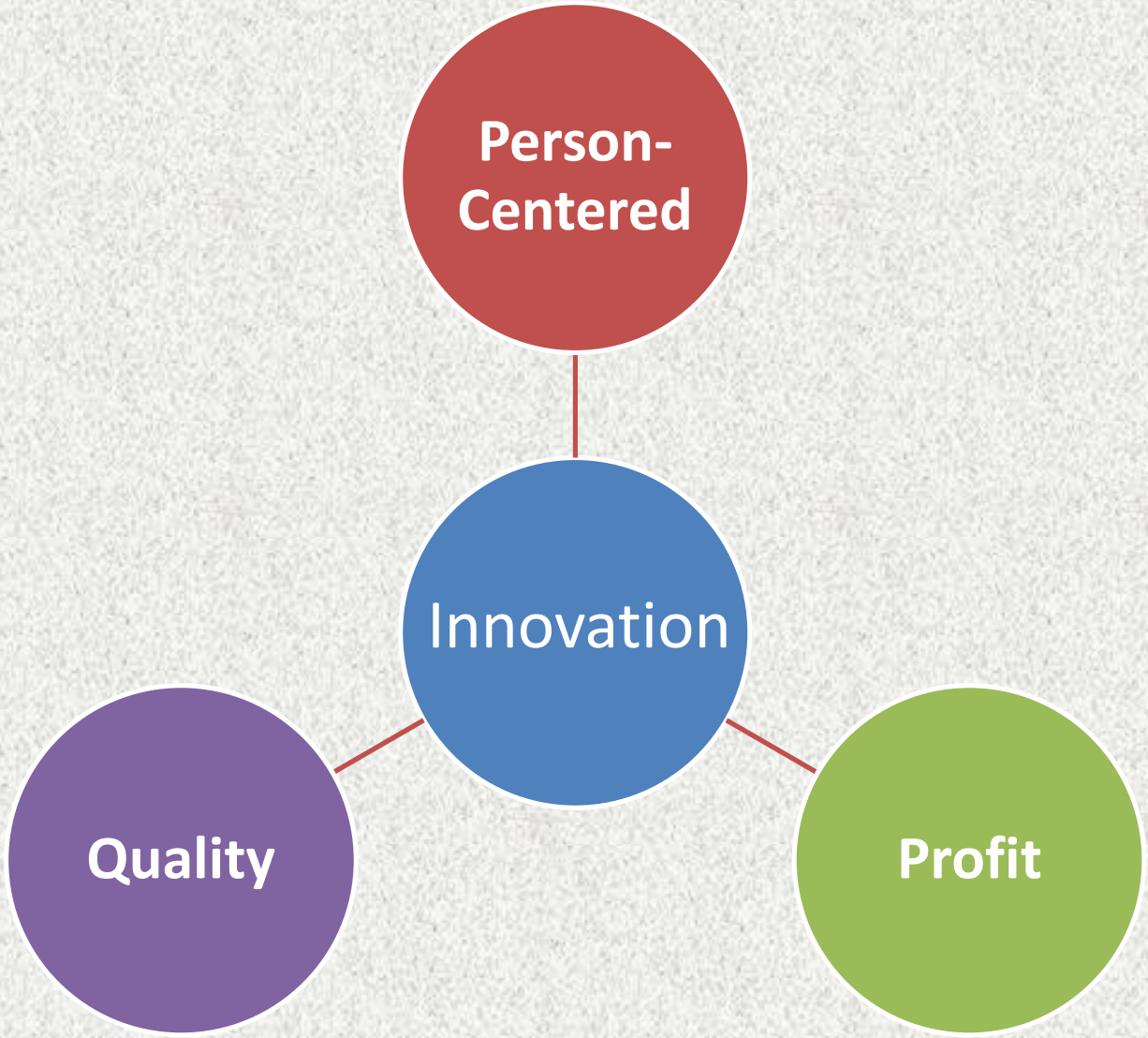
Is There a Room for Innovations in Aortic Surgery?

Khalil Fattouch, MD, PhD.

“We must focus on innovations that improve humanity.”

– Earl Bakken

Founder of Medtronic
Inventor of the Pacemaker


Person-Centered
Innovation
Quality
Profit

Wellbeing Checklist

- [x] Reconnect patient to purpose
- [x] Address emotional needs
- [x] Relies physicians and industries objective
- [x] Create a healing environment - patient centered
- [x] Best performance

‘Gold Standard in AVR’

- Avoid mechanical valve / anticoagulation
- Easy implant
- Safe procedure (Low mortality and morbidity)
- Durability

‘Gold Standard in AVR’

- No mechanical valve / avoid anticoagulation
- Easy implant
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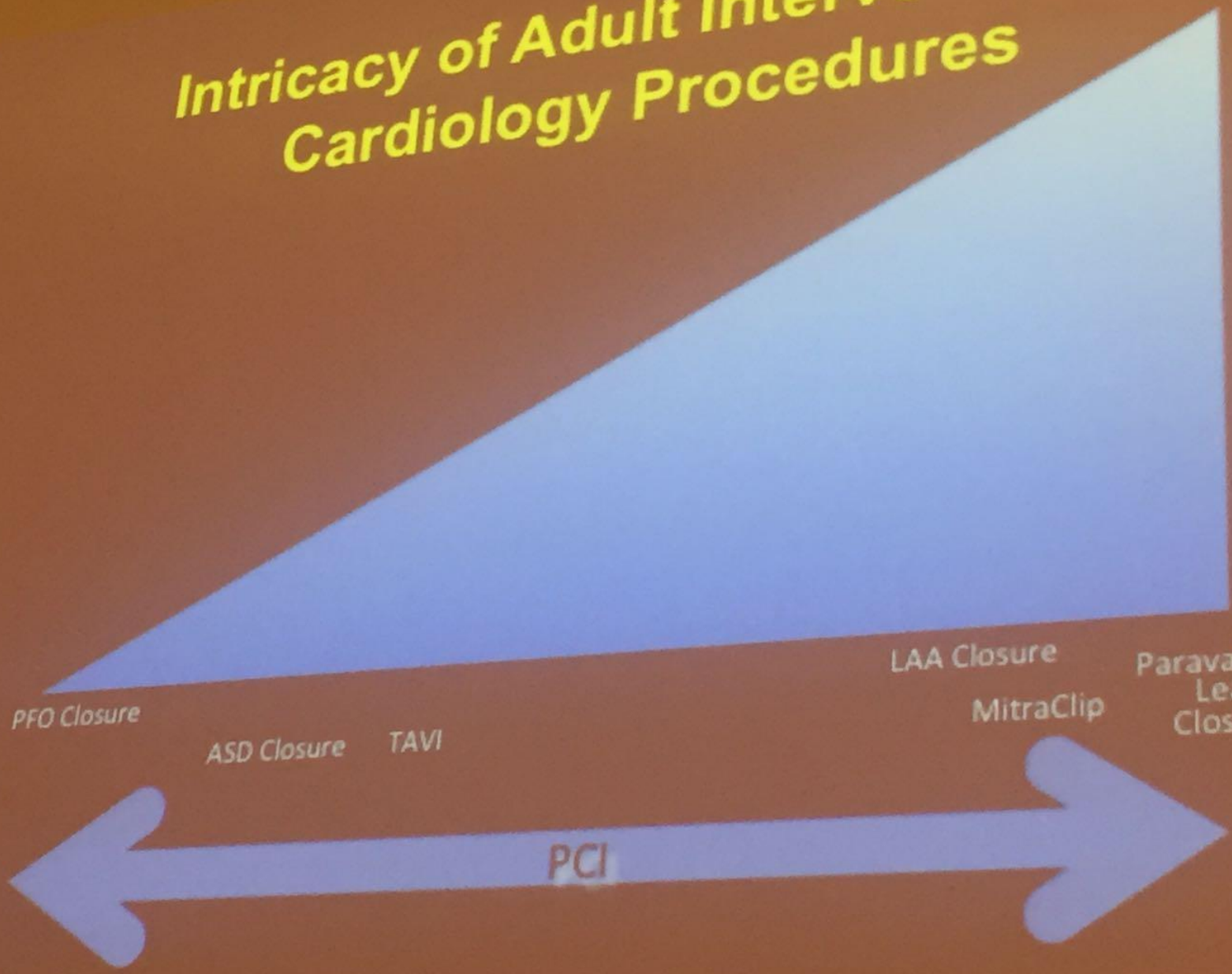
‘TAVI implant is more easy than surgical AVR?’

