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JUN 2019



TAVI: Dernière données cliniques en 2019

T.CUISSET (Marseille)

M.GODIN (Rouen)

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APPAQ
Ensemble, imaginons la cardiologie de demain

The NEW ENGLAND
JOURNAL *of* MEDICINE

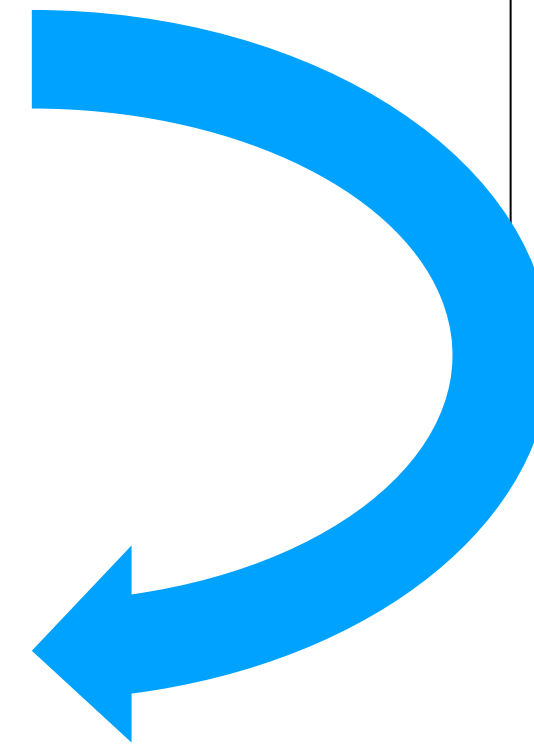
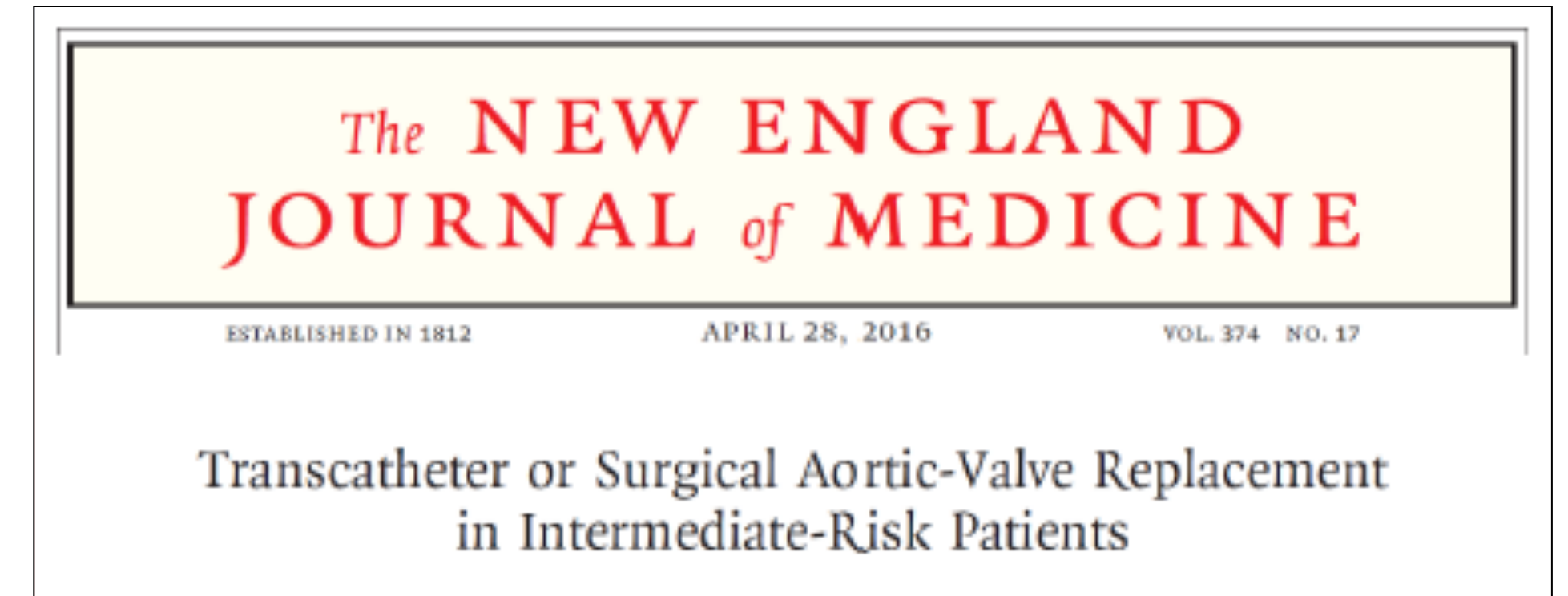
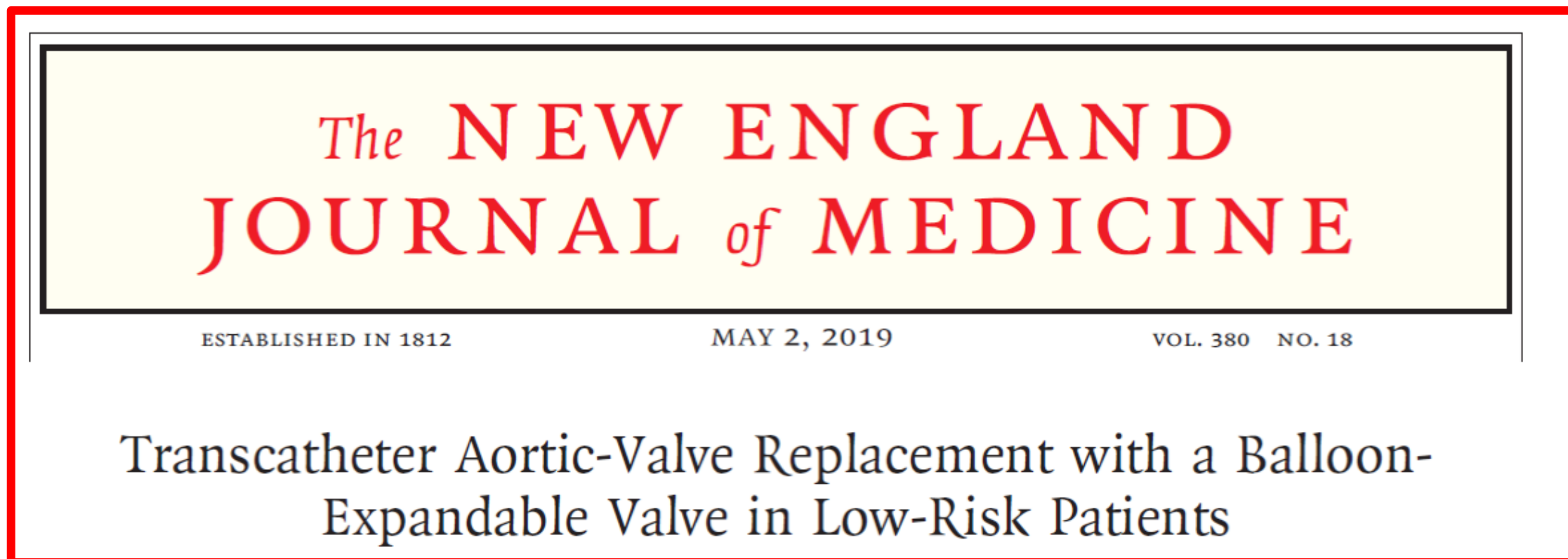
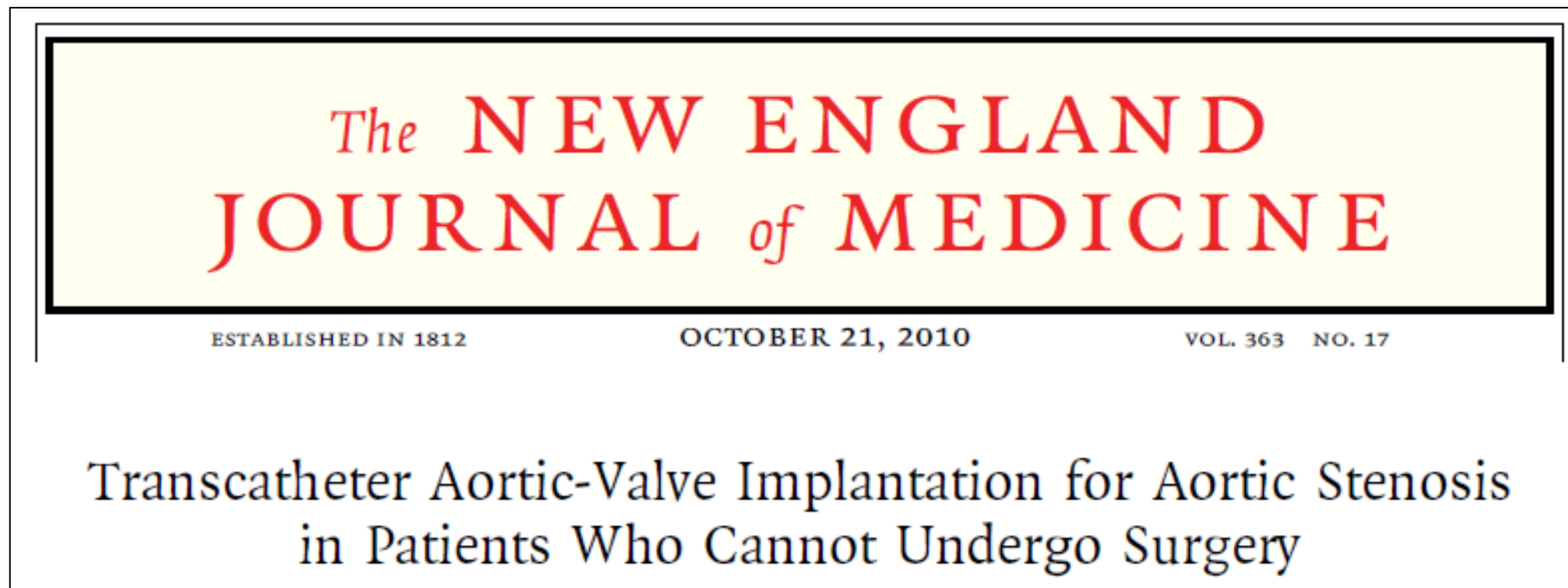
ESTABLISHED IN 1812

