GALILEO

Global Study Comparing a rivAroxaban-based Antithrombotic Strategy to an antipLatelet-based Strategy After TAVR: Main Results of The GALILEO Trial

Discussant: Elaine M. Hylek, MD MPH
Boston University School of Medicine
Professor of Medicine

RATIONALE for STUDY and UNMET NEED

Optimal antithrombotic strategy post-TAVR is unknown.

Risk of stroke remains high early and late post TAVR despite antiplatelet Rx.

Tissue factor and thrombin triggered by native valve leaflets, turbulent flow around leaflets and frame, and aortic wall injury.

Observation of reduced subclinical valve thrombosis and resolution with oral anticoagulation.

GALILEO First randomized assessment of OAC+ASA versus DAPT post-TAVR

Primary hypothesis: rivaroxaban-based strategy would be superior to the antiplatelet-based strategy with respect to incidence of death or thromboembolic events

Trial was stopped early due to increase in all-cause mortality, thromboembolic and bleeding events in rivaroxaban-treated patients

Result interpretation/clarification

- Patient population
- Dosing Strategy
- Timing of intervention: risk-laden periods
- ? Association of TE events and death with treatment interruption/discontinuation/physician response to bleeding
- ? Association of AF incidence, dose escalation, and bleeding
- Unknown incidence of subclinical paroxysmal AF

1. **AGE AND COMPLEXITY OF PATIENT POPULATION**

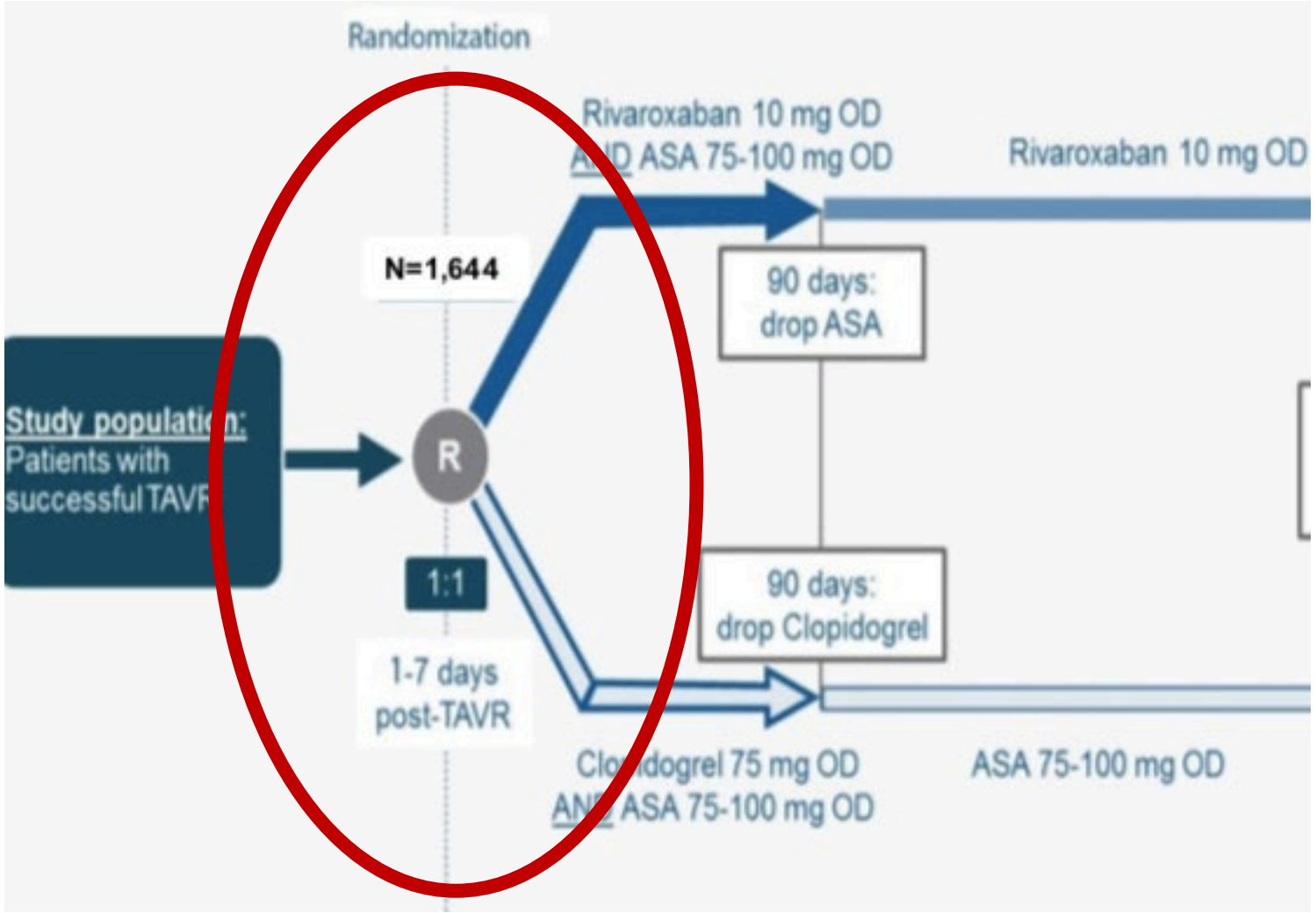
Indication	Ortho ppx	Acute VTE Rx	Stable CVD	AF	Post TAVR
AGE	63	56	68	73	80

- High prevalence of vascular disease, cerebral angiopathy, abnormal renal function-**Rivaroxaban arm treatment naive**

2. **DOSING STRATEGY STUDIED**

Indication	Ortho ppx	Acute VTE Rx	Stable CVD	AF	Post TAVR
Dose	10 mg QD	15 BID; 20 mg QD	2.5 BID	20 mg or 15 mg QD	10 mg QD

3. Period-specific treatment effects



- ? Association of TE events and death with treatment

  interruption/discontinuation/reversal with major bleeds/physician response to any bleed

- AF incidence-reported to be as high as 30% post TAVR.

  Did patients with dose escalation affect bleeding rates/Rx discontinuation?

  Subclinical AF may have contributed to mortality and stroke

Scientific Sessions 2019

Implications of Galileo

- Await results of other trials in the TAVR population
- Rivaroxaban 2.5 mg BID may be a reasonable next study
- Potential population for Factor Xla inhibition-contact pathway
- Medically complicated high risk population with mean age 80 years, combination therapy may not be feasible

Thank you!

American Heart Association®
Scientific Sessions