Intricacy of Adult Interventional Cardiology Procedures



‘TAVI implant is more easy than surgical AVR?’

- Recapture valve improve implant

- Differents access reduce vascular complications and increase patients cohorts

- New surgival valves open up new horizons

Rapid deployment valves

- Edwards Intuity Valve System
- Perceval S Sorin/Livanova

Edwards Intuity Valve System

One-year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: A prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY Valve System

Kocher et al

The Journal of Thoracic and Cardiovascular Surgery • January 2013

Reported mean EOA was 1.7 ± 0.2 cm^2 at discharge (n = 90) and remained unchanged at 3 months (n = 99) and 1 year (n = 65). Mean and peak systolic gradients were 9.8 ± 3.3 mm Hg and 18.7 ± 6.5 mm Hg at discharge, respectively (n = 108). Mean and peak pressure gradients were 8.8 ± 3.0 mm Hg and 16.7 ± 6.0 mm Hg at 3 months (n = 106), respectively, and decreased to 8.4 ± 3.4 mm Hg and 15.8 ± 5.7 mm Hg at 1 year (n = 68), respectively.

The majority of patients showed improvement (75.0%) (99/132) or remained in the same NYHA class (22.7%) at

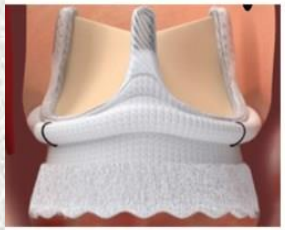
TABLE 4. Postoperative permanent pacemaker implants

Time period	Patient description	No baseline conduction disturbance n (%)	Previous conduction disturbance n (%)	All subjects n (%)
≤30 d	No. of patients at risk	102	39	141
	Valve related	0 (0.0%)	7 (17.9%)	7 (5.0%)
	Non–valve related	1 (1.0%)	2 (5.1%)	3 (2.1%)
>30 d	No. of patients at risk	98	29	127
	Valve related	1 (1.0%)	0 (0.0%)	1 (0.8%)
	Non–valve related	0 (0.0%)	2 (6.9%)	2 (1.6%)

Patients at risk have reached the start of the interval without a permanent pacemaker implant. Percentages are based on the number of patients with a postoperative pacemaker implant by the end of the interval divided by the number at risk at the start of the interval. Patients with "no baseline conduction disturbances" are those with "sinus" at the baseline electrocardiogram with no other conditions checked. Patients with a baseline pacemaker or pacemaker implanted intraoperatively are not included in this analysis.

Excellent 3-year hemodynamics[1]

Single-digit mean gradients (8.7 mmHg overall n = 59) demonstrated in the prospective, multi-center TRITON trial of 287 patients.[1]



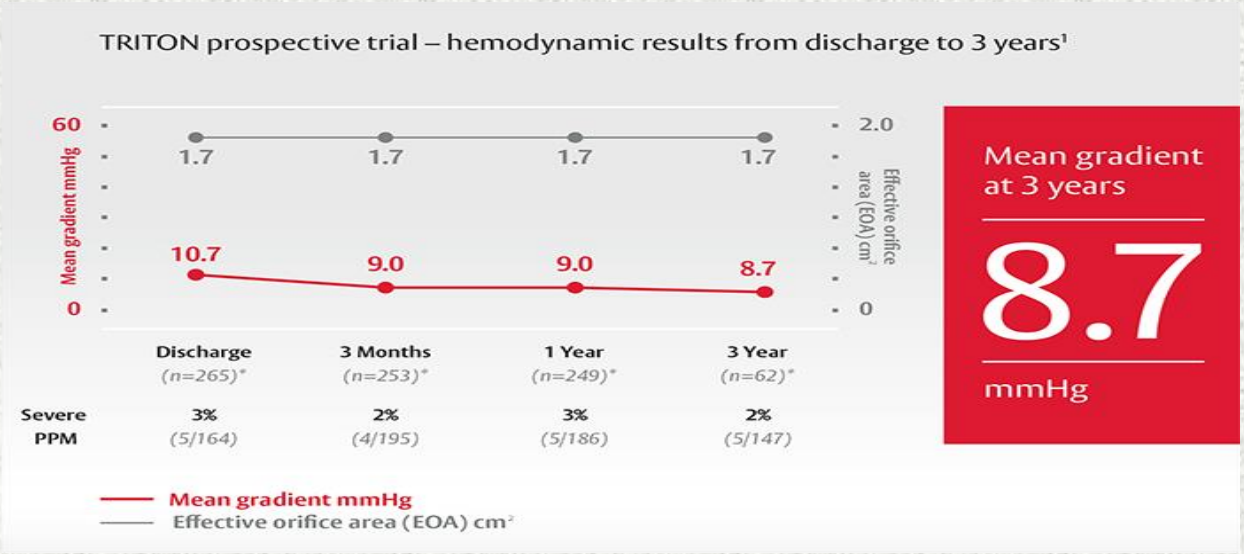
Low supra-annular profile for maximum options

Low supra-annular profile facilitates use with any aortotomy and provides excellent clearance from the coronary ostia.

Built on the PERIMOUNT valve performance

The EDWARDS INTUITY Elite valve system is built upon the proven performance and long-term durability of the PERIMOUNT valve design. By mounting matched leaflets under the flexible stent, commissural stress points are minimized.

FIGURE 1. Rapid-deployment aortic valve: EDWARDS INTUITY Valve System, Model 8300A (Edwards Lifesciences LLC, Irvine, Calif).



Perceval S Sorin/Livanova

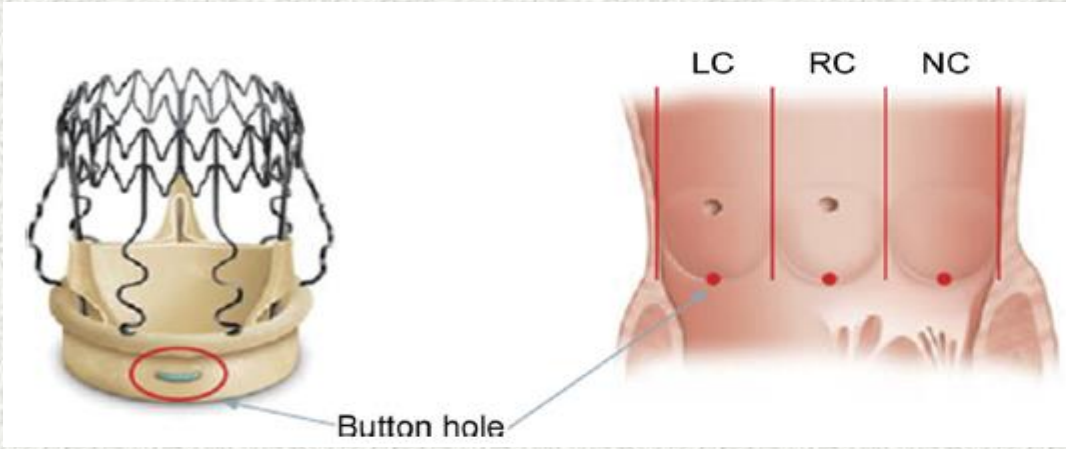


Fig 1. Valve design features: button holes. Button holes allow correct axial-rotational positioning in the native aortic root. (LC = left coronary; NC = noncoronary; RC = right coronary.)