MAY 2, 2019

VOL. 380 NO. 18

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

La quatrième pièce du puzzle !



PARTNER 3 Study Design

Symptomatic Severe Aortic Stenosis

Low Risk/TF ASSESSMENT by Heart Team
(STS < 4%)

1:1 Randomization
1000 Patients

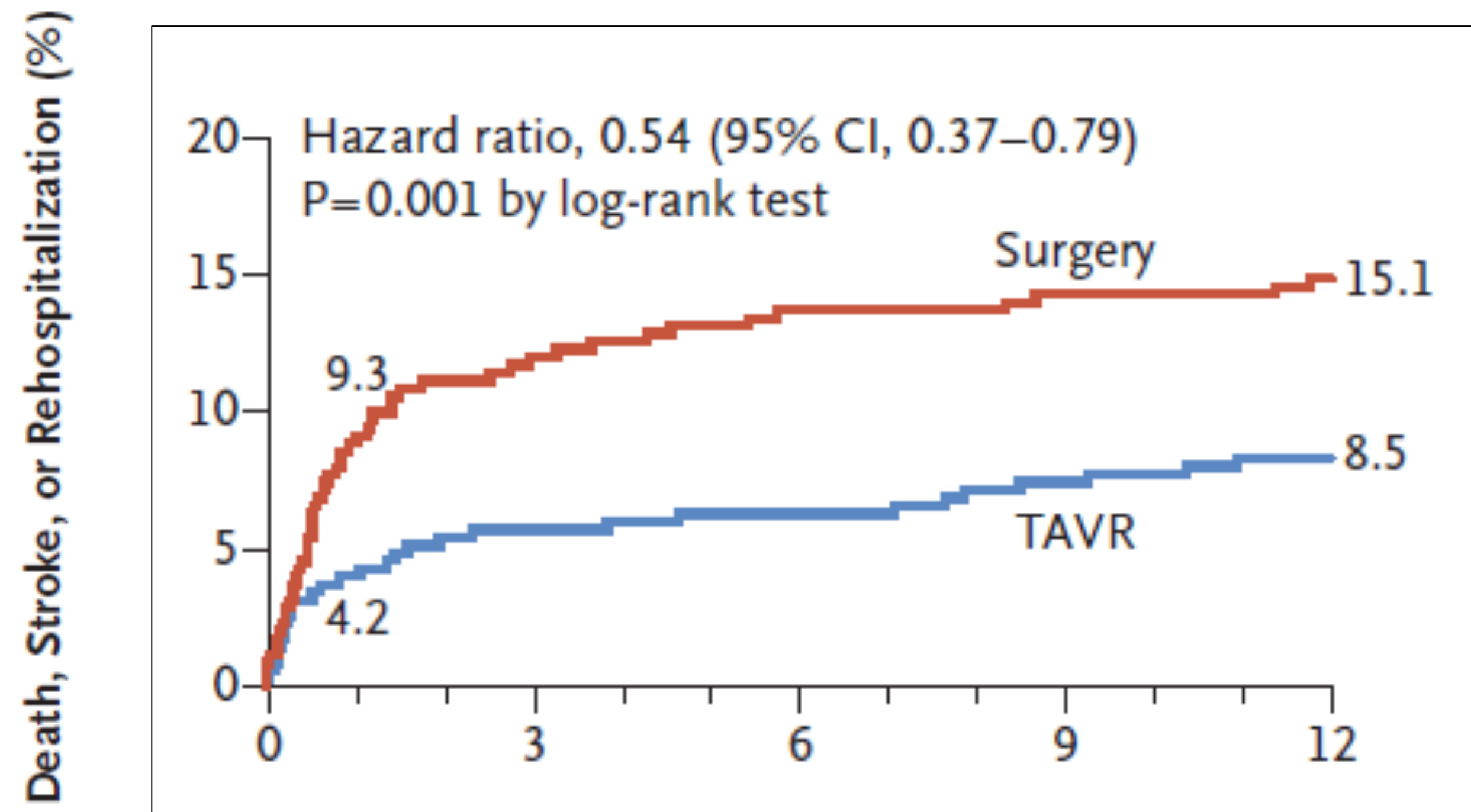
TAVR
(SAPIEN 3 THV)

Surgery
(Surgical Bioprosthetic Valve)

Follow-up: 30 day, 6 mos, and annually through 10 years

PRIMARY ENDPOINT:
Composite of all-cause mortality, stroke, or CV re-hospitalization
at 1 year post-procedure

Critère primaire de jugement



TAVI meilleur que chirurgie sur PEP

Rien d'autre à retenir ??

Regardons cette étude de plus près !

Quels « RAO » sont dans PARTNER 3 ?

Severe Calcific Aortic Stenosis

- $AVA \leq 1.0 \text{ cm}^2$ or $AVA \text{ index} \leq 0.6 \text{ cm}^2/\text{m}^2$
- Jet velocity $\geq 4.0 \text{ m/s}$ or mean gradient $\geq 40 \text{ mmHg}$, AND
 - NYHA Functional Class ≥ 2 , OR
 - Abnormal exercise test with severe SOB, abnormal BP response, or arrhythmia, OR
 - Asymptomatic with LVEF $< 50\%$

Low Surgical Risk

- Determined by multi-disciplinary heart team
- STS $< 4\%$
- Adjudicated by case review board

Quels « RAo » ne sont pas dans PARTNER 3 ?

