Role of
Sutureless/Rapid Deployment Valve Replacement

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Current Options for AVR

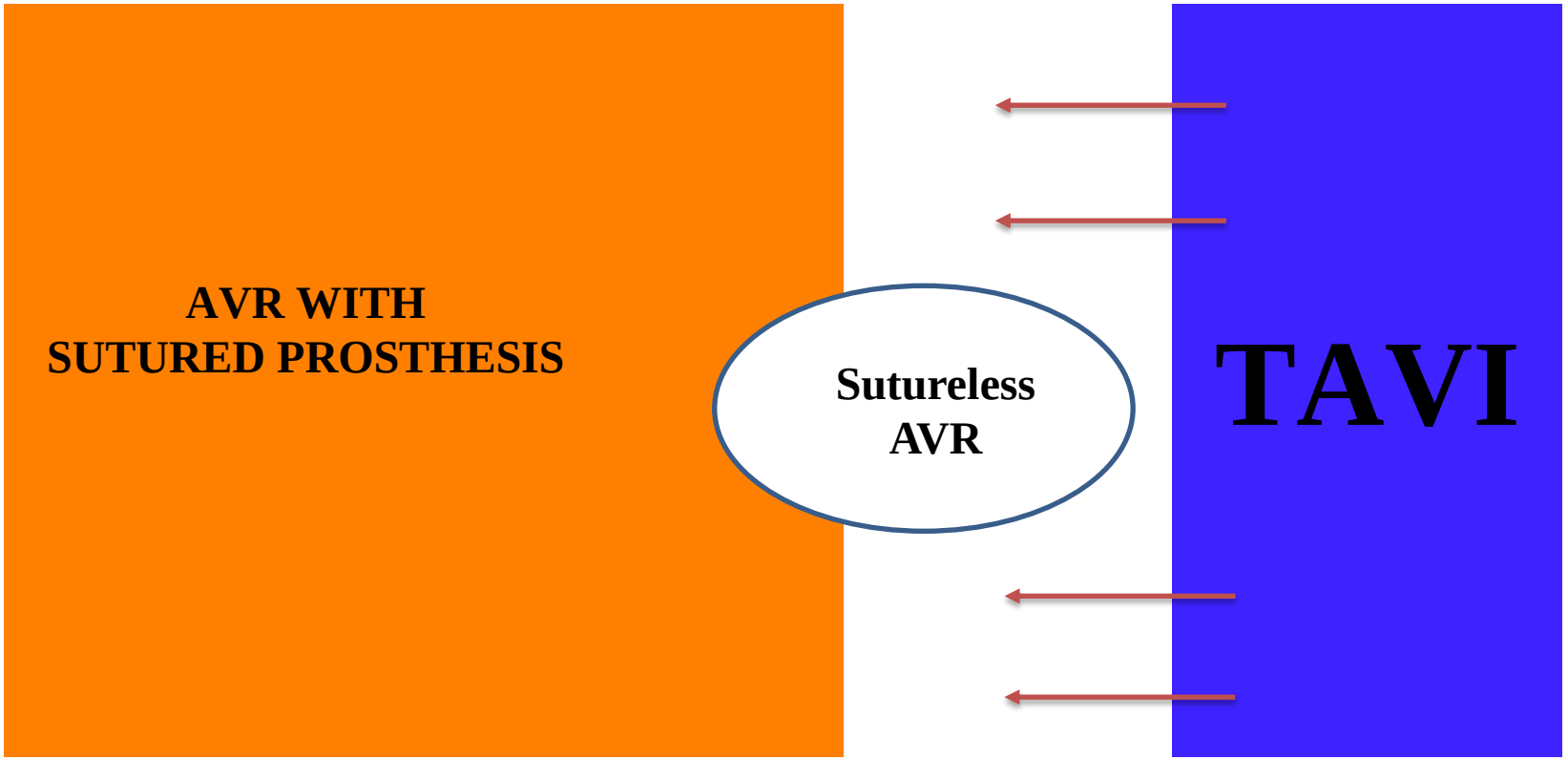
✓ Surgical aortic valve replacement (Gold standard therapy)

- Traditional valve replacement
- Sutureless valve replacement

✓ TAVI

- Alternative procedure for treating aortic stenosis in high risk patients
- Expansion of indications from inoperable pts to high risk pts

Current Indications



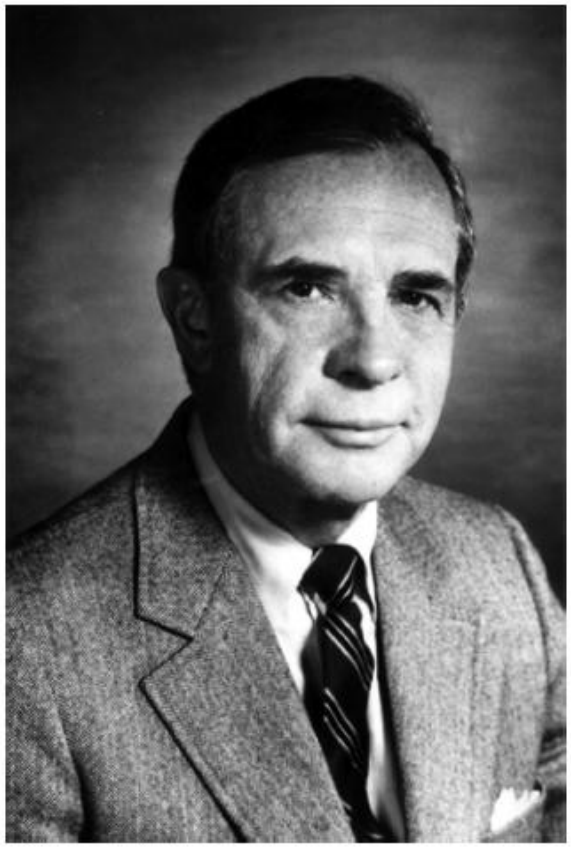
LOW RISK	MEDIUM RISK	HIGH RISK

OPERABLE	NOT OPERABLE

Expansion of TAVI is justified to low or medium risk patients ?

Concept of Sutureless Valve Replacement

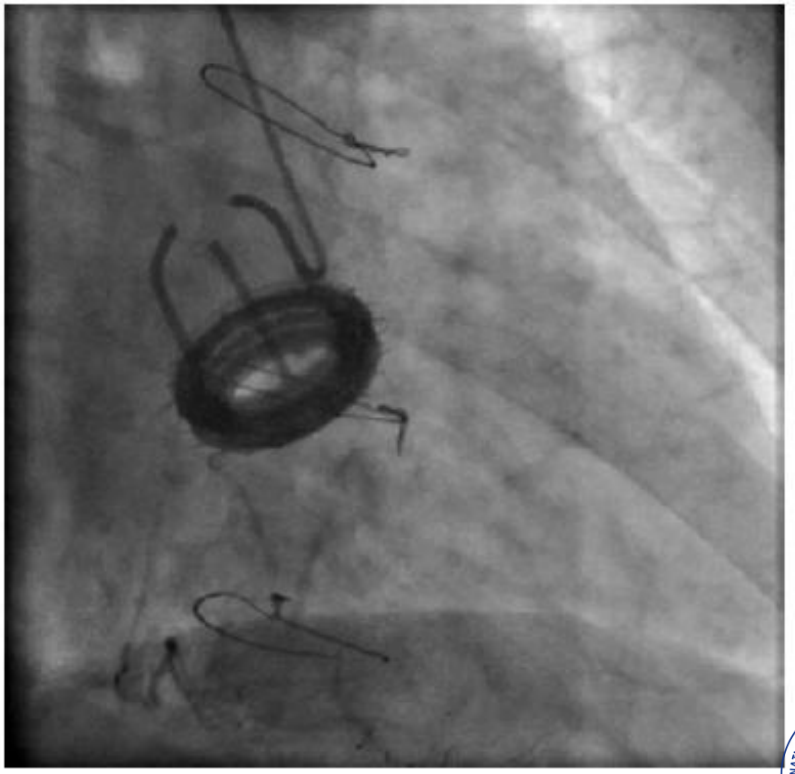
- ✓ George Jerome Magovern (1923 – 2013)
- ✓ The 20th president of the Society of Thoracic Surgeons
- ✓ First use of sutureless valve
  - 1962. 4.13
  - Magovern-Cromie sutureless prosthetic aortic valve