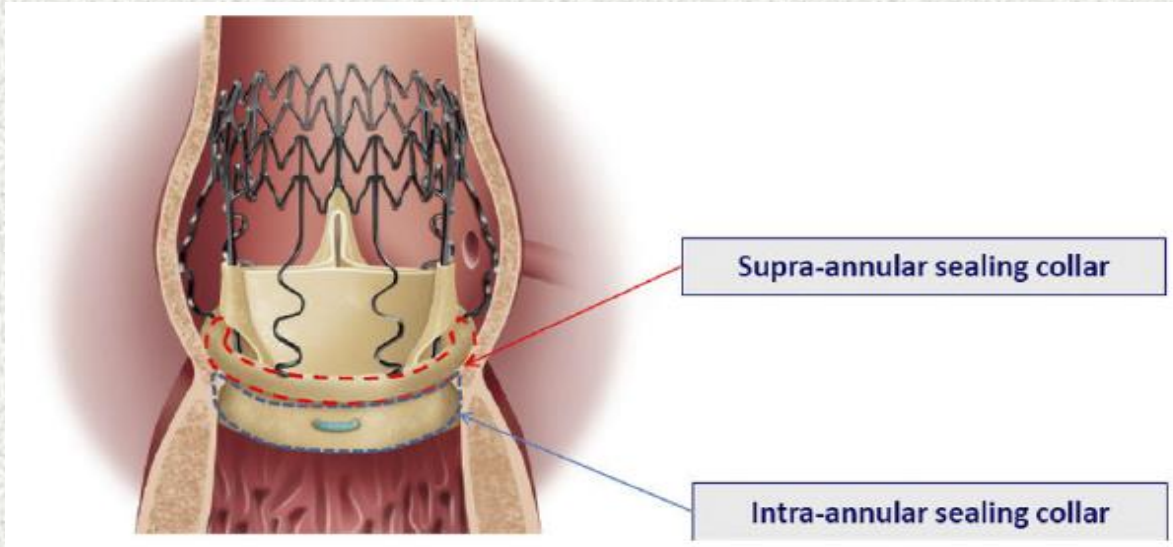


Fig 2. Valve design features dual collar design, with supraannular and intraannular sealing collar.

Table 3. Perceval S, Intraoperative Characteristics

Intra/Postoperative Data Patients (n = 208)	Median Sternotomy (n = 163)	Mini Sternotomy (n = 45)	With Concomitant CABG (n = 48)	Isolated AVR Patients (n = 160)
Cross-clamp time [min] 33.5 ± 13.8	33.5 ± 14.9	33.6 ± 9.5	44.2 ± 13.4	30.1± 12.2
CPB-time [min] 54.5 ± 24.2	51.1 ± 24	65.7 ± 21.4	67.6 ± 23.9	50.3 ± 22.8
Valve size [mm]				
21 = 32				
23 = 112				
25 = 64				

AVR = aortic valve replacement; CABG = coronary artery bypass grafting; CPB = cardiopulmonary bypass; min = minutes.

Table 1. Indications and Contraindications for the Sutureless Perceval S

Indications	Contraindications
Inclusion Criteria	*Exclusion Criteria*
• Subjects of age > 65 years; • Subjects with aortic valve stenosis or steno-insufficiency; • Subjects in NYHA functional classes III and IV with the logistic EuroSCORE greater than 5%; • Subjects who have agreed to participation in the clinical evaluation and who have signed the informed consent.	• Subjects with aneurysmal dilation or dissection of the ascending aortic wall needing surgical correction; • Subjects needing nonelective intervention; • Subjects with aortic annulus (after procedure for decalcification) of dimensions such that the implantation of a valve of size 21 or 23 mm is not possible (direct intraoperative measurement with sizer); • Subjects with congenital bicuspid aortic valve; • Subjects with aortic root enlargement, where the ratio between observed and expected diameters (calculated as a function of age and patient body surface area) is > 1.3; • Subjects with known hypersensitivity to nickel alloys.

EuroSCORE = European system for cardiac operative risk evaluation; NYHA = New York Heart Association.

Future perspective

- TAVI

- Suturless valve will replace standard aortic valve prosthesis (allows minimally invasive procedures)

Gold Standard in AVR

- No mechanical valve / avoid anticoagulation
- Easy implant
- **Safety (Low mortality and morbidity)**
- Durability

Surgical AVR vs TAVI

Trial	Risk	Outcome
Partner 1B CoreValve Extreme Risk	Inoperable	TAVI > Medical Therapy
Partner 1A CoreValve High Risk	High Risk	TAVI = SAVR TAVI > SAVR
Partner 2A SURTAVI	Intermediate Risk	TAVI ≈ SAVR
Partner 3 CoreValve EvolutRT	Low Risk	??

- Conversion of TAVI to surgery:30 day mortality 45%
- (Outcome of patients after emergency conversion from transcatheter aortic valve implantation to surgery, Hein et al, EuroIntervention 2013;9:446-451)

- AVR reoperation ‘Mortality rate for reoperation was 2.3%.’
- (Very Long-Term Outcomes of the Carpentier-Edwards Perimount Aortic Valve in Patients Aged 60 or Younger, Bourguignon T et al, Ann Thorac Surg 2015)

European Journal of Cardio-Thoracic Surgery 41 (2012) 1247–1253
doi:10.1093/ejcts/ezr204 Advance Access publication 12 January 2012

ORIGINAL ARTICLE

Contemporary outcomes of conventional aortic valve replacement in 638 octogenarians: insights from an Italian Regional Cardiac Surgery Registry (RERIC)†

Marco Di Eusanio[a,*], Daniela Fortuna[b], Donald Cristell[c], Peppino Pugliese[d], Francesco Nicolini[e], Davide Pacini[a], Davide Gabbieri[f] and Mauro Lamarra[g], on behalf of RERIC (Emilia Romagna Cardiac Surgery Registry) Investigators[‡]

Table 3: Post-operative outcome after aortic valve replacement in octogenarian and non-octogenarian patients

	Age < 80 (*n* = 2540)		Age ≥ 80 (*n* = 638)		*P*-value
	n	%	*n*	%	
Hospital death	52	2.0	29	4.5	0.0003
Intubation time > 48 h	61	2.4	20	3.4	0.29
Stroke	15	0.6	8	1.3	0.056
Renal insufficiency (without dialysis)	46	1.8	23	3.6	0.004
Dialysis	28	1.1	8	1.3	0.75
Acute myocardial infarction	5	0.2	2	0.3	0.57
Atrial fibrillation	645	25.4	216	33.9	<0.0001
Complete atrio-ventricular block	56	2.2	28	4.4	0.002
Rethoracotomy for bleeding	79	3.1	24	3.7	0.51
ICU length of stay (days; mean ± SE)	2.1 ± 0.1		2.4 ± 0.3		0.18
Hospital length of stay (days; mean ± SE)	14.2 ± 0.2		16.6 ± 0.5		<0.0001

Minimally invasive aortic valve replacement in octogenarian, high-risk, transcatheter aortic valve implantation candidates

Andrew W. ElBardissi, MD, MPH, Prem Shekar, MD, Gregory S. Couper, MD, and Lawrence H. Cohn, MD

