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BUILDING ENDOVASCULAR SYNERGIES

TRANSAPICAL AORTIC VALVE REPAIR

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Treatment Options and Timing Matter

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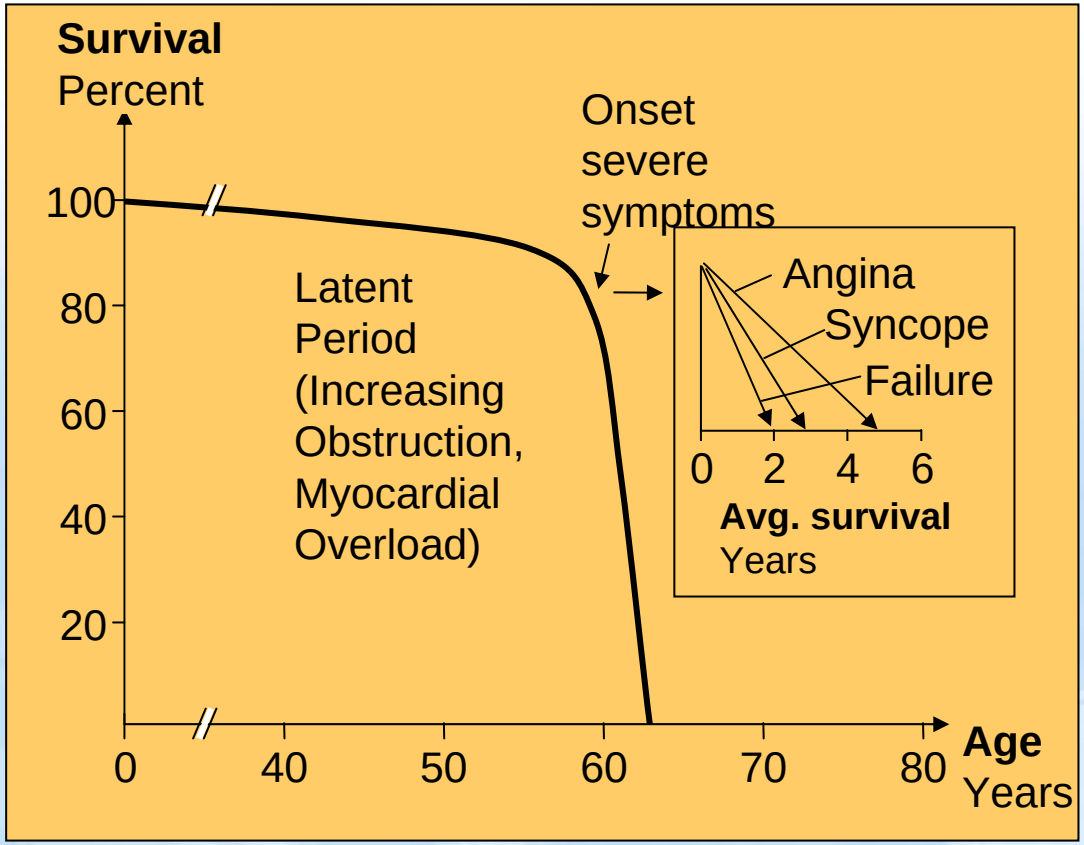
Aortic stenosis is life-threatening and progresses rapidly



"Survival after onset of symptoms is 50% at two years and 20% at five years."[1]

"Surgical intervention [for severe AS] should be performed promptly once even … minor symptoms occur."[2]

Sources: [1] S.J. Lester et al., "The Natural History and Rate of Progression of Aortic Stenosis," *Chest* 1998