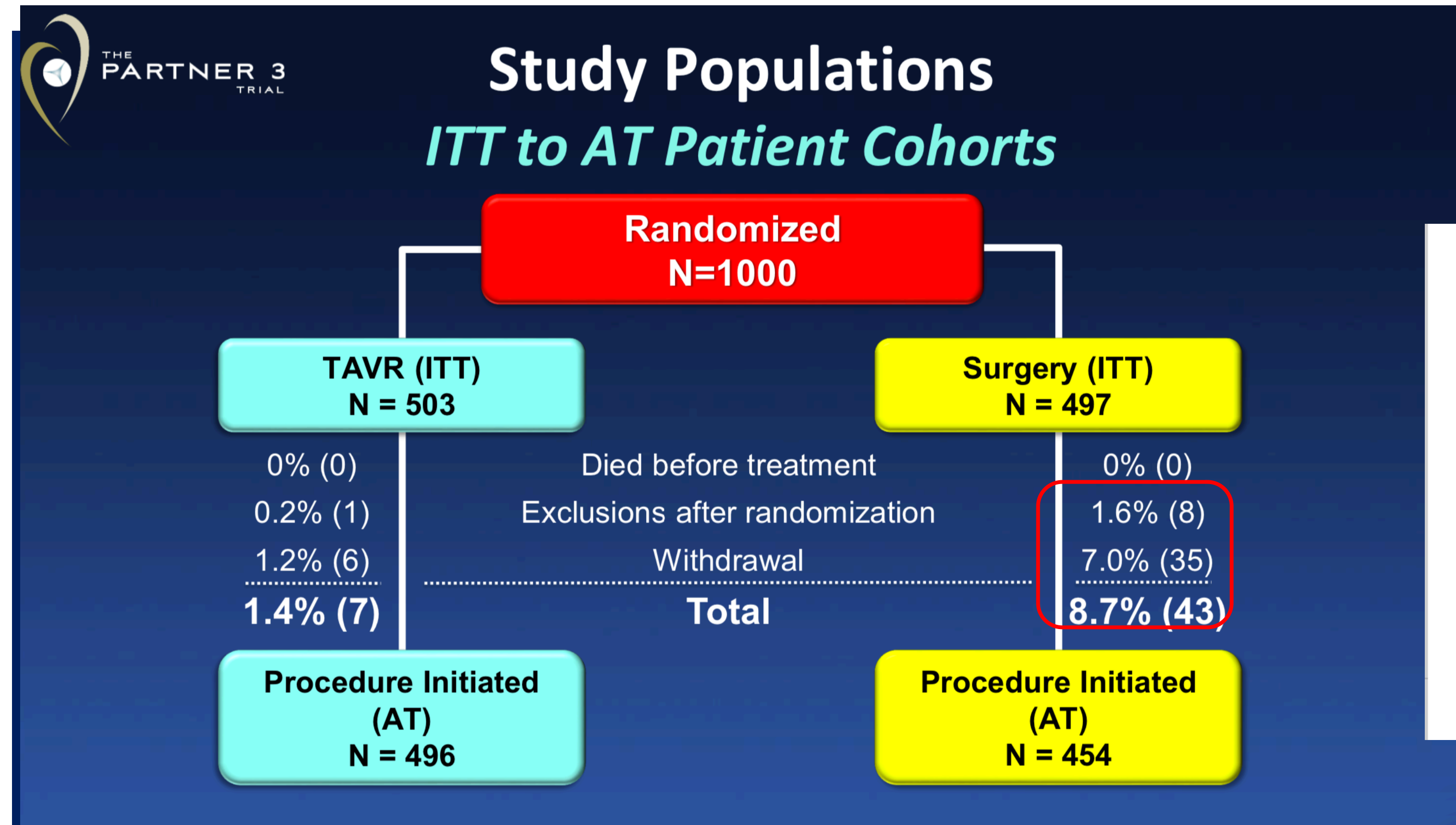
Anatomic

- Aortic annulus diameter < 16 mm or > 28 mm (3D imaging)
- Bicuspid valve (CT imaging)
- Severe AR (> 3+) or MR (> 3+)
- Severe LV dysfunction (LVEF < 30%)
- Severe calcification of aortic valvar complex (esp. LVOT)
- Vascular anatomy not suitable for safe femoral access
- Complex CAD: ULM, Syntax score > 32, or not amenable for PCI
- Low coronary takeoff (high risk for obstruction)

Clinical

- Acute MI within 1 month
- Stroke or TIA within 90 days
- Renal insufficiency (eGFR < 30 ml/min) and/or renal replacement Rx
- Hemodynamic or respiratory instability
- Frailty (objective assessment; > 2/4+ metrics)

Quels « RAO » ne sont pas dans PARTNER 3 ?



Quels patients ont été inclus dans PARTNER 3 ?

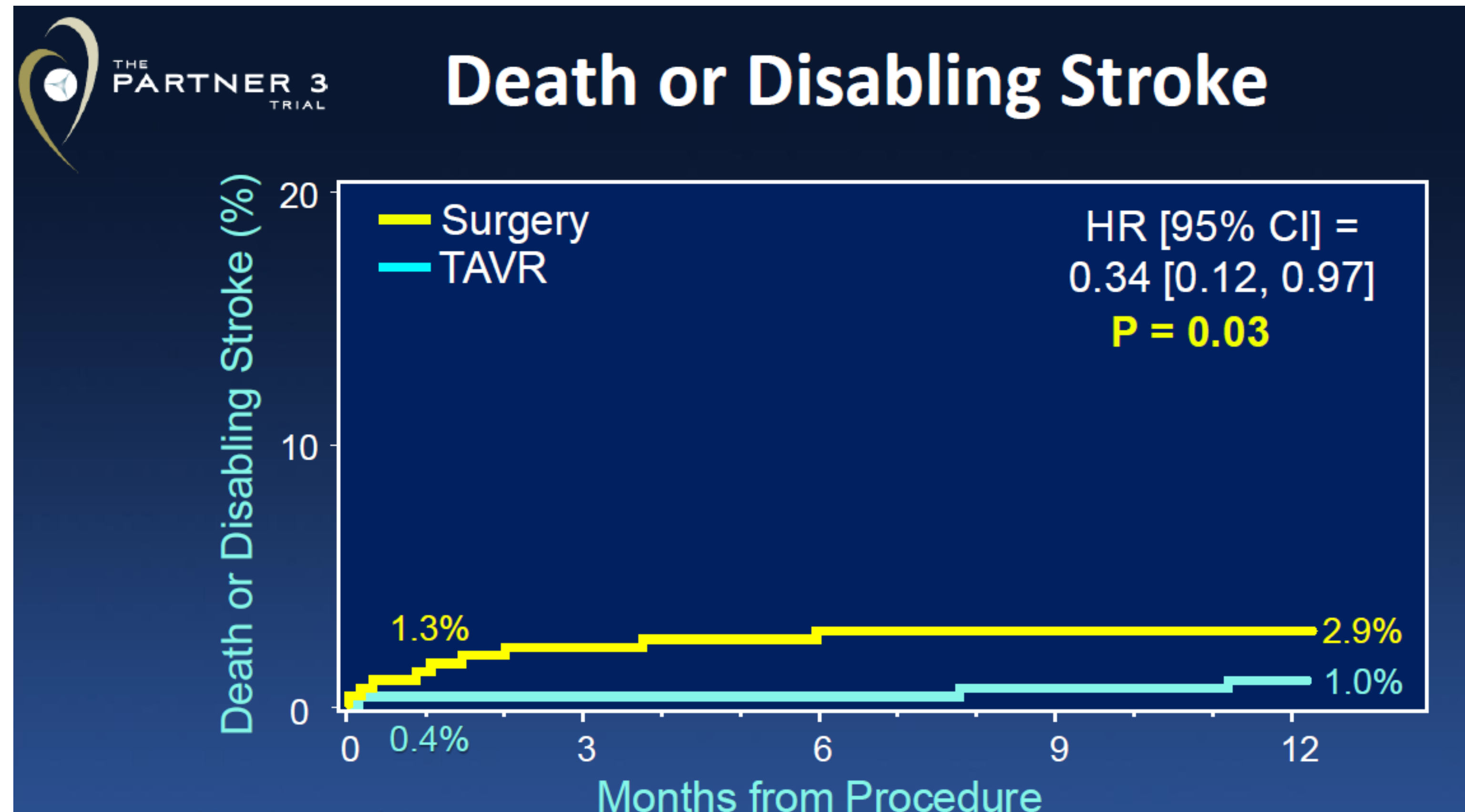
Demographics & Vascular Disease	TAVR (N=496)	Surgery (N=454)	Other Co-Morbidities	TAVR (N=496)	Surgery (N=454)
Age (years)	73.3 ± 5.8	73.6 ± 6.1	Diabetes	31.3%	30.2%
Male	67.5%	71.1%	COPD (any)	5.1%	6.2%
BMI – kg/m ²	30.7 ± 5.5	30.3 ± 5.1	Pulmonary Hypertension	4.6%	5.3%
STS Score	1.9 ± 0.7	1.9 ± 0.6	Creatinine > 2mg/dL	0.2%	0.2%
NYHA Class III or IV*	31.3%	23.8%	Frailty (overall; > 2/4+)	0	0
Coronary Disease	27.7%	28.0%	Atrial Fibrillation (h/o)	15.7%	18.8%
Prior CABG	3.0%	1.8%	Permanent Pacemaker	2.4%	2.9%
Prior CVA	3.4%	5.1%	Left Bundle Branch Block	3.0%	3.3%
Peripheral Vascular Disease	6.9%	7.3%	Right Bundle Branch Block	10.3%	13.7%

Données Procédure / Hospitalisation ?