Concept of Sutureless Valve Replacement

A Perfectly Functioning Magovern-Cromie Sutureless Prosthetic Aortic Valve 42 Years After Implantation

Amnon Y. Zlotnick, MD; Avinoam Shiran, MD; Basil S. Lewis, MD; Dan Aravot, MD



Circulation 2008;117:e1-e2

Concept of Sutureless Valve Replacement

- Absence or reduction of anchoring suture

→ Shortening the time required for valve replacement

- Shortening the aortic cross clamp time
- Shortening the cardiopulmonary bypass time
- Enhancing minimal invasive surgery

Current products of Sutureless Valve

TABLE 1. Design Characteristics

	Edwards INTUITY	Sorin Perceval S	Medtronic 3F Enable
CE mark	2012	2011	2012
Available patient follow-up	3 y	5 y	5 y
Design platform	Bovine pericardium, trileaflet, balloon expandable, stainless steel cloth-covered frame	Bovine pericardium, trileaflet, self-expandable nitinol frame with additional proximal and distal rings for annulus fixation	Three equal sections of equine pericardial tissue forming tubular structure, self-expandable nitinol frame covered in polyester fabric, equally spaced commissural tabs reinforced with polyester material
Available sizes	19, 21, 23, 25, 27 mm	21, 23, 25 mm	19, 21, 23, 25, 27, 29 mm
Rinsing	2 times, 60 s each	Not required	3 times 120 s each
Sutures	3 actual sutures	None/only guiding sutures	0/1 actual suture
Collapsible	Crimped	Yes, with collapsing tool	Yes, manual folding

CE, Conformité Européenne.

Innovations 2016;11:7-14, Barnhart

Advantage of sutureless valve

✓ Compared to traditional AVR

- Rapid delivery (Reduced CPB and ACC time)

→ Suitable for high risk patients or requiring concomitant operation

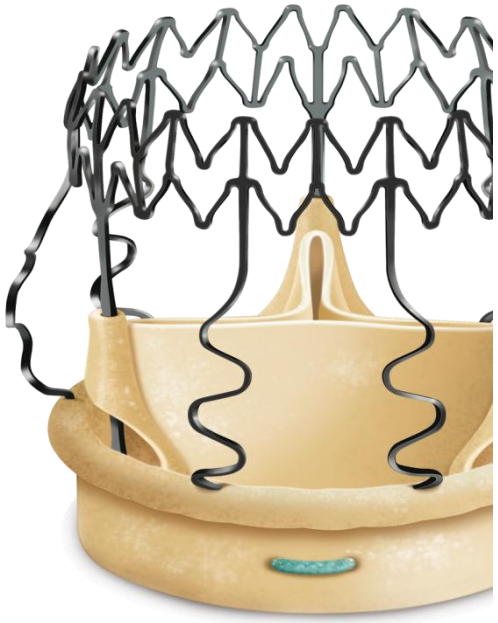
- Enhances MICS procedure

✓ Compared to TAVI

- Removal of diseased valve
- Decalcification of the annulus
- Implantation under direct vision : proper fitting

What is Perceval?

Perceval is pericardial heart valve with a sutureless and collapsible design that simplifies the surgical implantation, reducing operative trauma and post-operative complications and enables faster pt recovery. [1,2,3]

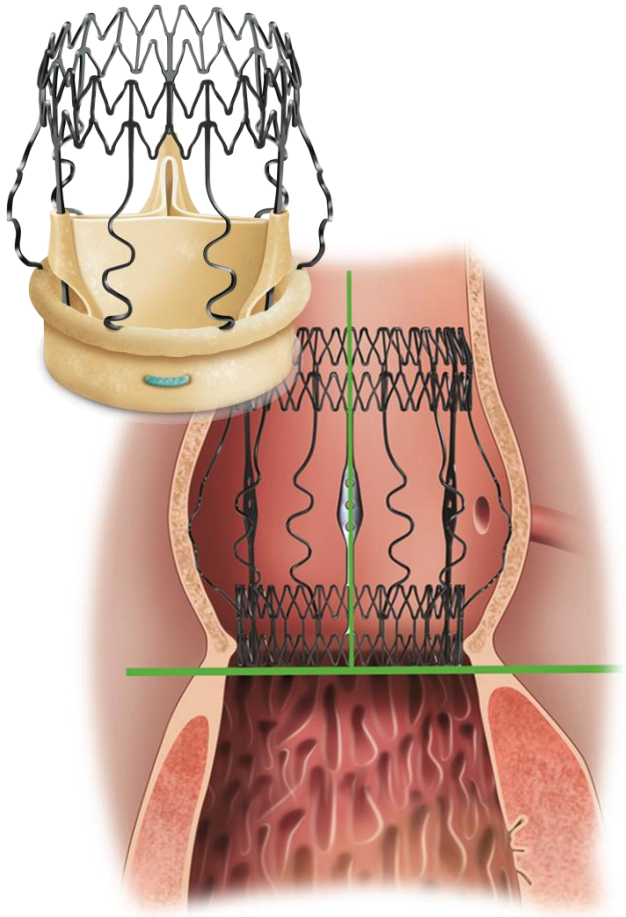


1. Santarpino et al. - Ann Thorac Surg 2013 ; 96(1) 77-81
2. Santarpino et al. - Ann Thorac Surg 2012;94:504
3. Gilmanov et al. - Ann Thorac Surg 2013;96:2101–8

What is Perceval?
Key Features

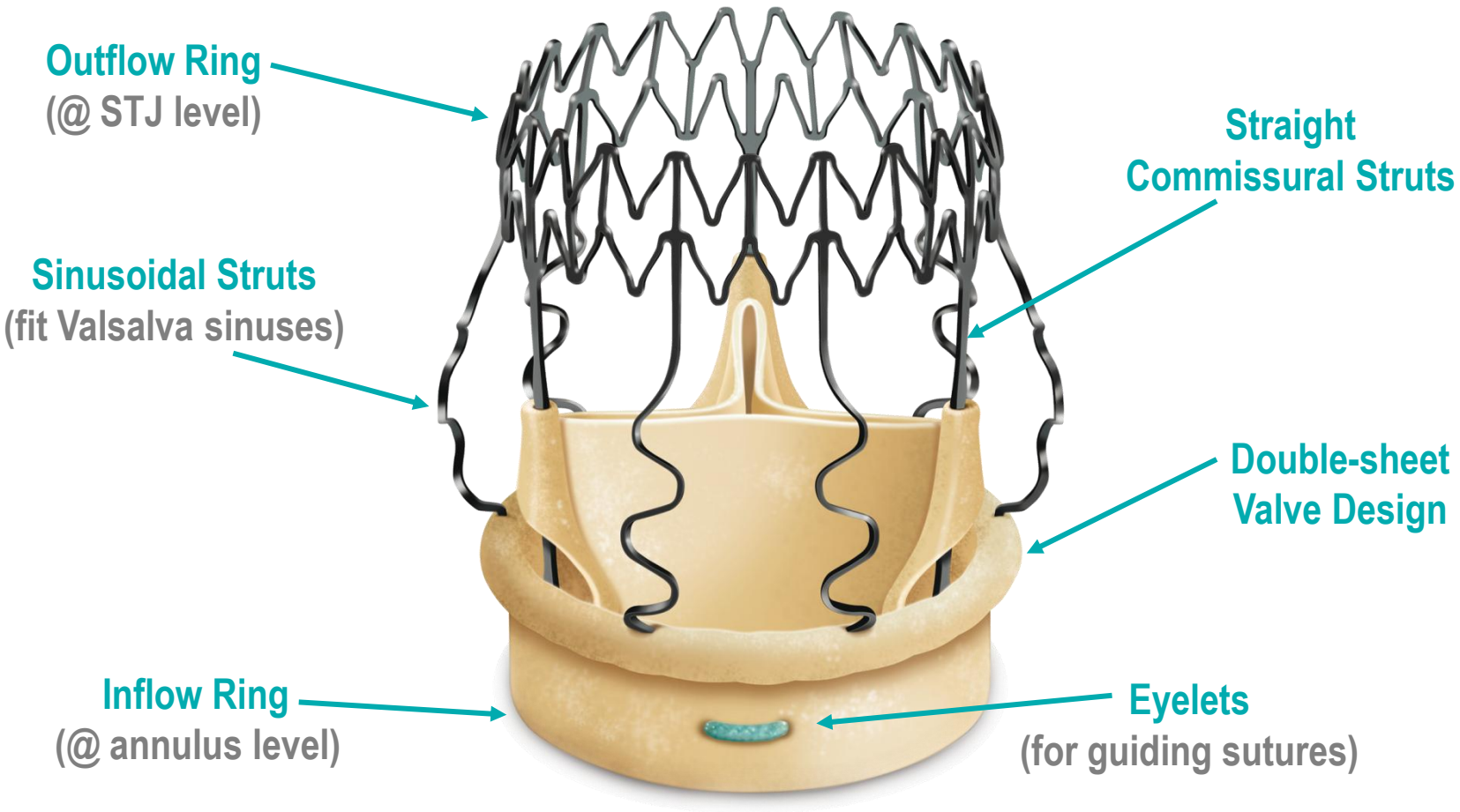
Valve features
– bovine pericardium
– eyelets for guiding suture positioning

