

Scientific Sessions 2019

Randomized Clinical Trial Comparing a Rivaroxaban-based Strategy With an Antiplatelet-based Strategy for the Prevention of Subclinical Leaflet Thrombosis in Transcatheter Aortic Valves

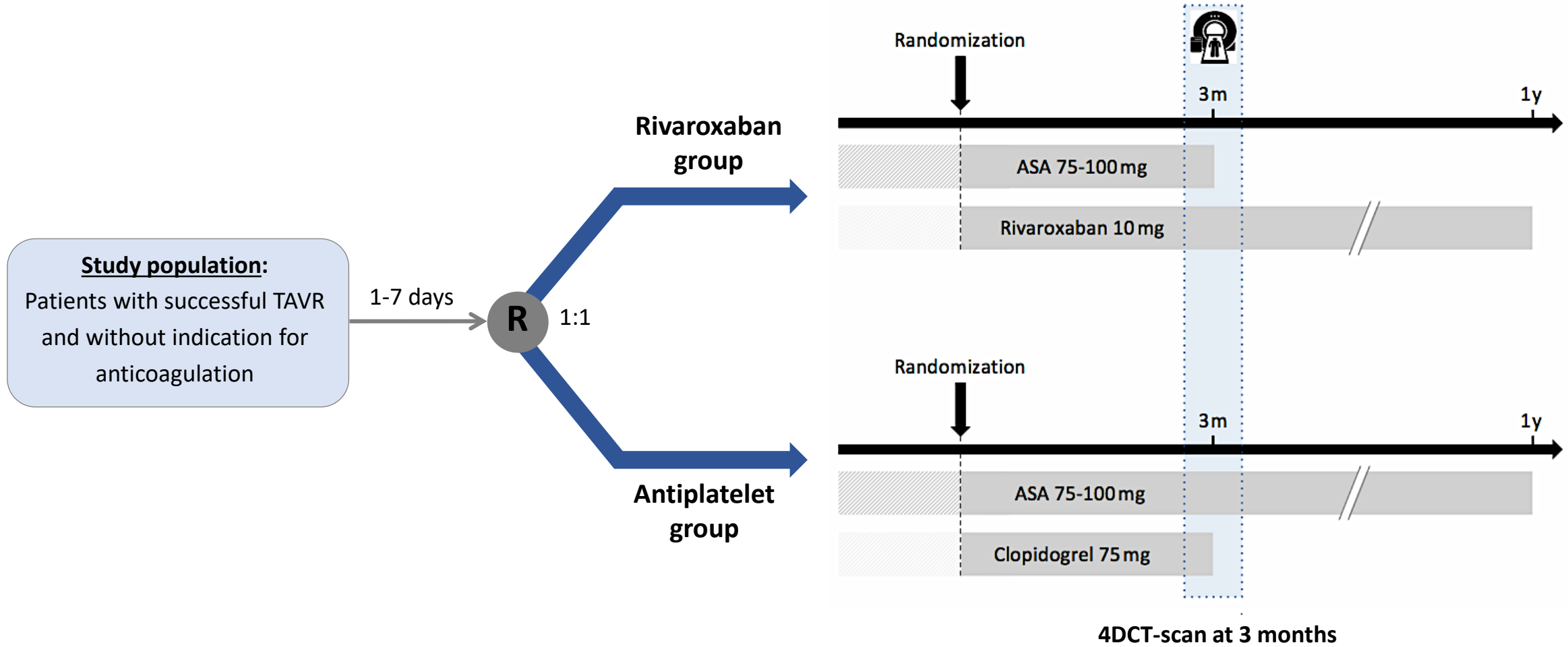
— GALILEO 4D  —

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Background

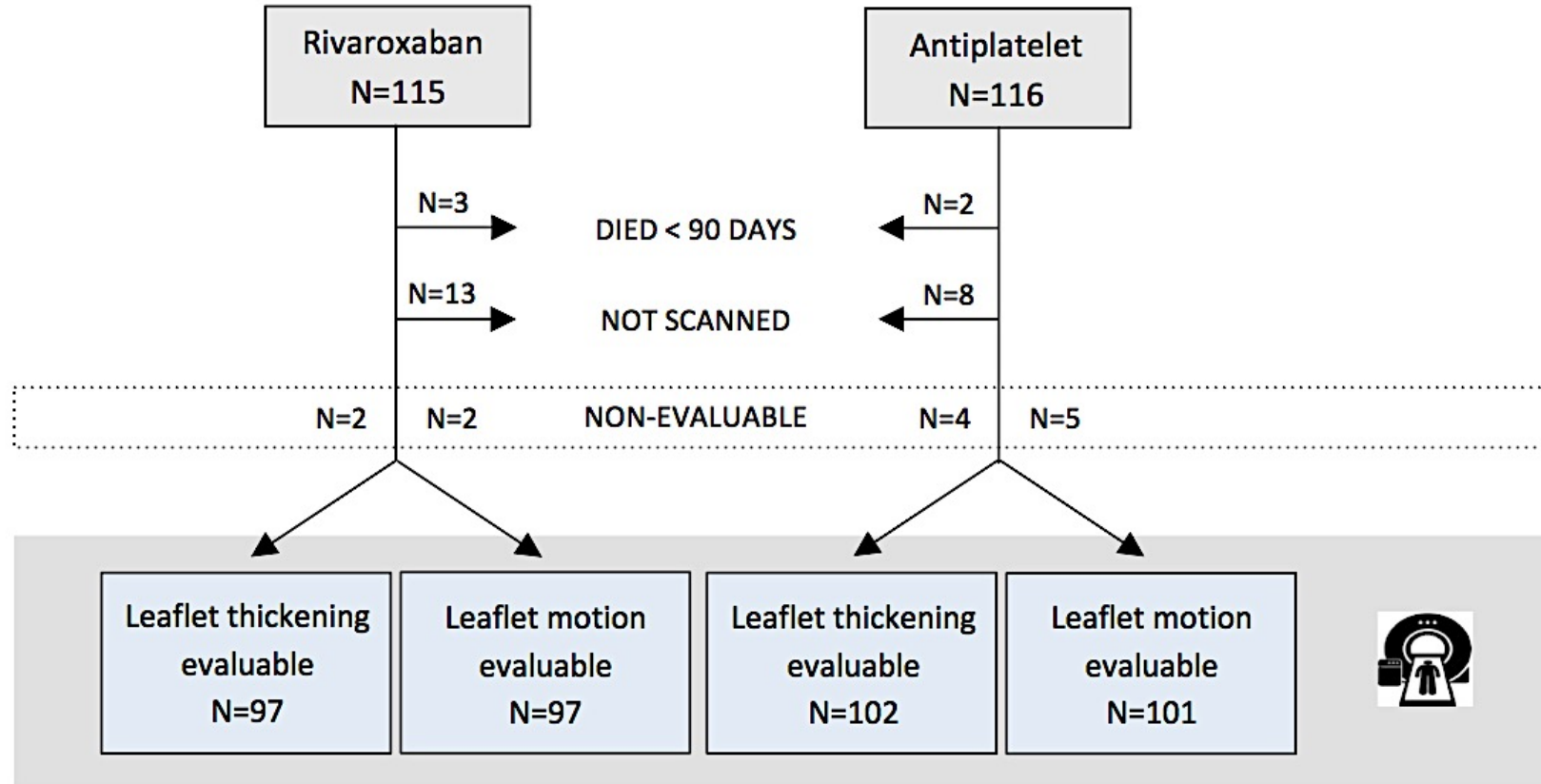
- Subclinical hypoattenuated leaflet thickening (HALT) and reduced leaflet motion (RLM) of bioprosthetic aortic valves have been demonstrated by four-dimensional computed tomography (4DCT).
- In a substudy of the large randomized GALILEO trial, we investigated whether anticoagulation can reduce these phenomena after transcatheter aortic valve replacement (TAVR).

Study design



All patients enrolled in GALILEO-4D were also enrolled in the main GALILEO trial.