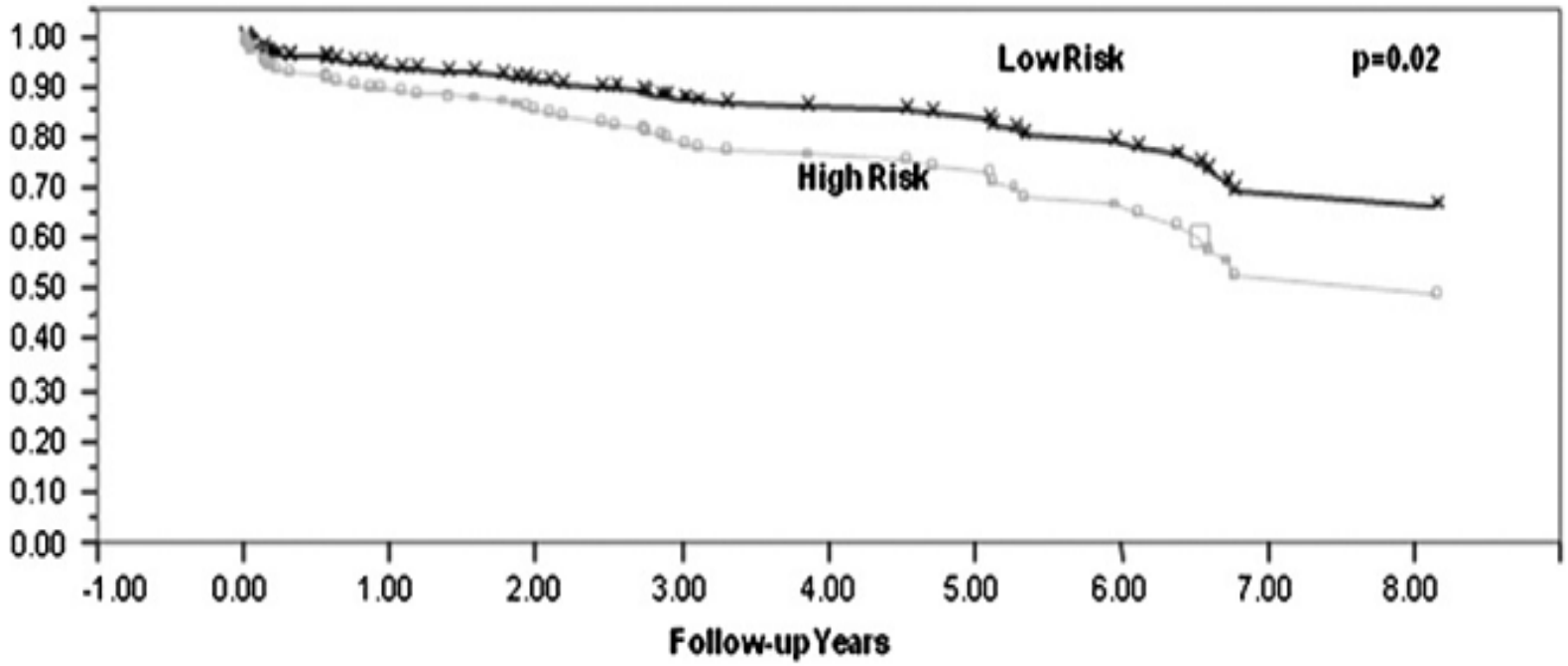


FIGURE 3. Long-term survival clinical prediction model.

Influence of Transcatheter Aortic Valve Replacement Strategy and Valve Design on Stroke After Transcatheter Aortic Valve Replacement

A Meta-Analysis and Systematic Review of Literature

Ganesh Athappan, MD,* R. Dilip Gajulapalli, MD,† Prasanna Sengodan, MD,* Anju Bhardwaj, MD,* Stephen G. Ellis, MD,† Lars Svensson, MD, PhD,† Emin Murat Tuzcu, MD,† Samir R. Kapadia, MD†

Cleveland, Ohio

Neurological outcomes

25 multicenter registries and 33 single-center studies were included in the analysis. There was no difference in pooled **30-day stroke post-TAVR between the TF and TA** approach in multicenter (**2.8%** [95% confidence interval (CI): 2.4 to 3.4] vs. **2.8%** [95% CI: 2.0 to 3.9])
and single-center studies (**3.8%** [95% CI: 3.1 to 4.6] vs. **3.4%** [95% CI: 2.5 to 4.5]).
Similarly, there was no difference in pooled 30-day stroke post TAVR **between the CoreValve and Edwards**
Valve in multicenter (**2.4%** [95% CI: 1.9 to 3.2] vs. **3.0%** [95% CI: 2.4 to 3.7]) and single-center studies (**3.8%** [95% CI: 2.8 to 4.9] vs. **3.2%** [95% CI: 2.4 to 4.3]).
There was a decline in stroke risk with experience and technological advancement.
There was no difference in the outcome of 30-day stroke between TAVR and surgical aortic valve replacement

J Am Coll Cardiol 2014;63:2101–10)

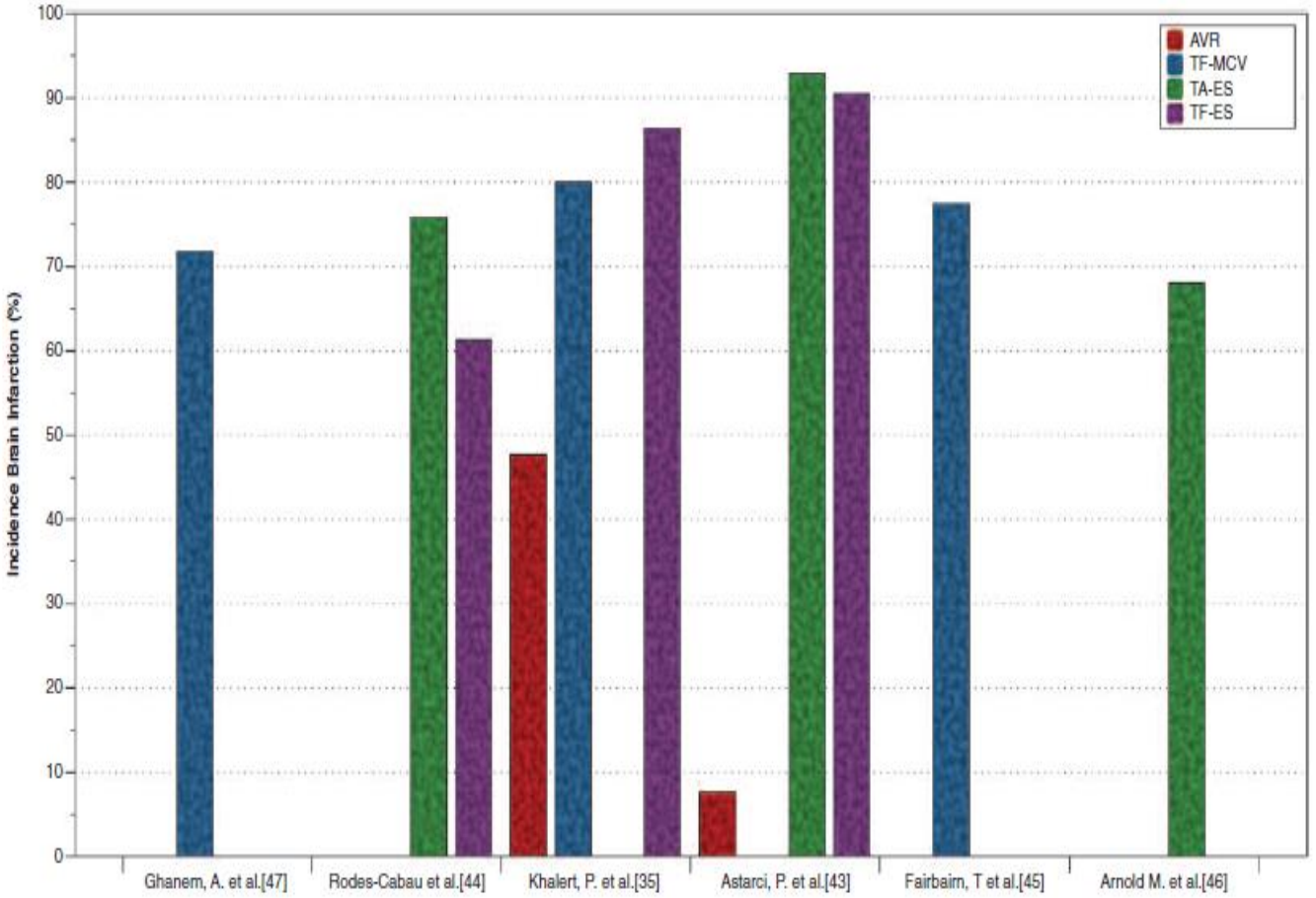


Figure 5. Silent cerebral ischemic lesions on DW-MRI post-TAVI. AVR indicates aortic valve replacement; DW-MRI, diffusion-weighted MRI; ES, Edwards SAPIEN valve; MCV, Medtronic CoreValve; TA, transapical; TAVI, transcatheter aortic valve implantation; and TF, transfemoral.