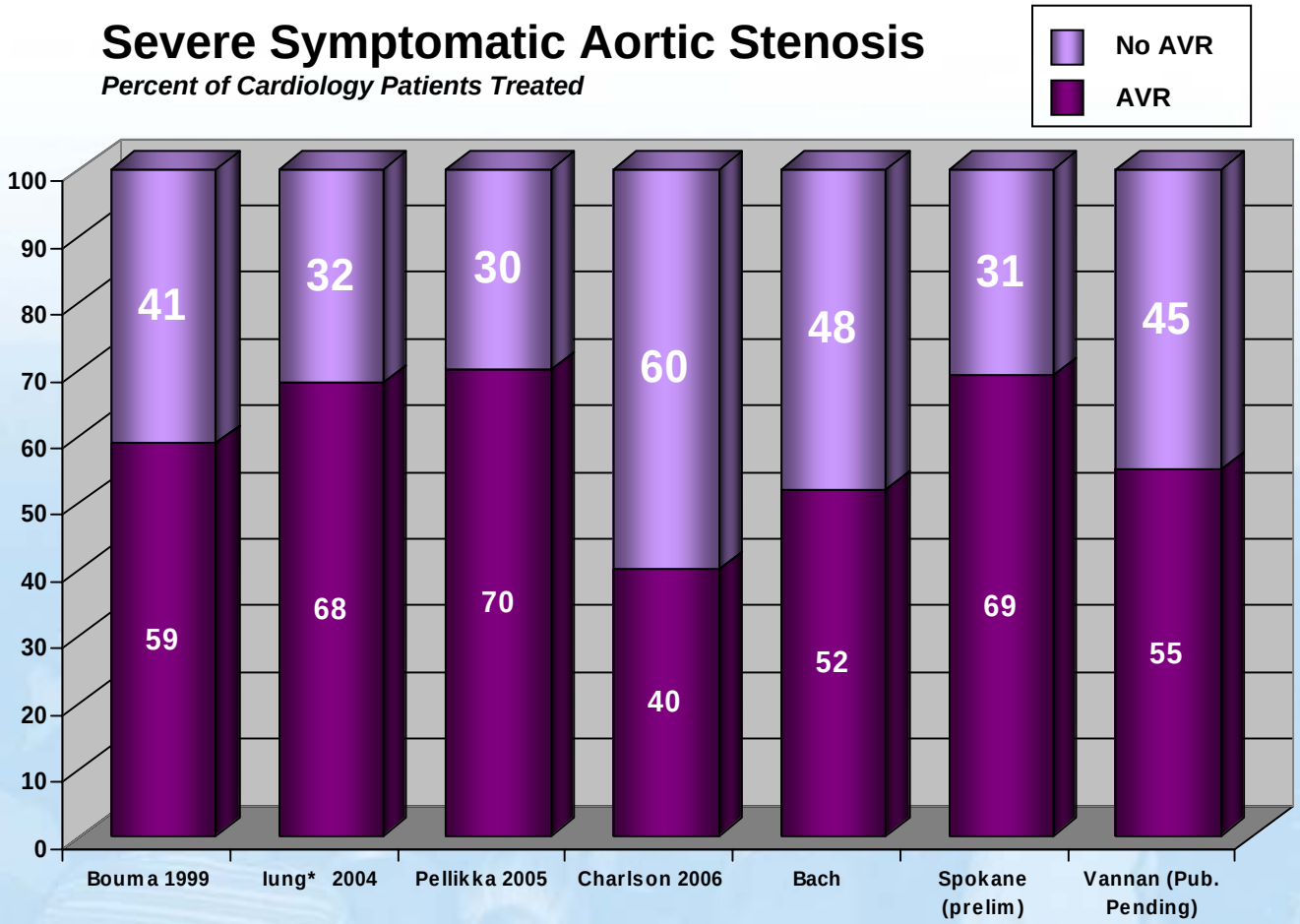
[2] C.M. Otto, "Valve Disease: Timing of Aortic Valve Surgery," *Heart* 2000

Chart: Ross J Jr, Braunwald E. Aortic stenosis. *Circulation*. 1968;38 (Suppl 1):61-7.

