Paravalvular leak: a characteristic complication post-TAVI?

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Eurovalve 2016, Bruxelles

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Disclosure

- Medtronic – Consultant, Proctor, study investigator
- Boston scientific: Consultant, Proctor, steering committee
- Edwards: consultant
- GE: Consultant
- Direct flow: consultant
- CardiaQ: study investigator
- Tendyne: study investigator
- Twelve: study investigator
- Cephea: consultant
- Micrport: consultant

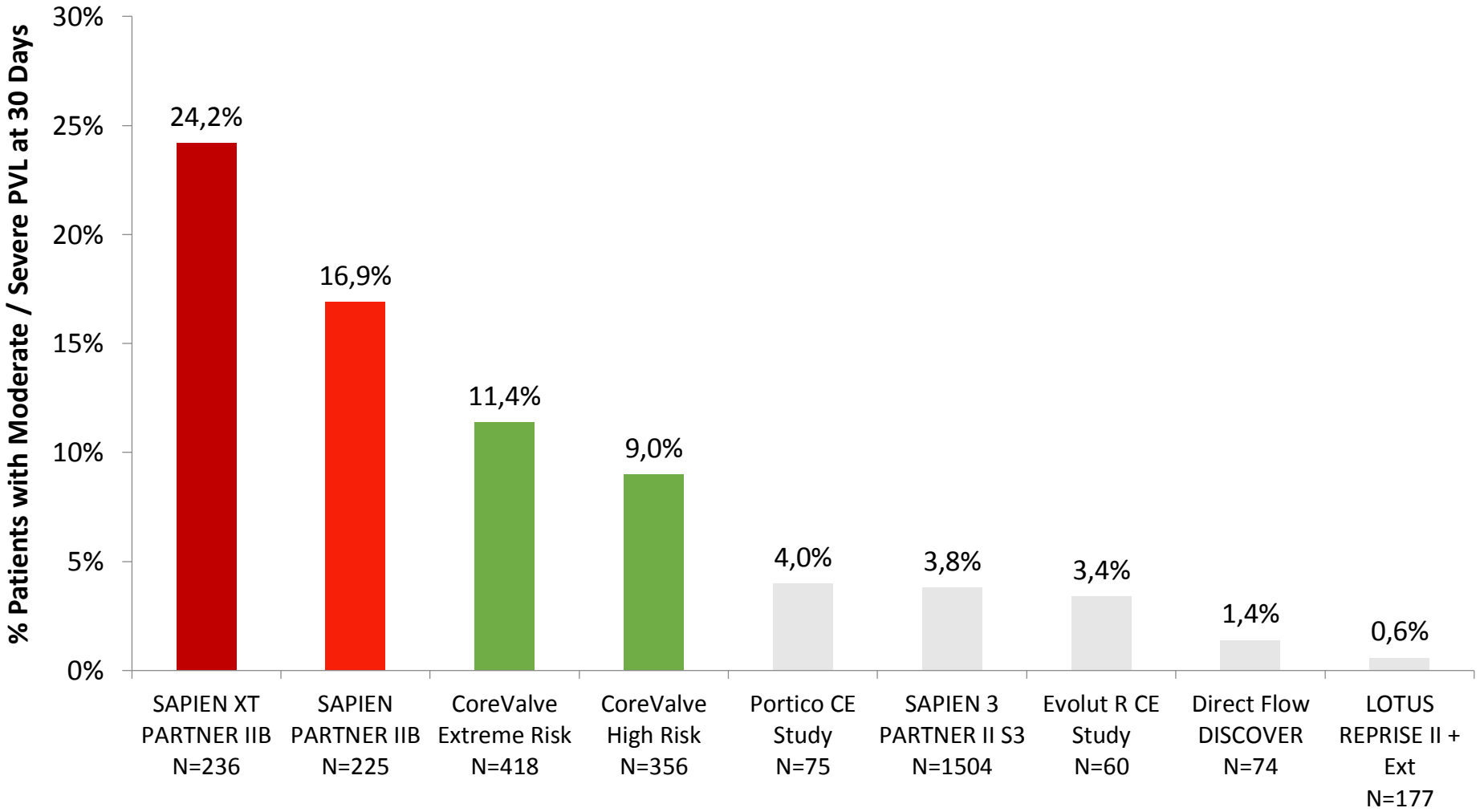
State of the Art

Paravalvular Leak After Transcatheter Aortic Valve Replacement : The New Achilles' Heel?

Philippe Généreux, Stuart J. Head, Rebecca Hahn, Benoit Daneault, Susheel Kodali, Mathew R. Williams, Nicolas M. van Mieghem, Maria C. Alu, Patrick W. Serruys, A. Pieter Kappetein, Martin B. Leon

JACC, Volume 61, Issue 11, 19 March 2013

Moderate to severe PVL



[1]Leon, et. al. presented at ACC 2013; [2]Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; [3]Adams, et al., *N Engl J Med* 2014; 370: 1790-8; [4]Manoharan, et al., et. al. presented at TCT 2014; [5]Kodali, et al., presented at ACC 2015; [6]Meredith, et al., presented at ACC 2015; [7]Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; [8]Meredith, et al., presented at PCR London Valves 2014

Table 1 – Incidence of moderate/severe paravalvular aortic regurgitation after TAVR

TF = trans-femoral; TS = trans-subclavian; TA = trans-apical; CV = Medtronic CoreValve; ES = Edwards-SAPIEN prosthesis

Study	Patients	EuroSCORE	Access route	THV type	PAR rate	Assessed by	Mortality for > mild PAR
Abdel-Wahab et al.[8]	690	20.4 ± 13.1	92.4% TF, 3.5% TA	84.3% CV, 15.7% ES	17.2%	Angiography	n.a.
Leon et al.[1]	179	26.4 ± 17.2	100% TF	100% ES	15.2%	Echocardiography	n.a.
Tamburino et al.[9]	663	23.0 ± 13.7	90.3% TF, 9.7% TS	100% CV	21.0%	Echocardiography	n.a.
Smith et al.[2]	348	29.3 ± 16.5	70.1% TF, 29.9% TA	100% ES	13.1%	Echocardiography	n.a.
Moat et al.[12]	870	18.5 (11.7-27.9)	68.9% TF, 26.4% TA	52.0% CV, 48.0% ES	13.6%	Angiography	n.a.
Sinning et al.[6]	146	30.2 ± 18.0	91.8% TF, 8.2% TS	100% CV	15.1%	Echocardiography, Angiography, Hemodynamics	30-day: 22.7%, 1-year:63.6%
Gilard et al.[11]	1915*	21.9 ± 14.3	73.9% TF, 17.7% TA	66.9% ES, 33.1% CV	16.5%	Echocardiography	n.a.
Gotzmann et al.[16]	198	22.0 ± 16.0	97.5% TF, 2.5% TS	100% CV	14.1%	Echocardiography, Hemodynamics	30-day: 21.0%, 1-year: 57.0%
Vasa-Nicotera et al.[13]	122	22.4 ± 13.0	97.5% TF, 1.7%	79.5% CV, 20.5%	16.4%	Echocardiograph,	30-day: 30.0%, 1-year: 60.0%

Sinning j-m et al; JACC 2013

PVL: Need for standardization

ASE / VARC Criteria (2011)