Circulation. 2014;129:504-515

Neurological protection

2016 euro PCR

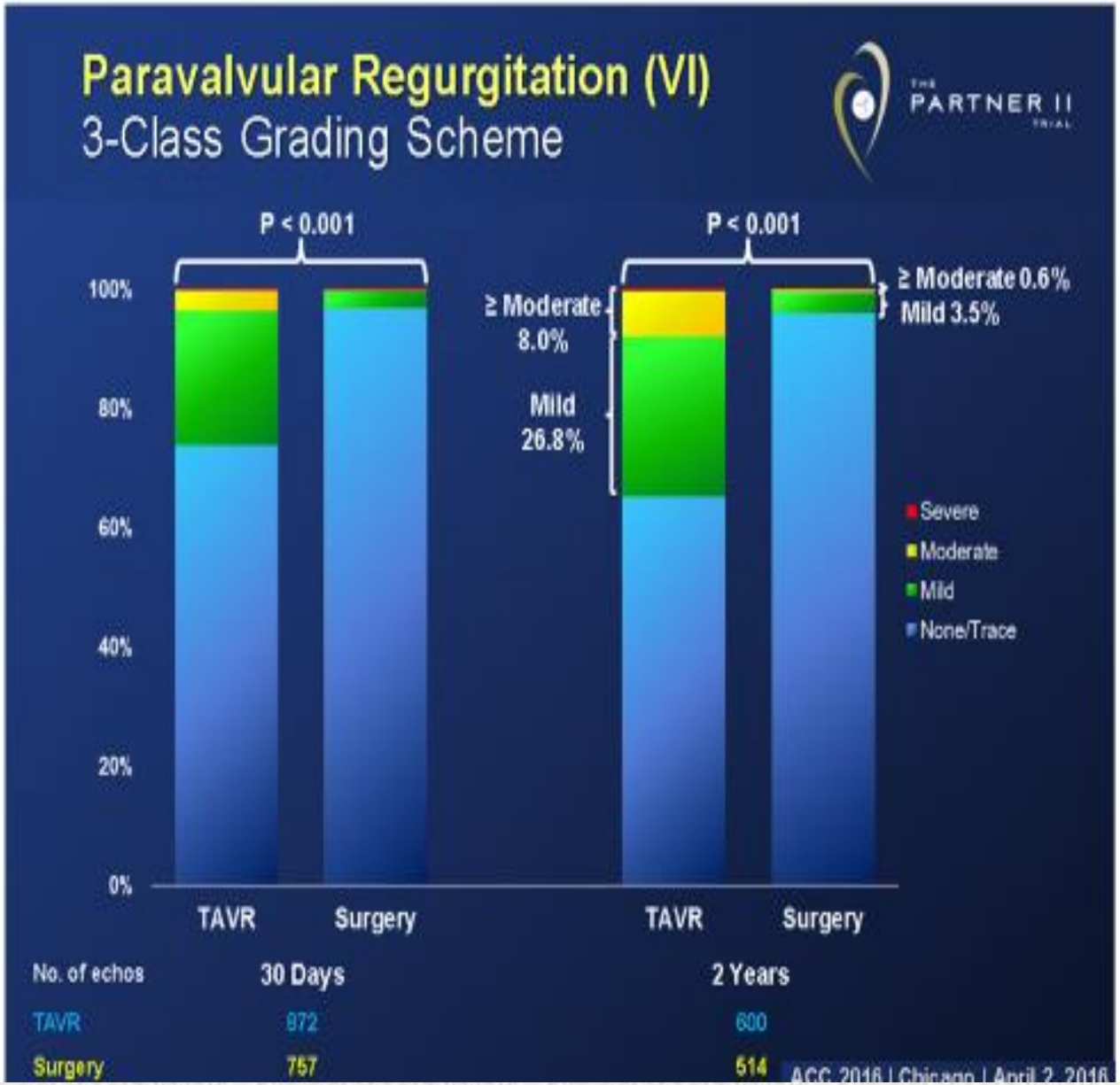
A Patient Level Pooled Analysis of NeuroProtection with the TriGuard Embolic DEFLECTion Device Compared to Unprotected Transcatheter Aortic Valve Replacement

Alexandra Lansky, MD
Yale University School of Medicine
New Haven, CT

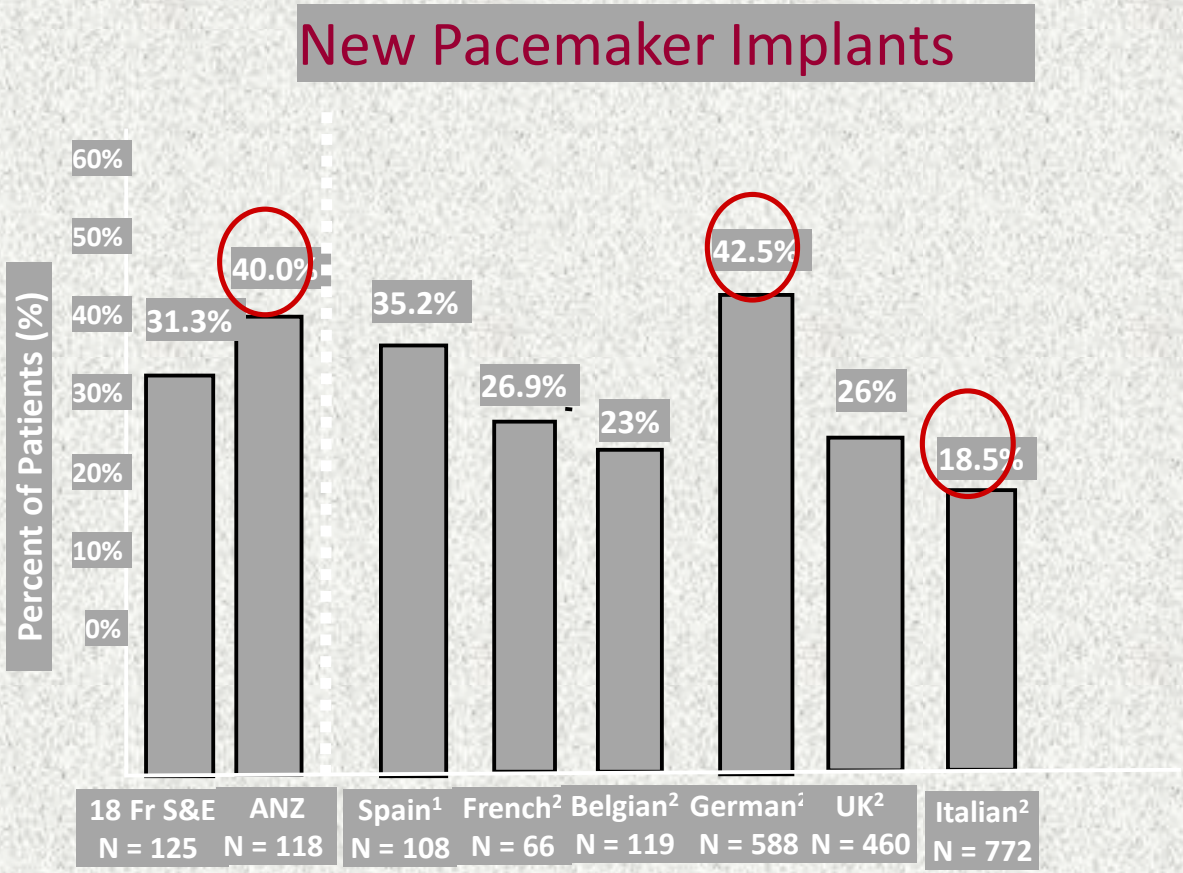
	TriGuard N=59	Controls N=83	P value
Incidence of CNS Infarction	72%	92%	0.008
Number of Lesions	3 [0-8]	4.5 [2-10]	0.07
Total DWI volume mm^3 [IQR]	101.4 [0-337]	174 [67-575]	0.04
Average DWI volume mm^3 IQR]	25 [0-8]	43 [18-67]	0.07
Total Volume			
None	27.9%	8.3%	0.008
Small (1-50mm^3)	14%	10%	0.54
Medium (>50-150mm^3)	14%	28%	0.08
Large (>150mm^3)	44%	53%	0.36

Conclusions

- Neuroprotection with TriGuard
  - Is safe
  - Associated with reduced Cerebral Infarction :
    - 40% reduction in volume of brain lesions
    - 28% freedom from any cerebral ischemic lesions
  - Associated with reduced stroke:
    - Reduction in VARC defined Stroke (p=0.05)
    - Reduction in new neurologic deficits (0% vs 19%, p=0.001) post-procedure by systematic NIHSS assessment and bain imaging
- The pivotal REFLECT RCT is designed to confirm our results.



CoreValve Pacemaker Implantation Varies Between Studies



1. Avanzas P, et al. *Rev Esp Cardiol.* 2010;63:141-148.
2. TAVI Facts, Figures and National Registries. EuroPCR

Eugene Braunwald….

We are facing a new cardiology : the A-V block is not a complication and the use of pace-maker has no consequences, the valve regurgitation becames acceptable , the stroke is accepted because a presumed minimal invasive procedure is performed . Amazing !!!!!!

We can't stop this trend , but it is not for me !