At least 30-40% of Cardiologists' AS Patients Go Untreated

Severe Symptomatic Aortic Stenosis

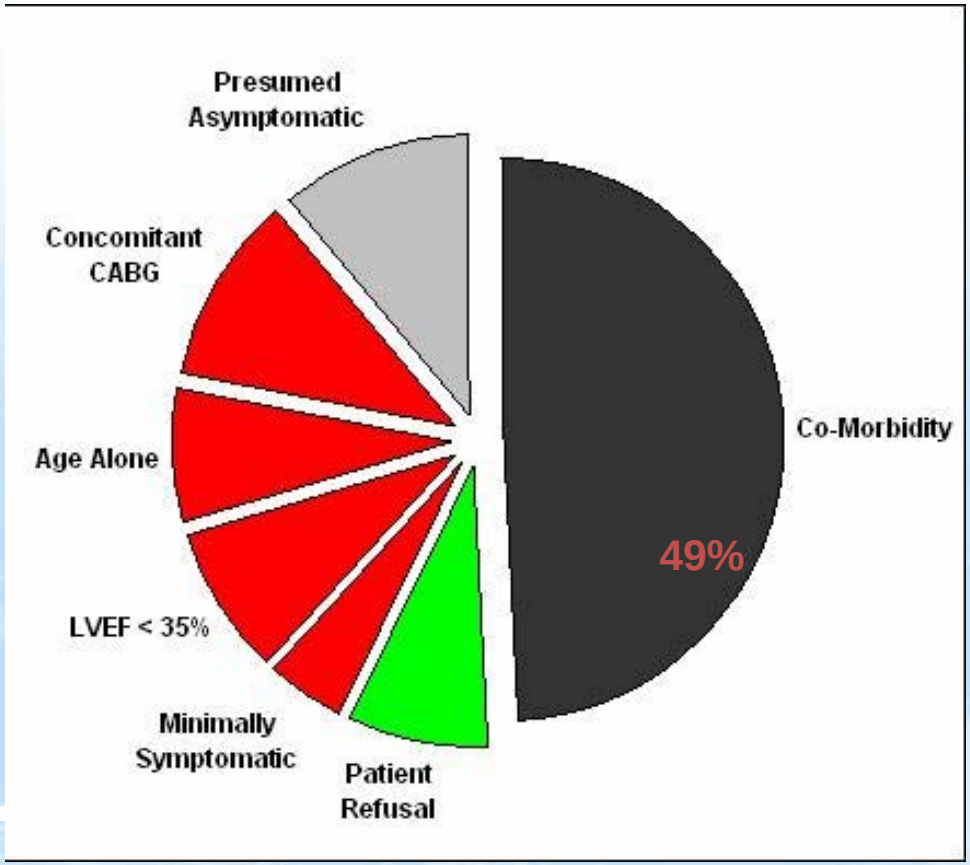
Percent of Cardiology Patients Treated



Under-treatment especially prevalent among patients managed by *Primary Care* physicians

1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. Heart 1999;82:143-148
2. Iung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. European Heart Journal 2003;24:1231-1243 (*includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pellikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. Circulation 2005
4. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. J Heart Valve Dis2006;15:312-321

Reasons Severe AS Patients Are Not Referred to Surgery[1]



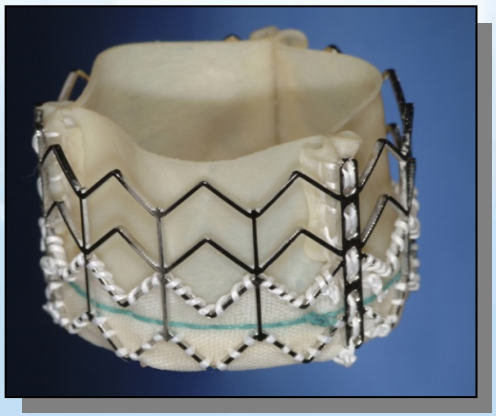
- Nearly **half** of untreated patients are considered **too sick** for surgery

- **Transcatheter Heart Valve technology may ultimately expand options for untreated patients**

1. L.E.K. Consulting Firm, Interviews and Analysis.

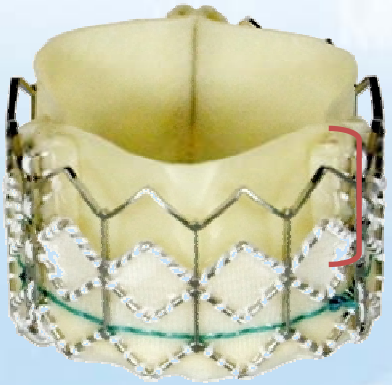
Trans catheter heart valve: new opportunity for severe AS patients

