Essential Publications Euro/Asia Intervention

Valvular/Structural Interventions

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Speaker's name : Pieter, STELLA, Utrecht

☑ I have the following potential conflicts of interest to report:

Receipt of consultation fees: Keystone Heart, DEKRA

Physician Proctor : Acurate Valve, Boston Scientific

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EuroIntervention

July 2017

Left ventricular function determines the survival benefit for women over men after transcatheter aortic valve implantation (TAVI)

Bauer T.

Combined mitro-aortic pathology: impact of pr
of MitraClip therapy (from the German transca
D'Ancona G.

September 2017

Repositionable percutaneous aortic valve implan
outcomes in 250 high-risk surgical patients
Meredith I.

Insights into the need for permanent pacemaker
valve for transcatheter aortic valve replacement
with extended cohort
Dumonteil N.
Hawkins K.

Impact of pulmonary hypertension on in-hospital
replacement
Sutmann A.

Effect of reduced cardiac output on blood stasis
for valve thrombosis
Vahidkhah K.

October 2017

High-pressure balloon fracturing of small dysfunc
transcatheter aortic valve-in-valve implantation

October 2017

High-pressure balloon fracturing of small dysfunctiona
transcatheter aortic valve-in-valve implantation
Nielsen-Kudsk J.

Fracturing mechanics before valve-in-valve therapy o
Ihansen P.

Self-expanding transcatheter aortic valve implantation
early and midterm outcomes
Adamo M.

Transfemoral TAVI using the self-expanding ACURAT
multicentre "CE-approval cohort"
Möllmann H.

Transcatheter mitral valve replacement: long-term out
apically tethered device– a case series from a single
Duncan A.

Survival and cause of death after transcatheter aortic
and sex-matched background population
Thiele M.

Subclinical leaflet thickening and stent frame geometr
Buchs A.

Printed MDCT 3D models for prediction of left atrial ap
feasibility study
Goitein O.

Volume-outcome relationship with transfemoral transcatheter aortic valve implantation (TAVI): insights from the compulsory German Quality Assurance Registry on Aortic Valve Replacement (AQUA)
Nesthorn K.

Quantification of aortic valve calcification on contrast-enhanced CT of patients prior to transcatheter aortic valve implantation
Matthias Eberhardt*,

Parallel suture technique with ProGlide: a novel method for management of vascular access during transcatheter aortic valve implantation (TAVI)
Ott I.

November 2017

Transcatheter aortic valve implantation versus redo surgery for failing surgical aortic bioprostheses: a multicentre propensity score analysis
Spaziano M.

Transcatheter aortic valve implantation for mixed versus pure stenotic aortic valve disease
Abdelghani M.

Transcatheter edge-to-edge repair of lead-associated tricuspid regurgitation
Nam N.

December 2017

More than Enough !!

Topics I picked

1) New self expanding valve for TF TAVR & Reduction of Pacemaker rate post TAVR
2) Optimal anticoagulation after TAVR
3) (Optimal operator volumes)
4) New device for PFO closure

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Valvular/Structural Interventions

New self expanding valve for TF TAVR & Reduction of Pacemaker rate post TAVR

Real-world experience using the ACURATE neo prosthesis: 30-day outcomes of 1,000 patients enrolled in the SAVI TF registry; EuroIntervention 2018;13:e1764-e1770 published online November 2017 published online e-edition February 2018, By Helge Möllmann et al.

Very low pacemaker rate following ACURATE neo transcatheter heart valve implantation; EuroIntervention 2017;13:1274-1281 published online September 2017, by Stefan Toggweiler etal.

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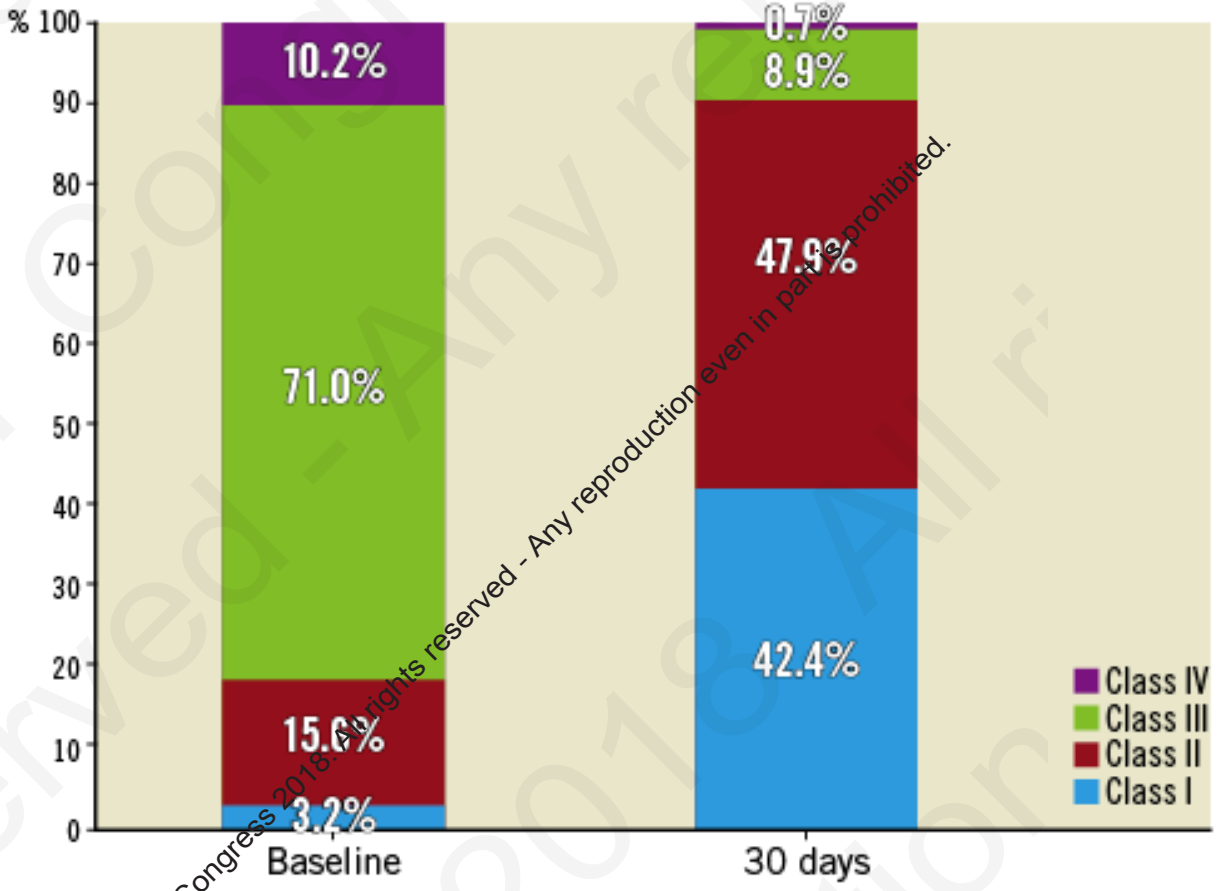
Table 2. Procedural characteristics.