Future Perspective

- Device for neuroprotection
- Improve design to reduce paravalvular leak
- PM implant is around 10%

- **TAVI is for all except for Eugene Braunwald**

Gold Standard in AVR

- No mecchanical valve / avoid anticoagulation
- Easy implant
- Safe procedure (Low mortality and morbidity)
- Durability

Very Long-Term Outcomes of the Carpentier-Edwards Perimount Aortic Valve in Patients Aged 60 or Younger

(Ann Thorac Surg 2015;■:■–■)

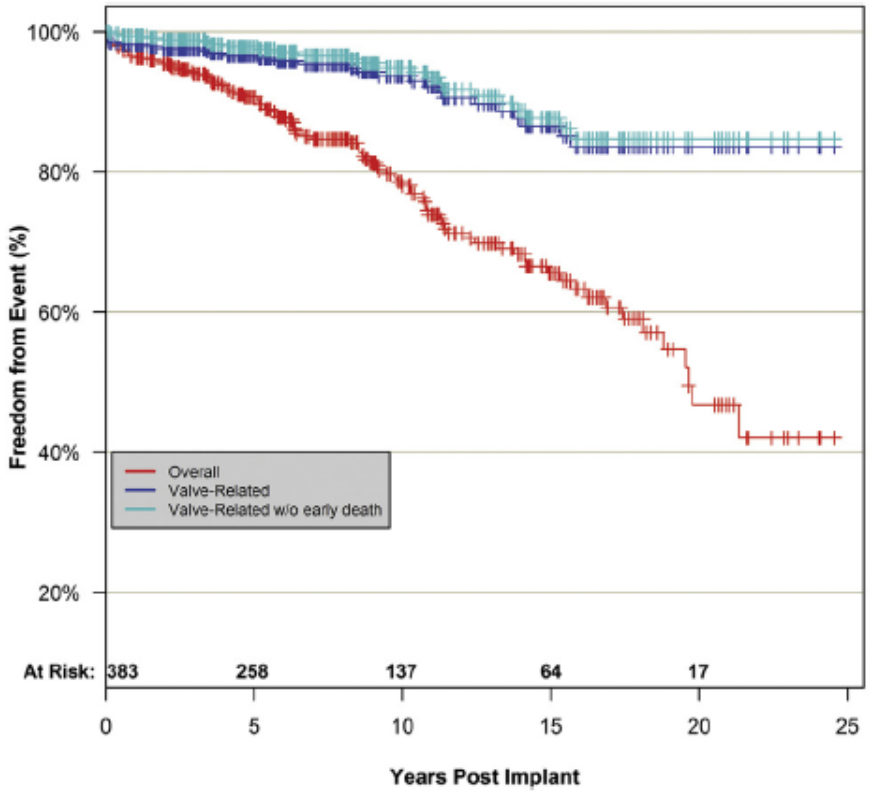


Fig 1. Kaplan-Meier estimates of overall (red) and valve-related survival with (blue) and without early death (green).

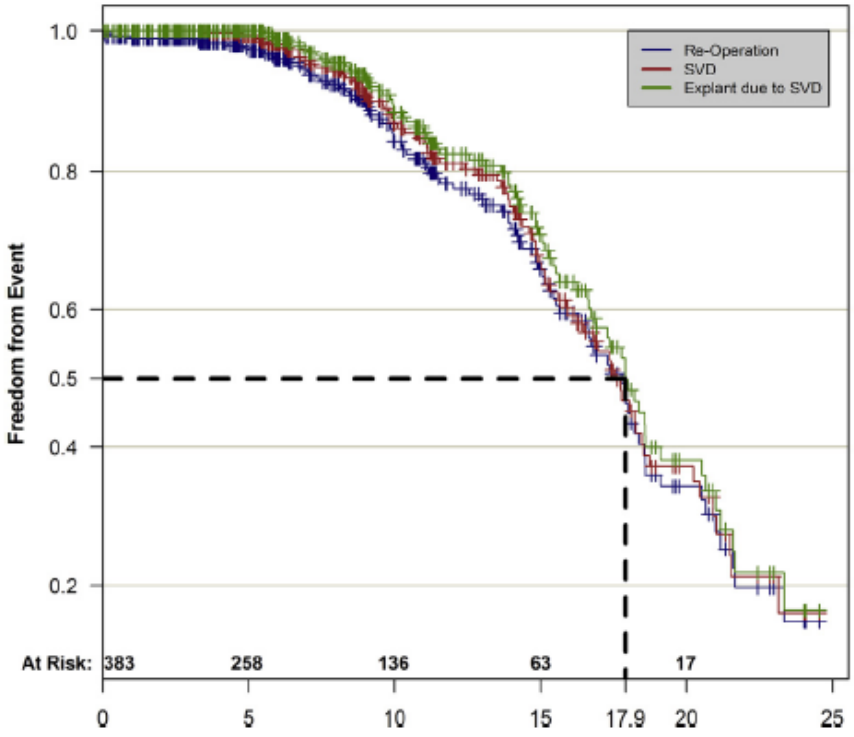


Fig 3. Kaplan-Meier estimates of freedom from reoperation (blue), structural valve deterioration (SVD; red), and explant as a result of structural valve deterioration (green). The expected valve durability (median survival time without structural valve deterioration) was 17.6 years.

Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

2016 euro PCR

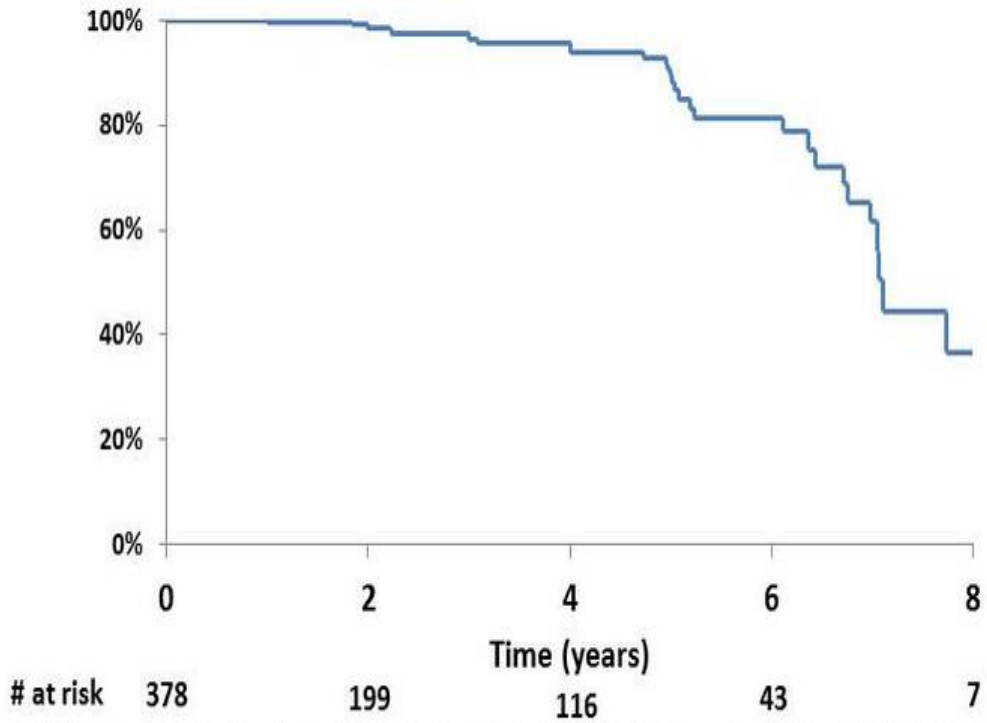
First look at long-term durability of transcatheter heart valves:

Assessment of valve function up to 10-years after implantation

Danny Dvir, St. Paul's Hospital, Vancouver, Canada.

