



P. Guedeney<sup>1</sup>, F. Huchet<sup>2</sup>, P. Overtchouk<sup>1</sup>, S. Rouanet<sup>3</sup>, E. Vicault<sup>4</sup> T. Manigold<sup>2</sup>, P. Balagny<sup>1</sup>, P. Leprince<sup>1</sup>, L. De Decker<sup>2</sup>, G. Lebreton<sup>1</sup>, A.S. Boureau<sup>2</sup>, O. Barthelemy<sup>1</sup>, G. Montalescot<sup>1</sup>, P. Guerin<sup>2</sup>, J.P. Collet<sup>1</sup> for the ACTION study group 1: ACTION study group, Sorbonne université, INSERM UMRS 1166, Institute of cardiology, Pitié Salpétrière Hospital, Paris France; 2: UNIVERSITAIRE DE NAN Nantes University Hospital, Cardiology department; 3:Statistician unit, StatEthic, Levallois-Perret, France; 4: ACTION study group, unité de recherche clinique, Lariboisière Hospital (AP-HP), Paris, France

## Introduction

- Transcatheter aortic valve replacement (TAVR), is validated therapeutic alternative to patients with symptomatic severe aortic stenosis
- Patients undergoing TAVR remain at high risk of both ischemic and bleeding events after the procedure
- Nonetheless, optimal antithrombotic treatment after transcatheter aortic valve replacement (TAVR) is not yet established

### Objective

• We evaluated the impact of oral anticoagulation (OAC) on clinical outcome and valvular hemodynamic deterioration (VHD) within the first year of TAVR

#### Methods

- All consecutive patients undergoing successful TAVR, in 2 large-volume French centers were prospectively enrolled.
- Clinical endpoint of interest was the composite of death, stroke, hospitalization for heart failure or major/lifethreatening (MLT) bleeding within one-year of hospital discharge. Clinical events were defined according to the VARC-2 criteria.
- Echocardiographic follow-up, as performed by local physician, was collected. VHD was defined as mean transprothetic gradient≥20mmHg or an increase ≥10mmHg compared to baseline
- Determinants of clinical endpoint and VHD were assessed using Cox proportional Hazard model and Logistic regression model, respectively. All variables with p-value < 0.2 in univariate analysis were considered, including both OAC at discharge and AF

# Impact of oral anticoagulation on clinical outcomes and hemodynamic parameters after successful TAVR

A total of 1,139 patients were enrolled, including 400 (35.1%) patients discharged with OAC. Table 1 Recoling characteristics

[anic ]. Daschinc characteristics									
	Overall	No OAC	OAC						
	(N=1139)	(n=739)	(n=400)	p-value					
Age (years)	82.4 ± 7.7	81.9 ± 8.1	83.2 ± 6.8	0.009					
Male sex	594 (52.2%)	381 (51.6%)	213 (53.3%)	0.59					
BMI (kg/m²)	$26.7 \pm 5.4$	26.6 ± 5.4	26.8 ± 5.5	0.40					
Previous non-CABG surgery	78 (6.8%)	42 (5.7%)	36 (9.0%)	0.03					
Coronary artery disease	512 (45%)	347 (47%)	165 (41.3%)	0.065					
Peripheral artery disease	309 (27.1%)	201 (27.2%)	108 (27%)	0.94					
Chronic pulmonary disease	224 (19.7%)	137 (18.5%)	87 (21.8%)	0.19					
Diabetes mellitus	304 (26.7%)	198 (26.8%)	106 (26.5%)	0.92					
Systemic hypertension (N=1133)	894 (78.9%)	589 (80.2%)	305 (76.4%)	0.13					
Chronic kidney disease	617 (54.2%)	382 (51.7%)	235 (58.8%)	0.02					
History of atrial Fibrillation	422 (37.1%)	93 (12.6%)	329 (82.3%)	<0.001					
Procedural Characteristics									
Transfemoral approach	939 (82.4%)	602 (81.5%)	337 (84.3%)	0.44					
Balloon-expandable device	691 (60.7%)	433 (58.6%)	258 (64.5%)	0.051					
Self-expanding device	448 (39.3%)	306 (41.4%)	142 (35.5%)						
Valve-in-Valve procedure Device	54 (4.7%)	35 (4.7%)	19 (4.8%)	0.99					
diameter>23mm	903 (79.3%)	584 (79.1%)	319 (79.8%)	0.81					
Hospital discharge									
LVEF (%)	$55.4 \pm 10.5$	$55.8 \pm 10.4$	54.5 ± 10.6	0.047					
LVEF ≤ 30%	46 (4%)	29 (3.9%)	17 (4.3%)	0.79					
Mean gradient (mmHg) Severe	$10.6 \pm 5.4$	$10.9 \pm 5.6$	10 ± 5	0.009					
Aortic regurgitation	7 (0.6%)	4 (0.6%)	3 (0.8%)	0.70					
Antiplatelet therapy				< 0.001					
Single antiplatelet therapy	389 (34.2%)	264 (35.7%)	125 (31.3%)						
Dual antiplatelet therapy	488 (42.8%)	464 (62.8%)	24 (6%)						
No antiplatelet therapy	262 (23%)	11 (1.5%)	251 (62.8%)						

Echocardiogram follow-up was available with 746 (66%) of patients, with 58 (8%) presenting with VHD.

#### Table 2. Clinical outcomes

	Overall	OAC at discharge	No OAC at discharge	HR (95%CI)	p-value
Primary endpoint	21.5%	29.4%	17.3%	1.83 (1.42-2.35)	<0.001
Death	12.9%	18.8%	9.6%	2.07 (1.49-2.87)	<0.001
Stroke	1.6%	2.0%	1.4%	1.35 (0.51-3.55)	0.54
Heart failure	9.2%	12.4%	7.5%	1.70 (1.14-2.52)	0.008
MLT bleeding	3.7%	5.3%	2.8%	1.9 (1.02-3.5)	0.041

#### Results

Femoral vascular approach —

Chronic pulmonary disease

Chronic kidney disease

LVEF < 30% at discharge

VALVE DIAMETER < 23mm





 One-year clinical outcomes were mainly driven by patient baseline characteristics and not OAC prescription

• Occurrence of VHD, however, was driven by procedurerelated variable and the prescription of OAC at discharge

Source of funding: None