Self-anchoringframe
– self-expanding, Ni-Ti alloy
– anatomical design to fit Valsalva sinuses
– tapered outflow ring design
– special inflow ring design
– Carbofilm™ coating



What is Perceval?

Valve Design

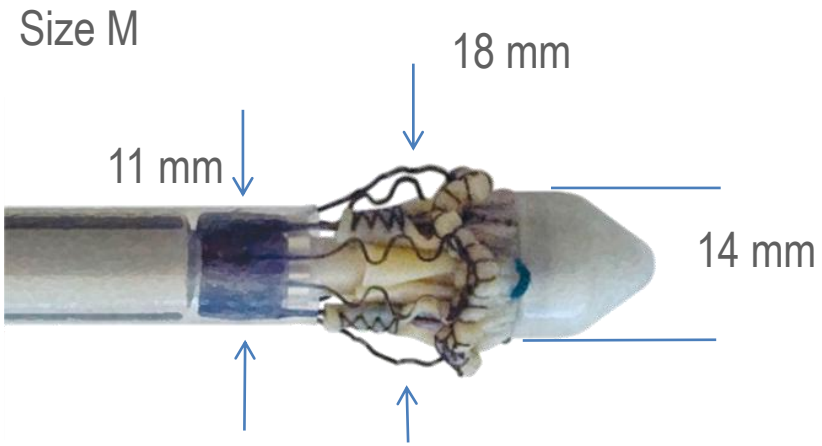


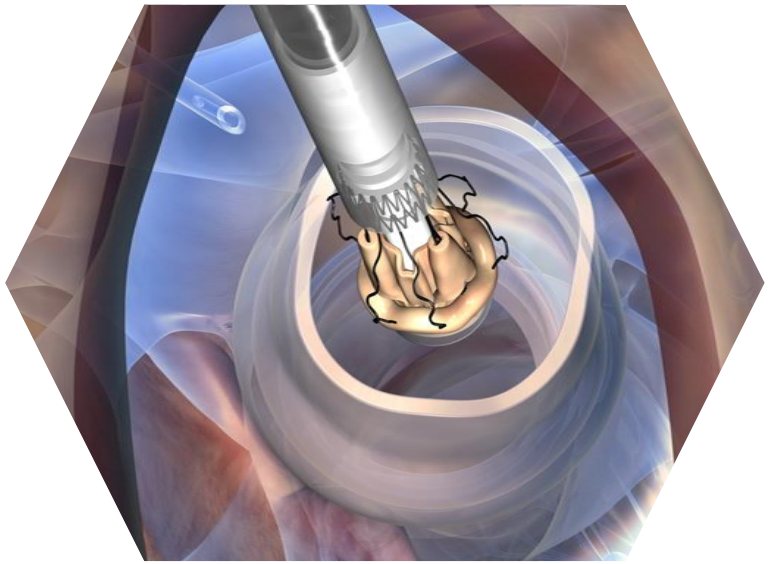
What Are the Main Advantages of Perceval?

Collapsible

Unique collapsible design

Thanks to dedicated accessories, the valve diameter can be reduced prior to the operation.
This increases the visualization and facilitates also more complex procedures.





Current Results

European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients†

Malakh Shrestha[a,*], Theodore Fischlein[b], Bart Meuris[c], Willem Flameng[c], Thierry Carrel[d], Francesco Madonna[e], Martin Misfeld[f], Thierry Folliguet[g], Axel Haverich[a] and Francois Laborde[g]

Excellent clinical results reported:

Conclusions : This European multicentre experience, with the largest cohort of patients with sutureless valves to date, shows excellent clinical and haemodynamic results that remain stable even up to the 5-year follow-up. Even in this elderly patient cohort with 40% octogenarians, both early and late mortality rates were very low. There were no valve migrations, structural valve degeneration or valve thrombosis in the follow-up. The sutureless technique is a promising alternative to biological aortic valve replacement.

Euc J Cardiothorac Surg 2016;49:234-41

Current Results

The sutureless aortic valve at 1 year: A large multicenter cohort study

TABLE 2. Mortality and morbidity events early (≤30 d), late (>30 d), at 6 months, and at 1 year after implantation

	Early (≤30 d)	Late (>30 d)	Total at 6 mo (0–180 d)	Total at 1 y (0–365 d)
N	628	599	628	628
Deaths	23 (3.7%)	28 (4.7%)	42 (6.7%)	51 (8.1%)
Cardiac-related deaths	16 (2.5%)	12 (2.0%)	25 (4.0%)	28 (4.5%)
Non–cardiac-related deaths	7 (1.1%)	16 (2.7%)	17 (2.7%)	23 (3.7%)
Explantation	6 (0.9%)	6 (1.0%)	12 (1.9%)	12 (1.9%)
Thromboembolism	27 (4.3%)	11 (1.8%)	36 (5.7%)	39 (6.2%)
Stroke	14 (2.2%)	5 (0.8%)	18 (2.9%)	19 (3.0%)
Primary paravalvular leak	5 (0.8%)	2 (0.3%)	6 (0.9%)	7 (1.1%)
Valve thrombosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Third-degree AV block leading to pacemaker implantation	51 (8.1%)	9 (1.5%)	55 (8.8%)	60 (9.6%)

All data are numbers and percentages of patients. *AV*, Atrioventricular.

Conclusions : The Perceval sutureless valve resulted in low 1-year event rates in intermediate-risk patients undergoing AVR. New York Heart Association class improved in more than three-quarters of patients and remained stable. These data support the safety and efficacy to 1 year of the Perceval sutureless valve in this intermediate-risk population.

J Thorac Cardiovasc Surg 2016 in press

Current Results
Sutureless vs Traditional AVR

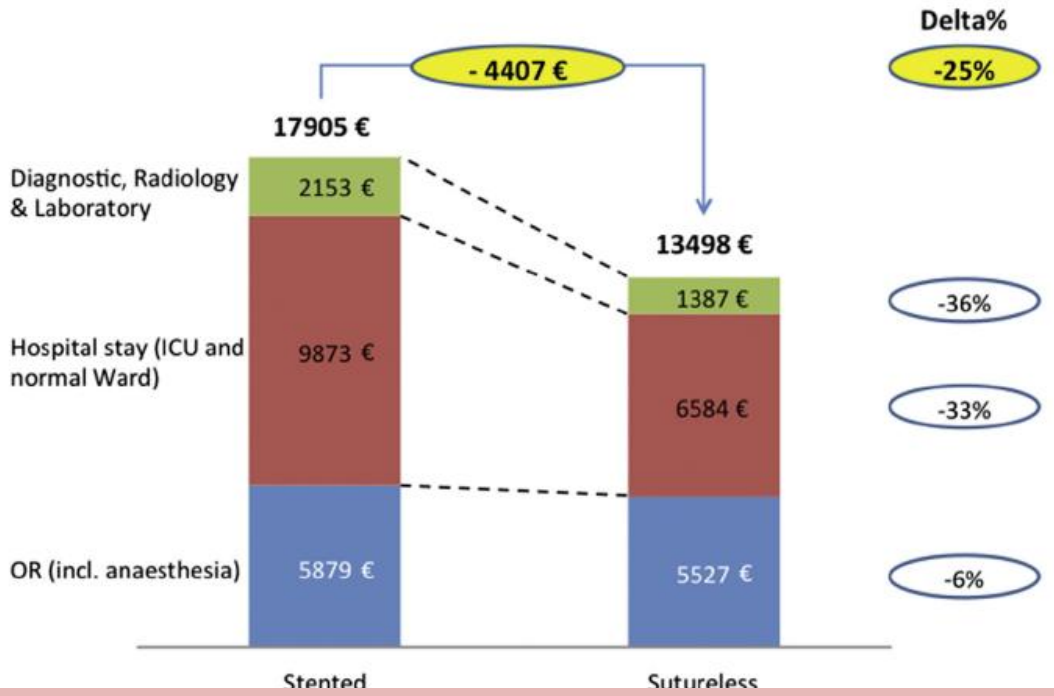
Better Short-Term Outcome by Using Sutureless Valves: A Propensity-Matched Score Analysis

