



TAVI: are we ready for low risk patients?

Christoph K. Naber

Klinik für Kardiologie

Stadtspital Triemli

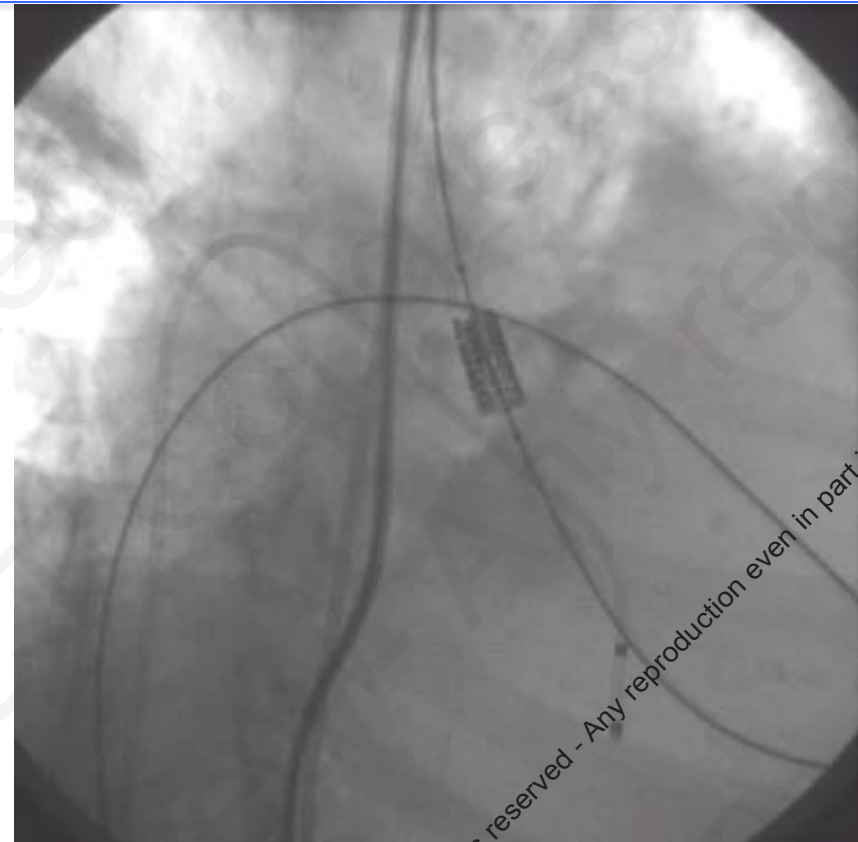
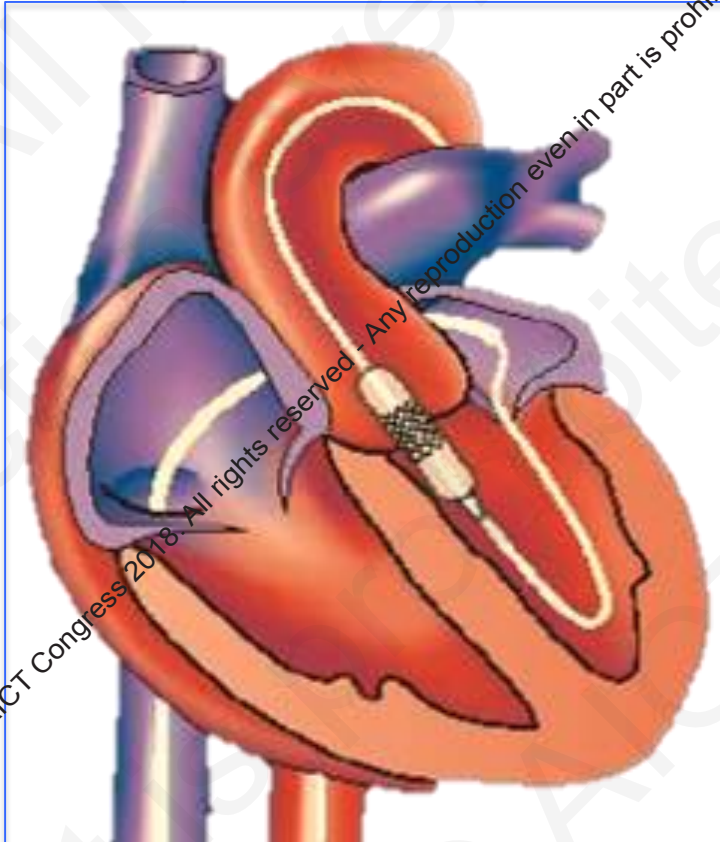
Zürich, Switzerland

2002: 1st TAVI in human



- **57-year-old patient**
- **severe AS**
- **cardiogenic shock**
- **major left ventricular dysfunction**
- **multiple comorbidities**

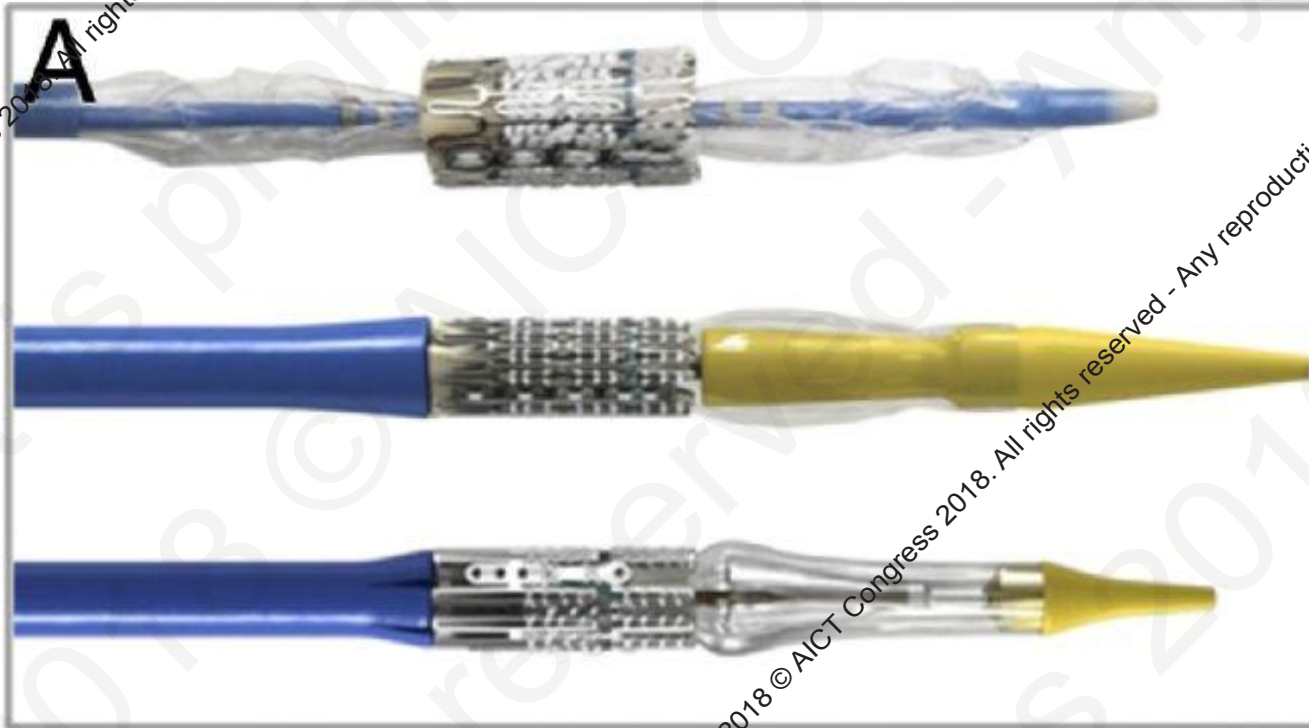
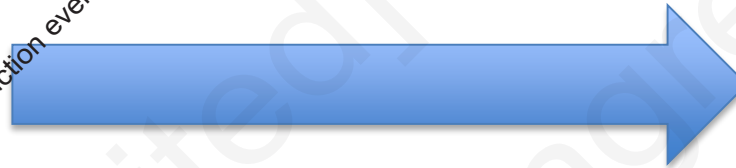
2002: first TAVI in human