Cribier-Edwards™ THV



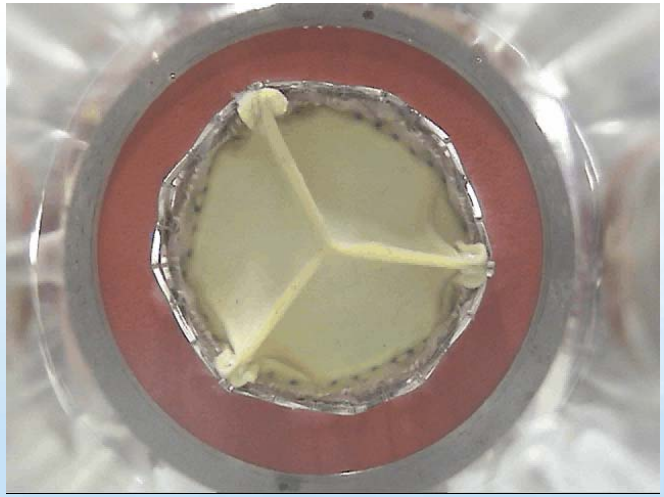
- Untreated Equine Tissue

Edwards SAPIEN™ THV 23mm, 26mm



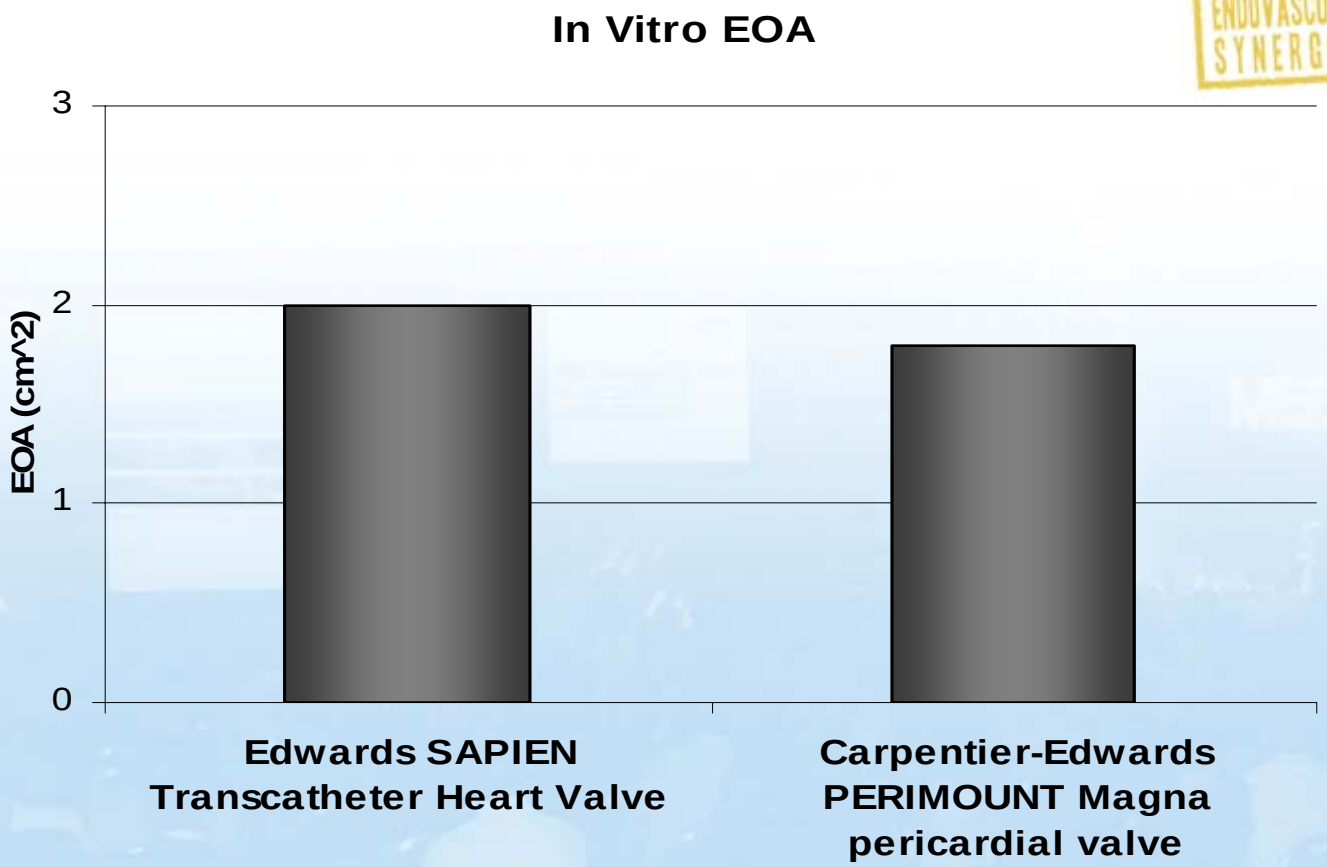
New Skirt Height

- Bovine PericardialTissue
- ThermaFix™ Tissue Treatment



- Excellent in-vitro durability exceeding 5 years
- Additional frame fatigue testing to 15 years