Variable	TAVR (N=496)	Surgery (N=454)	P-value
Conscious Sedation	65.1%	NA	NA
Procedure Time (min)	58.6 ± 36.5	208.3 ± 62.2	<0.001
Fluoroscopy Time (min)	13.9 ± 7.1	NA	NA
Aortic Cross-Clamp Time (min)	NA	74.3 ± 27.8	NA
Total CPB Time (min)	NA	97.7 ± 33.8	NA
Median ICU Stay (days)	2.0	3.0	<0.001
Median Total LOS (days)	3.0	7.0	<0.001
Discharge to Home/Self-care	96.0%	73.1%	<0.001
Concomitant Procedures	7.9%	26.4%	<0.001

Résultats en dehors critère primaire ?

Evénements « durs »

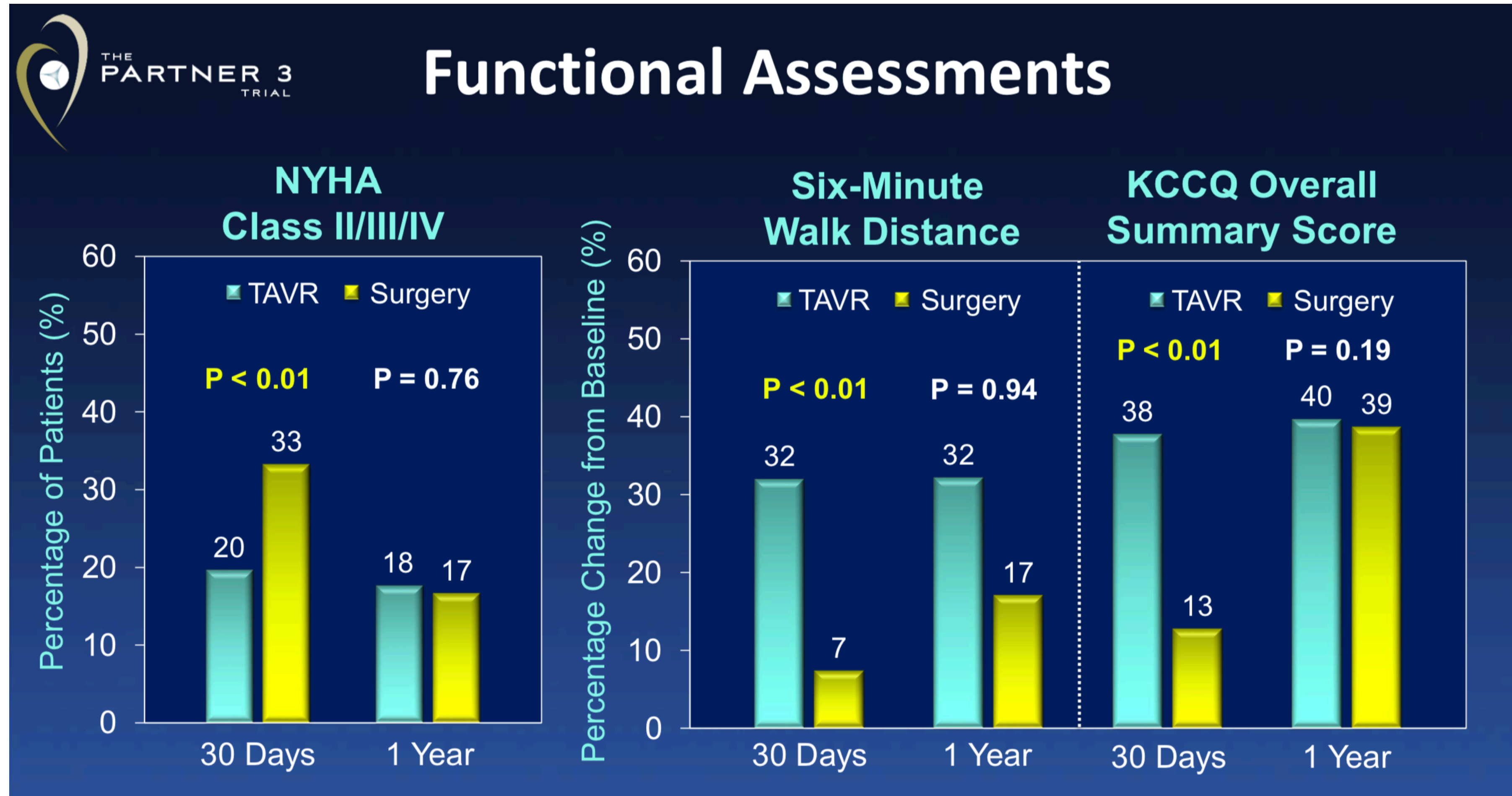


Résultats en dehors critère primaire ?

THE PARTNER 3 TRIAL **Pre-specified Secondary Endpoints**
Subject to Multiplicity Adjustment

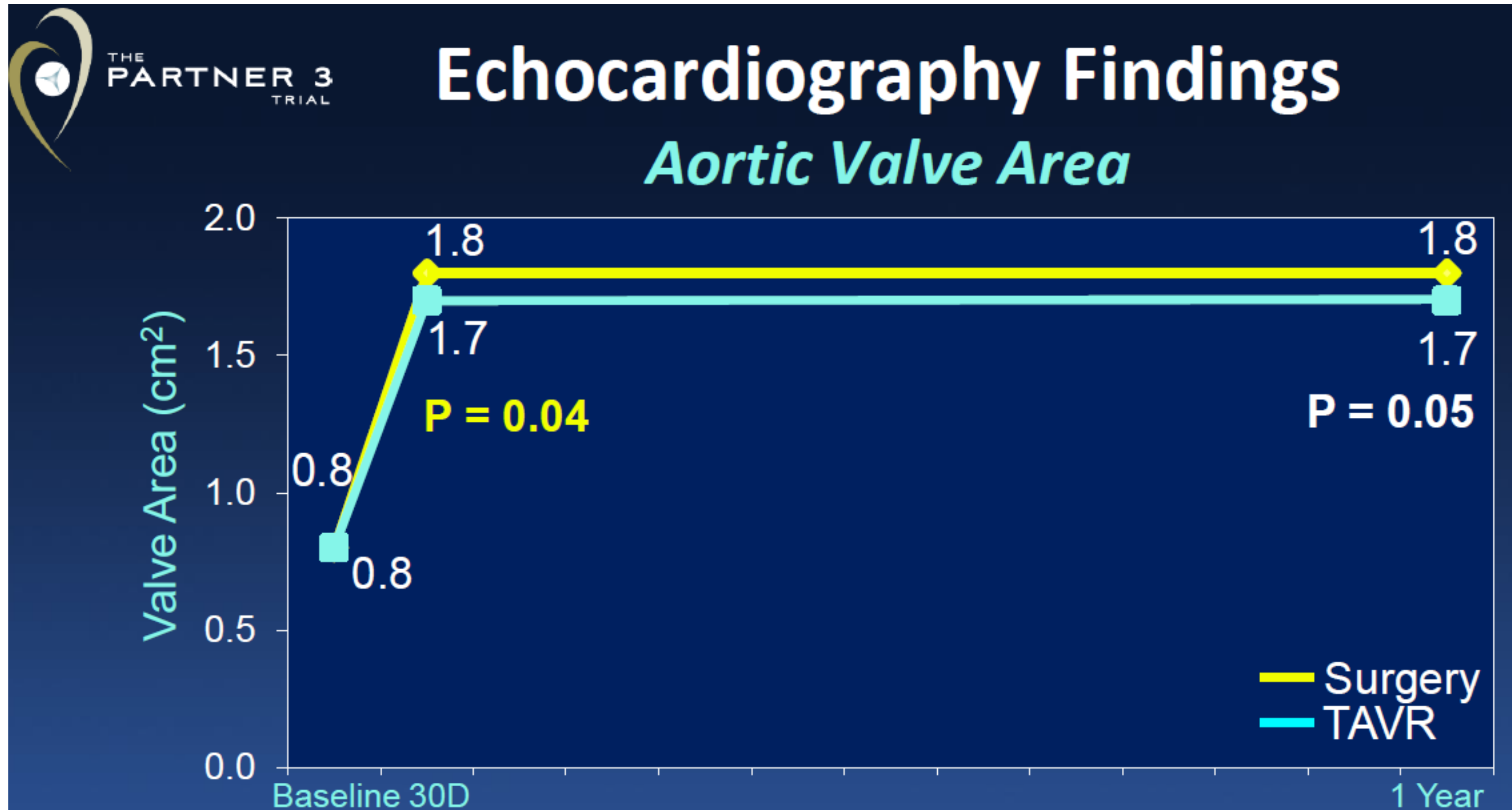
Order of Testing	Endpoint	TAVR (N=496)	Surgery (N=454)	Treatment Effect [95% CI]	P-value
1	New onset atrial fibrillation at 30 days	5.0%	39.5%	0.10 [0.06, 0.16]	<0.001
2	Length of index hospitalization (days)	3.0 (2.0, 3.0)	7.0 (6.0, 8.0)	-4.0 [-4.0, -3.0]	<0.001
3	All-cause death, all stroke, or rehospitalizations at 1 year	8.5%	15.1%	0.54 [0.37, 0.79]	0.001
4	Death, KCCQ < 45 or KCCQ decrease from baseline ≥ 10 points at 30 days	3.9%	30.6%	-26.7% [-31.4%, -22.1%]	<0.001
5	Death or all stroke at 30 days	1.0%	3.3%	0.30 [0.11, 0.83]	0.01
6	All stroke at 30 days	0.6%	2.4%	0.25 [0.07, 0.88]	0.02