		N=1,000
Predilatation		961 (96.1%)
Valve size	S	261 (26.1)
	M	431 (43.1)
	L	308 (38.0)
Device usage time[a] [min:sec]		6:34±6:18
Deployed with rapid pacing		487 (48.7)
Post-dilatation		448 (44.8)
Mitral valve apparatus damage or dysfunction		0 (0.0)
Annular rupture		0 (0.0)
Ventricular septal perforation		0 (0.0)
Procedural/device success		987 (98.7)
Valve-in-valve		9 (0.9)
Conversion to surgery		3 (0.3)
Aborted procedure		1 (0.1)

Data are displayed as n (%) or mean±SD. [a]Delivery system into sheath to delivery system removal post implant.



1 month outcomes in 1000 pts

Valvular/Structural Interventions

Table 3. Echocardiographic parameters at baseline and early follow-up.

	Baseline	7 days/discharge
Effective orifice area, cm²	N=865 0.72±0.20	N=416 1.77±0.46
Mean gradient, mmHg	N=872 42.7±15.2	N=807 8.4±4.0
Aortic regurgitation	N=871	N=844[a]
≤ Grade 1 (none to mild)	719 (82.5)	809 (95.9)
Grade 2 (moderate)	122 (14.0)	35 (4.1)
Grade 3 (moderate to severe)	22 (2.5)	0 (0.0)
Grade 4 (severe)	8 (0.9)	0 (0.0)

Data are displayed as n (%), unpaired data. [a]paravalvular leak.

Table 4. Clinical outcomes at 30 days.

	Total N=998[a]
Early safety[b]	86 (8.6)
Mortality	14 (1.4)
cardiovascular	10 (1.0)
Stroke	19 (1.9)
disabling	12 (1.2)
Life-threatening bleeding	13 (1.3)
Major bleeding	44 (4.4)
Acute kidney injury stage 2 or 3	13 (1.3)
Major vascular complication	32 (3.2)
Coronary obstruction requiring reintervention[c]	0 (0)
Repeat procedure	0 (0)
Myocardial infarction	3 (0.3)
Endocarditis	0 (0)
Valve thrombosis	0 (0)
Cardiac tamponade	4 (0.4)
New pacemaker implantation	83 (8.3)

Data are displayed as n (%). [a]1 patient withdrew consent after treatment, 1 did not return for 30-day visit. [b]a composite of all-cause mortality, all stroke, life-threatening bleeding, coronary obstruction requiring intervention, major vascular complication, acute kidney injury stage 2 or 3, and repeat procedure for valve-related dysfunction. [c]1 partial occlusion reported without need for intervention.

Abstract

Aims: The aim of the SAVI TF registry was to assess the safety and performance of the self-expanding ACURATE *neo* transfemoral transcatheter heart valve in a large patient population with severe aortic stenosis and to investigate whether the outcomes obtained in the CE-mark cohort can be replicated in an unselected all-comers population.

Methods and results: From October 2014 until April 2016, 1,000 patients were enrolled in this prospective, European multicentre registry. Patients were 81.1±5.2 years and had a logistic EuroSCORE II and STS score of 6.6±7.5% and 6.0±5.6%, respectively. Predilatation was performed in 96.1% of patients and post-dilatation in 44.8%. Procedural and device success were both obtained in 98.7%; failure comprised nine valve-in-valve procedures, three conversions to surgery, and one aborted procedure. The primary endpoint was 30-day mortality, which was observed in 14 patients (1.4% [95% CI: 0.7-2.1]). Disabling stroke was seen in 1.2% (95% CI: 0.5-1.9) and new pacemaker implantation in 8.3% (95% CI: 6.6-10.0). At discharge, mean effective orifice area was 1.77±0.46 cm² and mean gradient 8.4±4.0 mmHg; 4.1% of patients had a more than mild paravalvular leak.

Conclusions: In this initial experience, treatment with the ACURATE *neo* prosthesis resulted in good clinical outcomes with very low complication rates.

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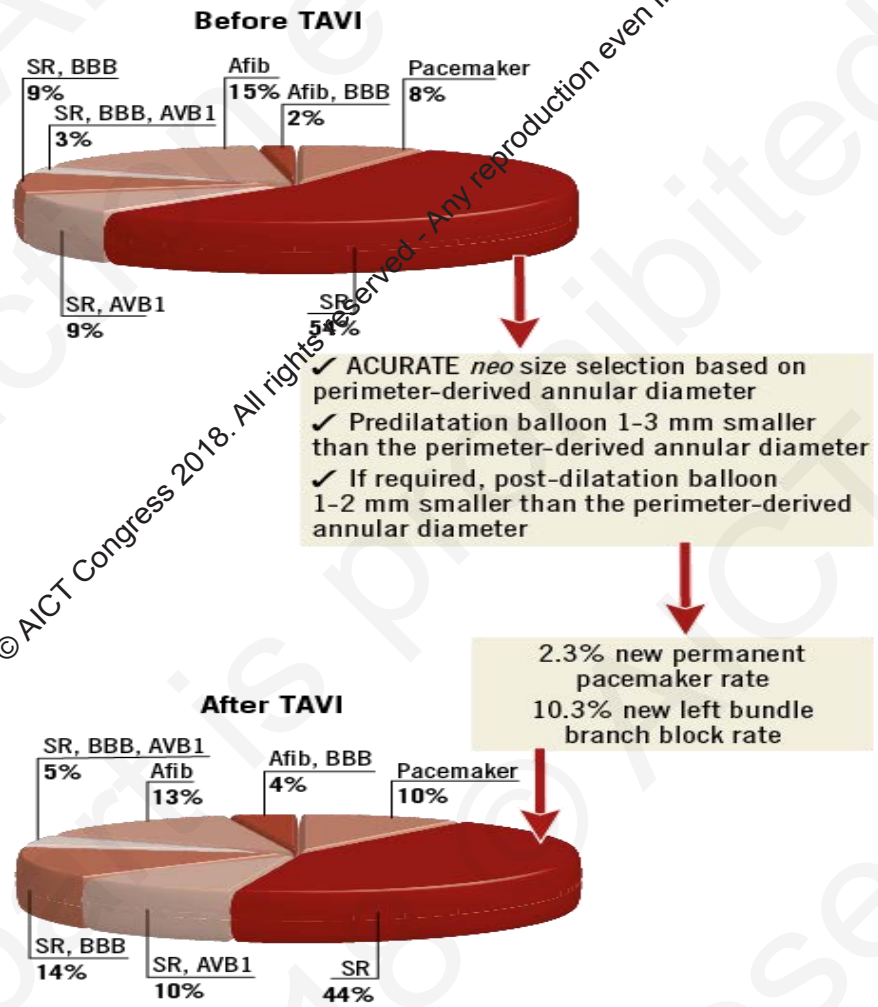