2002: 1st TAVI in human



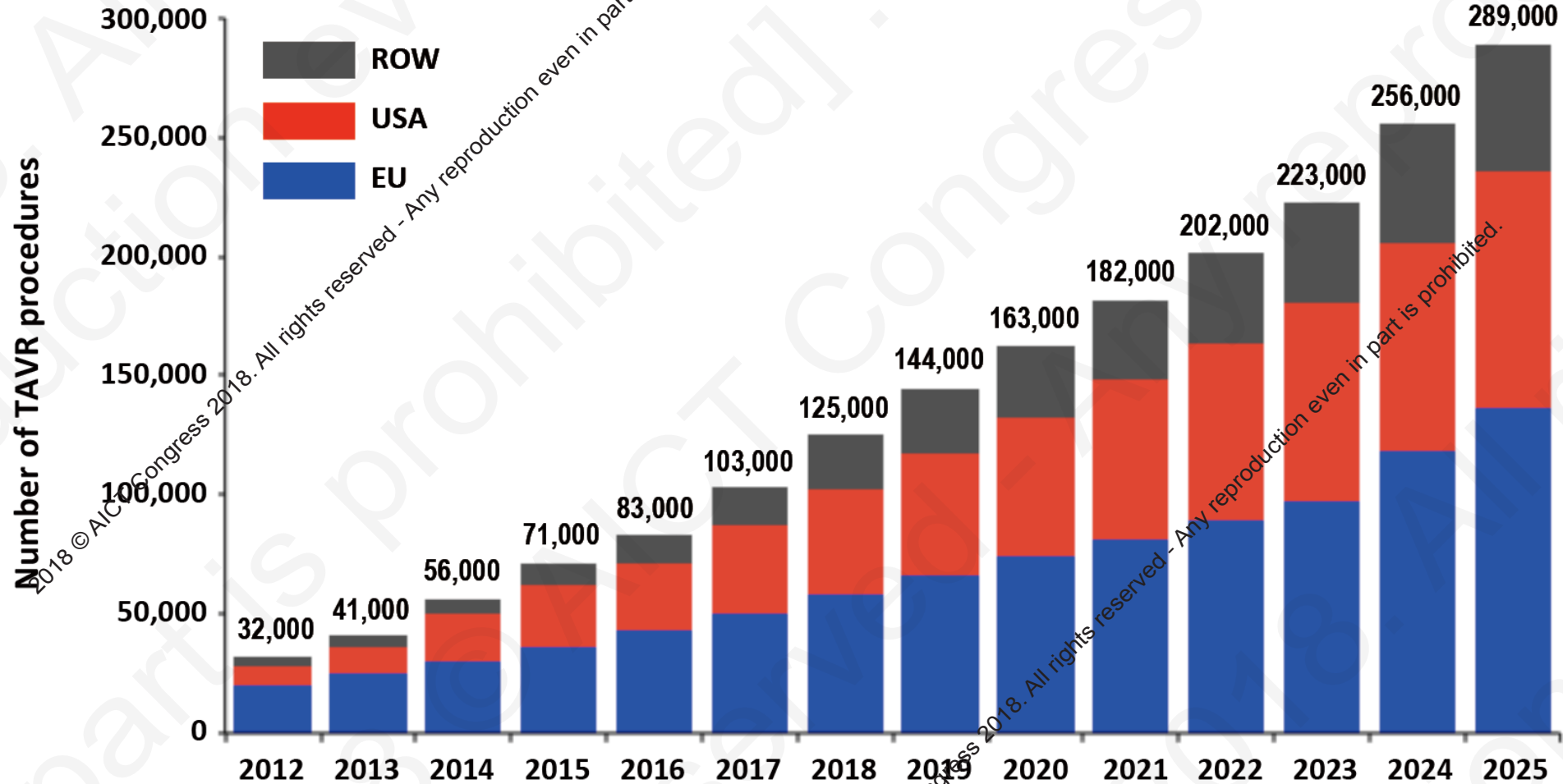
TAVI > 10 years



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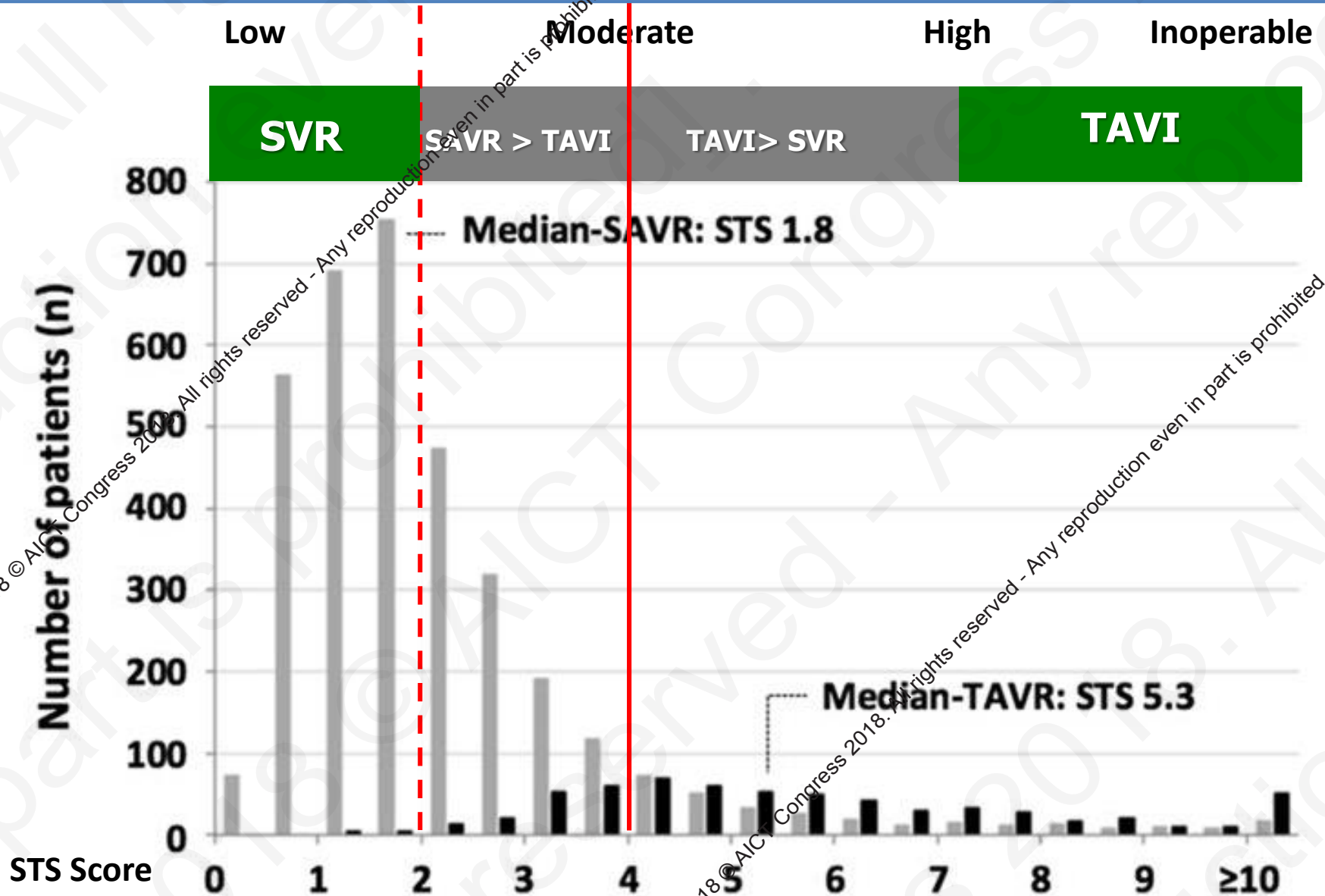
TAVI Worldwide



Credite Suisse 2015

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TAVI - Eligibility



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Operative Risk in TAVI Trials