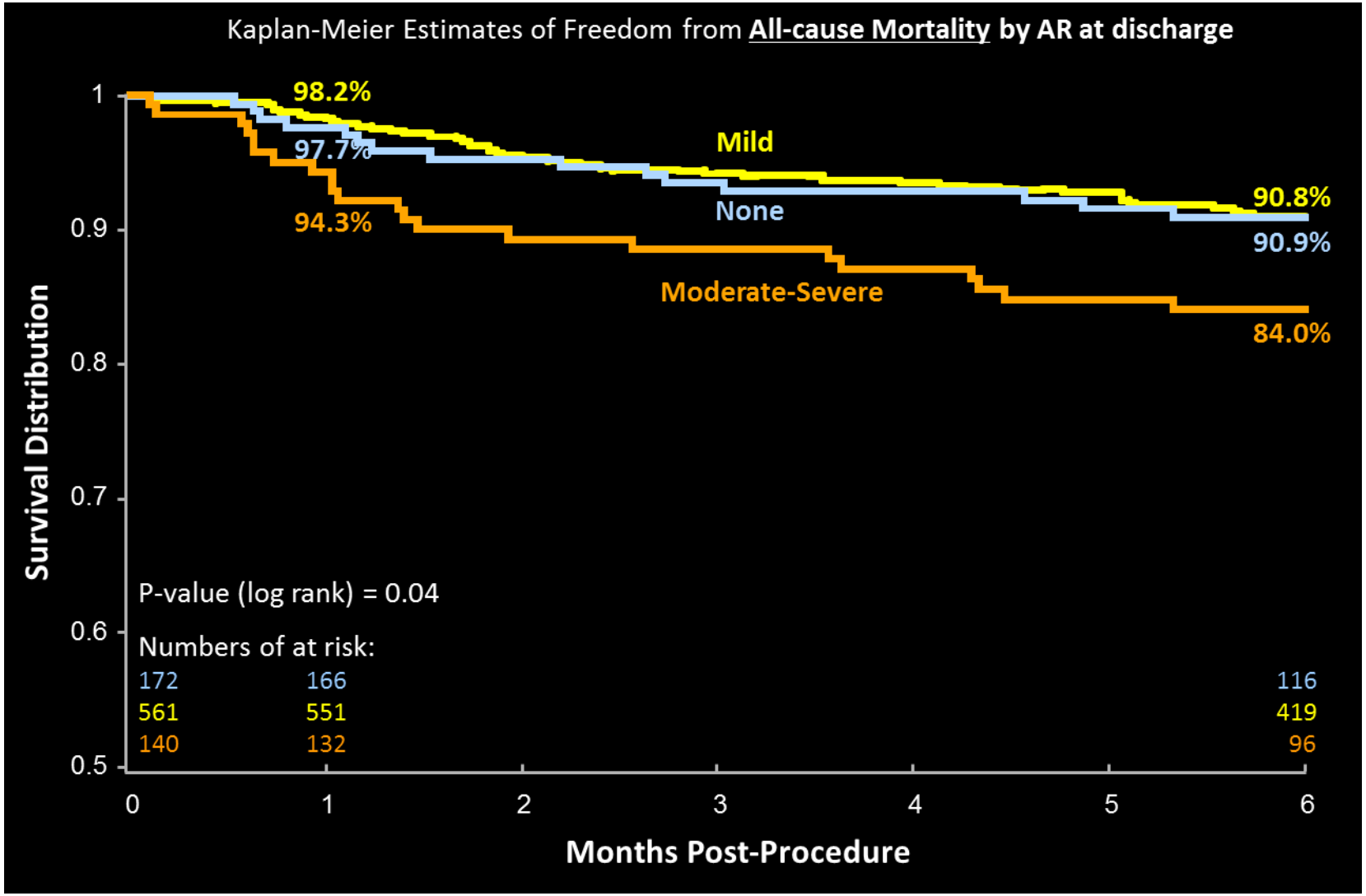
Parameter	Mild	Moderate	Severe
Valve structure and motion	Usually normal	Usually abnormal	Usually normal
- Mechanical or bioprosthetic			
Structural parameters			
- Left ventricular size	Normal	Norm / Mildly dilated	Normal
Color Jet width in central jets (% LVOT diameter)	Narrow (≤ 25%)	Intermediate (26-64%)	Large (≥ 65%)
Jet density : CW Doppler	Incomplete / faint	Dense	Dense
Jet deceleration rate (RHT, mesc) : CW Doppler	Slow (> 500 ms)	Variable (200-500)	Steep (< 200 ms)
LV outflow vs pulmonary outflow : PW Doppler	Slightly increased	Intermediate	Greatly increased
Diastolic flow reversal in descending Aorta : PWD	Absent or brief early diastolic	Intermediate	Prominent holodiastolic
Circumferential extent of periprosthetic AR (%)	< 10 %	10 - 20 %	> 20 %
Regurgitant volume (ml/beat)	< 30 ml	30 - 59 ml	> 60 ml
Regurgitant fraction (%)	< 30 %	30 - 50 %	> 50 %

Zoghbi WA et al. J Am Soc Echocardiogr 2009. 22(9): 975 - 1014. doi:10.1016/j.echo.2009.07.013
Leon MB et al. (Valve Academic Research Consortium) Eur Heart J 2011. 32:205-217 doi:10.1093/eurheartj/ehq406
J Am Coll Cardiol 2011. 57(3): . doi:10.1016/j.jacc.2010.12.005

	Grade	Description
1	Mild	Partial LV contrast diastolic filling Clearing with every cardiac cycle
2	Moderate	Entire LV contrast diastolic filling Density LV < Ascending aorta
3	Moderate to severe	Entire LV contrast diastolic filling Density LV = Ascending aorta
4	severe	Entire LV contrast diastolic filling < 1 beat Density LV > Ascending aorta

Genereux P et al. J Am Coll Cardiol 2013. 61(11):1125-1136

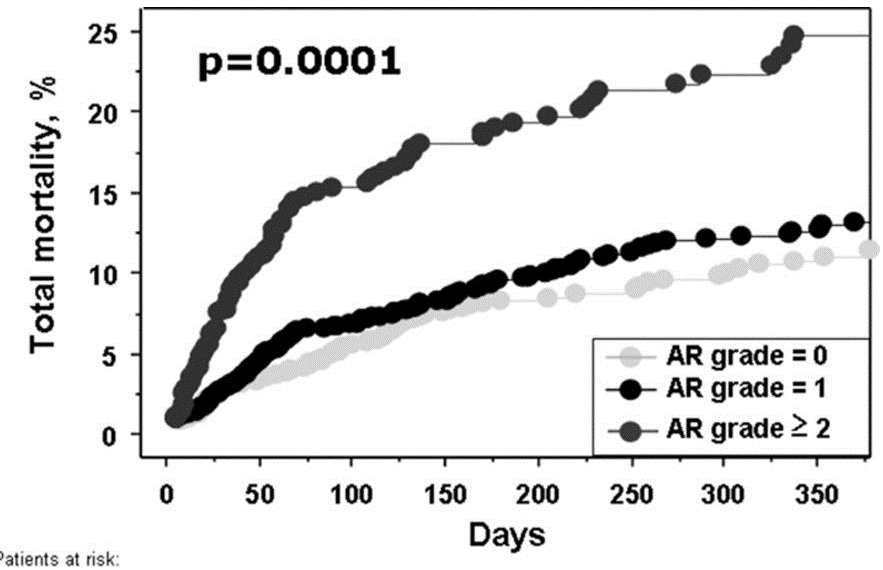
COREVALVE ADVANCE REGISTRY



Linke et al ***EHJ 2014***

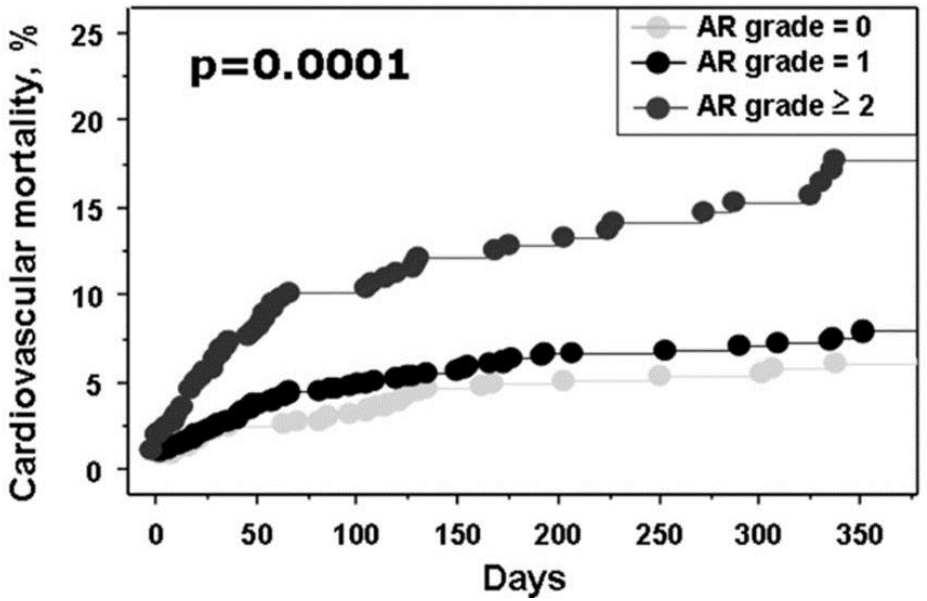
FRANCE 2 REGISTRY

One-year mortality rate according to postprocedural aortic regurgitation grade.