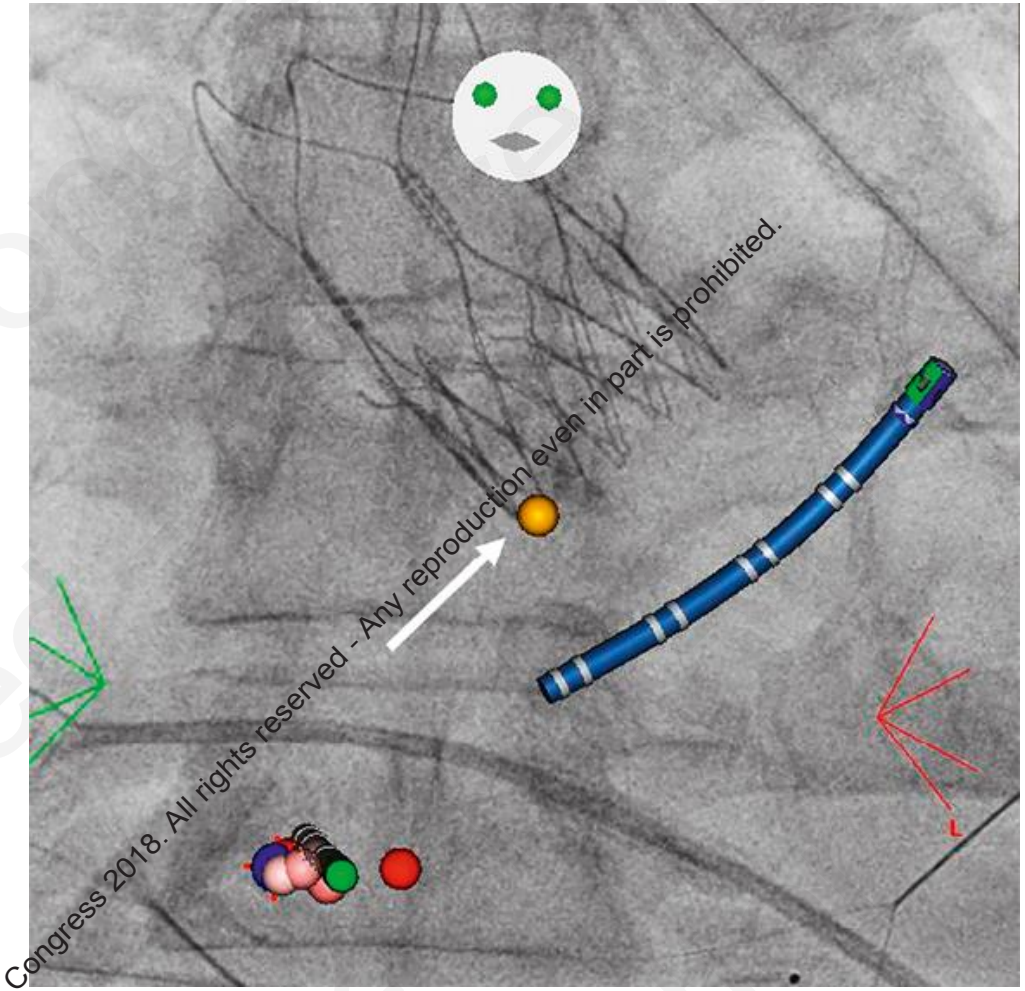

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Table 2. Procedural characteristics and post-procedural outcomes.

		All patients (n=175)	Patients without new conduction disorders (n=124)*	Patients with new conduction disorders (n=37)*	*p*-value
Perimeter-derived annular diameter, mm		24.0±1.5	23.9±1.5	24.1±1.2	0.11
Area-derived annular diameter, mm		23.5±1.4	23.4±1.5	23.9±1.1	0.16
Mean annular diameter, mm		23.6±1.5	23.5±1.6	24.0±1.1	0.20
Implanted valve size	S	31 (18%)	25 (20%)	4 (11%)	0.25
	M	75 (43%)	56 (44%)	15 (41%)	
	L	69 (39%)	44 (36%)	18 (47%)	
Valve oversizing, mm		1.4±0.8	1.4±0.8	1.4±0.8	0.99
Predilatation balloon size, mm		22.2±1.6	22.1±1.6	22.5±1.5	0.15
Predilatation balloon undersizing, mm		1.9±0.9	1.8±0.8	1.9±1.1	0.84
Need for post-dilatation		46 (26%)	37 (30%)	6 (16%)	0.10
Post-dilatation balloon size, mm		23.5±1.5	22.9±2.4	24.0±1.1	0.08
Post-dilatation balloon undersizing, mm		1.1±0.9	1.1±0.8	1.1±1.5	0.99
Implantation depth, mm		4.2±1.6	4.1±1.5	4.5±1.5	0.34
Aortic valve area, cm²		2.0±0.4	2.0±0.4	1.8±0.4	0.06
Mean gradient, mmHg		6.9±3.7	6.8±3.8	6.9±3.4	0.95
Para-valvular regurgitation	none/trace	66 (38%)	46 (37%)	12 (32%)	0.57
	mild	101 (58%)	73 (59%)	22 (59%)	
	moderate	8 (5%)	5 (4%)	3 (8%)	
Major vascular complication		12 (7%)	7 (6%)	5 (14%)	0.27
Major or life-threatening bleeding		13 (7%)	7 (6%)	5 (14%)	0.26
Median duration of hospitalisation, range		3 (1-38)	3 (1-38)	4 (2-28)	0.95
Any stroke at 30 days		3 (2%)	3 (2%)	0 (0%)	0.34
Mortality at 30 days		1 (1%)	0 (0%)	1 (3%)	0.07

*Patients with a prior pacemaker were excluded from subgroup analysis.

Table 3. ECGs in patients requiring a permanent pacemaker.

Patient	ECG at baseline	ECG after 24 hrs	Reason for pacemaker	Timing pacemaker implant
1	RBBB	Third-degree AVB	Third-degree AVB	Procedure day
2	Unremarkable	Short episode of high-degree AVB on telemetry	Third-degree AVB	Day 4
3	RBBB, atrial fibrillation	Third-degree AVB	Third-degree AVB	Next day
4	RBBB	RBBB, first-degree AVB	Delayed high-degree AVB on day 5	Day 6

4/175 = 2.3 % new PM rate !

Abstract

Aims: The aim of this study was to investigate whether minimising trauma to the aortic annulus and left ventricular outflow tract reduces the occurrence of new conduction disorders and the need for permanent pacemakers.

Methods and results: A total of 175 patients (58% female, mean age 83±6 years) underwent transfemoral TAVI with the Boston Scientific ACURATE *neo* at three centres in Europe. Prosthesis size selection was based on perimeter-derived annular diameter. Predilatation was performed in all with a balloon 1.9±0.9 mm smaller than the perimeter-derived annular diameter. Post-dilatation was performed in 46 (26.3%) with a balloon 1.2±0.9 mm smaller than the perimeter-derived annular diameter. Eighteen patients (10.3%) developed a new left bundle branch block, 13 (7%) a new first-degree AV block, and four (2.3%) received a new permanent pacemaker. Paravalvular regurgitation was none/trace in 66 (37.7%), mild in 101 (57.7%) and moderate in eight (4.6%). At 30 days, the rate of any stroke was 1.7% (3/175), and one patient (0.6%) had died.

Conclusions: With careful selection of the balloon and the ACURATE *neo* prosthesis size, very low rates of new conduction disorders and permanent pacemaker implantation may be achieved without increasing the amount of paravalvular regurgitation.