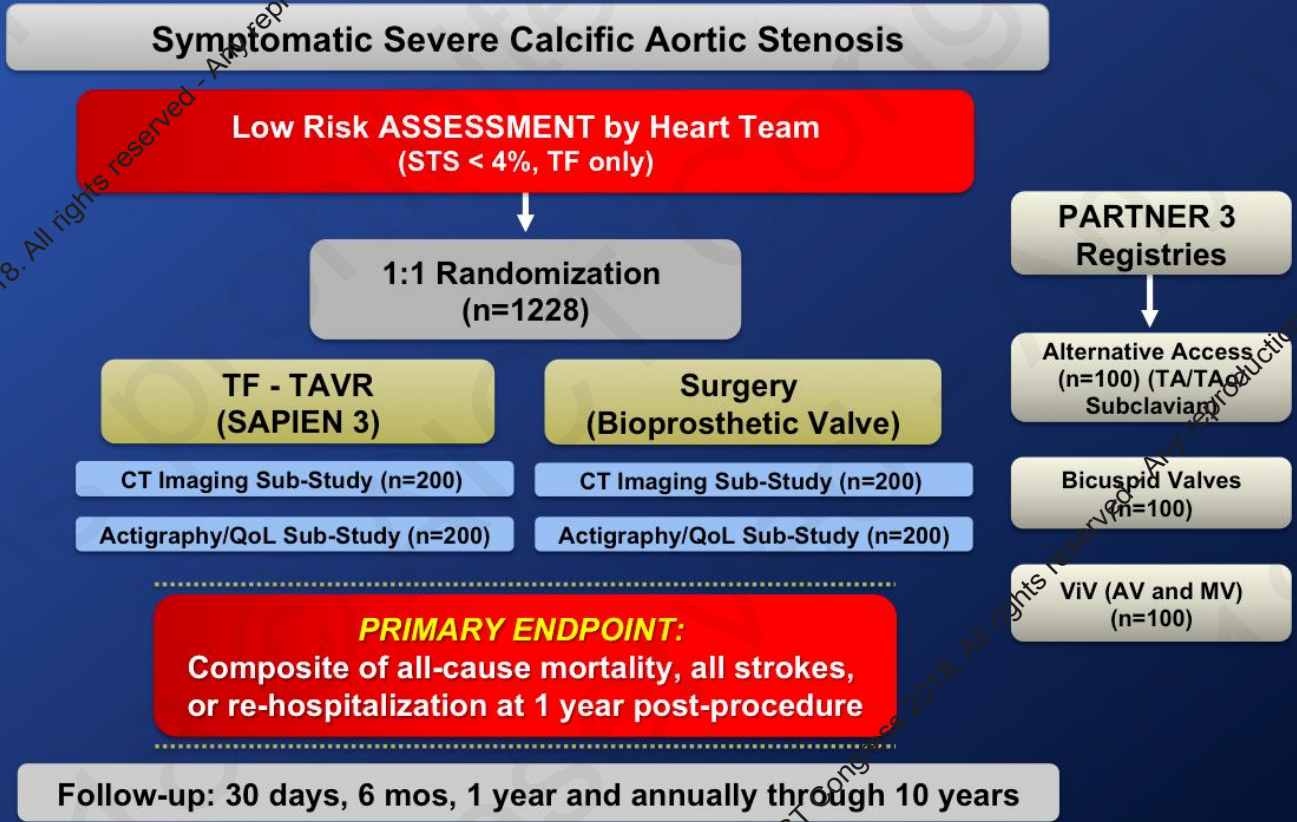


Trial	STS-PROM		Logistic Euroscore	
	SAVR/ST	TAVI	SAVR/ST	TAVI
PARTNER B	12.1 ± 6.1	11.2 ± 5.8	30.4 ± 19.1	26.4 ± 17.2
PARTNER A	11.7 ± 3.5	11.8 ± 3.3	29.2 ± 15.6	29.3 ± 16.5
US COREVALVE	7.5 ± 3.2	7.3 ± 3.0	18.4 ± 12.8	17.6 ± 13.0
PARTNER 2	5.8 ± 1.9	5.8 ± 2.1	NA	NA
SURTAVI	4.5 ± 1.6	4.4 ± 1.5	11.6 ± 8.0	11.9 ± 7.6
NOTION	3.1 ± 1.7	2.9 ± 1.6	8.9 ± 5.5	8.4 ± 4.0