On behalf of coauthors: Helene Eltchaninoff, Jian Ye, Arohumam Kan, Eric Durand, Anna Bizios, Anson Cheung, Mina Aziz, Matheus Simonato, Christophe Tron, Yaron Arbel, Robert Moss, Jonathon Leipsic, Hadas Ofek, Gidon Perlman, Marco Barbanti, Michael A. Seidman, Philippe Blanke, Robert Yao, Robert Boone, Sandra Lauck, Sam Lichtenstein, David Wood, Alain Cribier, John Webb

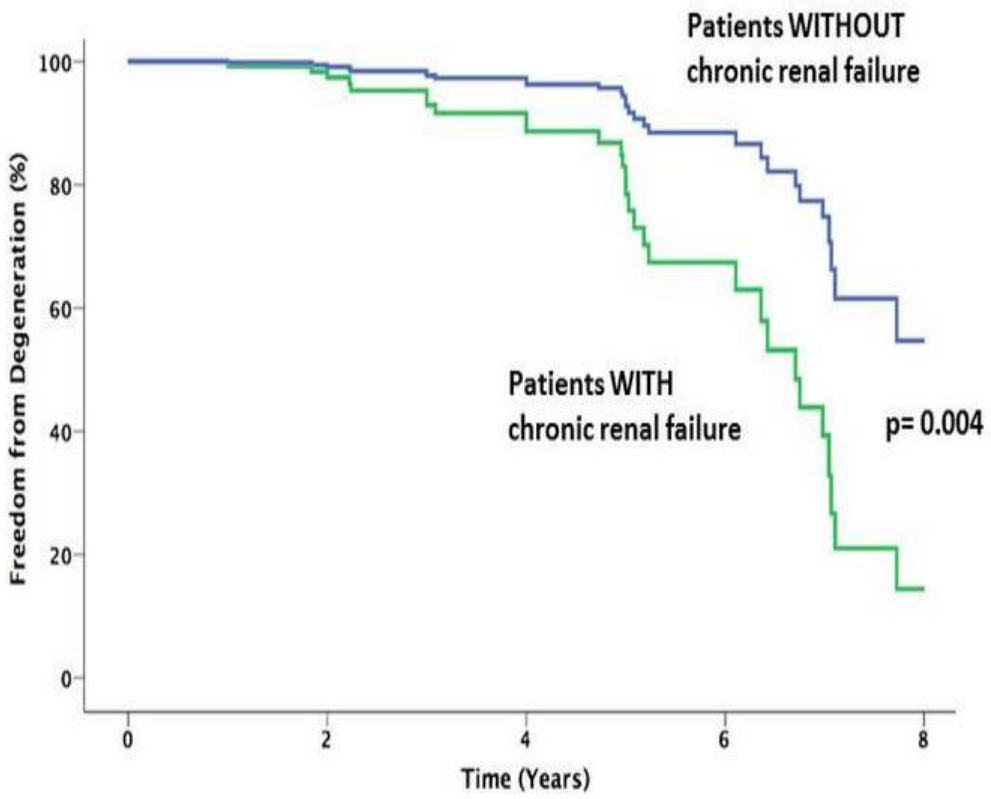
Freedom from THV degeneration



THV degeneration was defined as at least moderate regurgitation AND/OR mean gradient ≥ 20mmHg, which did not appear within 30 days of the procedure and is not related to endocarditis.

KM estimate of THV degeneration included censoring of patients at their date of last known THV functioning well without evidence for degeneration per study definition.

Freedom from THV degeneration



Objectives

phisicians

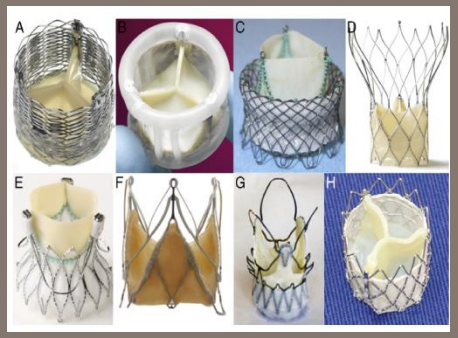
Efficiency

Quality, Safety, durability

+

industries

innovations



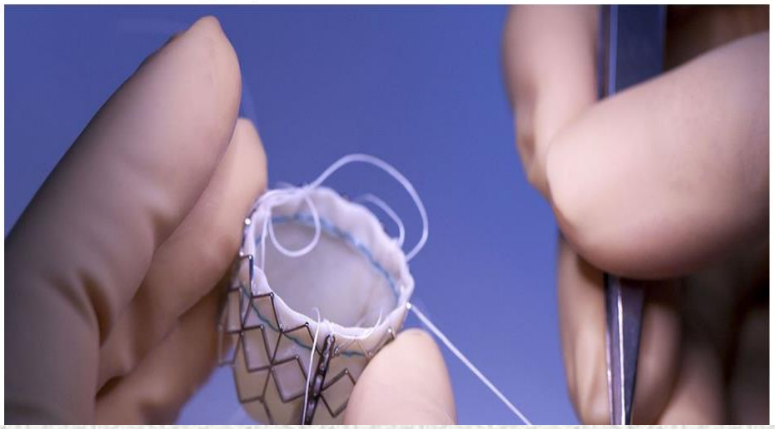
Improve technologies lead to better outcomes