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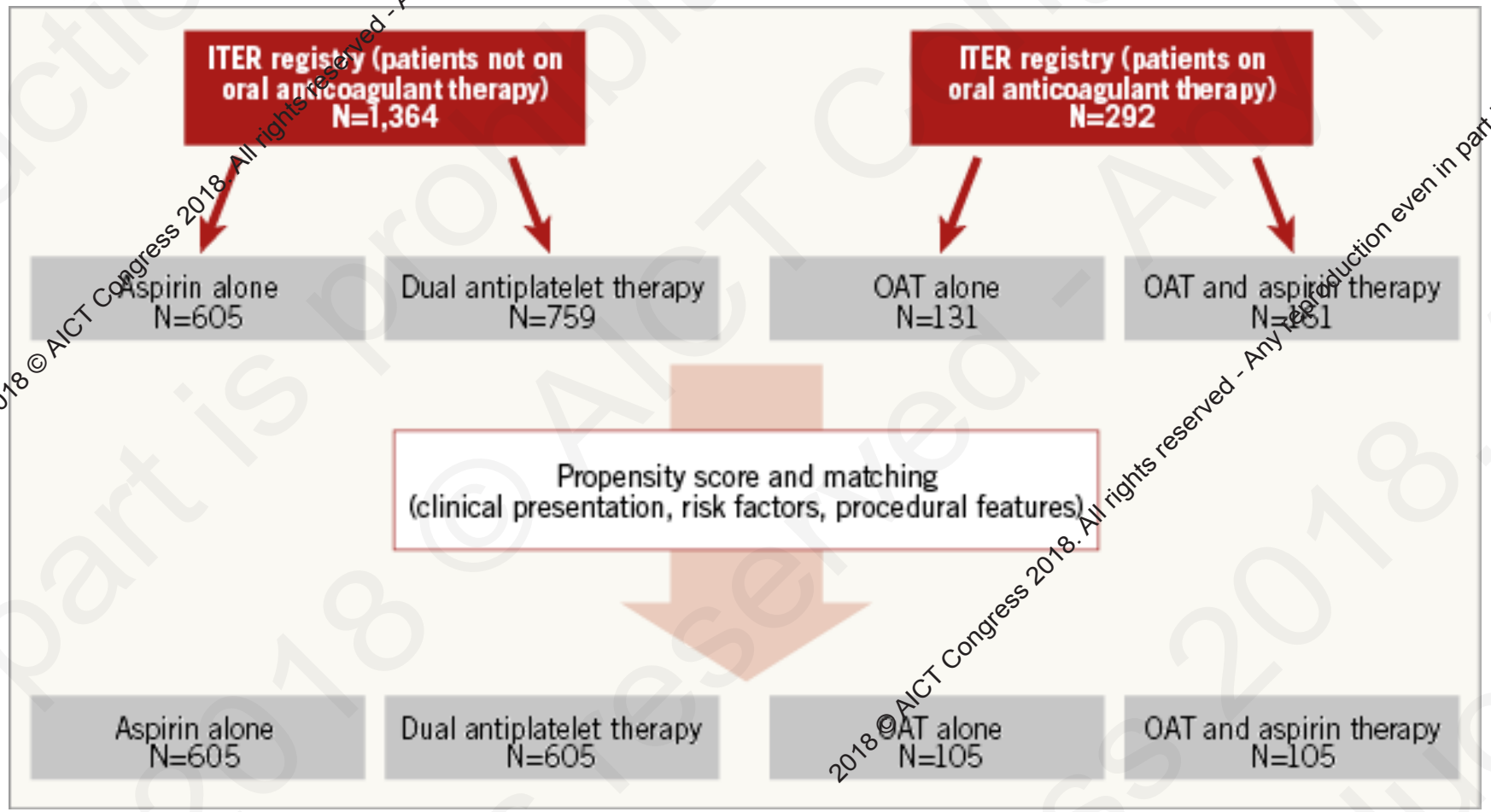
Which is the best antiaggregant or anticoagulant therapy after TAVI? A propensity-matched analysis from the ITER registry. The management of DAPT after TAVI; EuroIntervention 2017;13:e1392-e1400 published online September 2017 published online e-edition December 2017, by Fabrizio d'Ascenzo etal.



Valvular/Structural Interventions

Table 4. Summary of the main results of the study in patients treated with antiplatelet/anticoagulation therapy.

	Aspirin only (N=605) (%)	DAPT (N=605) (%)	*p*-value
30-day follow-up			
All-cause death	1.5	4.5	0.002
Major vascular complication	5.3	12.3	<0.001
Minor vascular complication	4.6	7.9	<0.001
Major bleeding	6.7	12.3	<0.001
Minor bleeding	2.0	7.3	<0.001
Life-threatening bleeding	7.6	9.8	0.65
Stroke	1.6	1.8	0.58
Long-term follow-up			
Prosthetic heart valve dysfunction	2.8	3.0	0.50
All-cause death	26.0	27.0	0.69
Major bleeding	1.4	4.0	<0.001
Stroke/TIA	0.7	1.5	0.13
	OAT only (N=105) (%)	**OAT and aspirin (N=105) (%)**	***p*-value**
30-day follow-up			
All-cause death	2.9	5.7	0.44
Life-threatening bleeding	4.8	11.4	<0.001
Long-term follow-up			
Prosthetic heart valve dysfunction	2.9	2.9	0.65
Major bleeding	2.9	4.8	0.36
Stroke/TIA	2.9	3.8	0.50

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Abstract

Aims: The safety and efficacy of single vs. dual antiplatelet therapy (DAPT) in patients undergoing TAVI remain to be addressed. The aim of our study was to evaluate the usefulness of a DAPT compared to a single platelet therapy in patients undergoing TAVI with a balloon-expandable prosthesis.

Methods and results: All consecutive patients enrolled in the ITER registry were included. Patients undergoing TAVI discharged with aspirin alone were compared to those taking DAPT before and after selection using propensity score with matching. Subgroup analysis was performed for those on OAT. Prosthetic heart valve dysfunction at follow-up was the primary endpoint, whereas all-cause death, cardiovascular death, bleedings, vascular complications and cerebrovascular accidents were the secondary ones. From 1,364 patients, after propensity score with matching, 605 were selected for each group (aspirin alone vs. DAPT). At 30 days, rates of VARC mortality were lower in patients with aspirin alone (1.5% vs. 4.1%, p=0.003), mainly driven by a reduction of major vascular complications (5.3% vs. 10.7%, p<0.001) and of major bleedings (6.6% vs. 11.5%, p<0.001), without a difference in prosthetic heart valve dysfunction after 45±14 months (2.8% vs. 3.0%, p=0.50). These results were confirmed on multivariable analysis.

Conclusions: After TAVI with a balloon-expandable prosthesis, aspirin alone does not increase the risk of prosthetic valve dysfunction, and reduces the risk of peripro-cedural complications and of 30-day all-cause death.

Volume-outcome relationship with transfemoral transcatheter aortic valve implantation (TAVI): insights from the compulsory German Quality Assurance Registry on Aortic Valve Replacement (AQUA; EuroIntervention 2017;13:914-920, by Kurt Bestehorn etal