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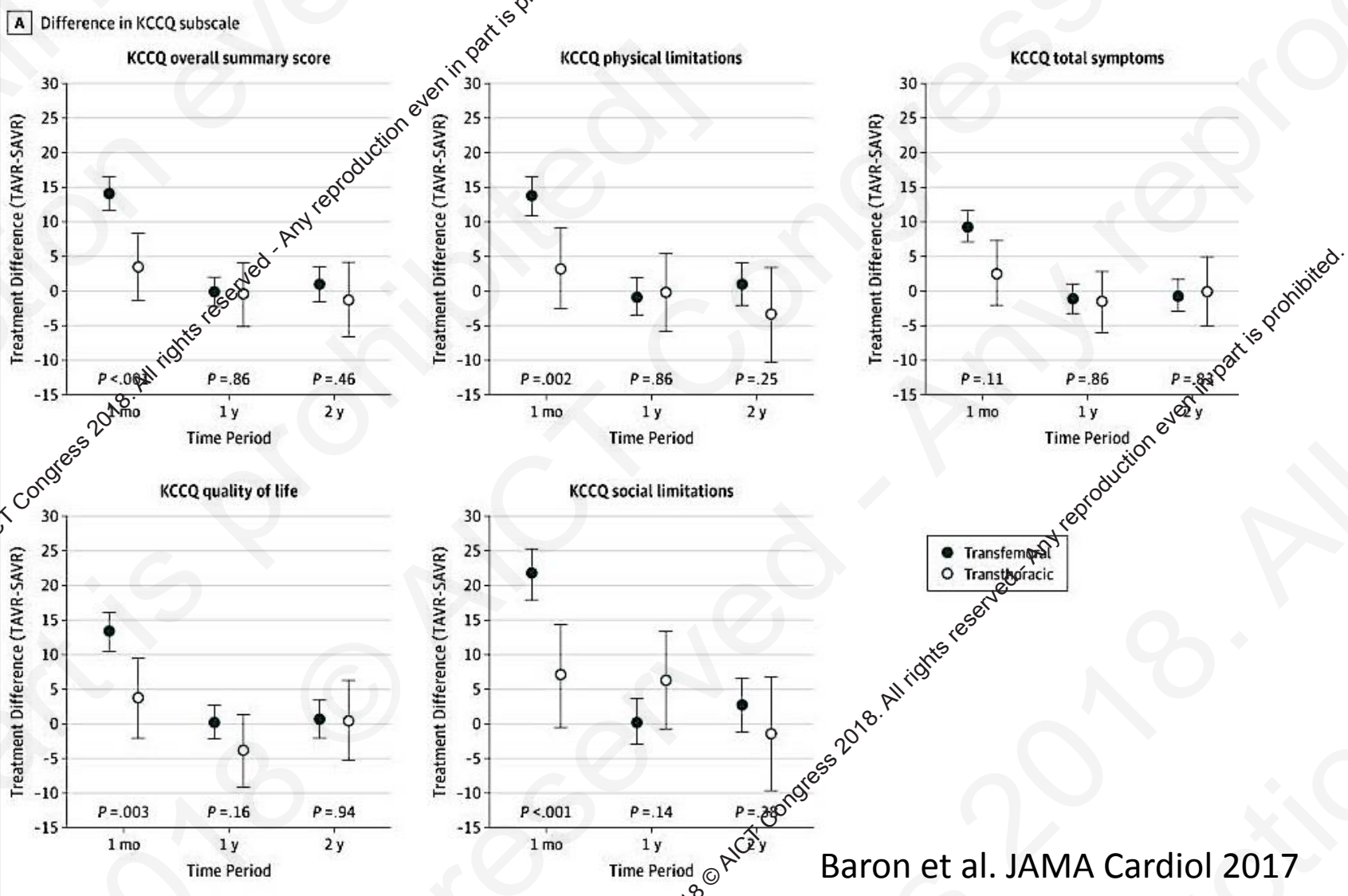
The PARTNER 3 Trial Study Design



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Partner 2: QoL TAVI vs. SAVR



Baron et al. JAMA Cardiol 2017

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AQUA 2015: Outcomes



AV Risk Score	In-hospital mortality		
	SAVR	TA-TAVI	TF TAVI
0 - < 3 %	1,08 % 82 / 7.606	2,43 % 17 / 700	1,92 % 56 / 2.914
3 - < 6 %	4,16 % 62 / 1.491	4,08 % 53 / 1.300	2,99 % 140 / 4.676
6 - < 10 %	9,33 % 32 / 343	7,30 % 36 / 493	5,23 % 78 / 1.491
≥ 10 %	27,68 % 75 / 271	13,14 % 51 / 388	10,72 % 108 / 1.007

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Metaanalysis: low risk TAVI

TABLE 1 Characteristics of studies included in the meta-analysis

Study	Publication year	Design	Sample size	Follow up	STS (mean)	EuroScore (mean)	Age (mean)	Female	Femoral access	NCOQA Score	Risk of bias ^a
Nielsen et al. [11]	2012	RCT	TAVR-34	3 months	3.1 ± 1.5	9.4 ± 3.9	80 ± 3.6	26.5%	0%	NA	Low
			SAVR-36		3.4 ± 1.2	10.3 ± 5.8	82 ± 4.4	33.3%	NA		
Thyregod et al. [10]	2015	RCT	TAVR-145	1 year	2.9 ± 1.6	8.4 ± 4.0	79.2 ± 4.9	53.8%	96.5%	NA	Low
			SAVR-135		3.1 ± 1.7	8.9 ± 5.5	79.0 ± 4.7	52.6%	NA		
Piazza et al. [21]	2013	PSM	TAVR-191	1 year	<4 ^b		NA	NA	NA	7	NA
			SAVR-191		<4 ^b		NA	NA	NA		
Schymik et al. [25]	2015	PSM	TAVR-216	3 years	-	8.7 ± 2.7	78.3 ± 5.2	46.3%	NA	8	NA
			SAVR-216			8.8 ± 2.8	78.2 ± 4.6	51.4%	NA		
Freker et al. [20]	2017	PSM	TAVR-805	In hospital	-	6.8 ± 1.7	77.5 ± 4.4	39.6%	100%	8	NA
			SAVR-805			4.2 ± 1.4	77.5 ± 4.4	39.6%	NA		
Rosato et al. [22]	2016	PSM	TAVR-355	3 years	-	6.3 ± 2.7	80.1 ± 6.4	58.0%	NA	9	NA
			SAVR-355			6.3 ± 3.0	80.0 ± 5.1	58.9%	NA		

^aAssessment included, selection, performance, attrition and reporting bias. Since none of the RCTs was blinded, detection bias was not relevant for assessment. assessment of bias was performed according to the Cochrane collaboration's tool for assessing risk of bias.