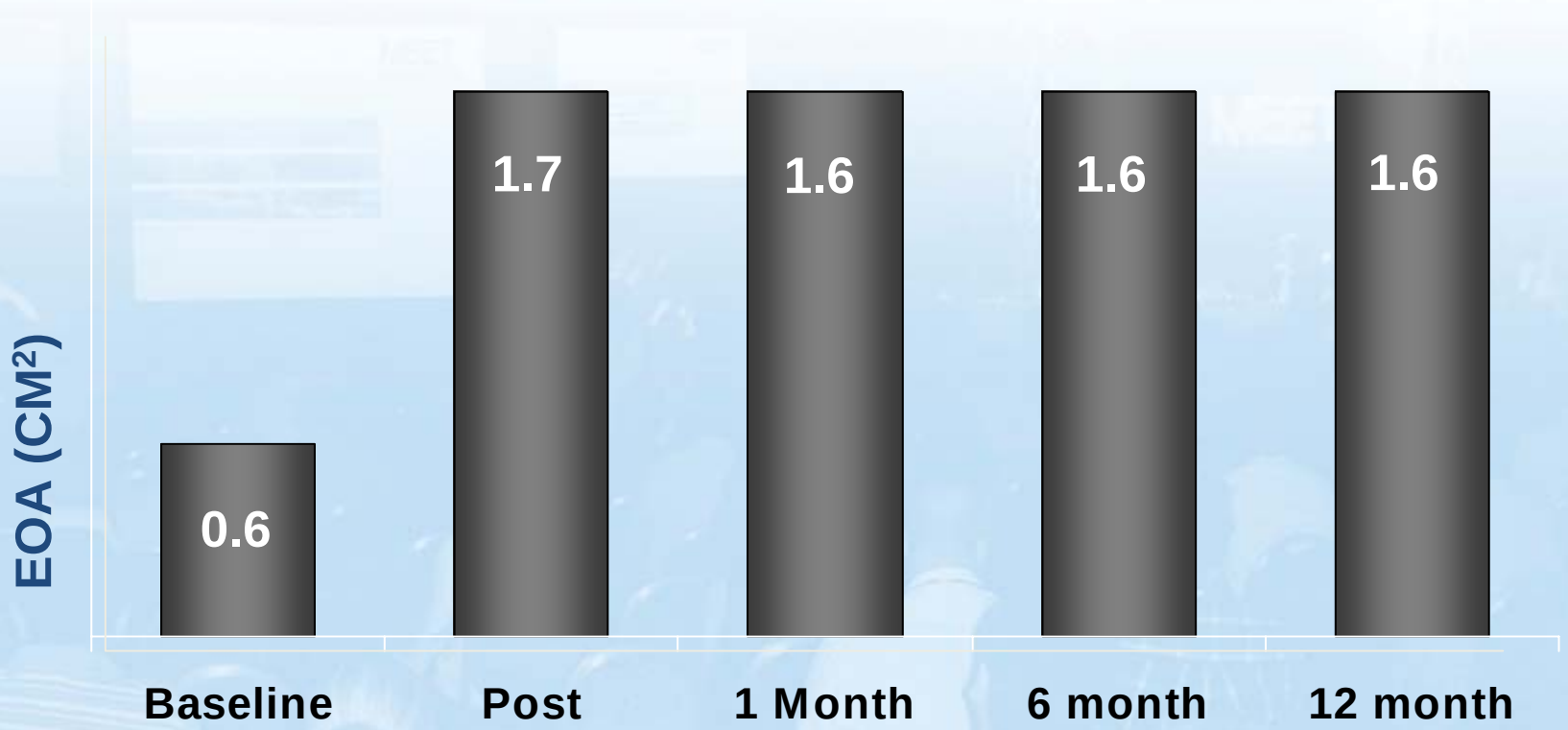
Edwards SAPIEN™ THV Hydrodynamics



- In vitro hydrodynamic testing demonstrates that the Edwards SAPIEN™ THV *performs equivalently* to the same size Carpentier-Edwards™ PERIMOUNT Magna™ Aortic pericardial valve