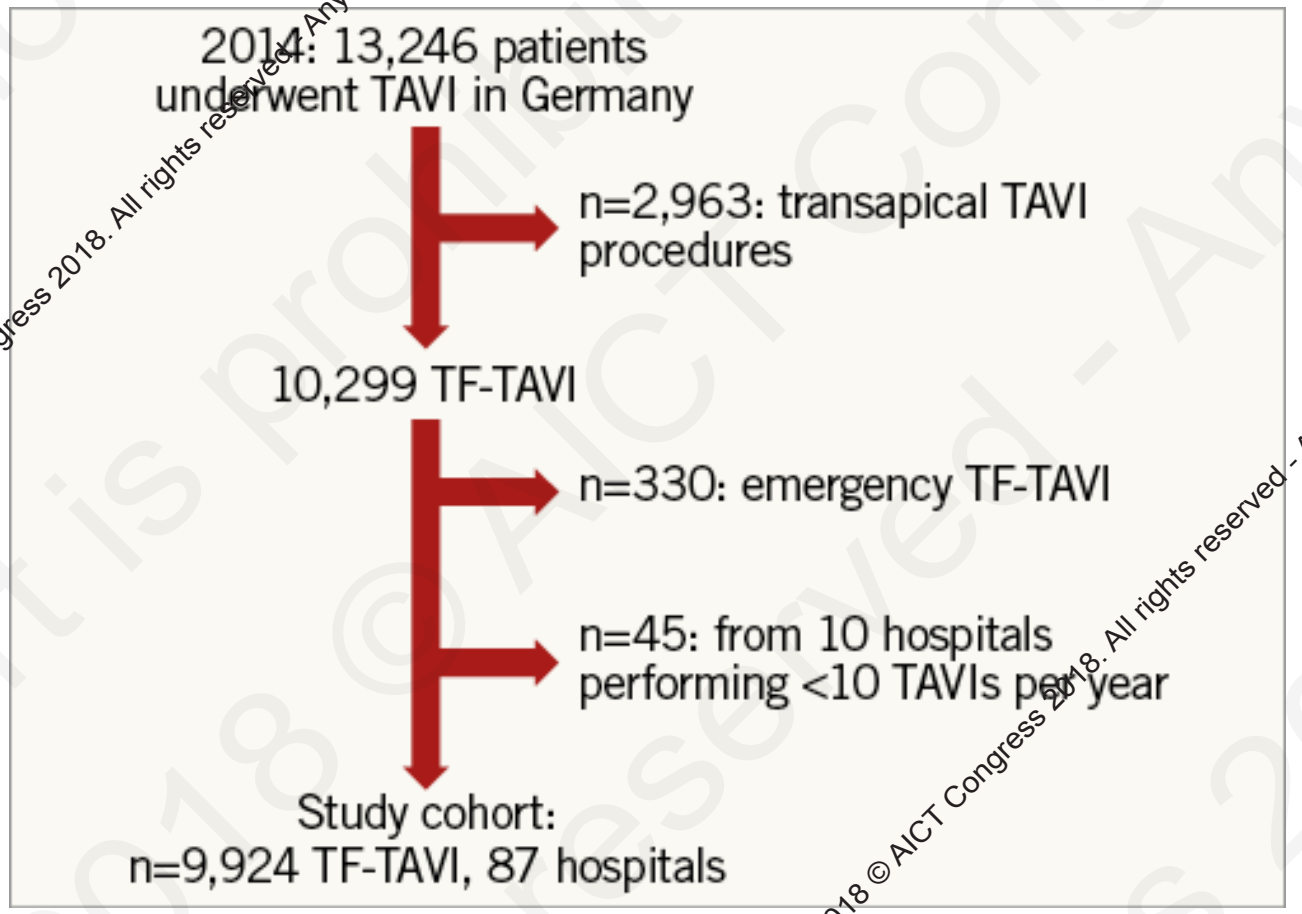

Table 2. Periprocedural and post-procedural data according to annual number of TAVI procedures performed per hospital.

Annual number of TF-TAVI procedures	<50	50-99	100-149	150-199	≥200	*p*-value (Welch's test)
Number of hospitals	22	19	25	7	14	–
In-hospital mortality (%)	5.6±5.0	5.0±2.9	4.0±2.6	3.4±1.8	2.4±1.0	<0.001
Cerebrovascular event (%)	2.4±2.9	3.2±1.8	1.9±1.9	2.9±1.9	2.1±0.9	<0.001
Myocardial infarction (%)	0.1±0.5	0.5±1.1	0.3±0.6	0.1±0.2	0.3±0.4	0.1659
Low cardiac output (%)	4.2±6.5	3.0±2.8	2.2±2.2	2.6±2.6	0.9±0.7	<0.001
Resuscitation (%)	3.7±4.5	3.5±2.7	2.5±1.6	2.2±1.4	2.0±1.2	<0.001
Need for transient dialysis (%)	2.6±3.2	2.5±2.7	1.8±1.3	1.2±1.0	1.5±0.8	<0.001
Need for permanent dialysis (%)	1.7±2.7	2.5±3.3	2.0±1.7	0.6±1.0	1.9±1.3	<0.001
Overall length of stay (days)	19±6	20±5	17±3	15±3	14±4	<0.001
Days from TAVI to discharge	11±3	12±2	10±1	10±2	9±2	<0.001
Procedure times (min)	96.2±25.3	98.8±20.6	74.2±19.3	71.2±18.3	78.9±22.9	<0.001

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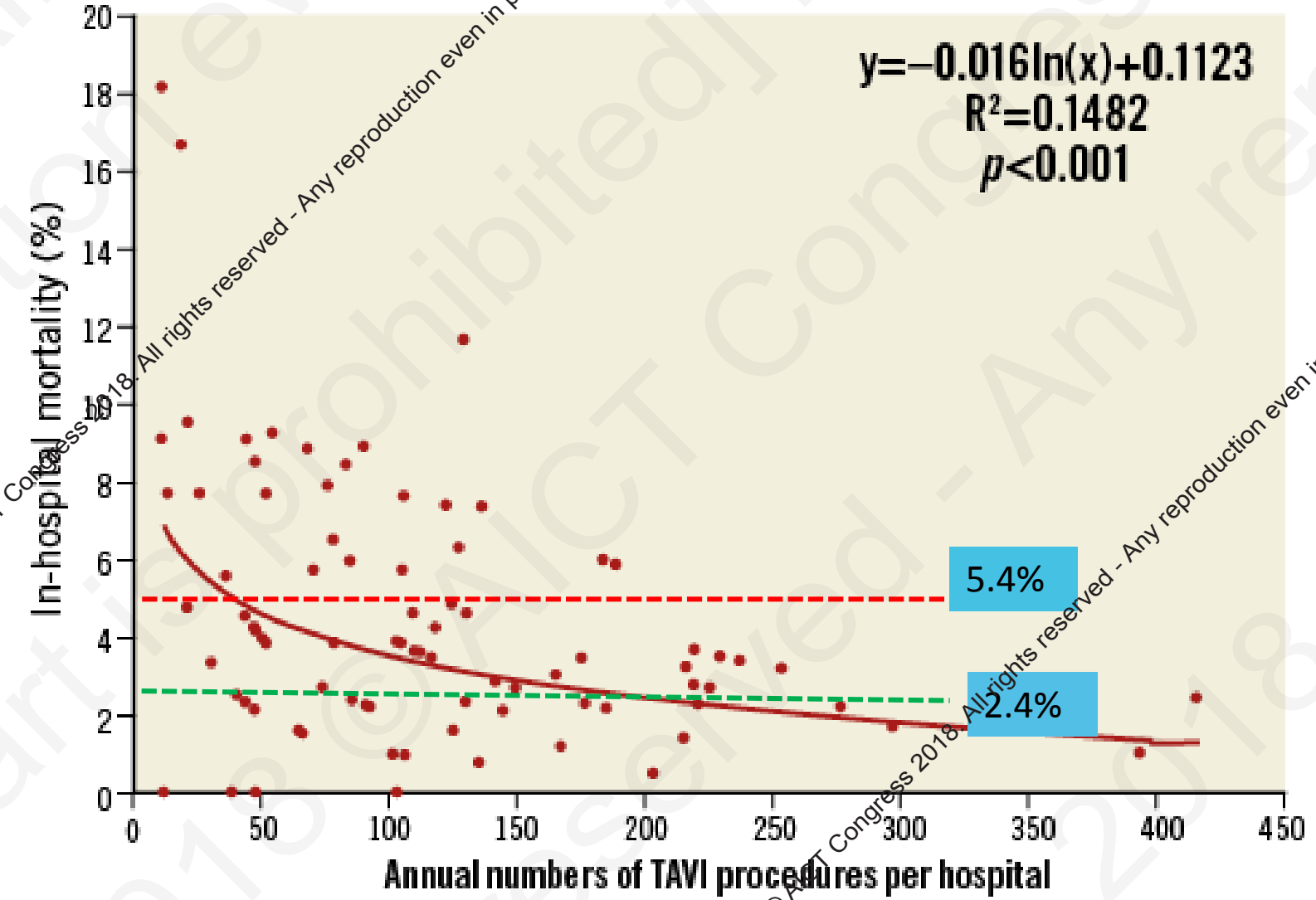

Abstract

Aims: Previous studies have shown lower rates of in-hospital complications and mortality for patients undergoing surgical aortic valve replacement (sAVR) in high-volume compared with lower-volume hospitals. It was the aim of our study to analyse whether there is a similar volume-outcome relationship for transcatheter aortic valve implantation (TAVI), which is increasingly used in clinical practice.