Patients at risk:

AR grade=0	964	890	822	744	659	592	511	434
AR grade=1	1369	1264	1165	1051	953	828	709	622
AR grade≥2	436	363	329	293	266	234	196	166

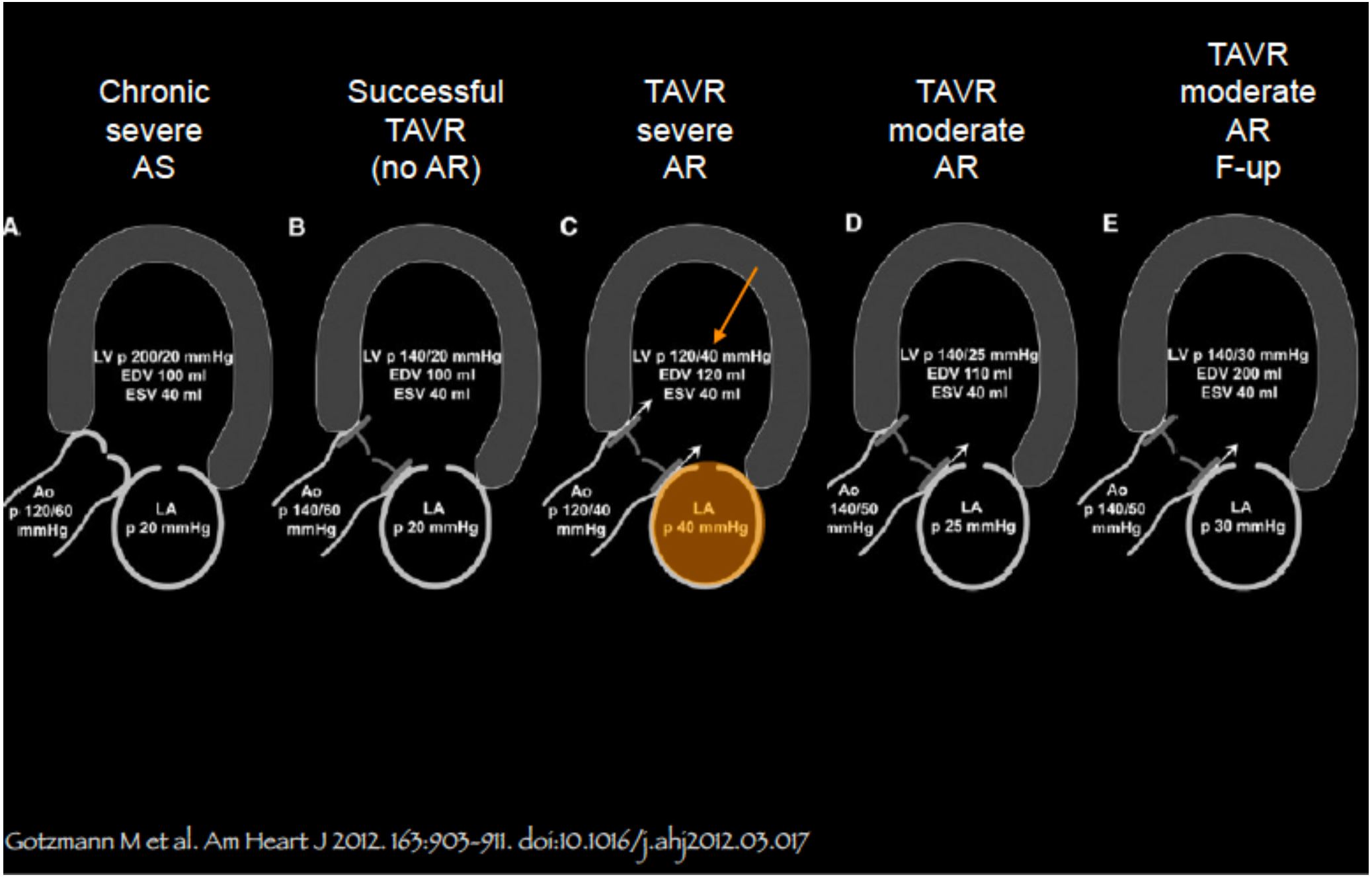


Van Belle E et al. Circulation. 2014;129:1415-1427

Physiopathology

- In moderate and severe AR after TAVI, a normal-sized LV with increased myocardial stiffness has been exposed to ***volume overload.***

- Because the ***noncompliant LV*** is unable to raise end-diastolic volume, the end-diastolic pressure increases, and ***the forward stroke volume decreases***.



Gotzmann M et al. Am Heart J 2012. 163:903-911. doi:10.1016/j.ahj2012.03.017

Mechanisms

- Anatomical:
  - Cacifications
  - Bicuspid

- Technical:
  - Oversizing: underexpansion
  - Undersizing: sealing, cover index
  - Malpositionning: too low, too high

Aortic valve calcium load before TAVI: Is it important?

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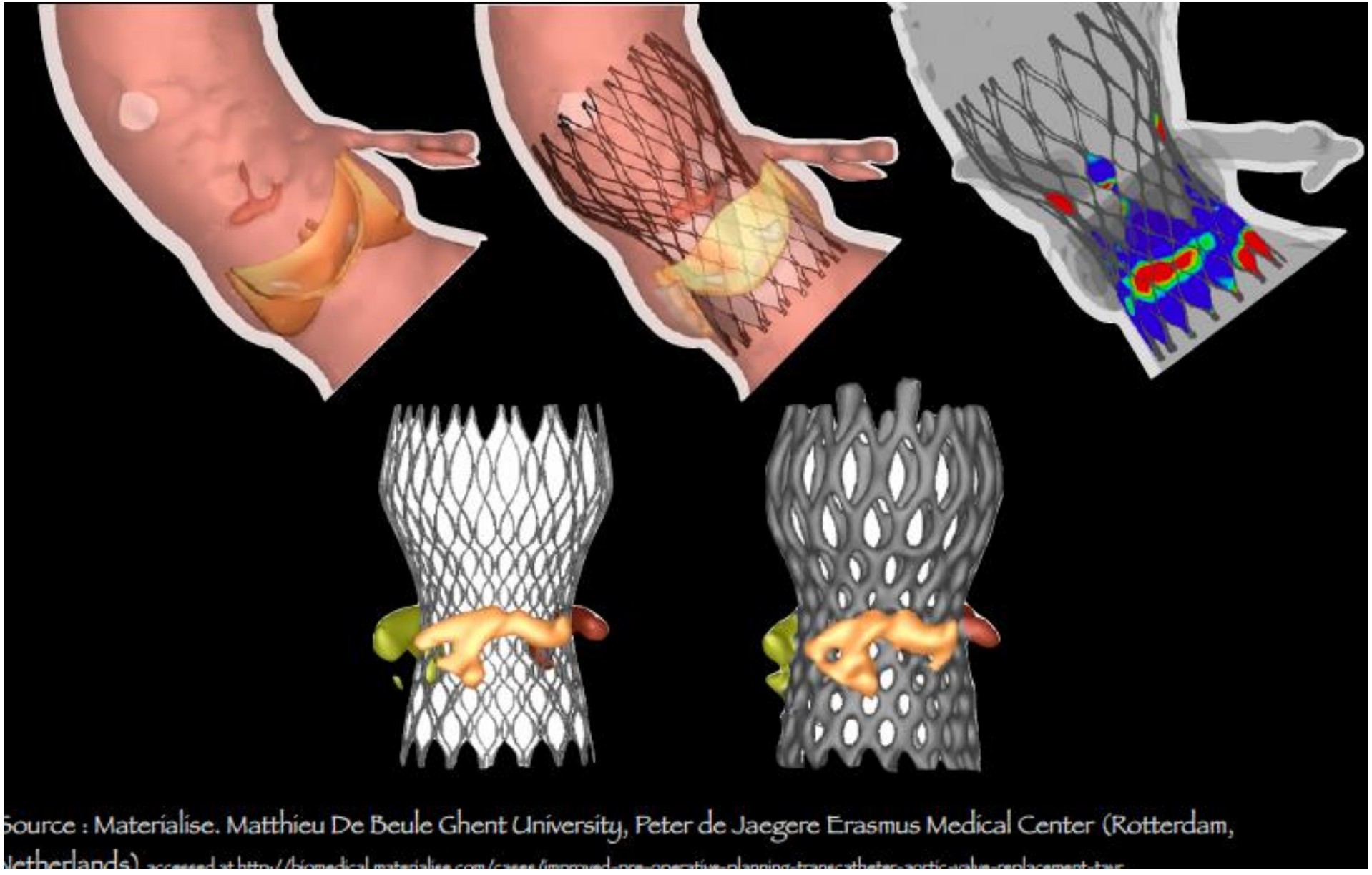
Corresponding to: Ardawan Julian Rastan, MD, PhD. Department of Cardiac Surgery, Cardiovascular Center Rotenburg/Fulda, Heinz-Meise-Str. 100, 36199 Rotenburg a. d. Fulda, Germany. Email: a.rastan@hkz-rotenburg.de.