Résultats en dehors critère primaire ?



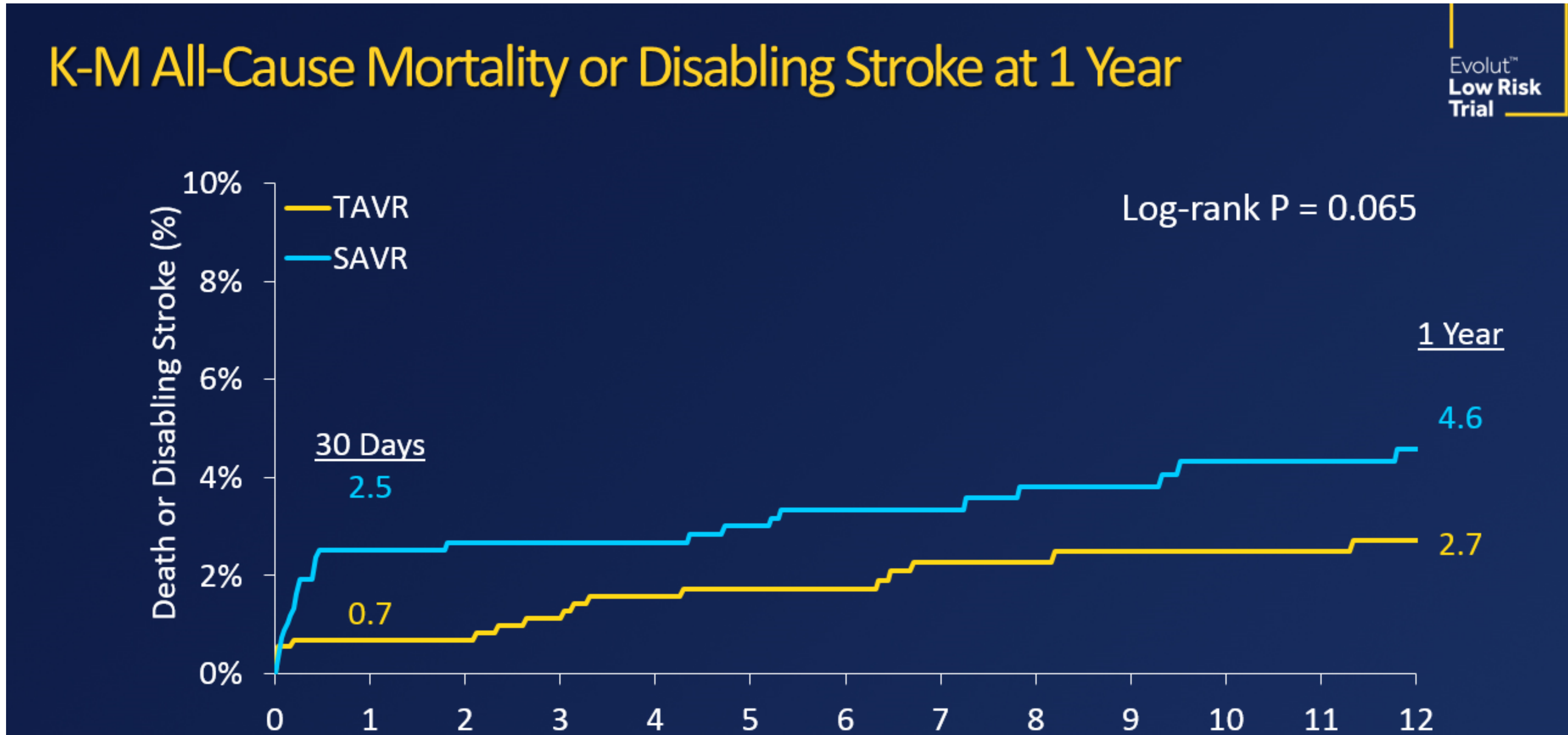
Résultats en dehors critère primaire ?

Paramètres hémodynamiques



Et les autres ?

Evolute Low Risk Trial



Résultats contemporains et concordants

Changement de paradigme ?

2009

Rao Serré dégénératif > 75-80 ans
Chirurgie impossible ou à très haut risque

TAVI

Amélioration matériel
Expérience des équipes : sizing, procédure
Simplification de la procédure



Fabien Doguet remplace Michel Cymes

**Fabien Doguet remplace
Michel Cymes**

Chaque mardi depuis le départ du très populaire

2019

Rao Serré dégénératif > 75-80 ans
TAVI non réalisable (anatomie)

Chirurgie

Quels « Low Risk » vers la chirurgie ?
Quels critères ?

L'âge est un bon paramètre ?

TF vs non-TF ?

Coronaropathie complexe associée ?

En fonction anatomie de l'anneau en CT ?

Effect Volume

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement

Sreekanth Vemulapalli, M.D., John D. Carroll, M.D., Michael J. Mack, M.D., Zhuokai Li, Ph.D., David Dai, Ph.D., Andrzej S. Kosinski, Ph.D., Dharam J. Kumbhani, M.D., S.M., Carlos E. Ruiz, M.D., Ph.D., Vinod H. Thourani, M.D., George Hanzel, M.D., Thomas G. Gleason, M.D., Howard C. Herrmann, M.D., Ralph G. Brindis, M.D., M.P.H., and Joseph E. Bavaria, M.D.