Methods and results: We analysed all patients with non-emergent transfemoral (TF) TAVI procedures performed in 2014 in 87 German hospitals. We used the German Aortic Valve score 2.0 to calculate the ratio of observed versus expected (O/E) in-hospital mortality. A total of 9,924 patients (age 81.4±1.1 years, 45.3% male, median log EuroSCORE 18.71%, IQR 4.55) were included. Average observed mortality was 4.3±3.3%, while the expected average mortality was 5.4±1.4% (mean O/E ratio: 0.8). Average in-hospital mortality was 5.6±5.0% (range, 0 to 16.7%) in the lowest volume group of hospitals performing <50 TF-TAVI annually compared to 2.4±1.0% (range, 0.5 to 3.7%) in the highest volume hospitals with ≥200 TF-TAVI procedures per year. There was a continuous, statistically significant association of lower O/E ratios with increasing TF-TAVI volumes ($p<0.001$), but without a clear-cut threshold. Major complications, neurologic events, and rates of new pacemaker implantation were not different between low- and high-volume hospitals.

Conclusions: Across the spectrum of hospital volumes from 11 to 415 patients undergoing TF-TAVI per year in Germany, there was a continuous, statistically significant association of lower average observed as well as risk-adjusted in-hospital mortality with increasing TF-TAVI volumes.

Novel percutaneous suture-mediated patent foramen ovale closure technique: early results of the NobleStitch EL Italian Registry;
EuroIntervention 2018;14:e272-e279 published online April 2018 published online e-edition June 2018, by Achille Gaspardone etal

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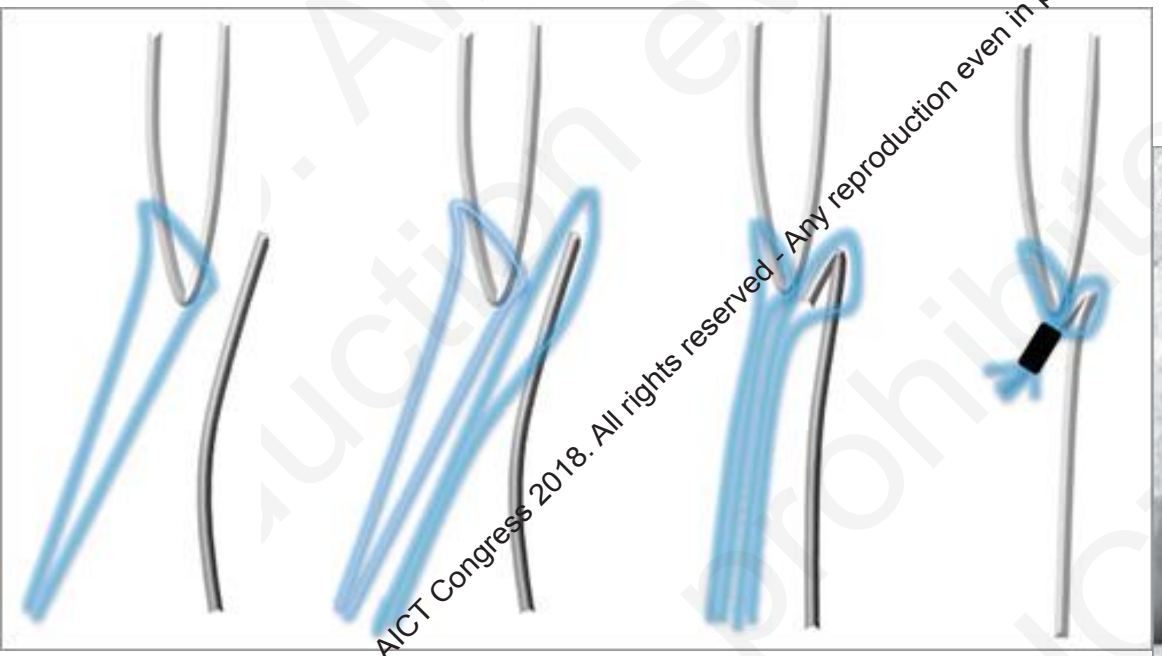