Study population (ITT) – evaluable CT-scans

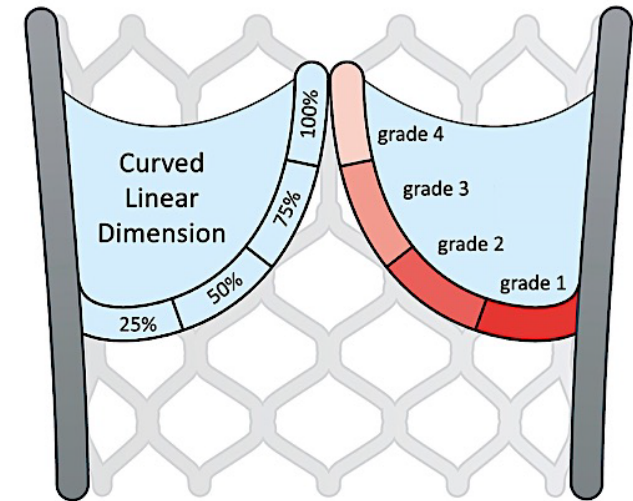


Study Methodology – 4DCT analysis

➤ Reduced leaflet motion (RLM) was defined as:

- **Grade 0:** normal/unrestricted
- **Grade 1:** minimally restricted (<25%)
- **Grade 2:** mildly restricted (25-50%)

- **Grade 3:** moderately restricted (50-75%)
- **Grade 4:** largely immobile (>75%)



Blanke P, et al. JACC Cardiovasc Imaging. 2019;12:1-24.

Study Endpoints

Primary endpoint

- The proportion of patients with at least one prosthetic valve leaflet with reduced leaflet motion (RLM) \geq grade 3

Secondary endpoints

- The proportion of patients with at least one thickened leaflet (HALT)
- The proportion of valve leaflets with HALT or RLM \geq grade 3
- Transprosthetic mean pressure gradient (TTE)
- Safety and efficacy outcomes identical to main GALILEO trial