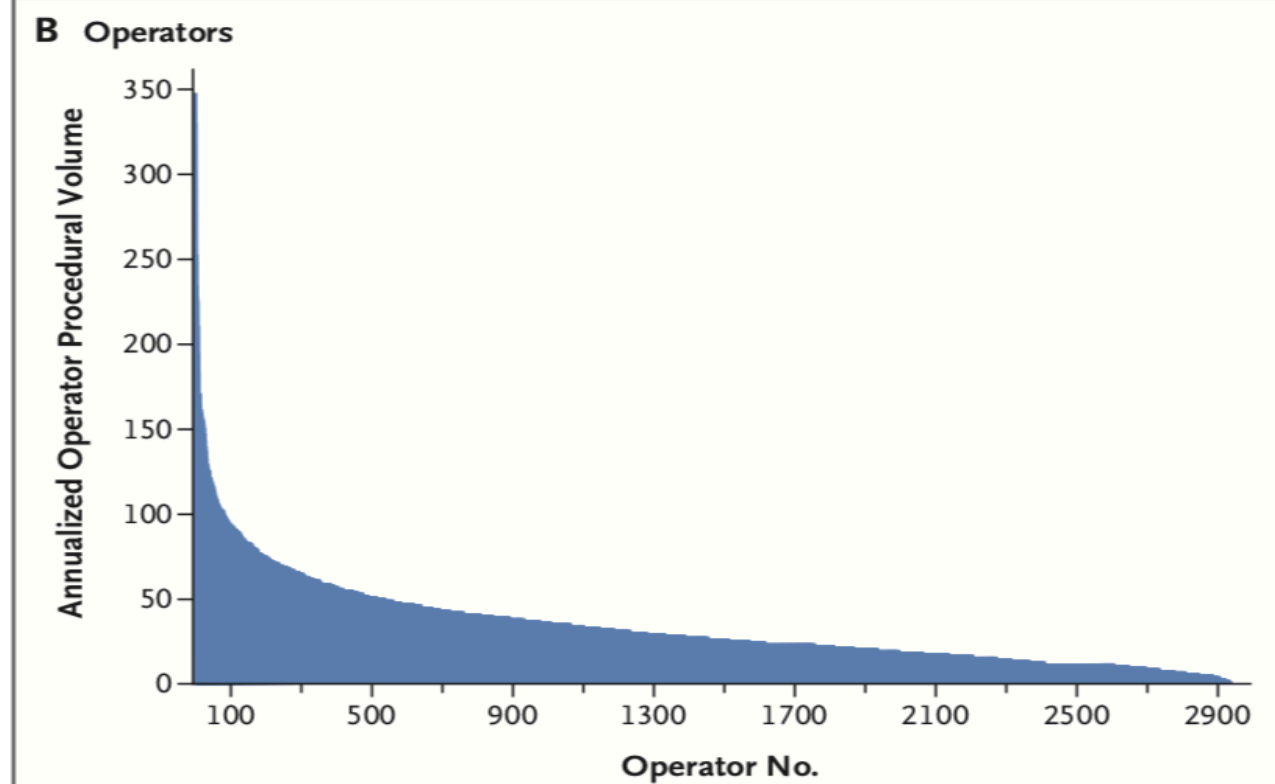
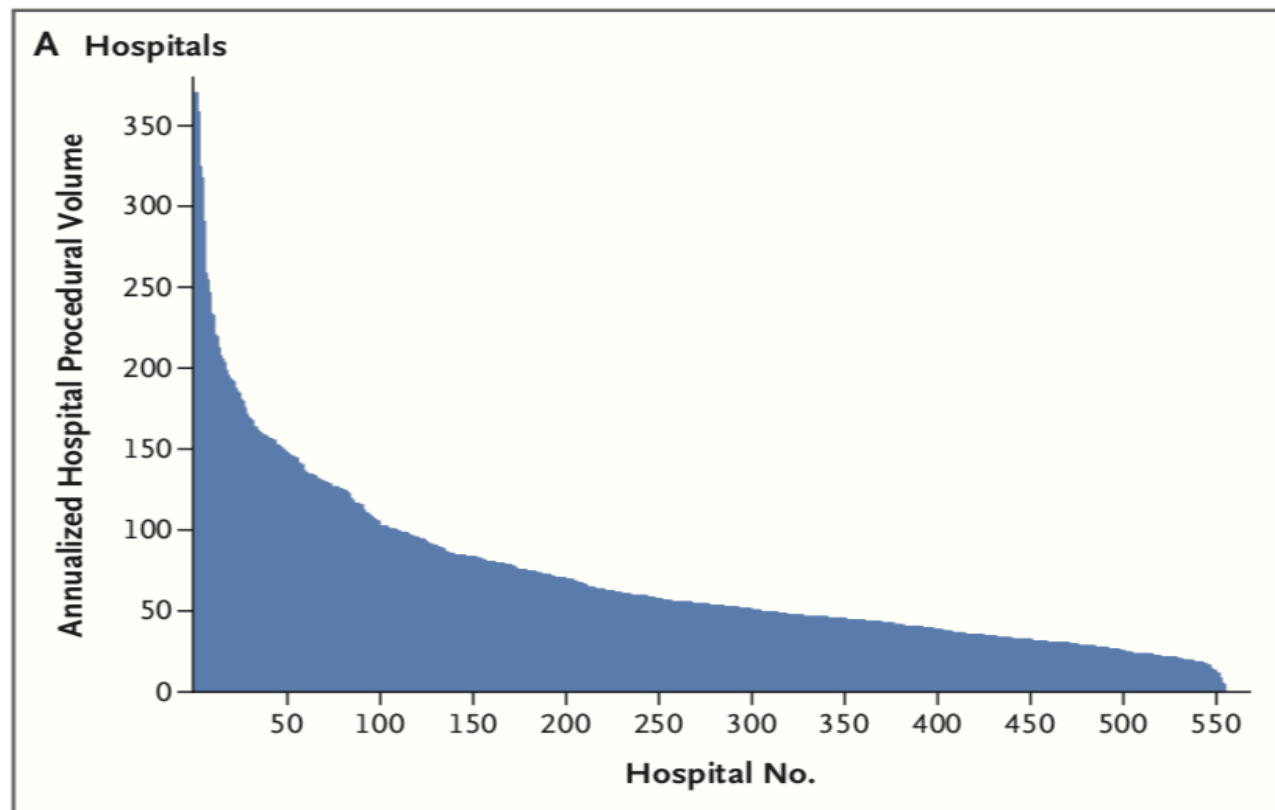
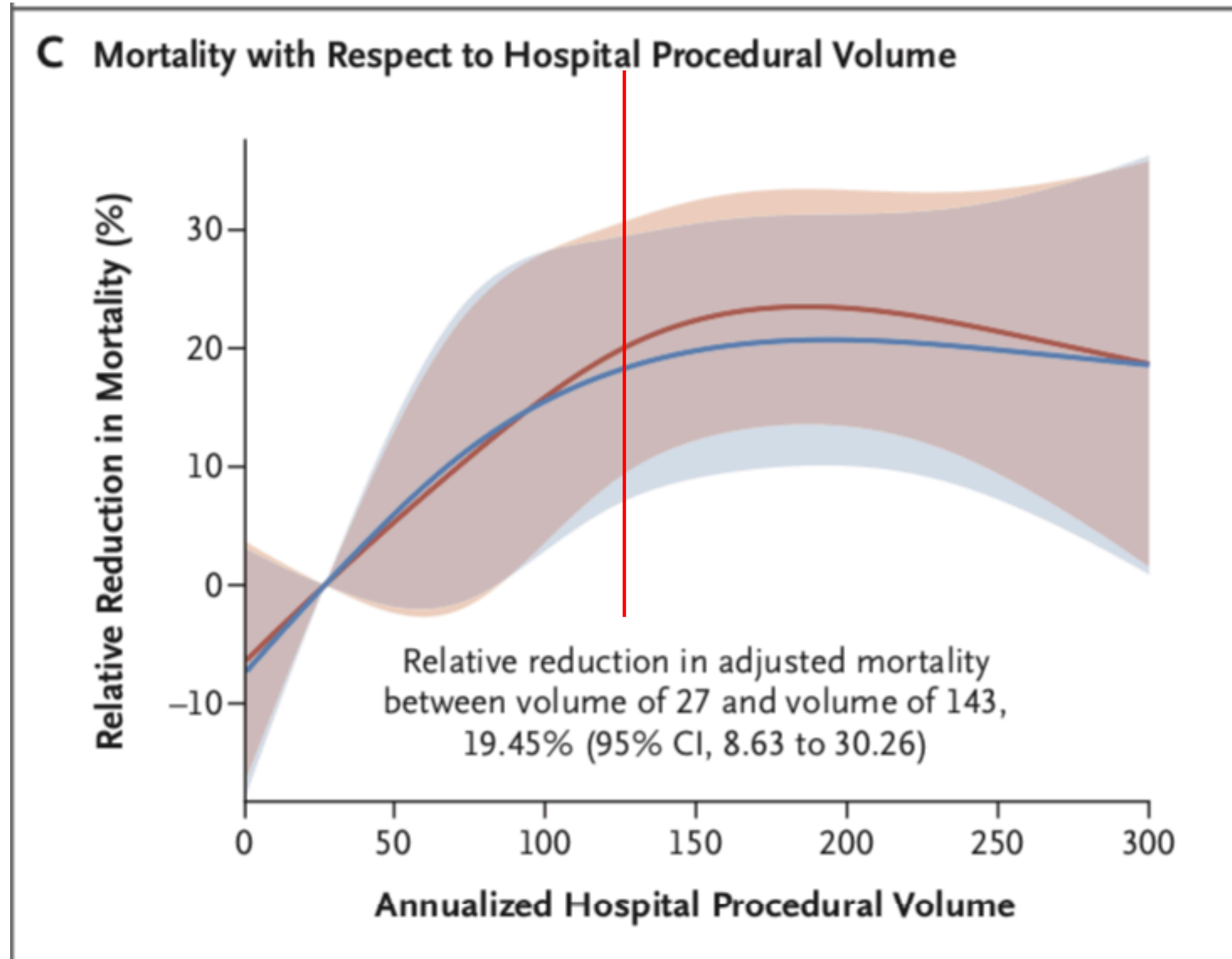


Figure 1. Annualized Hospital and Operator Volume of Transfemoral Transcatheter Aortic-Valve Replacement (TAVR) Procedures.