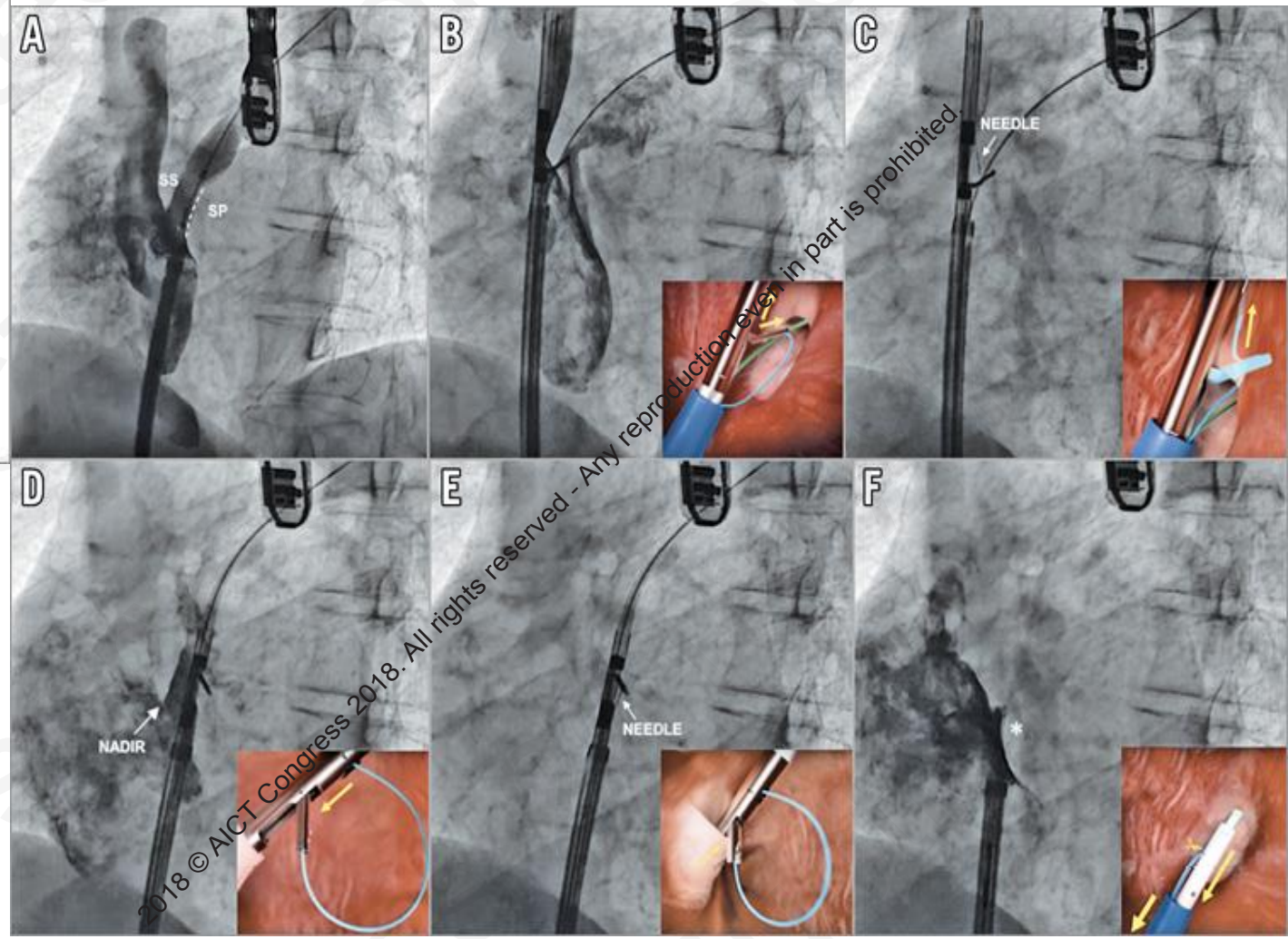

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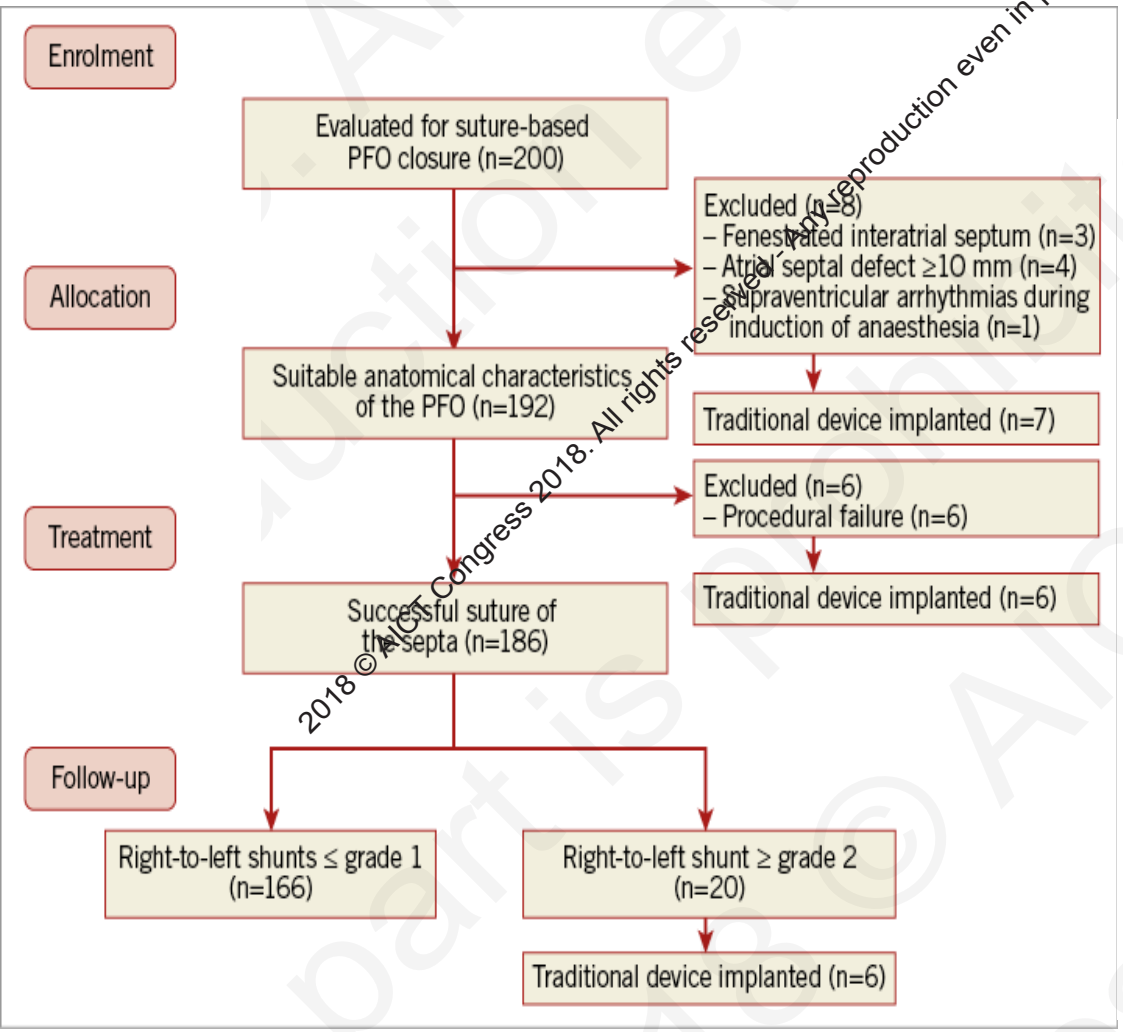