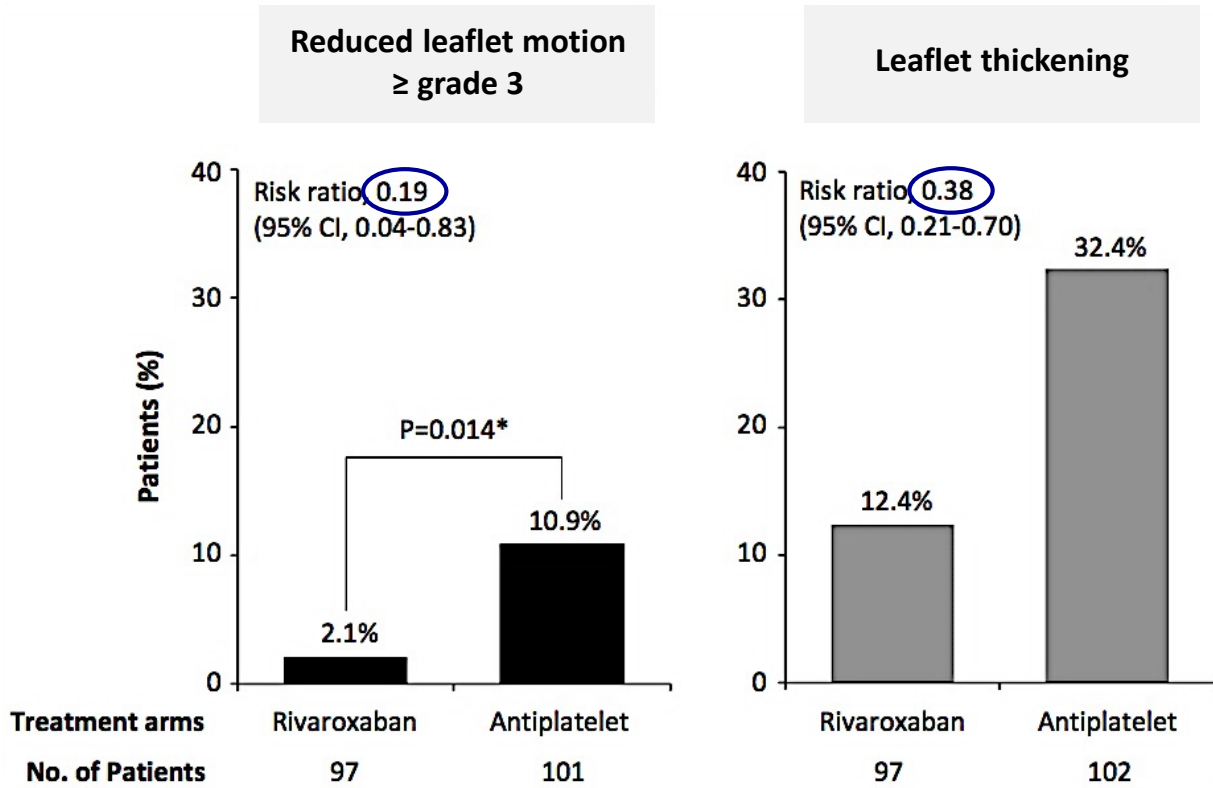
4DCT outcomes – ITT analysis

Reduced leaflet motion (RLM)			
Analysis at patient level	Rivaroxaban (N=97)	Antiplatelet (N=101)	Δ proportions (95%CI)
At least one leaflet with RLM grade ≥ 3	2.1%	10.9%	-8.8% (-16.5 to - 1.9%)
Analysis at leaflet level	Rivaroxaban (N=291)	Antiplatelet (N=303)	Δ proportions (95%CI)
Number of leaflets with RLM grade ≥ 3	1.0%	4.6%	-3.6% (-6.7 to -0.9%)

— Primary endpoint

4DCT outcomes

Intention-to-treat (ITT)



Echocardiographic outcomes

	Rivaroxaban N=102	Antiplatelet N=105	HALT (-) N=151	HALT (+) N=44	RLM ≥ 3 (-) N=181	RLM ≥ 3 (+) N=13
LVEF, %	55 ± 13	56 ± 8	56 ± 10	54 ± 12	55 ± 11	56 ± 13
Mean AV gradient, mmHg	10 ± 5	10 ± 5	10 ± 5	11 ± 4	10 ± 5	13 ± 4
AVA, cm ²	1.8 ± 0.5	1.8 ± 0.4	1.8 ± 0.5	1.7 ± 0.4	1.8 ± 0.5	1.5 ± 0.4
Central AR, mild	0	2 (1.9%)	1 (0.7%)	1 (2.3%)	2 (1.1%)	0
Central AR, moderate	0	0	0	0	0	0
PVR, mild	9 (8.8%)	8 (7.6%)	13 (8.6%)	4 (9.1%)	17 (9.4%)	0
PVR, ≥ moderate	1 (1.0%)	0	0	1 (2.3%)	1 (0.6%)	0

Clinical outcomes

Clinical end points – at time of 4DCT-scan	Rivaroxaban (N=115)	Antiplatelet (N=116)
Major or life-threatening bleeding	4 (3.5%)	1 (0.9%)
Thromboembolic event	4 (3.5%)	2 (1.7%)
Non-disabling stroke	1 (0.9%)	0
Disabling stroke	3 (2.6%)	2 (1.7%)
Death	3 (2.6%)	2 (1.7%)

Too few clinical events to permit any assessment of the impact of HALT and RLM on clinical outcomes

— Clinical outcomes in the **main GALILEO trial** should be considered —

Conclusions

- The overall proportions of patients with **reduced leaflet motion (grade 3 or more)** and **leaflet thickening** were 6.6% and 22.6%, respectively.
- Both findings were **less frequent** with the **rivaroxaban-based strategy** as compared to the antiplatelet-based strategy.
- Echocardiography was not useful in identifying patients with these valvular abnormalities.

- The **rivaroxaban-based strategy** was associated with a **higher risk of death or thromboembolic complications** and a **higher risk of bleeding** in the main GALILEO trial.

Thank you!



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