Table 3. Intraoperative and Postoperative Outcomes of the Propensity-Matched Population

Outcome[a]	Sutureless (n = 82)	Stented (n = 82)	*p* Value
Operation time, min	145 ± 36	173 ± 57	<0.001
Cross-clamp time, min	47 ± 16	59 ± 23	<0.001
For isolated AVR, min	35 ± 12 (n = 57)	49 ± 16 (n = 62)	<0.001
CPB time, min	71 ± 11	92 ± 33	<0.001
Ventilation time, h	9.5 ± 4.6	16.6 ± 6.4	<0.001
Intensive care unit, d	2 ± 1.2	2.8 ± 1.3	0.040
Pacemaker	5 (6.1)	7 (8.5)	0.360
Reexploration for bleeding	2 (2.4)	5 (6.1)	0.221
Paroxysmal AF	3/74 (4.1)	12/76 (15.8)	0.015
Pleural effusion	3 (3.7)	11 (13.4)	0.024
Stroke/TIA	3 (3.7)	6 (7.3)	0.248
Respiratory insufficiency	2 (2.4)	10 (12.2)	0.016
Blood transfusion, units			
Exitus, 30 d			
Hospital stay, d			

[a] Continuous data are pre categoric data as number (%).

AF = atrial fibrillation; AVR = aortic valve replacement; CPB = cardiopulmonary bypass; TIA = transient ischemic attack.



Conclusions : A shorter procedural time in the sutureless group is associated with better clinical outcomes and reduced hospital costs.

Ann Thorac Surg 2014;98:611-7

Current Results
Sutureless vs TAVI

Immediate outcome after sutureless versus transcatheter aortic valve replacement

Table 4 Immediate postoperative data on patients who underwent transcatheter (TAVI) and surgical aortic valve replacement with sutureless Perceval S bioprosthesis (SU-AVR)

Postoperative outcome	Overall series			25th–75th percentiles of ESII			PS-matched pairs		
	SU-AVR 379 patients	TAVI 394 patients	*P* value	SU-AVR 108 patients	TAVI 208 patients	*P* value	SU-AVR 144 patients	TAVI 144 patients	*P* value
Device success	305 (80.5)	309 (78.4)	0.481	146 (81.1)	168 (80.4)	0.856	115 (79.9)	112 (77.8)	0.665
Paravalvular regurgitation			<0.0001			<0.0001			<0.0001
None	370 (97.6)	163 (41.9)		174 (96.7)	93 (44.7)		140 (97.2)	66 (46.5)	
Reoperation for major bleeding									
In-hospital mortality	10 (2.6)	21 (5.3)	0.057	2 (1.1)	8 (3.8)	0.115	2 (1.4)	10 (6.9)	0.035

Continuous variables are reported as mean ± standard deviation; dichotomous variables are reported as counts and percentages in parentheses

ESII EuroSCORE II

- Sutureless valves may provide favorable early results vs. TAVI
- Sutureless AVR is associated with a rather low incidence of significant paravalvular regurgitation and excellent immediate postoperative survival.
- Sutureless AVR is a valid alternative to TAVI in intermediate risk patients.

Heart Vessels 2016;31:427-33

Enhances the MICS

Minimal access rapid deployment aortic valve replacement: Initial single-center experience and 12-month outcomes

, Vadim Moustafine, MD,
MD, PhD

TABLE 2. Intraoperative data

Parameter	Mean ± SD or % (n)
Valve size (mm) (n = 60)	
19 (%)	6 (n = 4)
21 (%)	29 (n = 17)
23 (%)	29 (n = 17)
25 (%)	27 (n = 16)
27 (%)	10 (n = 6)
Procedures (n = 60)	
AVR only (%)	100 (n = 60)
Partial sternotomy (%)	100 (n = 60)
Valve implant time (min)	9 ± 3
Crossclamp time (min)	26 ± 7

AVR, Aortic valve replacement; *CPB*, cardiopulmonary bypass; *SD*, standard deviation.

Conclusions : Reproducible short crossclamp and bypass times were achieved in a minimally invasive setting. The valve shows good hemodynamic performance comparable to other sutureless or rapid deployment valves.

orac Cardiovasc Surg 2015;149:434-40

Enhances the MICS

Minimally Invasive Implantation of the EDWARDS INTUITY Rapid Deployment Aortic Valve Via a Right Minithoracotomy

Aristidis Lenos, MD and Anno Diegeler, MD

- ✓ 2013.3 – 2013.7, 10pts
- ✓ Thoracotomy (7-10cm, 2nd or 3rd ICS)

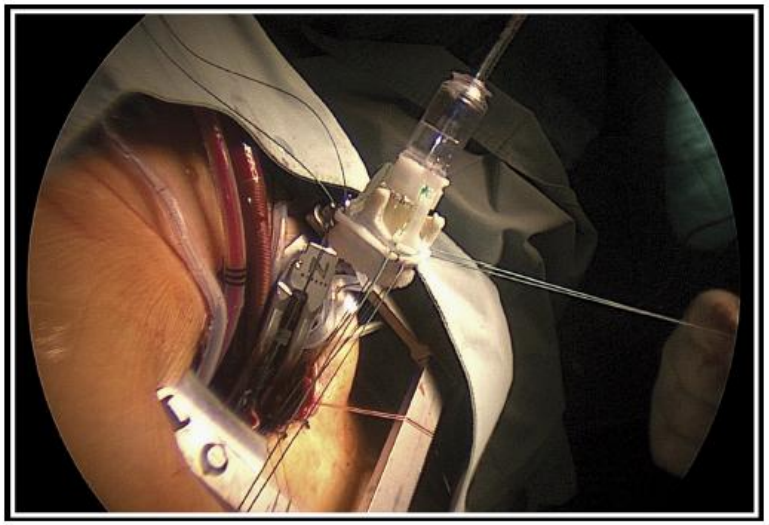


TABLE 2. Basic Postoperative Data

Survival	100%
Success of valve placement	100%
Max gradient, mean ± SD	22 ± 8
Mean gradient, mean ± SD	11 ± 4
RCC transfusion	n = 1 (1 U)
Length of intensive care unit time, mean	<1 day

Innovations 2015;10:215-217

Current weakness of sutureless valve

- Migration
- Paravalvular leakage
- Pacemaker implantion
- Long term durability – need more f/u

Migration – Reported only for 3f Enable

Interactive CardioVascular and Thoracic Surgery Advance Access published March 2, 2012

Interactive CardioVascular and Thoracic Surgery 0 (2012) 1–2
doi:10.1093/icvts/ivr015

CASE REPORT

Delayed dislocation of a sutureless aortic bioprosthesis: the first case

Giovanni Concistrè*, Antonio Miceli, Francesca Chiaramonti and Mattia Glauber

1 case

Acquired Cardiovascular Disease — Eichstaedt et al

Early single-center experience in sutureless aortic valve implantation in 120 patients

Harald C. Eichstaedt, MD,[a] Jerry Easo, MD,[a] Tobias Härle, MD,[b] and Otto E. Dapunt, MD, PhD[a]

3 case

Original article

Sutureless aortic valve bioprothesis '3F/
– 4.5 years of a single-centre experience

Jerzy Sadowski, Bogusław Kapelak, Roman Pfitzner, Krzysztof Bartuś

Department of Cardiovascular Surgery and Transplantology, Jagiellonian University Collegium Medicum, The John Paul II Hospital, Krakow, Poland

