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

Por: Rodes-Cabau, J (Rodes-Cabau, Josep); Masson, JB (Masson, Jean-Bernard); Welsh, RC (Welsh, Robert C.); del Blanco, BG (Garcia del Blanco, Bruno); Pelletier, M (Pelletier, Marcel); Webb, JG (Webb, John G.); Al-Qoofi, F (Al-Qoofi, Faisal); Genereux, P (Genereux, Philippe); Maluenda, G (Maluenda, Gabriel); Thoenes, M (Thoenes, Martin)...

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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%; SAT, 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

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Información del autor

Dirección para petición de copias: Rodes-Cabau, J (autor para petición de copias)

Direcciones:

[ 1 ] Laval Univ, Quebec Heart & Lung Inst, Quebec City, PQ G1V 4G5, Canada
[ 2 ] Ctr Hosp Univ Montreal, Montreal, PQ, Canada
[ 3 ] Mazankowski Alberta Heart Inst, Edmonton, AB, Canada
[ 4 ] Univ Alberta, Edmonton, AB, Canada
[ 5 ] Hosp Univ Vall d’Hebron, Barcelona, Spain
[ 6 ] St Johns Reg Hosp, St John, NB, Canada
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[ 9 ] Hop Sacre Coeur Montreal, Montreal, PQ, Canada
[ 10 ] Hosp San Borja Arriaran, Santiago, Chile
Direcciones de correo electrónico: josep.rodes@criucpq.ulaval.ca

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