

# Aspirin Versus Aspirin Plus Clopidogrel as Antithrombotic Treatment Following Transcatheter Aortic Valve Replacement With a Balloon-Expandable Valve The ARTE (Aspirin Versus Aspirin plus Clopidogrel Following Transcatheter Aortic Valve Implantation) Randomized Clinical Trial

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## JACC-CARDIOVASCULAR INTERVENTIONS

Volumen: 10

Número: 13

Páginas: 1357-1365

DOI: 10.1016/j.jcin.2017.04.014

Fecha de publicación: JUL 10 2017

Tipo de documento: Article

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## Resumen

**OBJECTIVES** The aim of this study was to compare aspirin plus clopidogrel with aspirin alone as antithrombotic treatment following transcatheter aortic valve replacement (TAVR) for the prevention of ischemic events, bleeding events, and death.

**BACKGROUND** Few data exist on the optimal antithrombotic therapy following TAVR.

**METHODS** This was a randomized controlled trial comparing aspirin (80 to 100 mg/day) plus clopidogrel (75 mg/day) (dual antiplatelet therapy [DAPT]) versus aspirin alone (single-antiplatelet therapy [SAPT]) in patients undergoing TAVR with a balloon-expandable valve. The primary endpoint was the occurrence of death, myocardial infarction (MI), stroke or transient ischemic attack, or major or life-threatening bleeding (according to Valve Academic Research Consortium 2 definitions) within the 3 months following the procedure. The trial was prematurely stopped after the inclusion of 74% of the planned study population.

**RESULTS** A total of 222 patients were included, 111 allocated to DAPT and 111 to SAPT. The composite of death, MI, stroke or transient ischemic attack, or major or life-threatening bleeding tended to occur more frequently in the DAPT group (15.3% vs. 7.2%,  $p = 0.065$ ). There were no differences between groups in the occurrence of death (DAPT, 6.3%; SAPT,

3.6%;  $p = 0.37$ ), MI (DAPT, 3.6%; SAT, 0.9%;  $p = 0.18$ ), or stroke or transient ischemic attack (DAPT, 2.7%; SAPT, 0.9%;  $p = 0.31$ ) at 3 months. DAPT was associated with a higher rate of major or life-threatening bleeding events (10.8% vs. 3.6% in the SAPT group,  $p = 0.038$ ). There were no differences between groups in valve hemodynamic status post-TAVR.

**CONCLUSIONS** This small trial showed that SAPT (vs. DAPT) tended to reduce the occurrence of major adverse events following TAVR. SAPT reduced the risk for major or life-threatening events while not increasing the risk for MI or stroke. Larger studies are needed to confirm these results. (Aspirin Versus Aspirin + Clopidogrel Following Transcatheter Aortic Valve Implantation: The ARTE Trial [ARTE], NCT01559298; Aspirin Versus Aspirin + Clopidogrel as Antithrombotic Treatment Following TAVI [ARTE], NCT02640794) (C) 2017 by the American College of Cardiology Foundation.

### Palabras clave

**Palabras clave de autor:** [aortic stenosis](#); [aspirin](#); [bleeding](#); [clopidogrel](#); [stroke](#); [transcatheter aortic valve replacement](#)

**KeyWords Plus:** [DUAL-ANTIPLATELET THERAPY](#); [CEREBROVASCULAR EVENTS](#); [ATRIAL-FIBRILLATION](#); [CONSENSUS DOCUMENT](#); [RISK](#); [SINGLE](#); [TAVI](#); [PREDICTORS](#); [PROTECTION](#); [STENOSIS](#)

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## Financiación

Entidad financiadora	Número de concesión
Edwards Lifesciences	
Foundation of the Research Center of the Quebec Heart Lung Institute	
AstraZeneca	
Amgen	
Bayer	
Janssen	
Bristol-Myers Squibb/Pfizer	
Boehringer Ingelheim	

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## Editorial

ELSEVIER SCIENCE INC, 360 PARK AVE SOUTH, NEW YORK, NY 10010-1710 USA

## Información de la revista

- Impact Factor: [Journal Citation Reports](#)

## Categorías / Clasificación

Áreas de investigación: Cardiovascular System & Cardiology

Categorías de Web of Science: Cardiac & Cardiovascular Systems