3f Enable valve

17 cases of migration reported at Nov, 2014

Valve discontinued at May, 2015

Paravalvular Leakage

European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients†

Malakh Shrestha[a,*], Theodore Fischlein[b], Bart Meuris[c], Willem Flameng[c], Thierry Carrel[d], Francesco Madonna[e], Martin Misfeld[f], Thierry Folliguet[g], Axel Haverich[a] and Francois Laborde[g]

	Early events (≤30 days)		Late events (>30 days)			
	n	%	*n*	%	%/pts-yr	
Paravalvular leak	10	1.4	9	1.2	1.2	(0.6–1.9)
Minor	0	0.0	2	0.3	0.3	(0.0–0.6)
Major	10	1.4	7	1.0	1.0	(0.4–1.6))
Secondary paravalvular leak	1	0.1	1	0.1	0.1	(0.0–0.3)

Early PVL rate : 1.4%

TAVI – PVL (moderate to severe) **11.8% - 30days, 10.5% - 1 year**

(*JACC Cardiovasc Interv 2012;8:858-65****)***

Pacemaker Implantation

European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients†

Malakh Shrestha[a,*], Theodore Fischlein[b], Bart Meuris[c], Willem Flameng[c], Thierry Carrel[d], Francesco Madonna[e], Martin Misfeld[f], Thierry Folliguet[g], Axel Haverich[a] and Francois Laborde[g]

	Early events (≤30 days)		Late events (>30 days)			
	n	%	*n*	%	%/pts-yr	
AV block III in patients without preoperative cardiac rhythm abnormalities	44	6.0	14	1.4	1.4	(1.2–1.6)

PM Implantation rate in sutureless valve: 6 %

8.1% ***(****J Thorac Cardiovasc Surg 2016 in press)*

TAVI – Edward SAPIEN <5%, CoreValve up to 30%

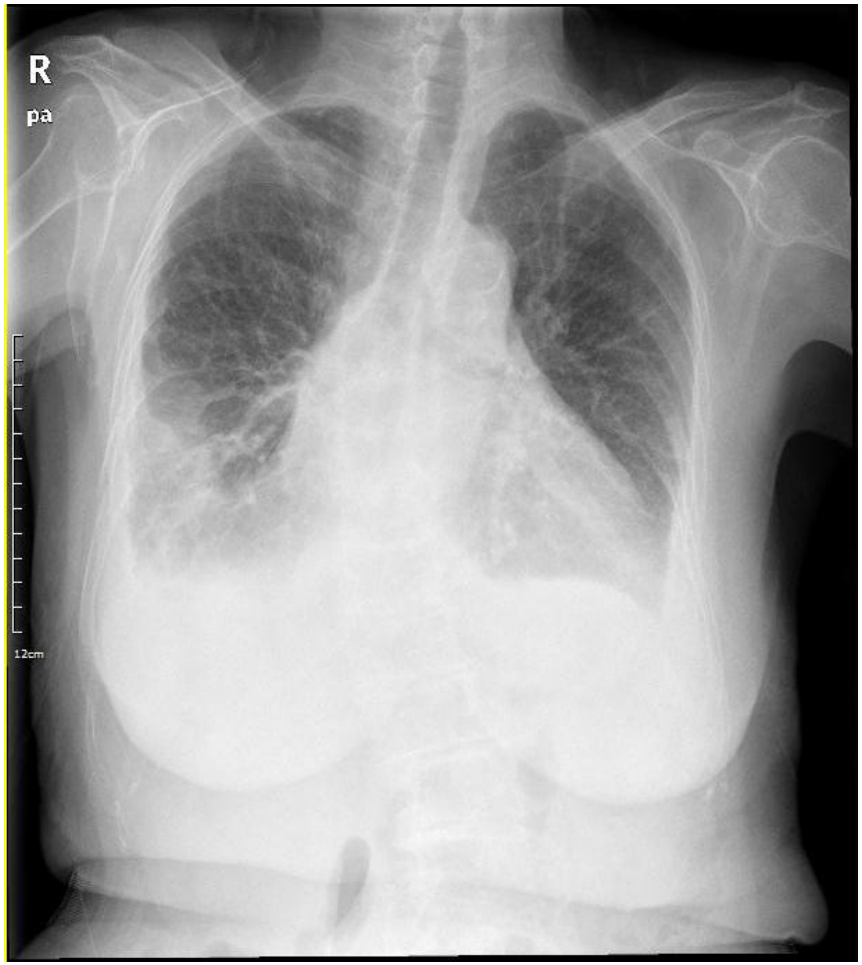
(*JACC Cardiovasc Interv 2012;8:858-65****)***

Case Presentation

- ✓ 88yr/ F (138.7cm, 51kg)
- \- Dyspnea on exercise (Onset : 1.5 YA, Aggravation : 1MA)
- ✓ severe AS, 1VD (RCA 80% stenosis)
- ✓ Past medical Hx :asthma (20YA), dyslipidemia
- ✓ Social Hx : smoking/alcohol (-/-)
- ✓ Family Hx : none

Chest X-ray

- Bilateral pleural effusion
- Cardiomegaly (C/T ratio : 0.6)