Table 1 Preoperative transesophageal echocardiography results and mean Aortic Valve Calcium Score's (AVCS) for the aortic valve, cusps and commissures depending on the presence of a paravalvular leak

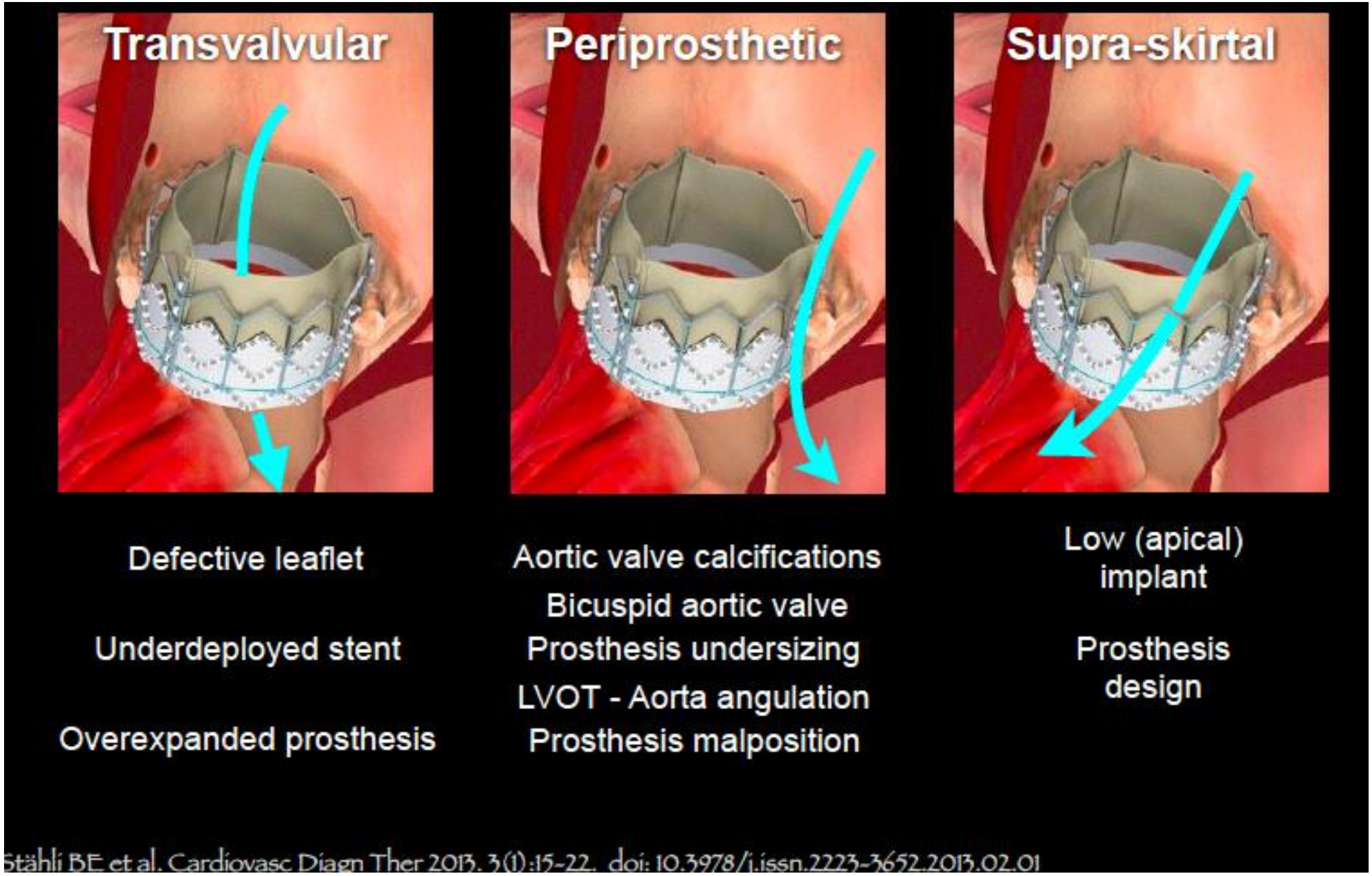
AVCS	No paravalvular leak*	Paravalvular leak*	P-value
Aortic valve	2694±1528	4153±479	0.006
Right coronary cusp	811±542	1189±882	0.025
Left coronary cusp	919±644	1669±1514	0.001
Non-coronary cusp	1013±671	1281±750	0.053
Right-left-coronary commissure	782±554	1295±1071	0.010
Left-non-coronary commissure	1049±656	1589±1104	0.012
Non-right-coronary commissure	918±560	1258±941	0.110

Aortic Valve Calcium Score's (AVCS) for the aortic valve, cusps and commissures depending on the presence of a paravalvular leak. *: confirmed by intraoperative transesophageal echocardiography (TEE) and root angiography