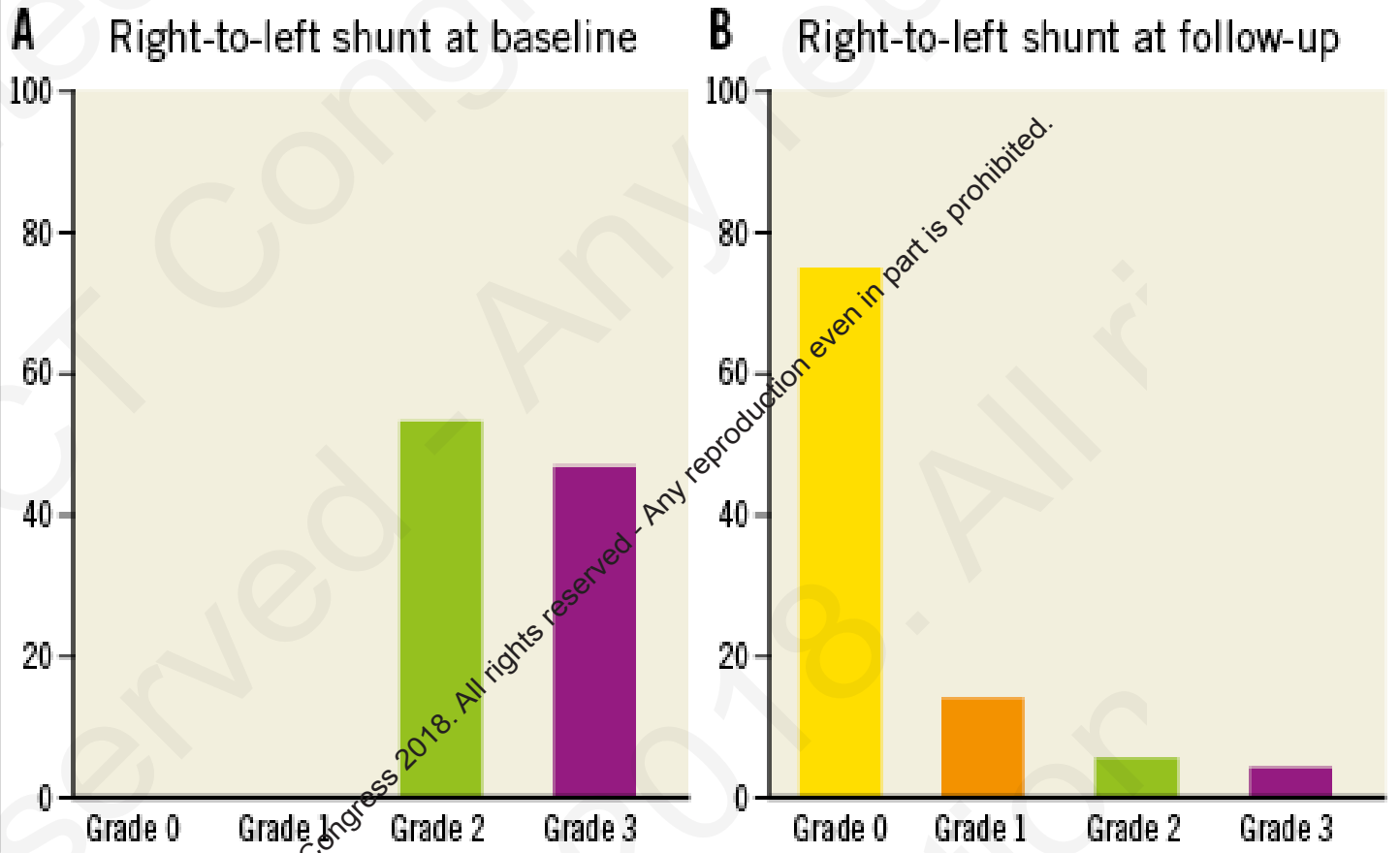

Abstract

Aims: The aim of this study was to assess the efficacy of a novel percutaneous "deviceless" suture-mediated patent foramen ovale (PFO) closure system.

Methods and results: Between June 2016 and October 2017, a prospective registry aimed at assessing the safety and efficacy of the NobleStitch EL (HeartStitch, Fountain Valley, CA, USA) suture-based PFO closure system was carried out at 12 sites in Italy. Among 200 consecutive patients evaluated, 192 were considered suitable for suture-mediated PFO closure (44±13 years, 114 female). Suture of the septum with the NobleStitch EL system was carried out successfully in 186 (96%) patients. Median fluoroscopy time was 16.1 (13.0-22.5) minutes and contrast volume 200 (150-270) ml. At 206±130 days follow-up, contrast transthoracic echocardiography with the Valsalva manoeuvre revealed no RLS (grade 0) in 139 (75%) patients and RLS grade ≤1 in 166 (89%) patients. Significant RLS was present in 20 (11%) patients (grade 2 and 3 in 11 and nine patients, respectively). There were no device-related complications.

Conclusions: The early results of this first Italian registry indicate that the suture-mediated "deviceless" closure of PFO is feasible in the majority of septal anatomies, and provides an effective closure of PFO comparable to traditional devices with a good safety profile at medium-term follow-up.

Summary

- Newer devices and understanding implantation techniques reduces PPM rates after TAVR
- Single aspirin therapy might prove sufficient after TAVR
- Higher volumes/operator provides better in hospital mortality outcomes
- Heart Stitch device for PFO treatment adepts to "***leave no footprint***" and seems effective.

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ASIAN INTERVENTIONAL CARDIOVASCULAR THERAPEUTICS

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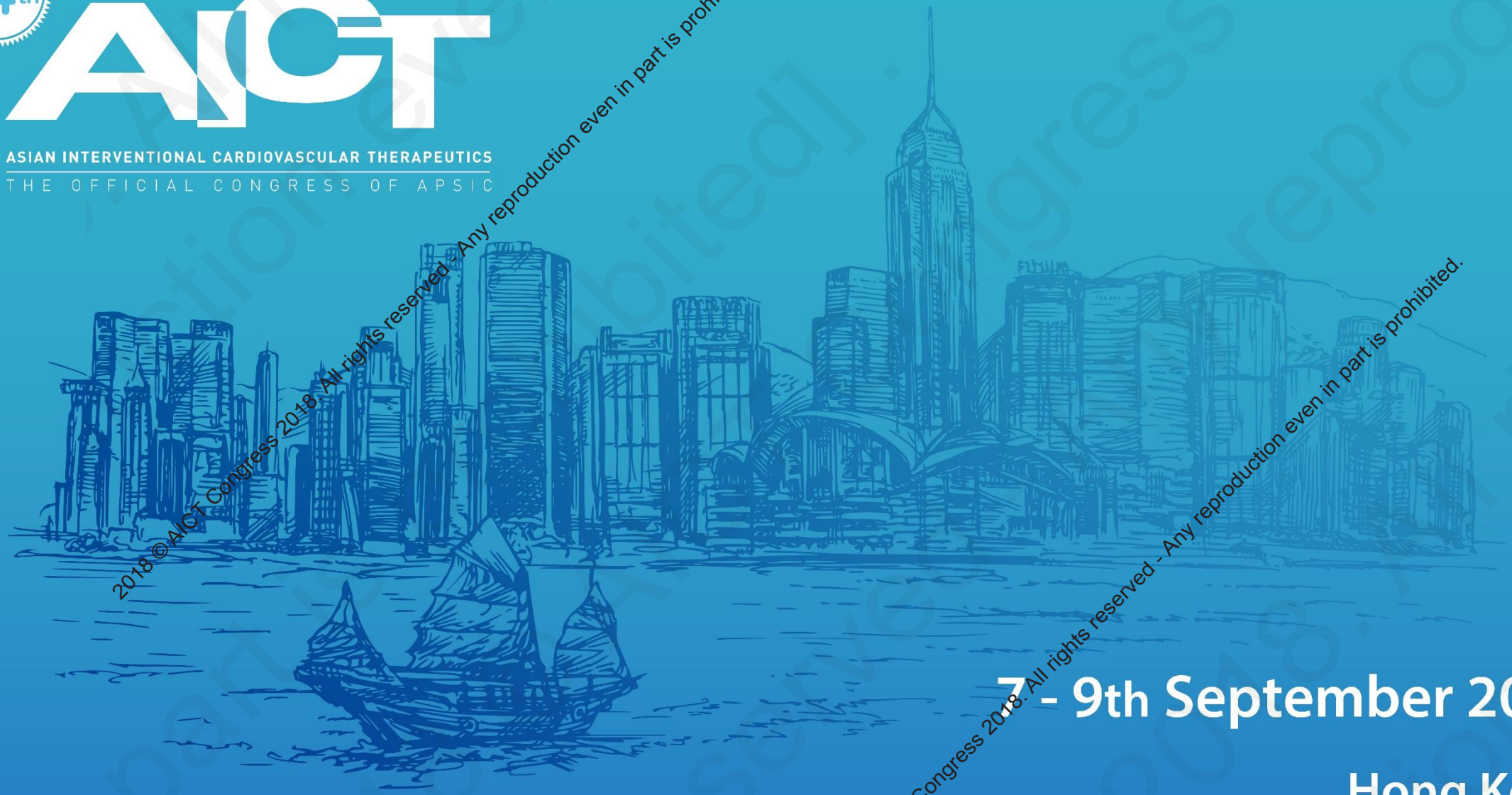

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