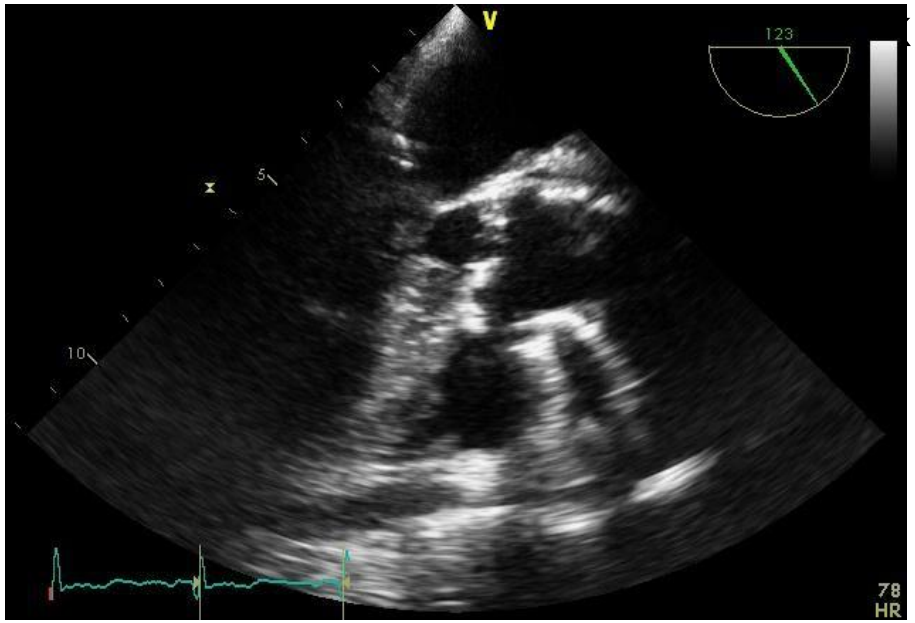


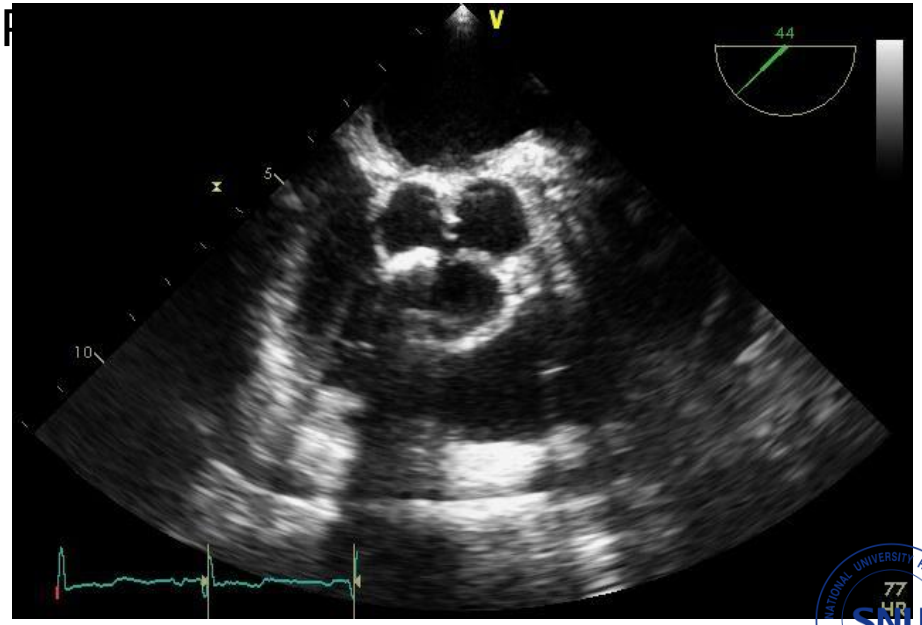
Echocardiography

1. Small LV and increased LV wall thickness ; EF 67%

2. Severe degenerative AS(tricuspid, annulus 20mm, S. valsalva 33mm)

3. Trivial TR with moderate resting pulmonary HTN (PASP = 58mmHg)





LV mass index 119.14 g/m^2

Operation

- Sutureless AoV replacement with

Sorin Perceval S medium-sized bioprosthesis

CPB time : 150min

ACC time : 77min

Postoperative Echocardiography

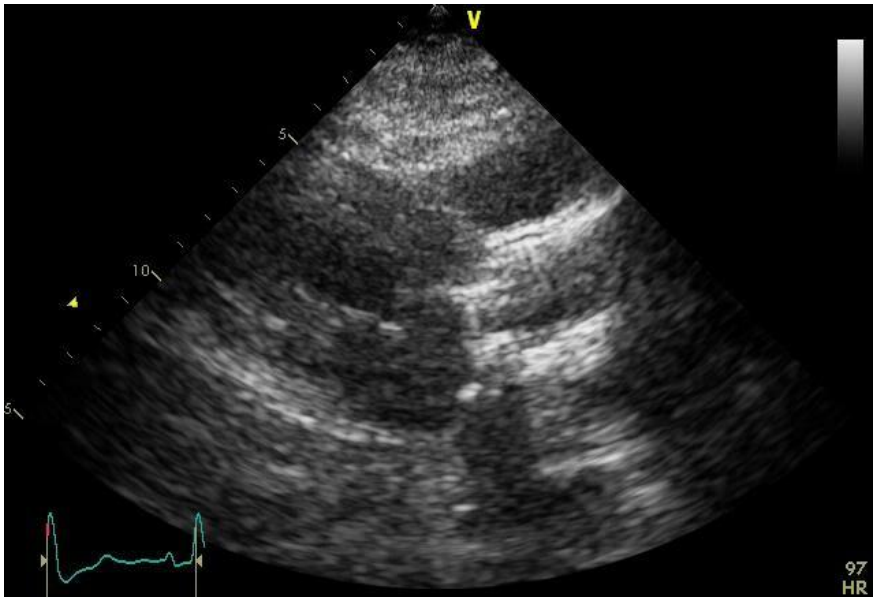
POD#8

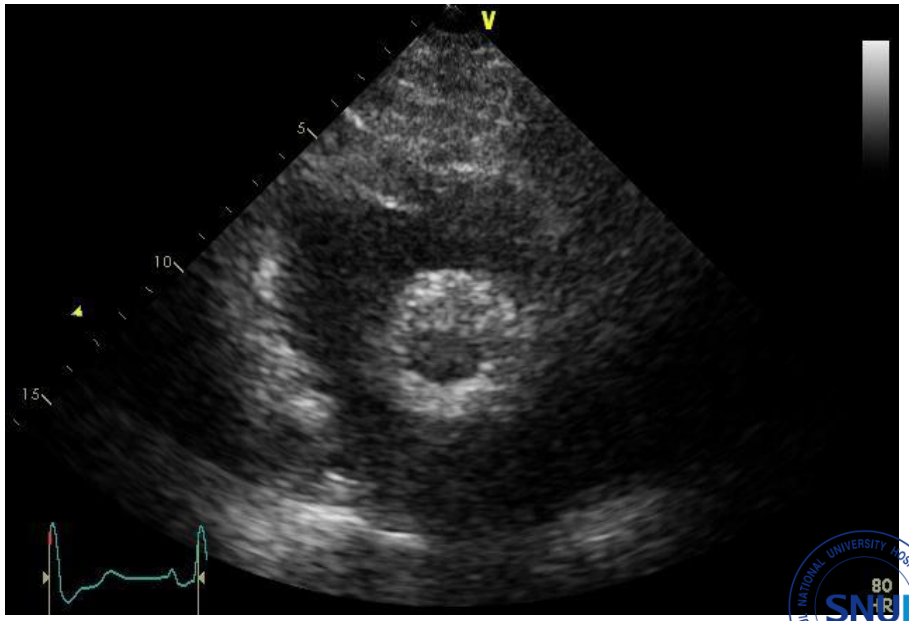
AV peak velocity 3.9m/s

AVA : 1.47m^2

AV mean PG 35mmHg

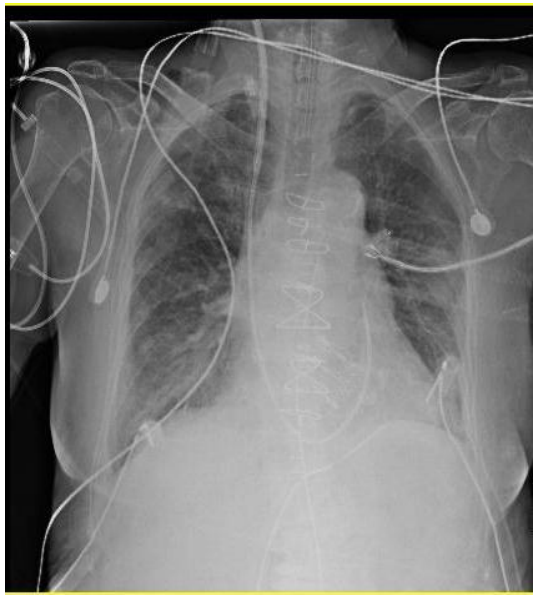
(R/O mild SAM)



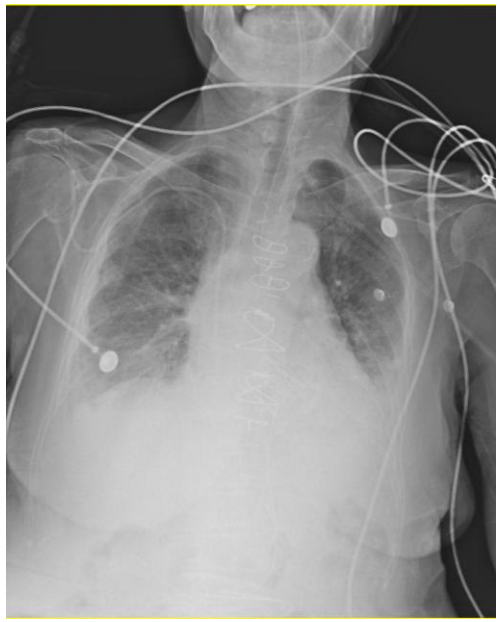


Postoperative course

- POD#1 extubation
- POD#3 Tf to general ward
- POD#15 chest tube removal (d/t prolonged pleural effusion)
- POD#22 Tf to Internal medicine d/t pneumonia



Operative Day



POD# 15

Rapid Deployment Valve

EDWARDS INTUITY Elite

VALVE SYSTEM

EDWARDS INTUITY Elite Valve System

Edwards

Rapid Deployment Valve: Intuity ELITE

Intuity valve
system(8300AB)

Intuity valve
Delivery system(8300DB)

Intuity valve
Inflation Device

EDWARDS INTUITY Elite Valve System

Proven Pericardial Technology

New Innovations

EDWARDS INTUITY Elite Valve System combines..

