery or intervention within the next 3 months
 - c. History of intracranial, intraocular, spinal, retroperitoneal or atraumatic intra-articular bleeding
 - d. Gastrointestinal hemorrhage within the past year
 - e. Symptomatic or endoscopically documented gastroduodenal ulcer disease in the previous 30 days
 - f. Hemorrhagic disorder or bleeding diathesis
 - g. Need for anticoagulant treatment of disorders other than atrial fibrillation
 - h. Fibrinolytic agents within 48 hours of study entry
 - i. Uncontrolled hypertension (systolic blood pressure greater than 180 mm Hg and/or diastolic blood pressure greater than 100 mm Hg)
 - j. Recent malignancy or radiation therapy (within 6 months) and not expected to survive 3 years
4. Contraindication to warfarin treatment
5. Reversible causes of atrial fibrillation (e.g., cardiac surgery, pulmonary embolism, untreated hyperthyroidism)
6. Plan to perform a pulmonary vein ablation or surgery for cure of the atrial fibrillation
7. Severe renal impairment (estimated creatinine clearance 30 mL/min or less)
8. Active infective endocarditis
9. Active liver disease, including but not limited to
 - a. Persistent ALT, AST, Alk Phos greater than twice the upper limit of the normal range
 - b. Active hepatitis C (positive HCV RNA)
 - c. Active hepatitis B (HBs antigen +, anti HBc IgM +)
 - d. Active hepatitis A
10. Women who are pregnant or of childbearing potential who refuse to use a medically acceptable form of contraception throughout the study

11. Anemia (hemoglobin level less than 100 g/L) or thrombocytopenia (platelet count less than $100 \times 10^9/L$)
12. Patients who have developed transaminase elevations upon exposure to ximelagatran
13. Patients who have received an investigational drug in the past 30 days
14. Patients considered unreliable by the investigator, or having a life expectancy less than the expected duration of the trial because of concomitant disease, or having any condition which, in the opinion of the investigator, would not allow safe participation in the study (e.g., drug addiction, alcohol abuse)

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