^bResults are from a subgroup analysis of patients with STS < 4 from a larger (405 patients) PSM study, the mean STS for this subgroup was not reported.

NA = not available, NCOQA = Newcastle Ottawa quality assessment, PSM = propensity score matching, RCT = randomized controlled trial, SAVR = surgical aortic valve replacement, STS = society of thoracic surgeons, TAVR = transcatheter aortic valve replacement.

Metaanalysis: low risk TAVI

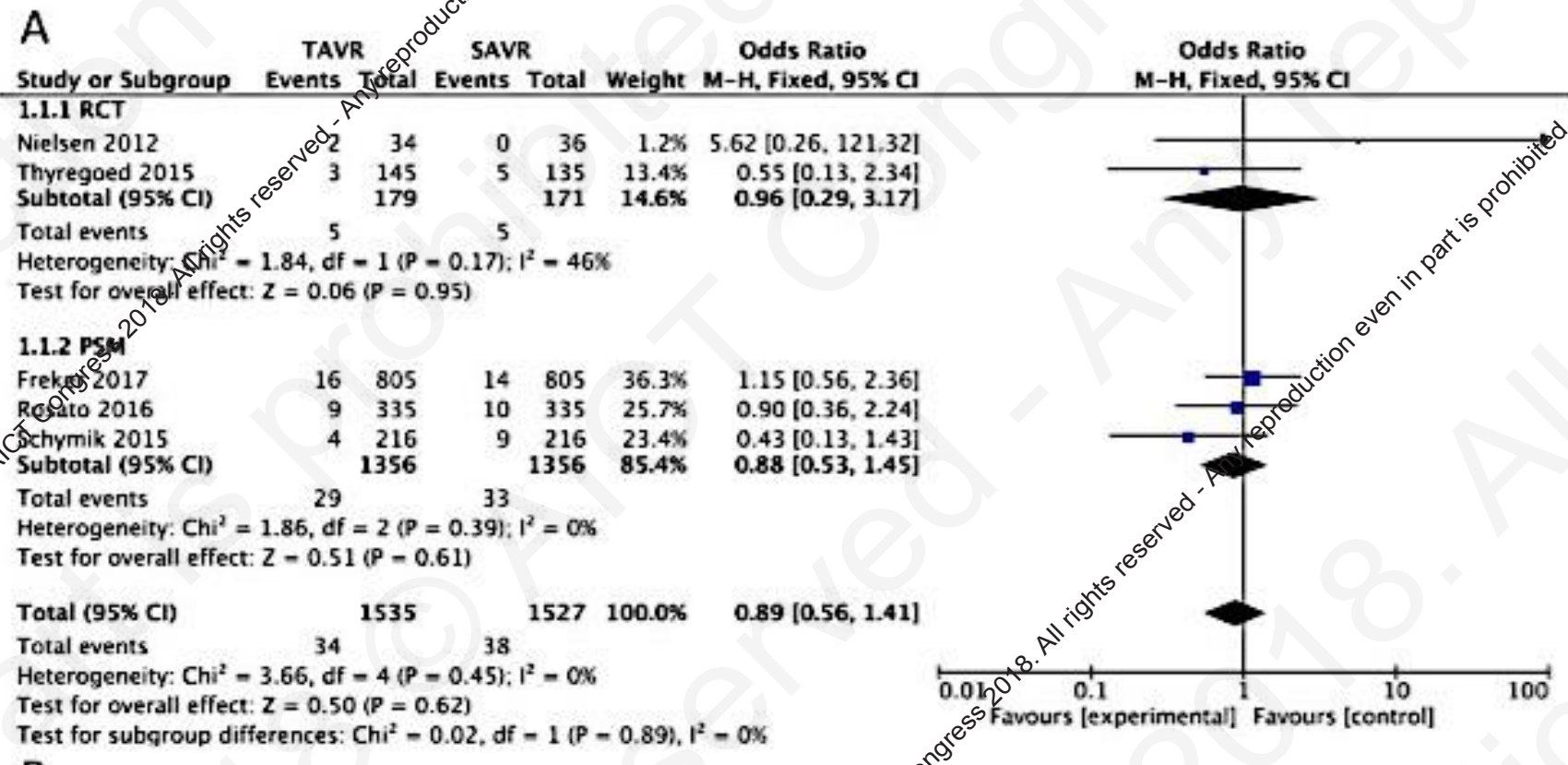


TABLE 3 Summary of periprocedural complications.

	TAVR rate	SAVR rate	OR(95% CI)
CVA			
Summary	22/1555 (1.4%)	24/1547 (1.5%)	0.91 (0.51-1.63)
MI			
Summary	9/1200 (0.75%)	15/1192 (1.26%)	0.59 (0.26-1.33)
AKI			
Summary	72/1555 (4.6%)	158/1547 (10.2%)	0.41 (0.31-0.55)
Bleeding			
Summary	36/1555 (2.3%)	86/1547 (5.5%)	0.39 (0.26-0.59)
PMI			
Summary	238/1555 (15.3%)	48/1547 (3.1%)	5.59 (4.07-7.67)
Vascular complications			
Summary	111/1521(7.3%)	8/1511 (0.5%)	13.14 (6.65-25.95)

AKI = acute kidney injury, CVA = cerebrovascular accident, MI = myocardial infarction, OR = odds ratio, PMI = pacemaker implantation, SAVR = surgical aortic valve replacement, TAVR = transcatheter aortic valve replacement.