- Proven Pericardial valve technology (Perimount Magna Ease valve)
- Innovation in transcatheter heart valve (Sapien valve)

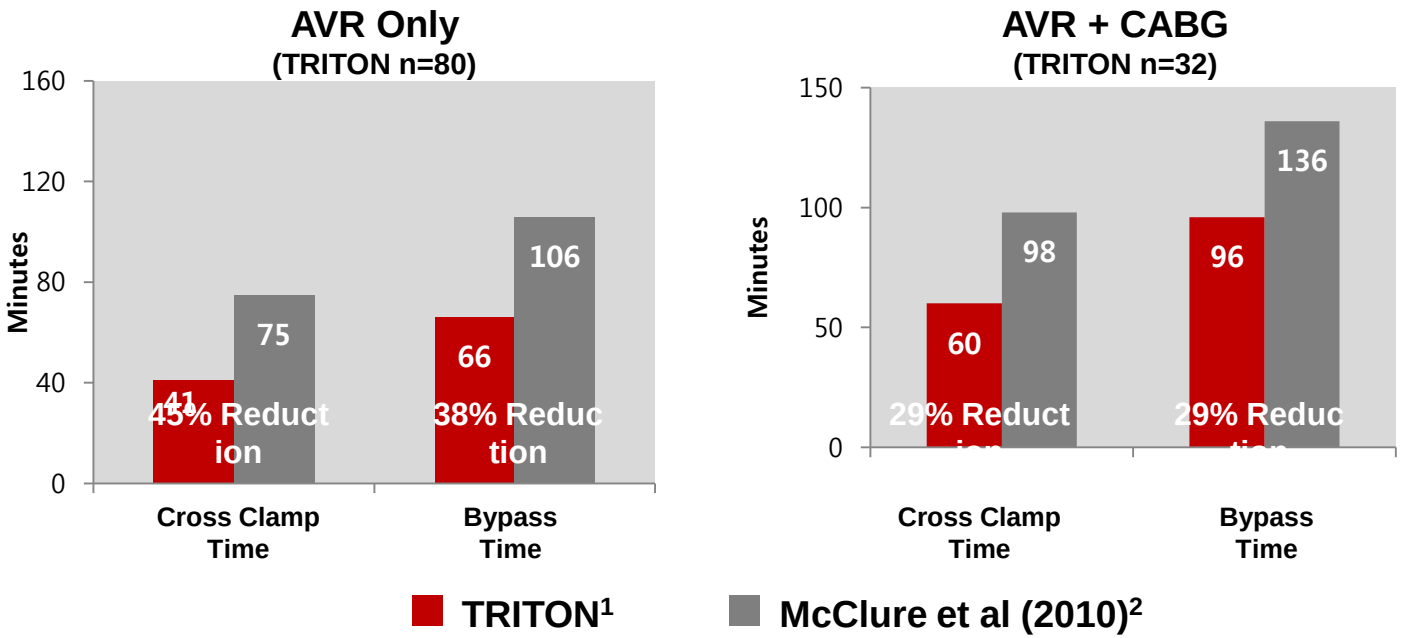
Rapid Deployment System with 3 guiding sutures & Balloon expandable system.

Case Description:

- 75 Y/O Male, 112 kg
- Symptomatic Aortic Stenosis with DOE
- NYHA III Symptoms
- Dilated LV
- Normal Coronaries
- Endocarditis in 2006
- Hypertension
- Existing AAA (4.2 X 3.4)

EDWARDS INTUITY Elite Valve System
Meaningful Time Savings

45% reductions in cross-clamp times demonstrated in isolated AVR procedures in the prospective, multi-center TRITON trial when compared to data published by McClure et al in 2010[1,*]



Reference

1. Kocher AA, Laufer G, Haverich A, et al. 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. J Thorac Cardiovasc Surg. 2013; 145(1):110-6.

2. McClure RS, Narayanasamy N, Wiegerinck E, et al. Late outcomes for aortic valve replacement with the Carpentier-Edwards pericardial bioprosthesis: up to 17-year follow-up in 1,000 patients. Ann Thorac Surg. 2010;89(5):1410-1416.

EDWARDS INTUITY Elite Valve System
Clinical Data

Procedure Times

CADENCE-MIS

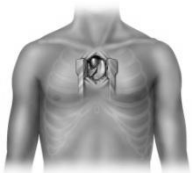
41.3 min XCT MIS RDAVR , p<0.0001 vs. FS AVR

Bochum

26 min XCT MIS RDAVR, 9 min implantation time

Leipzig

39 min XCT MIS RDAVR; 42 min XCT in all pts



Smaller Incision

CADENCE-MIS

Proven time benefit in MIS , comparable outcomes

Bochum

100% MIS AVR, very short XCT, excellent outcomes

Leipzig

72% MIS AVR, short XCT, excellent outcomes

Hemodynamics

TRITON 3-Yr

8.7 mm Hg @ 3 years, n=287

CADENCE-MIS

Statistically better gradients than conventional valves

Leipzig

8.8 mm Hg @ discharge, n=69

PVLs / Pacemaker

TRITON 3-Yr

0.7% early PVLs (>2+); 1.2% late PVLs

CADENCE-MIS

0% early PVLs (>2+); 4.3% (2) pacemaker

Bochum

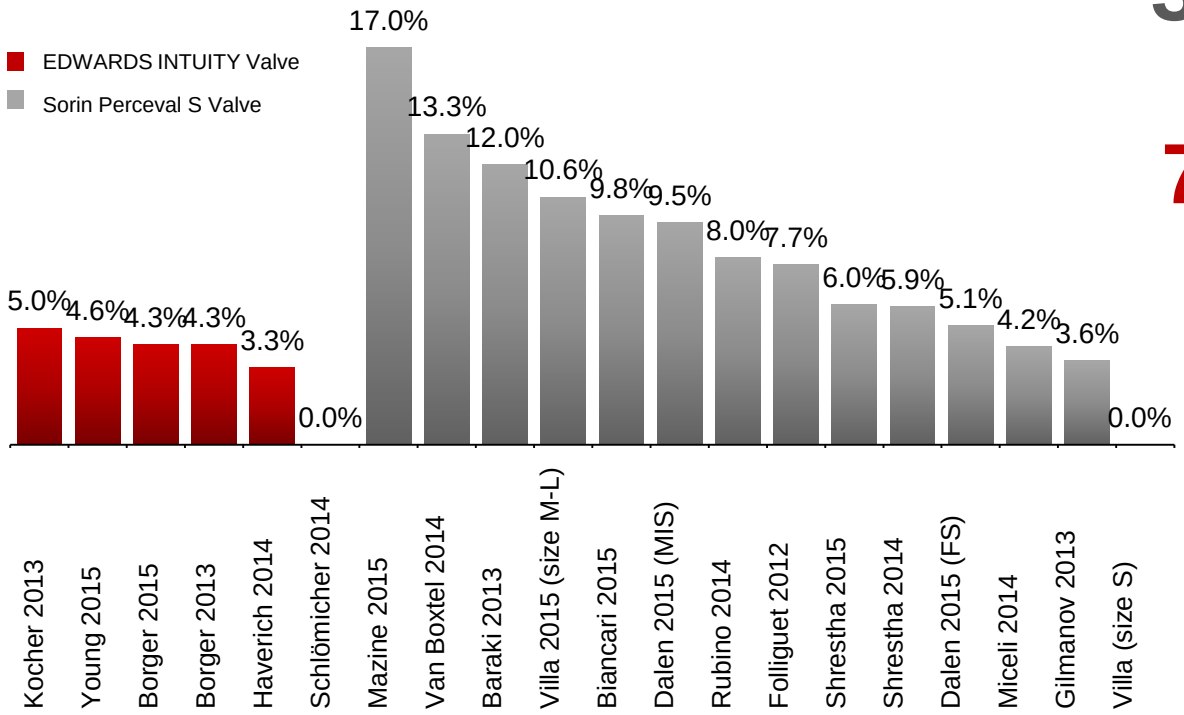
1.7% (1) early PVLs (>1+) and pacemaker; 0% late

Side-by-Side Comparison
INTUITY Elite & Perceval S

	EDWARDS INTUITY Elite Valve 	Perceval S Valve 
Tissue	Bovine Pericardium	Bovine Pericardium
Anti-Calcification Treatment	Yes	Yes
Valve Sizes	19, 21, 23, 25, 27 mm	S, M, L, XL (19-27 mm)
Frame Material	Stainless Steel	Nitinol
Frame Location	Sub-annular	Supra-annular
Rinsing Required	Yes (2-minute)	No
Valve Collapsed / Crimped	No	Yes
# of Guiding Sutures	3	3
Guiding Sutures Tied	Yes	No
Proven Durability Data	**Up to 20yrs** (Edwards Perimount Valve)	**Up to 5yrs**
CE Mark Approval	February 2012	January 2011