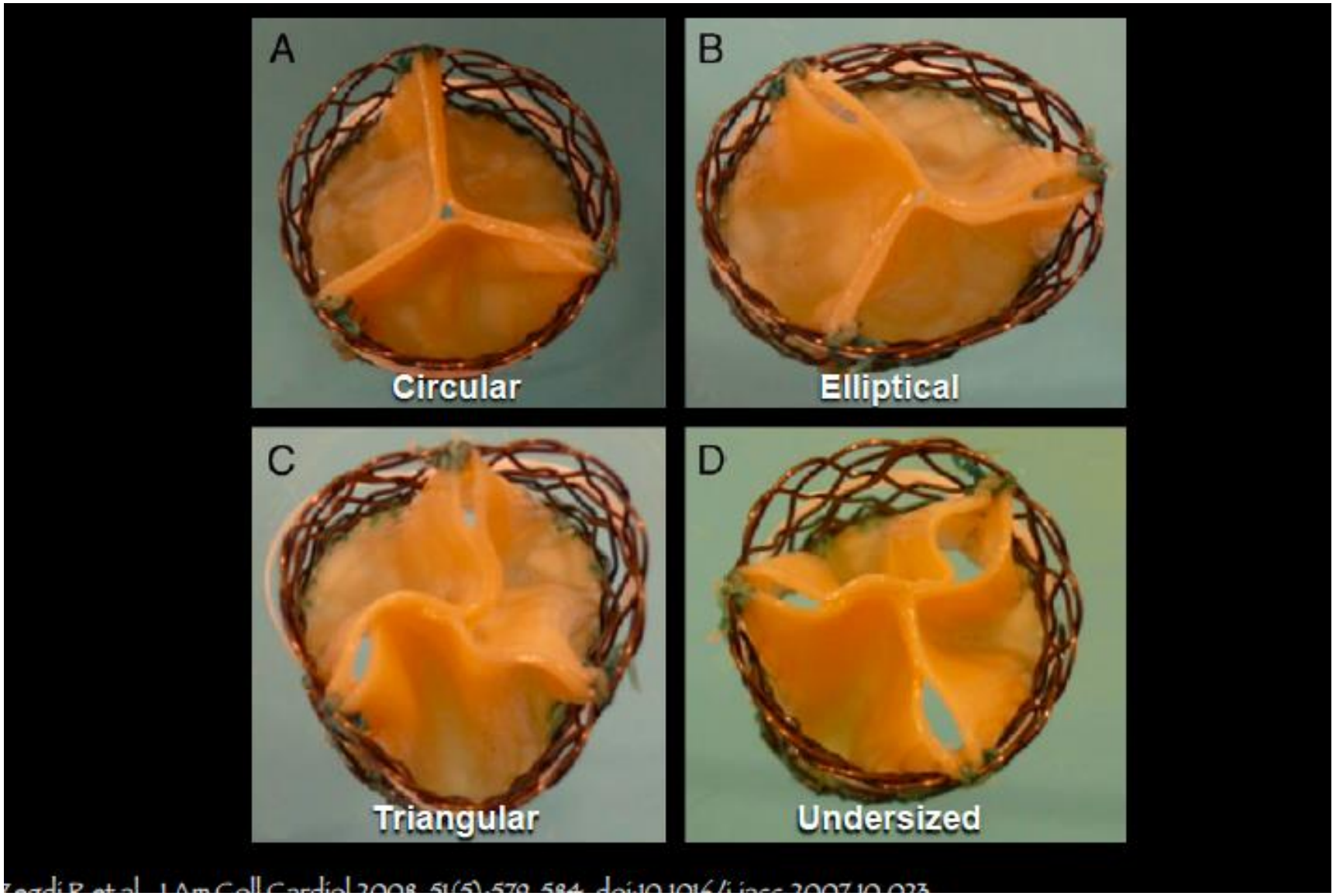
Anatomical: calcifications

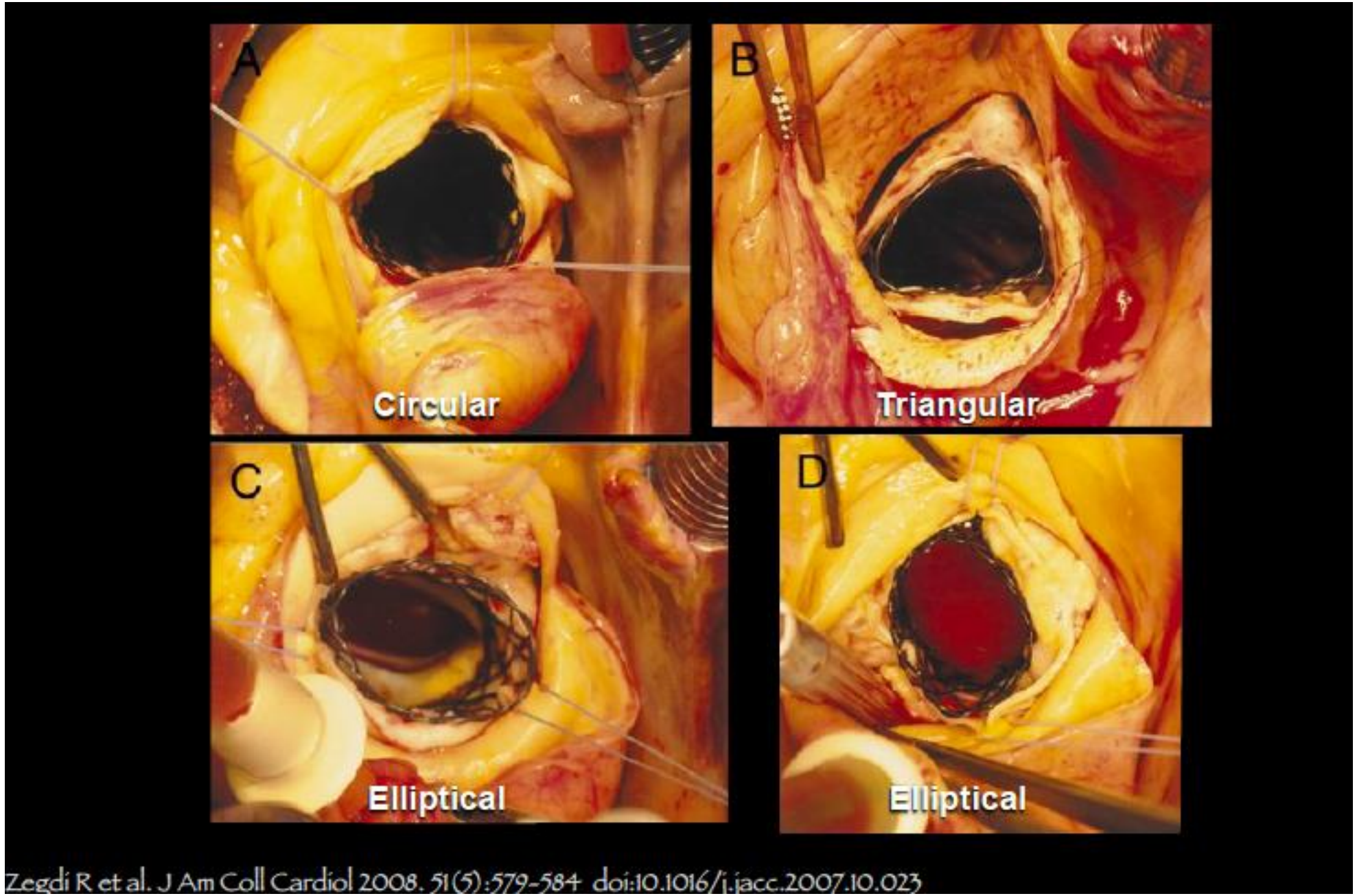


Anatomical: calcifications



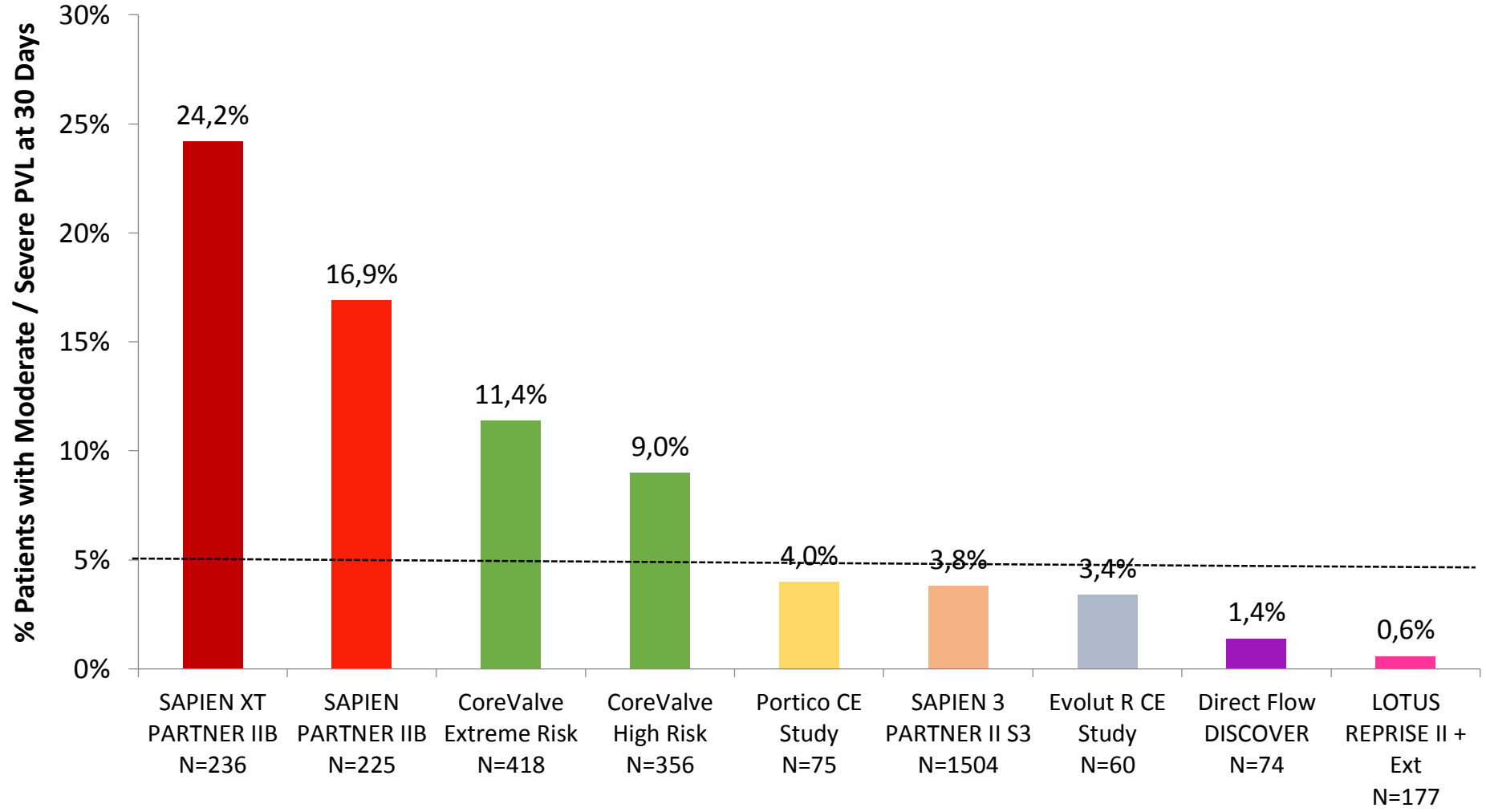
Technical: irregular shape





Zegdi R et al. J Am Coll Cardiol 2008. 51(5):579-584 doi:10.1016/j.jacc.2007.10.023