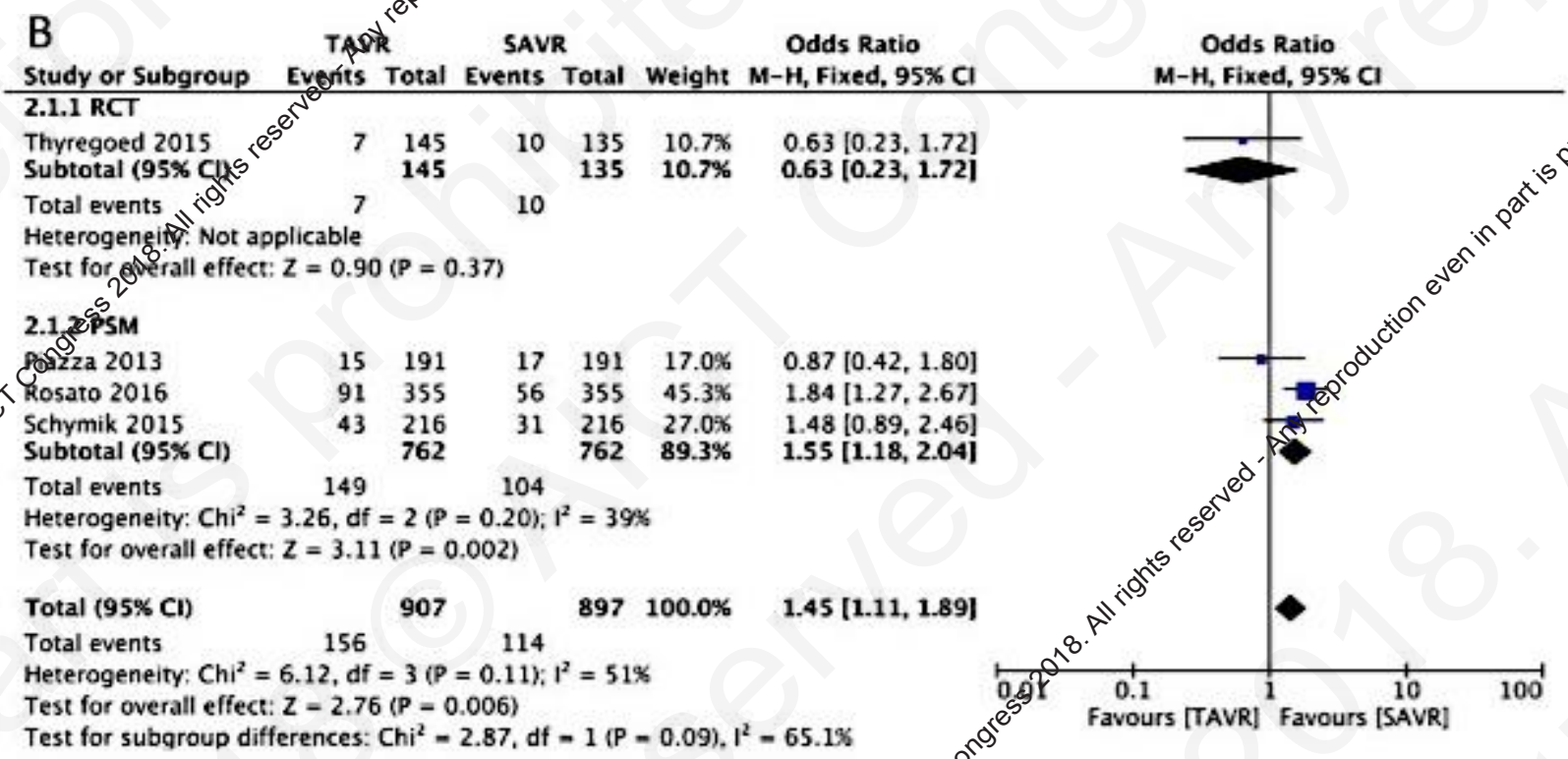
30 Day Mortality



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Late Mortality (1-3 years)



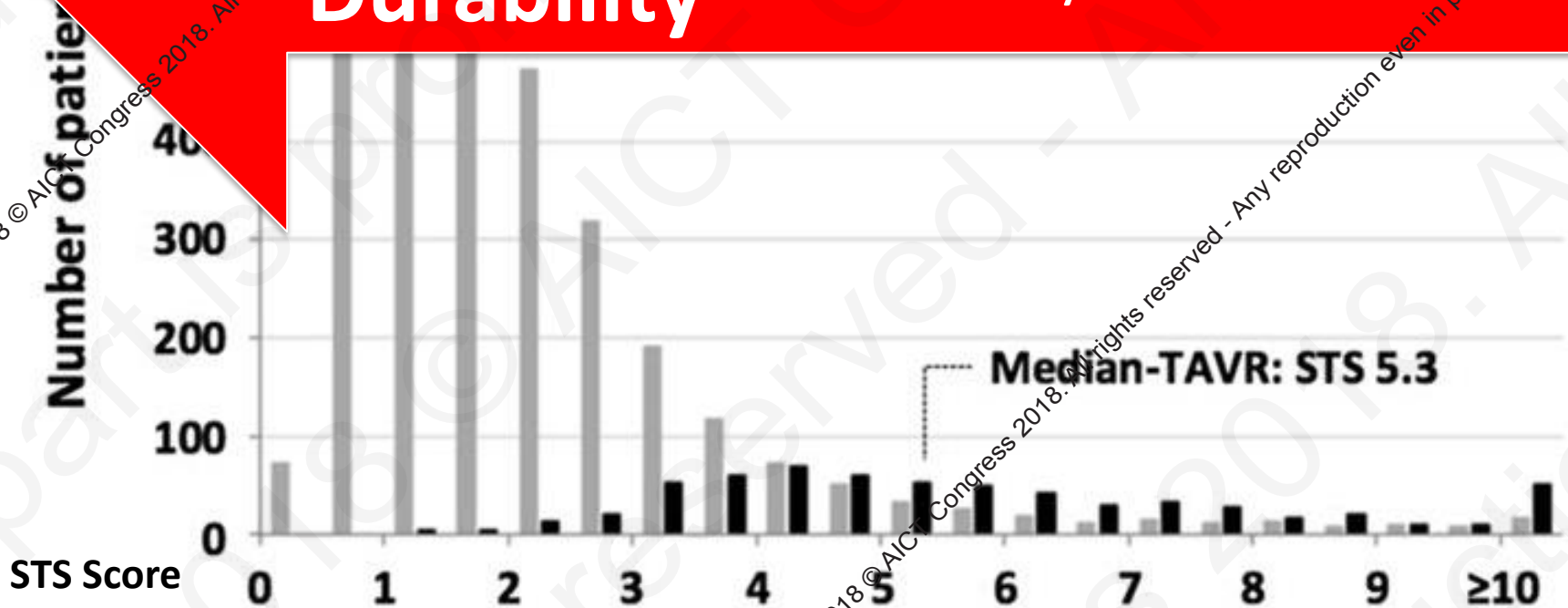
TAVI for low risk patients...