INVESTOR'S BUSINESS DAILY

RESEARCH

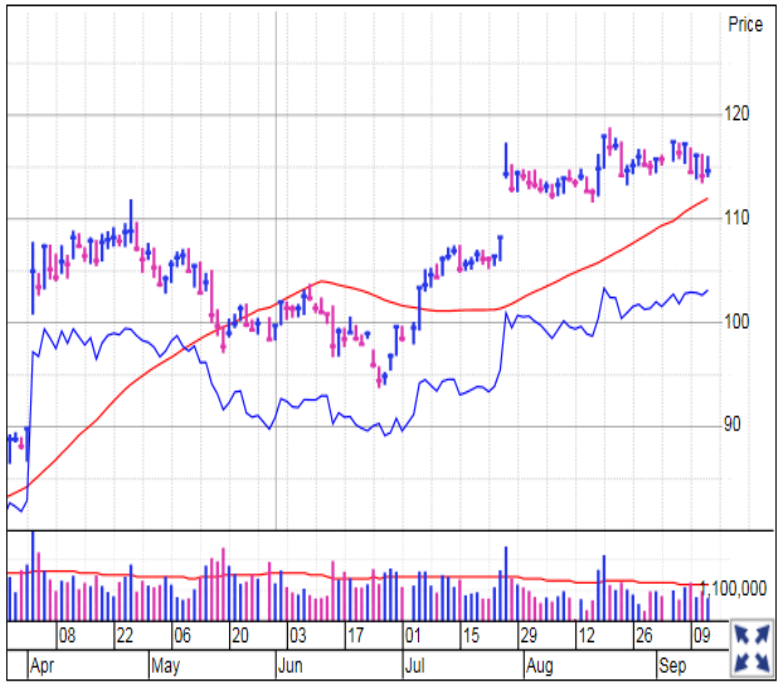
THE NEW AMERICA

Edwards Lifesciences Is Taking The Surgery Out Of Heart Surgery



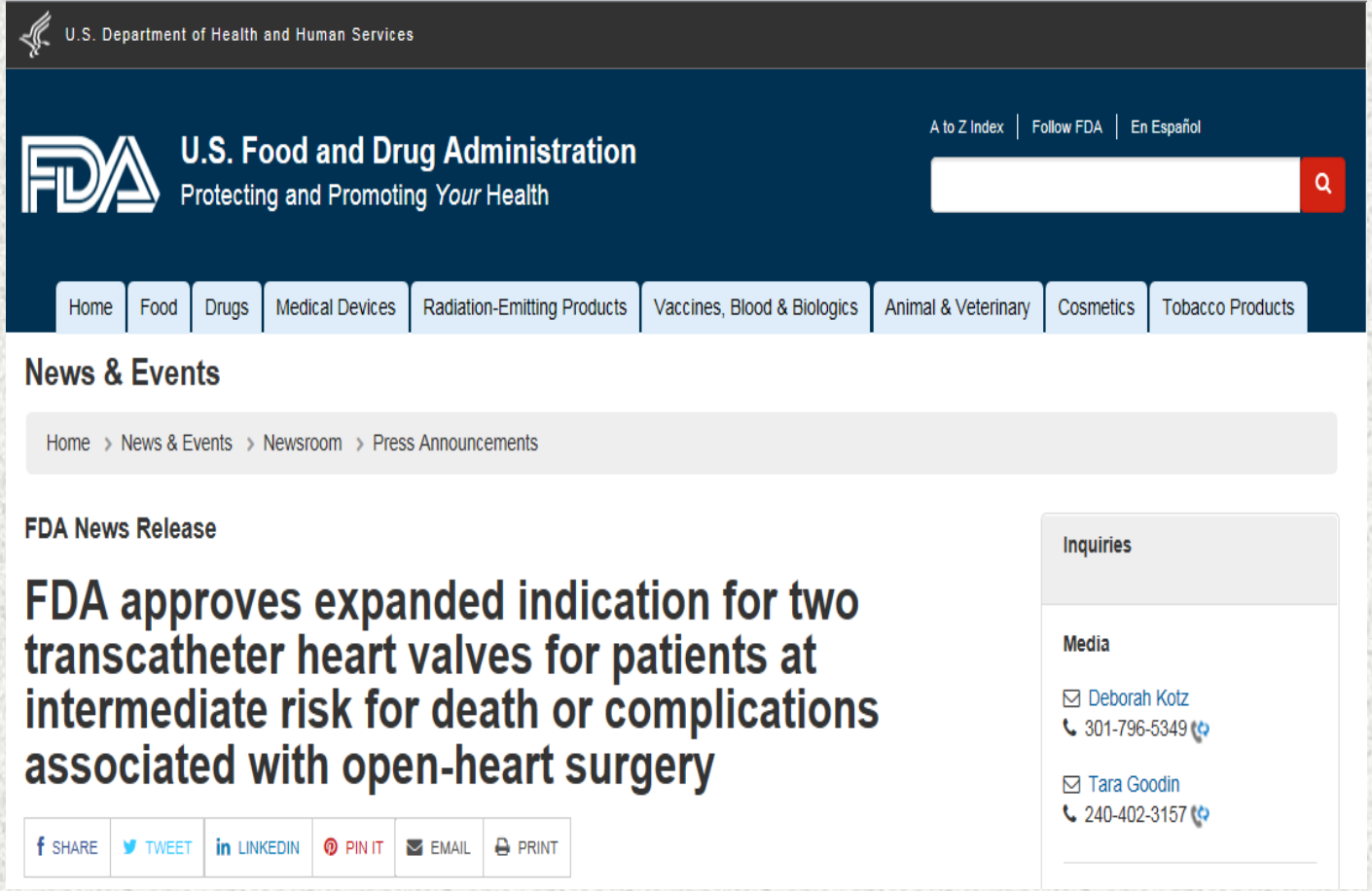
Edwards Lifesciences Cp (EW)

$114.72 ⬆0.47 (0.41%)



09/14/2016 (Market Close)

"To us, better-than-expected growth for now nine quarters in a row despite ramping competition both in the U.S. and Europe signifies that: (1) The TAVR market is clearly growing seemingly sustainably faster than expected, which we now expect to exceed $5.3 billion by 2021 (+22% over the 2015-2021 time frame); and (2) Edwards' Sapien 3 is best-in-class, particularly now with data demonstrating overwhelming superiority vs. surgery in intermediate-risk patients," Leerink analyst Danielle Antalffy wrote in a research note after Edwards' second-quarter report on July


U.S. Department of Health and Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

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FDA News Release

FDA approves expanded indication for two transcatheter heart valves for patients at intermediate risk for death or complications associated with open-heart surgery

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Inquiries

Media

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301-796-5349

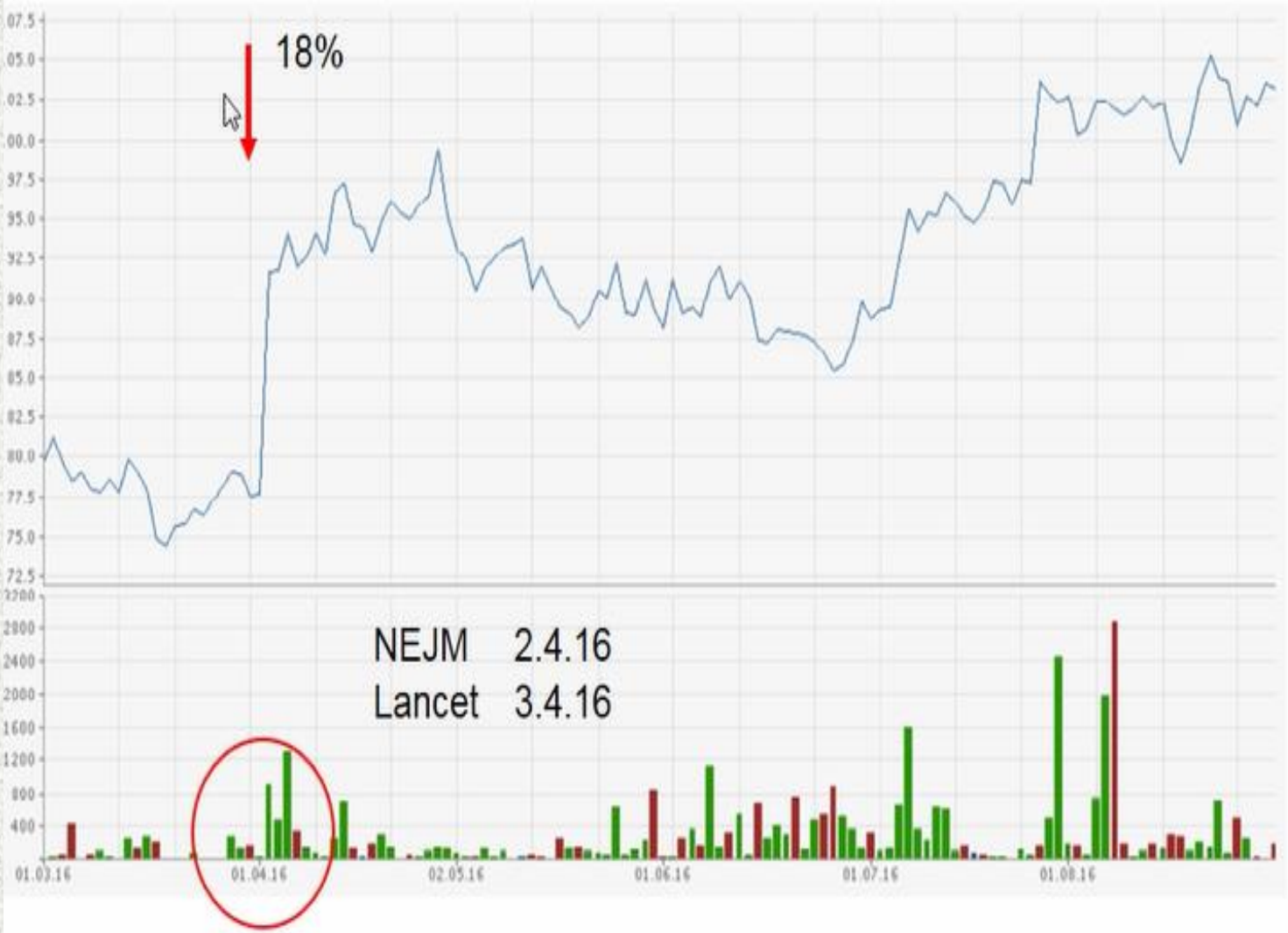
Tara Goodin
240-402-3157

As part of the approval of these devices, the FDA is requiring the manufacturer to conduct a post-approval study to follow the patients treated with either device in the first and second clinical studies for 10 years to further monitor safety and effectiveness.

Edwards shareholder value

01.03.2016 bis 31.08.2016

Quelle: www.finanzen.net /07.09.2016



The Key to the Ideal Experience

phisicians

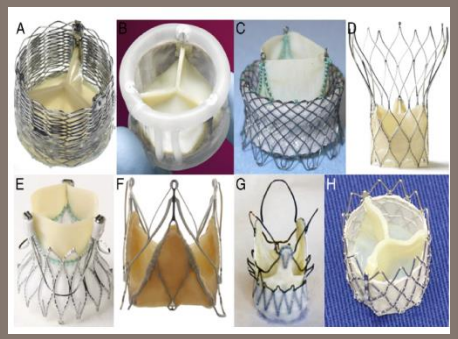
Efficiency

Quality, Safety, durability

\+

industries

innovations



Communication, Relationship,

=

Human Experience

Loyalty, Health Focus on patients purpose


“True Innovation Improves the Human Experience.” – Alexander Blass

Edwards Lifescience stock price

NEJM 2.3.2016., Lancet 3.4.2016.