Shown are histogram distributions for 96,256 transfemoral TAVR procedures performed at 554 hospitals (Panel A) by 2935 operators (Panel B).



Effet Volume

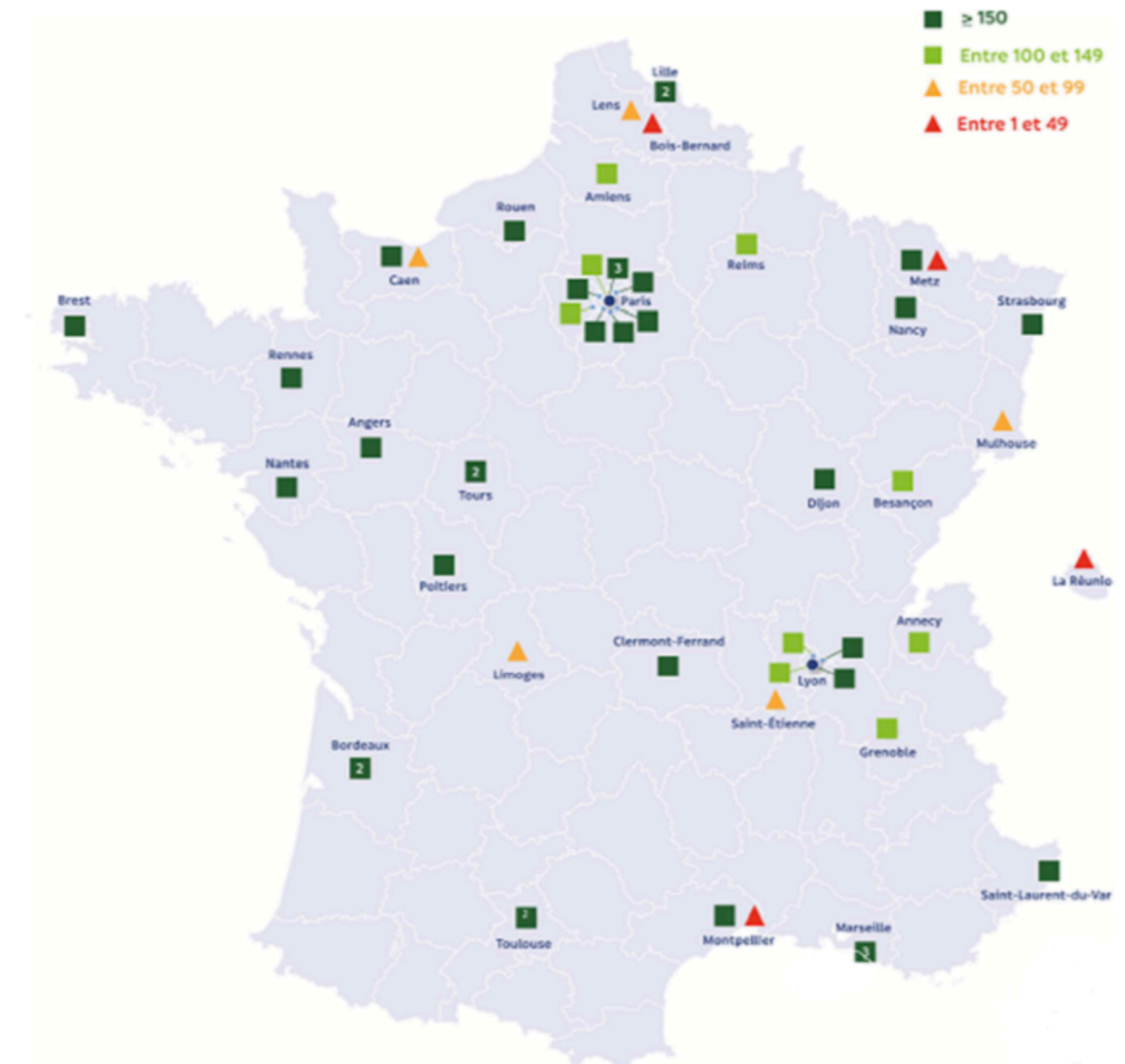
HAS

HAUTE AUTORITÉ DE SANTÉ

EVALUATION DES TECHNOLOGIES DE SANTE

Réévaluation des critères d'éligibilité
des centres implantant des
bioprothèses valvulaires aortiques par
voie artérielle transcutanée ou par
voie transapicale

Date de validation par le collège : décembre 2018



2017

Transfemoral TAVR at Hospitals Without On-Site Cardiac Surgery Department in Spain

A Multicenter Registry

TABLE 1 Clinical Profiles and Outcomes of Patients Undergoing TAVR in 10 Centers Without On-Site CS in Spain (N = 384)

Demographic characteristics	
Age, yrs	82.2 (77.2-87.2)
Females	202 (52.6)
Periprocedural complications	
Conversion to open-heart surgery	1 (0.3)
Coronary obstruction	3 (0.8)
Cardiac tamponade	6 (1.6)
Valve malposition	6 (1.6)
TAVR in TAVR deployment	6 (1.6)
Aortic dissection or annular rupture	0 (0)
Acute heart failure	13 (3.4)
Aortic regurgitation ≥2	56 (14.7)
Myocardial infarction	3 (0.8)
Stroke	2 (0.5)
Bleeding	
Major	28 (7.3)
Minor	52 (13.5)
Acute kidney injury	
Stage 1	28 (7.3)
Stage 2	6 (1.6)
Stage 3	11 (2.9)
Mortality rates	
In-hospital mortality	20 (5.2)
Intraprocedural death	3 (0.8)
Death in the first 72 h	4 (1)
Death after the first 72 h	13 (3.4)
In-hospital cardiovascular mortality	8 (2.1)
In-hospital no cardiovascular mortality	12 (3.1)
Mortality in the first 30 days	23 (6.1)
Mortality in the first year	47 (12.2)
Total mortality in the follow-up, 618 ± 591 days	72 (18.7)

TAVI sans Chirurgie

Impact of On-Site Cardiac Surgery on Clinical Outcomes After Transfemoral Transcatheter Aortic Valve Replacement

Florian Egger, MD,^{a,*} David Zweiker, MD,^{b,*} Matthias K. Freynhofer, MD,^a Verena Löffler,^a Miklos Rohla, MD, PhD,^{a,c} Alexander Geppert, MD,^a Serdar Farhan, MD,^{a,d} Birgit Vogel, MD,^{a,d} Jürgen Falkensammer, MD,^{e,f} Johannes Kastner, MD,^g Philipp Pichler, MD,^g Paul Vock, MD,^h Gudrun Lamm, MD,^h Olev Luha, MD,^b Albrecht Schmidt, MD,^b Daniel Scherr, MD,^{b,i} Matthias Hammerer, MD,^j Uta C. Hoppe, MD,^j Edwin Maurer, MD,^k Michael Grund, MD,^l Thomas Lambert, MD,^l Wolfgang Tkalec, MD,^m Thomas Sturmberger, MD,^m Eduard Zeindhofer, MD,ⁿ Martin Grabenwöger, MD,^{r,o} Kurt Huber, MD,^{a,f} for the Austrian TAVI Group

TABLE 1 Baseline Characteristics of No-iOSCS Patients, Complete iOSCS Group, and Matched iOSCS Patients

	No-iOSCS (n = 290)	iOSCS		p Value
		Before Matching (n = 1,532)	After Matching (n = 290)	
Female	63.4	59.1	63.4	0.931
Age, yrs	84 (80-87)	83 (79-86)	84 (81-87)	0.241
Height, cm	164 (159-170)	165 (159-170)	164 (158-170)	0.595
Weight, kg	70 (61-81)	70 (62-80)	70 (60-80)	0.527
BMI, kg/m ²	26 (23-29)	26 (23-29)	26 (23-28)	0.836
BSA, m ²	1.78 ± 0.20	1.79 ± 0.20	1.77 ± 0.21	0.538
COPD IV	4.7	10.9	8.6	0.088
Liver cirrhosis	1.2	1.3	1.1	1.000
Prior CAD	63.8	51.8	55.2	0.044
Prior stroke	6.3	9.0	10.4	0.114
Prior PCI	45.3	29.9	37.7	0.081
Prior pericardiectomy	8.3	11.9	7.6	0.874
LVEF				
30-50	38.7	26.2	33.6	<0.001
<30	10.7	8.8	12.5	0.344
Logistic EuroSCORE	20.9 (12.8-30.3)	14.2 (9.0-22.2)	19.6 (13.1-28.6)	<0.001
Porcelain aorta	4.3	7.5	6.7	0.083
Implanted pacemaker	13.0	8.4	12.7	0.024
First patients	27.6	10.1	24.1	<0.001
Echocardiography				
V _{max} , m/s	4.4 (4.0-4.8)	4.4 (4.0-4.8)	4.4 (4.0-5.0)	0.530
Mean gradient, mm Hg	48 (40-57)	47 (39-59)	50 (40-62)	0.748