Moderate to severe PVL



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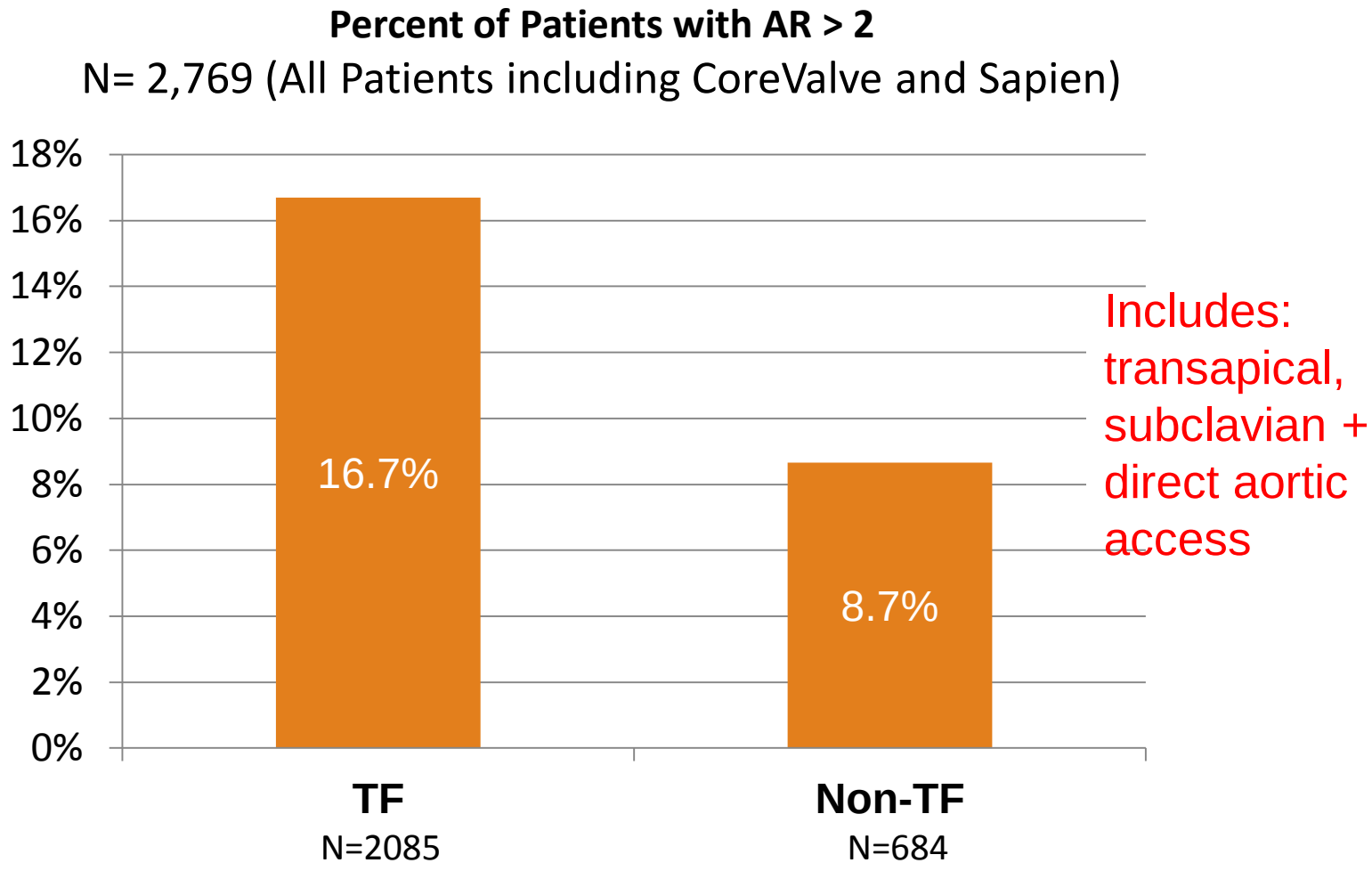
Implications and Management

- Patient ‘s selection
  - Preop. Imaging: CT scan: calcifications
  - Per-op imaging: echo: optimal poditionning

- New valve generation:
  - Evolut R; S3; Lotus; symetis
- Bailout startegies:
  - post- dilatation; VIV
- Access

“Proximal Access” May Reduce AR frequency

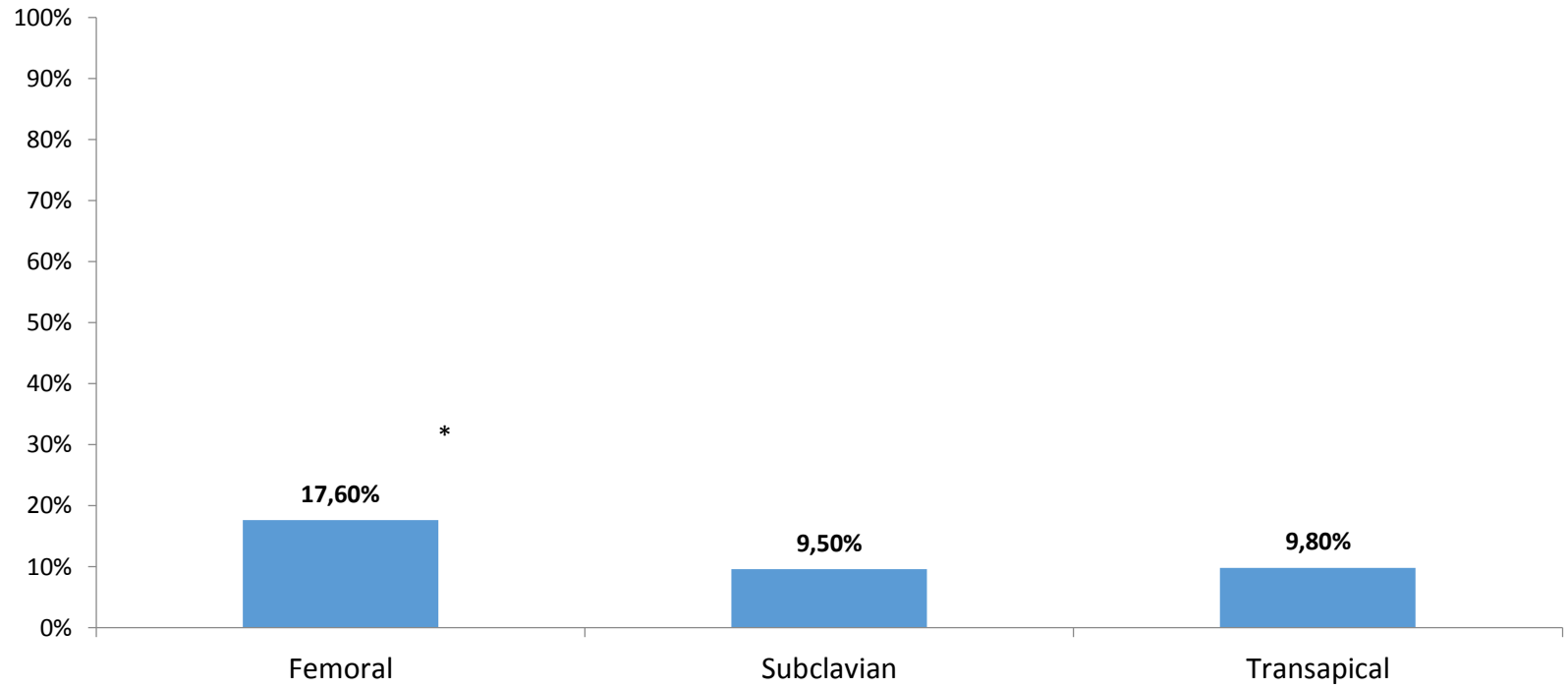
FRANCE 2 Registry



Van Belle, et. al. Peri-valvular Aortic Regurgitation in Balloon-expendable and Self-expendable TAVI procedures: Predictors and Impact on clinical outcome - Insights from the FRANCE2 Registrypresentation; TCT 2012.