Efficacy
Safety
Durability

Efficacy
Safety
Durability

Efficacy
Safety
Durability



Structural Valve Deterioration

Historically defined as reoperation for SVD

~20 definitions of SVD using echocardiographic criteria since 2006

Definition	Reference	Journal, Year
Leaflet calcification, leaflet tear	Amabile et al ¹¹	<i>Journal of Thoracic and Cardiovascular Surgery</i> , 2014
Dysfunction or deterioration of the prosthesis (excluding infection or thrombosis) evident on echocardiography or at reoperation	Anselmi et al ¹²	<i>Journal of Thoracic and Cardiovascular Surgery</i> , 2014
Echocardiographic evidence of SVD	Ashikhmina et al ¹³	<i>Circulation</i> , 2011
Echocardiographic criteria (mean gradient >40 mm Hg or aortic insufficiency of grade 3 or 4 (based on a scale of 1 to 4))	Aupart et al ¹⁴	<i>Journal of Heart and Valve Disease</i> , 2006
Leaflet tear, leaflet prolapse, primary valve failure with significant regurgitation and increased NYHA class	Auriemma et al ¹⁵	<i>Journal of Heart and Valve Disease</i> , 2006
Echocardiographic evidence of severe aortic stenosis (mean transvalvular gradient >40 mm Hg) or severe aortic regurgitation (effective regurgitant orifice area >0.30 cm ² , vena contracta >0.6 cm), even if the patient was asymptomatic	Bourguignon et al ^{16,17}	<i>Annals of Thoracic Surgery</i> , 2015; <i>European Journal of Cardio-Thoracic Surgery</i> , 2016
Severe hemodynamic SVD is defined as (1) mean gradient ≥ 40 mm Hg or ≥ 20 mm Hg change from baseline (before discharge or within 30 days of valve implantation), or (2) severe new or worsening (>2/4) intraprosthetic aortic regurgitation	Capodanno et al ¹⁸	<i>European Heart Journal</i> , 2017
Increase in mean gradient of >10 mm Hg, decrease in Doppler Velocity Index <0.25, or development of new severe aortic regurgitation on consecutive aortic echocardiograms	Daubert et al ¹⁸	<i>Journal of the American College of Cardiology</i> , 2017
≥ 10 mmHg increase in transprosthetic mean gradient during follow-up compared with discharge assessment	Del Trigo et al ¹⁹	<i>Journal of the American College of Cardiology</i> , 2017
In accordance with 1996 guidelines (ie, a decrease of 1 NYHA functional class resulting from an intrinsic abnormality of the valve that causes stenosis or regurgitation, or a mean pressure gradient >40 mm Hg was observed)		



Hufnagel 1952 Starr-Edwards 1961 Björk-Shilley 1969 Carpentier-Edwards 1975 Hancock II 1976 St. Jude Medical 1977 Livanova Perceval S 2007 Symetis Accurate 2009 Caisson 2016

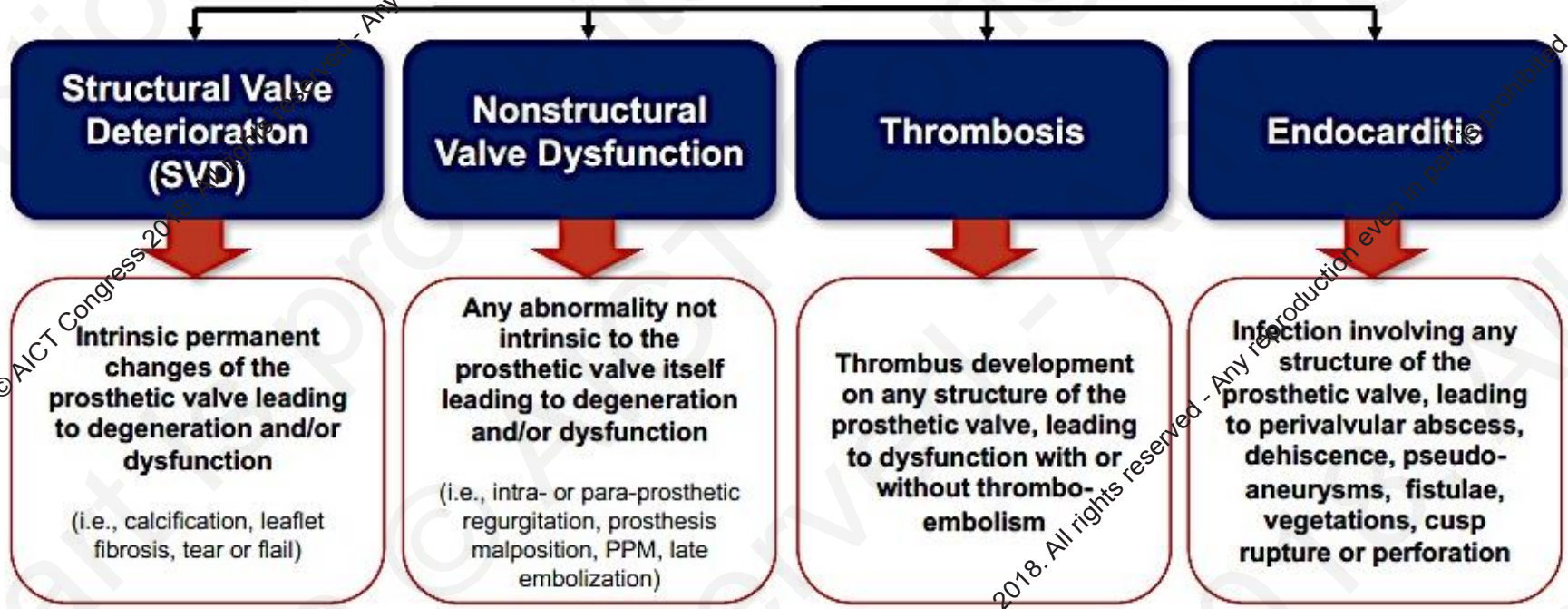
Dvir et al. *Circulation* 201

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EAPCI/ESC/EACTS Standardized Definitions

Bioprosthetic Valve Dysfunction (BVD)



Durability of Transcatheter Aortic Bioprostheses >5 Years Based on EAPCI/ESC/EACTS Definitions

Study	N	Valve	Follow-up	Survival*	Severe SVD	BVF
Sondergaard et al.	280	CoreValve	6 years	57.5%	0.7%	7.5%***
Deutsch et al.	300	Various	7 years	23.2%	- **	3.7%
Eltchaninoff et al.	378	Various BE	8 years	9.6%	3.2%	0.6%***
Barbanti et al.	288	Various	8 years	29.8%	5.9%	4.5%***
Holy et al.	152	CoreValve	8 years	27.0%	0%	4.5%***
Sokoloff et al.	589	Various	10 years	8%	8.0%	3.4%***
					~0-8%	~1-8%

*Actuarial analysis ** 14.3% moderate or severe SVD (cumulative incidence function)