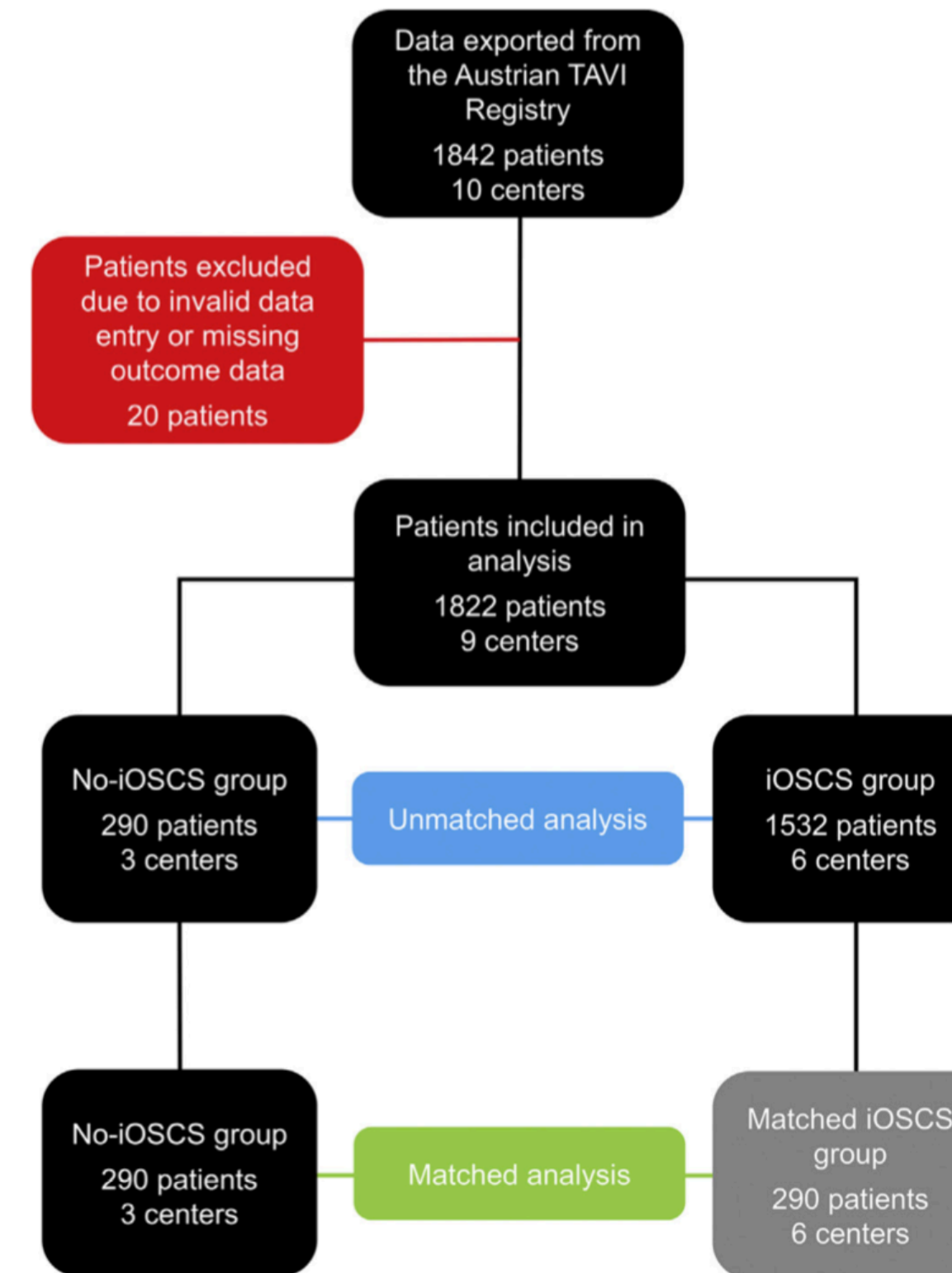
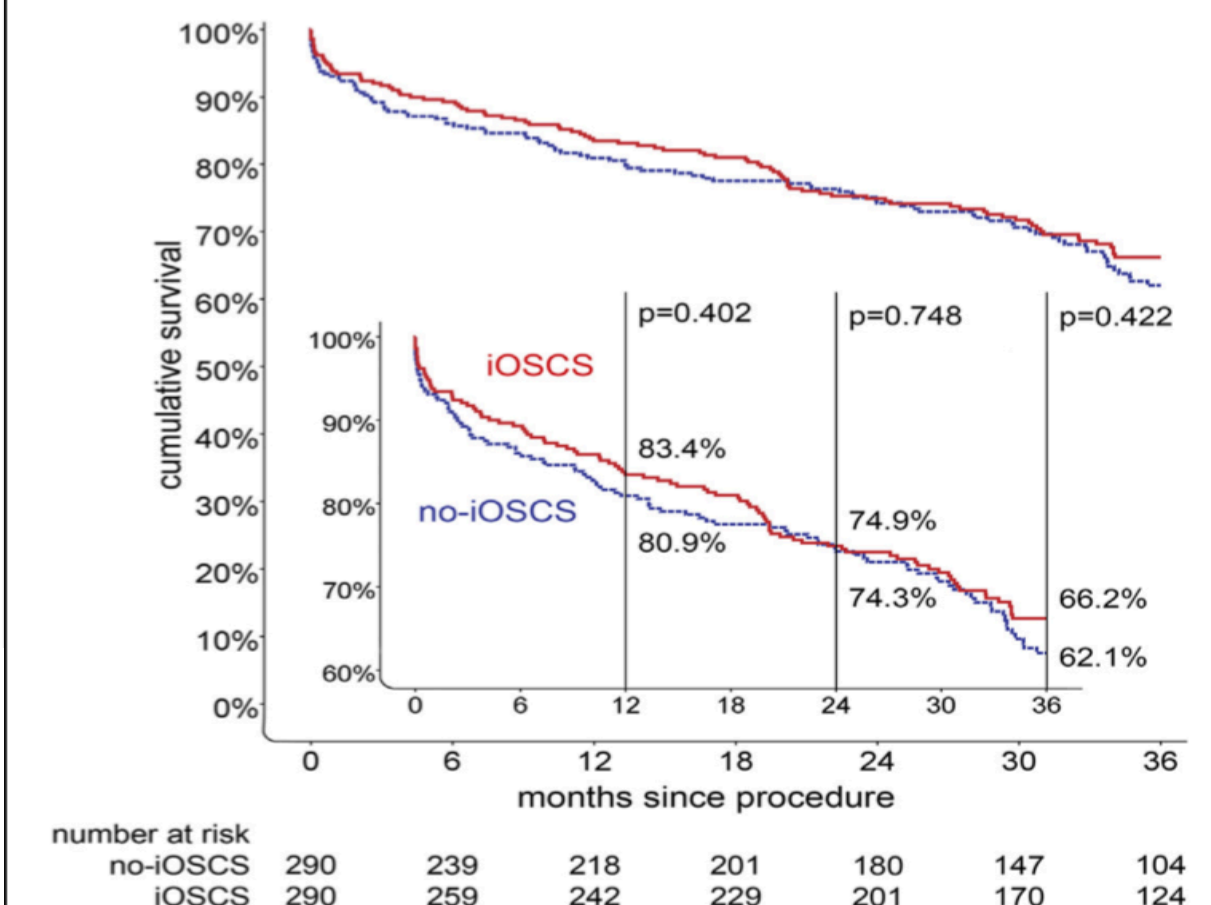


FIGURE 2 Three-Year Survival for the Propensity Score Matched Patient Population



Evolution du TAVI en France

Remboursement Risque intermédiaire-faible ?

Poursuite croissance d'activité dans centres restreints (50) ?

Niveau activité (100/an) ?

Place des nouvelles prothèses ?