FRANCE 2 registry

Patients experiencing grade 2, 3 or 4 aortic regurgitations post surgery



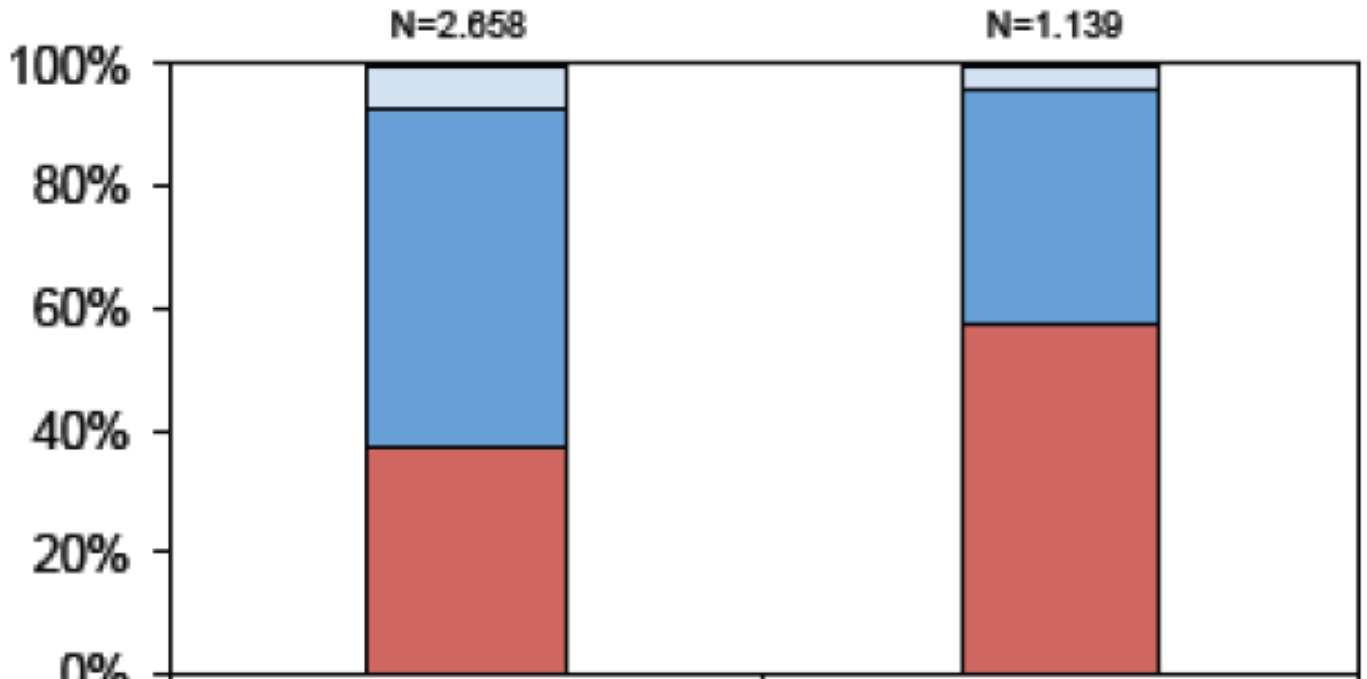
* p=0.020 compared to subclavian

Paper in progress

GARY

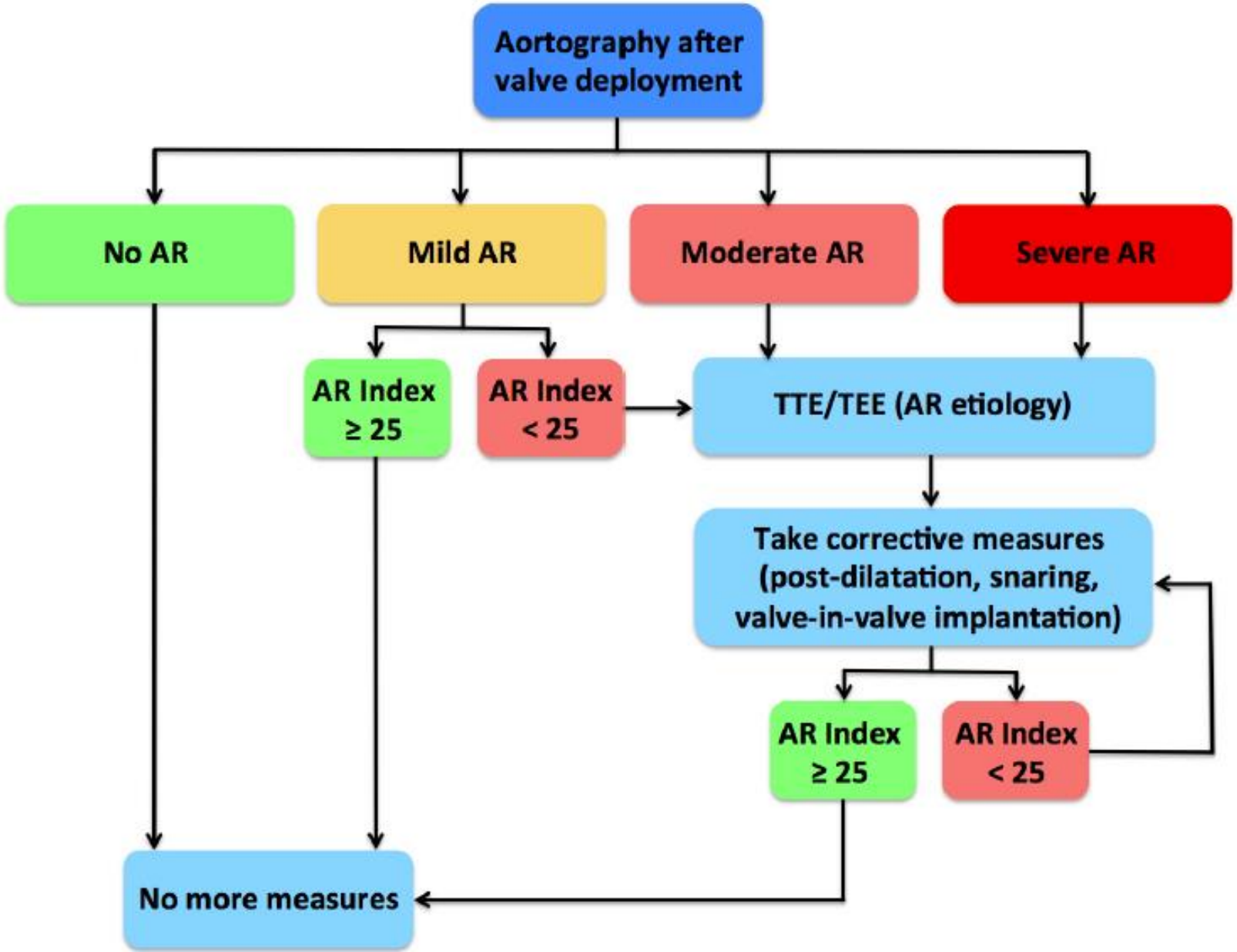
Residual aortic regurgitation

Deutsches Aortenklappenregister

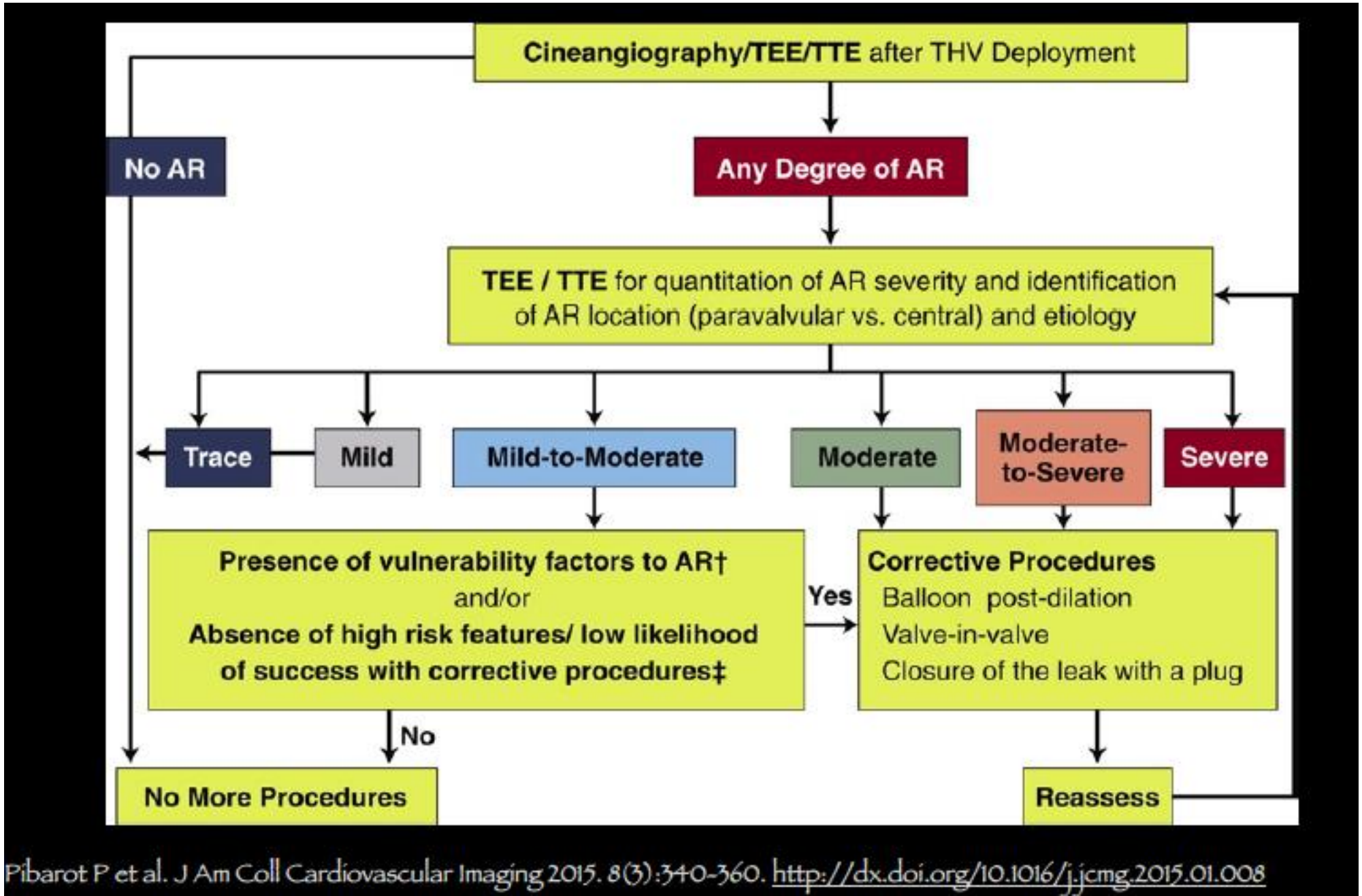


	transvascular	transapical
grade III / IV	0,3%	0,6%
grade II	7,0%	3,4%
grade I	55,5%	38,6%
Zero	37,2%	57,3%