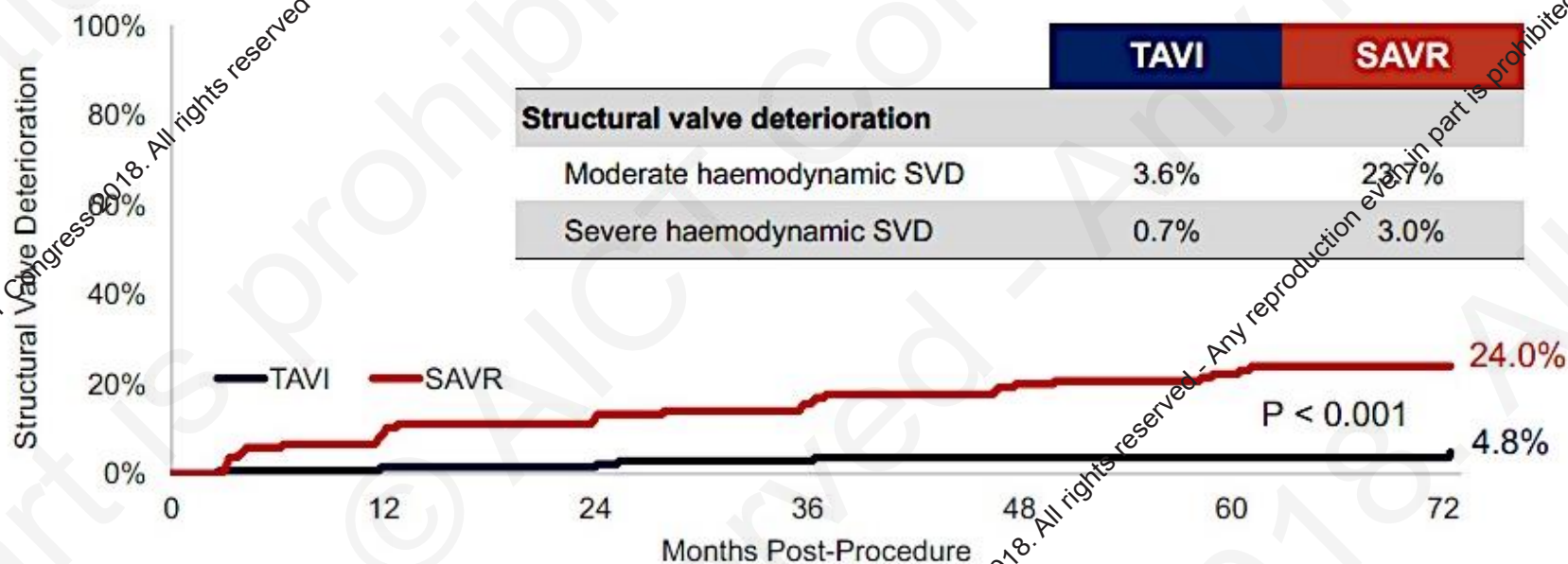
** Actual analysis (cumulative incidence function)

Abbreviations: BE, balloon-expandable

Eltchaninoff H, et al. EuroIntervention. 2018;14:264-71 | Deutsch MA, et al. EuroIntervention. 2018;14:41-9
 Barbanti et al. JAHA 2018 [Epub Ahead of print] | Holy EW, et al. EuroIntervention. 2018;14:e390-e396
 Sokoloff A, et al. Archives of Cardiovascular Diseases Supplements 2018; 10:220 (abstract)

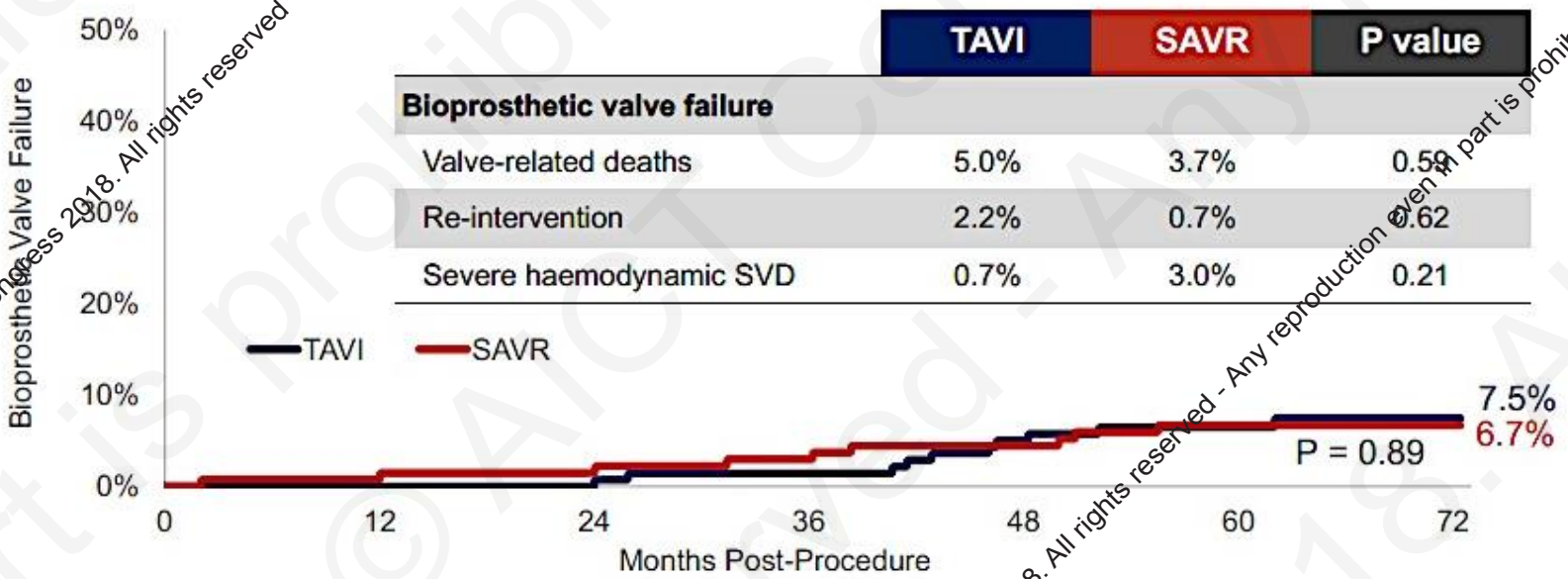
Head-to-Head Durability of TAVI vs SAVR 6-Year Outcomes of the NOTION trial 1/2

NOTION: 280 patients at low surgical risk randomized to TAVI or SAVR | Structural Valve Deterioration



Head-to-Head Durability of TAVI vs SAVR 6-Year Outcomes of the NOTION trial 2/2

NOTION: 280 patients at low surgical risk randomized to TAVI or SAVR | Bioprosthetic Valve Failure



ESC Congress
Munich 2018

Sondergaard L. Presented at: Structural Heart Disease Summit 2018, June 2018, Chicago

Pro:

- Periprocedural data show at least similar results for TAVI as for SAVR in low risk patients
- The immediate risk quality for each procedure is different, and mortality is similar, while TAVI patients usually have a shorter recovery time
- Current durability data indicate at least a similar durability for TAVI devices up to 10 years

Contra:

- current metaanalyses indicates a potentially higher late mortality for TAVI which requires further evaluation
- If „low-risk“ equals „younger“, then durability data beyond 10 years become important



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Thank you!

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7 - 9th September 2018

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