Pacemaker Implantation

PACEMAKER IMPLANTATION RATE



3.9% EDWARDS INTUITY Valve Weighted Mean Rate

7.9% Sorin Perceval S Valve Weighted Mean Rate

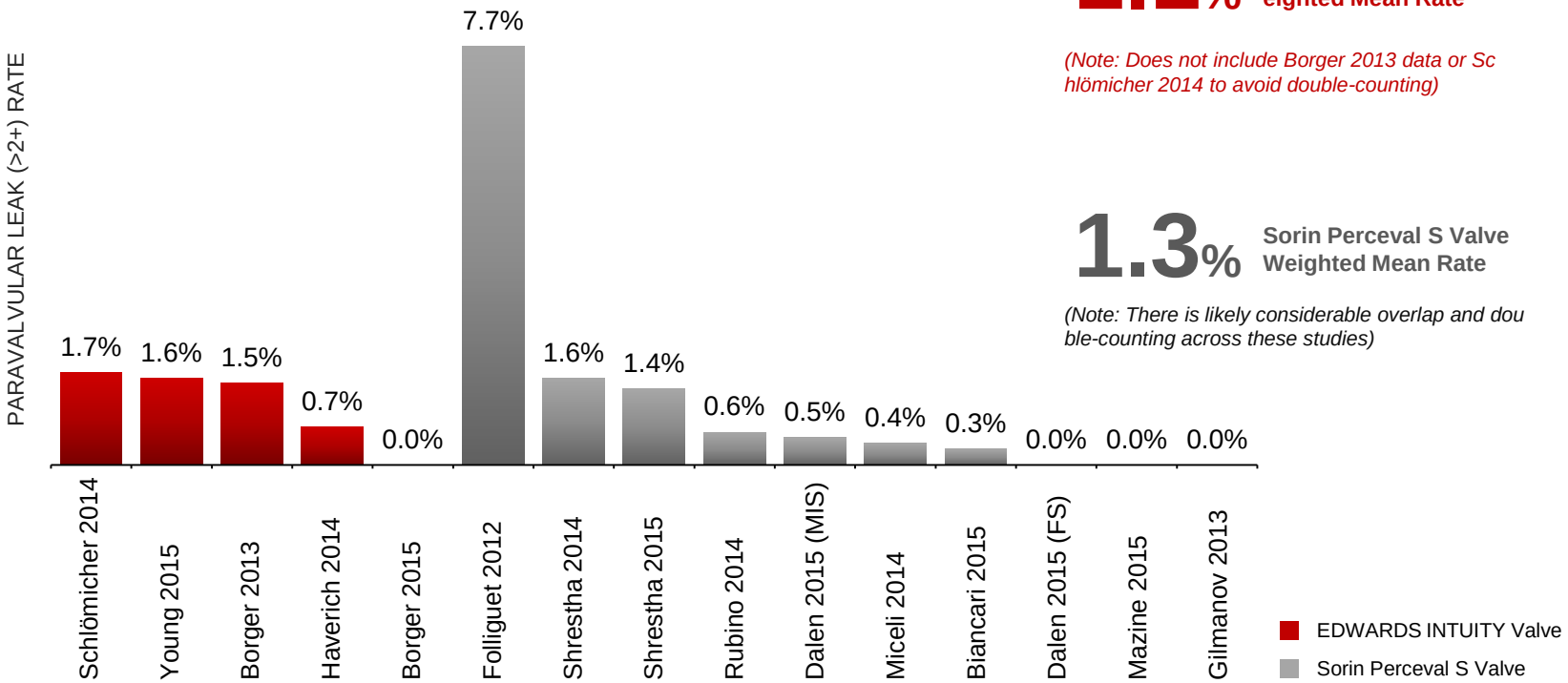
Paravalvular Leaks

1.1% **EDWARDS INTUITY Valve Weighted Mean Rate**

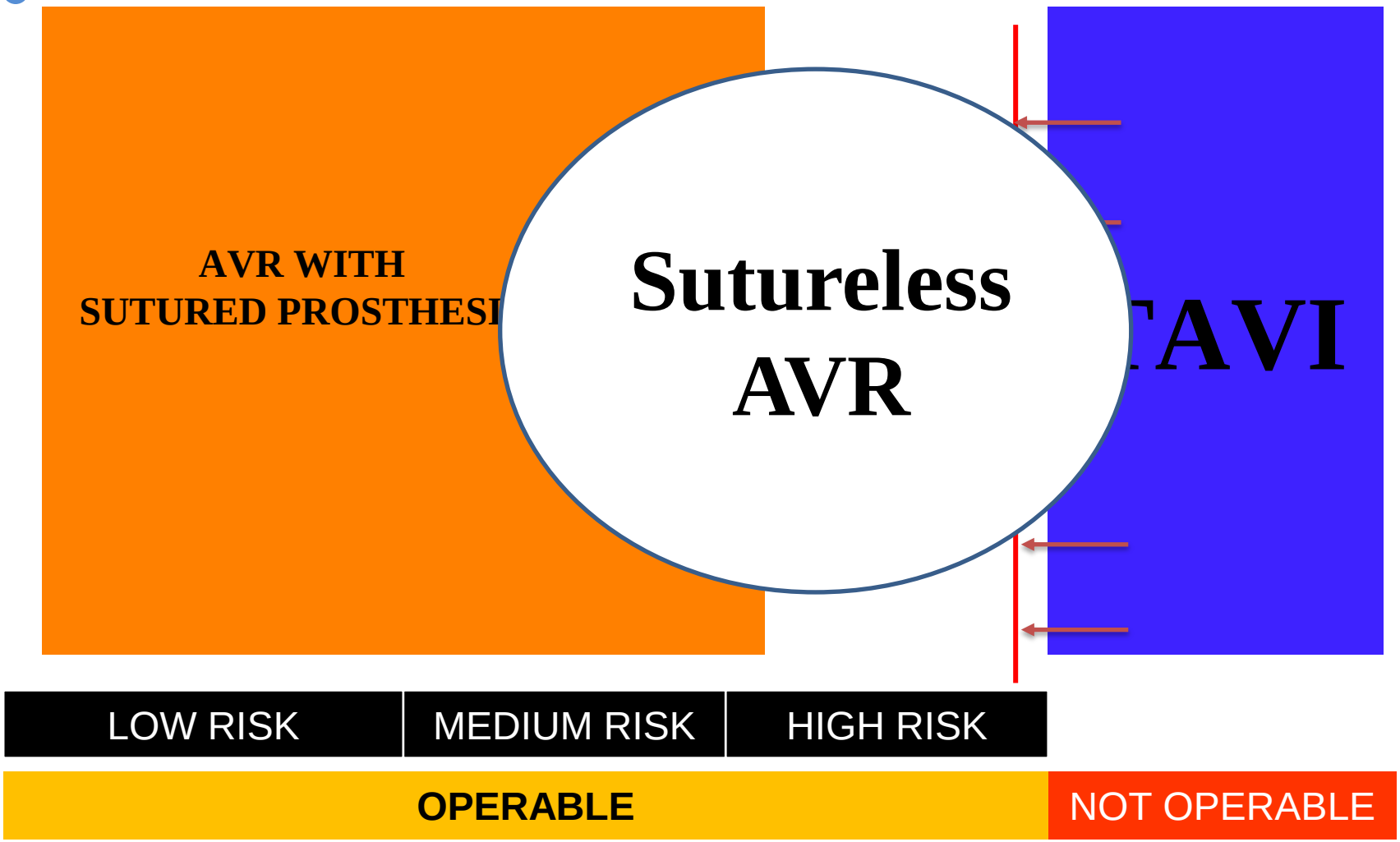
(Note: Does not include Borger 2013 data or Schlömicher 2014 to avoid double-counting)

1.3% **Sorin Perceval S Valve Weighted Mean Rate**

(Note: There is likely considerable overlap and double-counting across these studies)



Indications in the Future ?



Further studies would be required to compare the clinical outcomes between sutureless AVR and TAVI.

Conclusions

The sutureless aortic valve replacement showed good early clinical outcomes and is associated with low incidence of complications compared to TAVI and conventional AoV surgery.

The sutureless AVR would be a valid alternative method in high risk patients. However, further studies would be needed to identify the long term results.