Proposed management algorithm

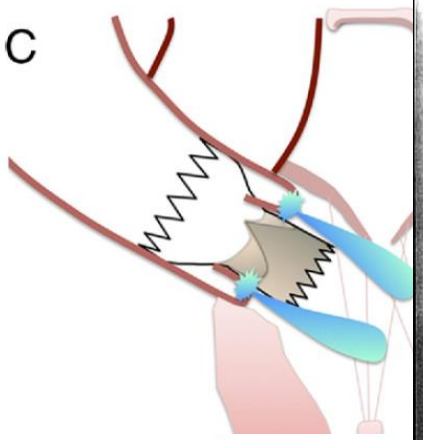


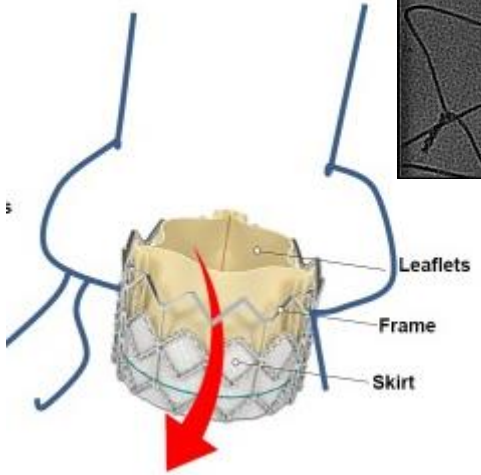
Sinning j-m et al; JACC 2013

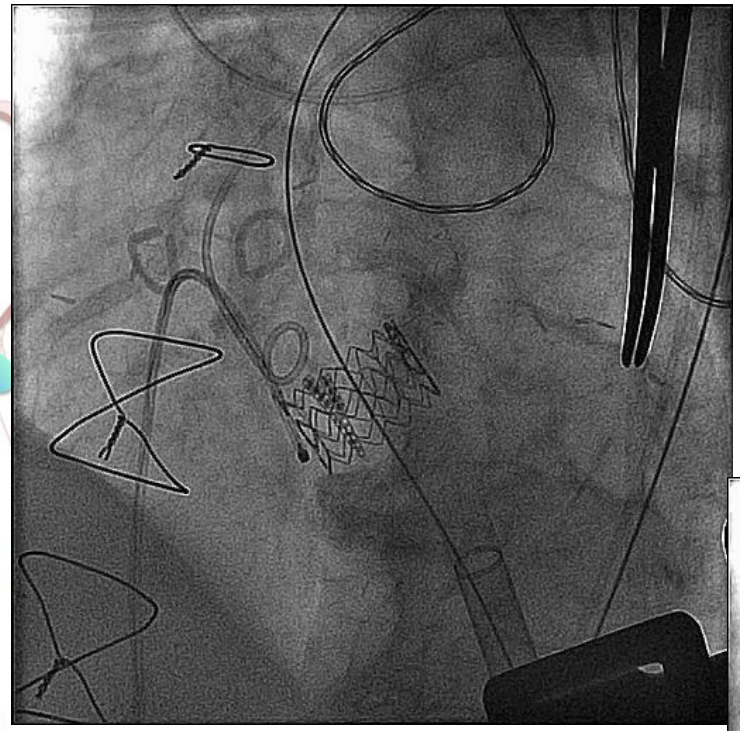


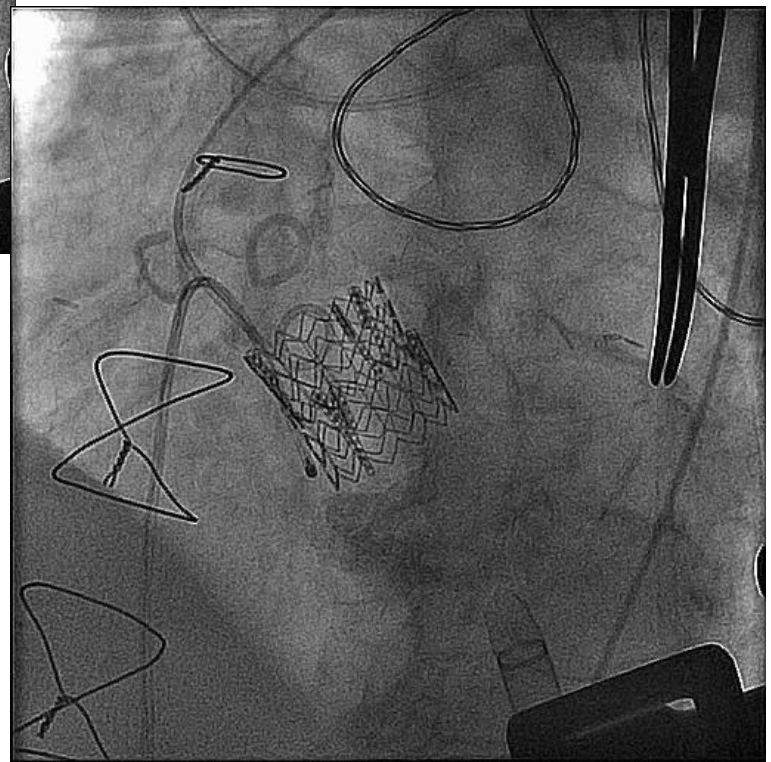
Pibarot P et al. J Am Coll Cardiovascular Imaging 2015. 8(3):340-360. http://dx.doi.org/10.1016/j.jcmg.2015.01.008

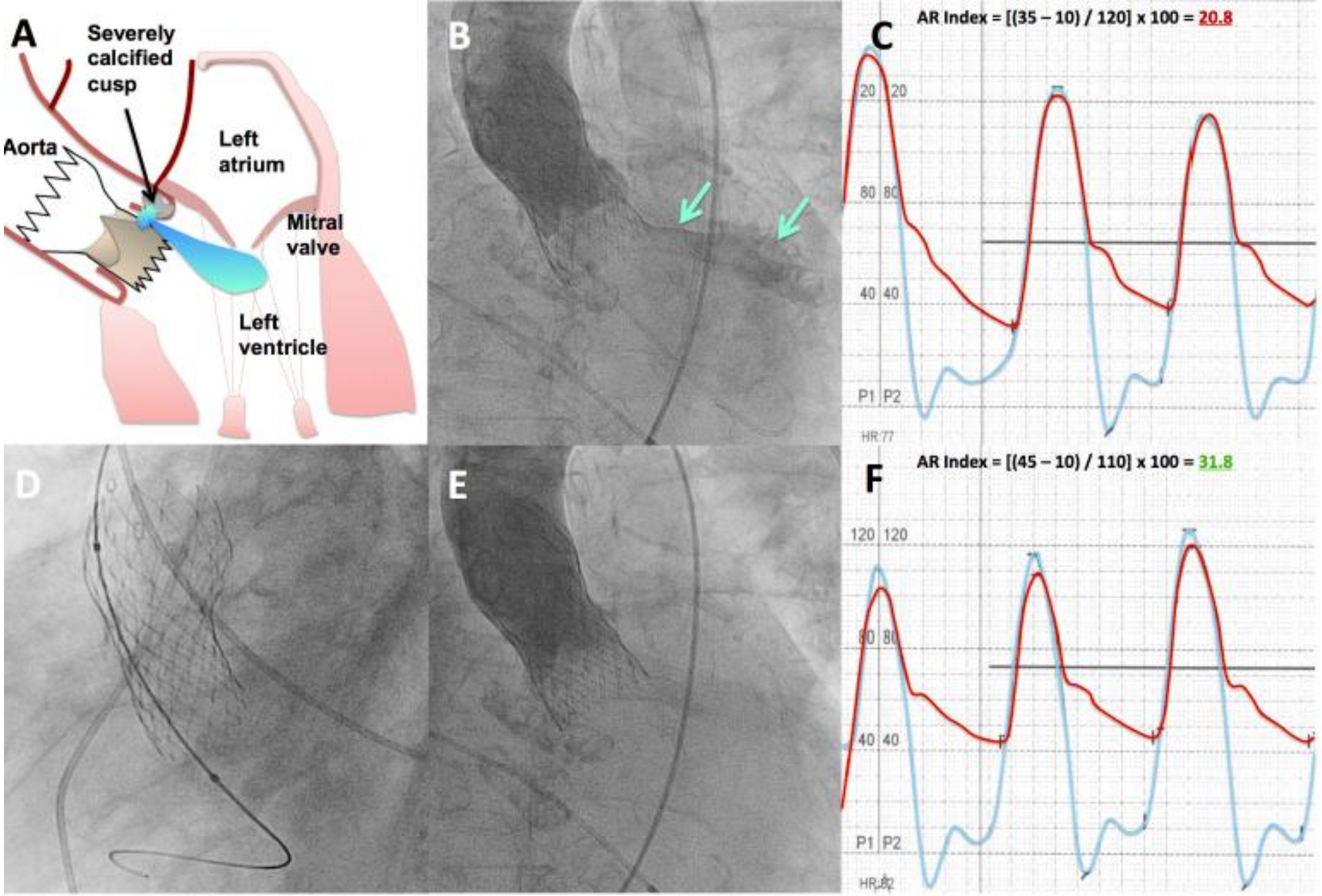
STRATEGY IN THE OR/CATHLAB











Sinning j-m et al; JACC 2013

Take home messages

- Improving results
- Need for standardization
  - Assessment
  - Actions taken

Merci