[1]Edwards HVT Study RD7460 – 23 MM valves

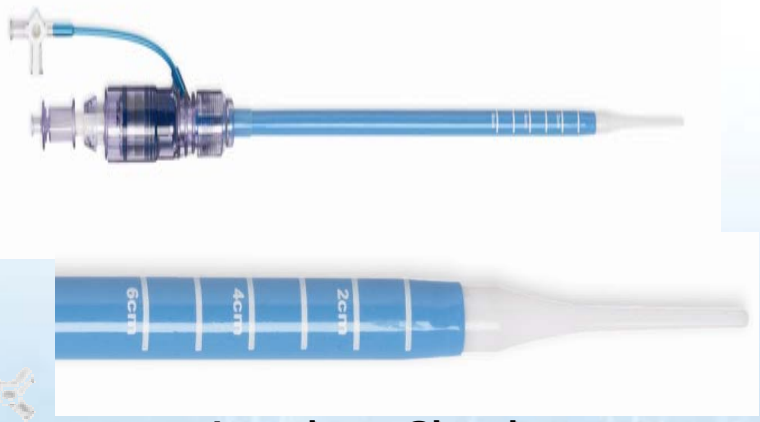
Echo assessment of Edwards SAPIEN™ THV performance



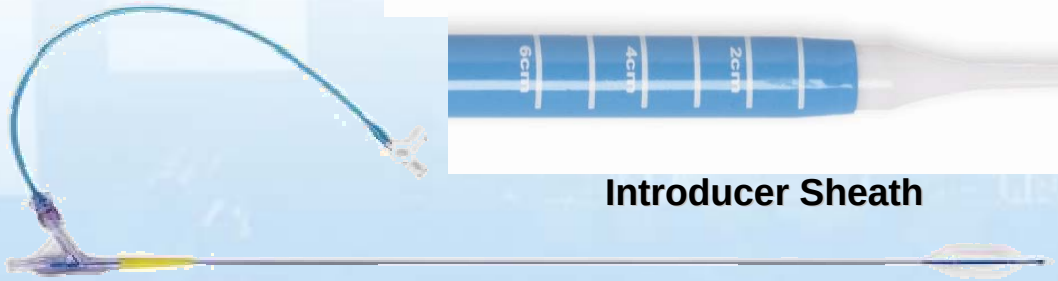
Courtesy: John G. Webb, M.D. Vancouver, Canada

Edwards SAPIEN™ THV Ascendra™ Transapical Delivery System

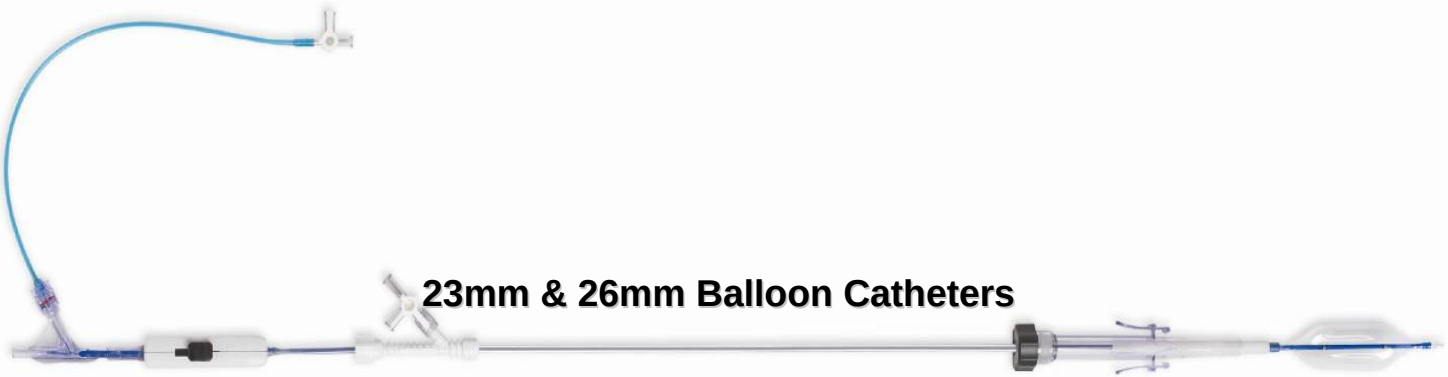
Edwards SAPIEN™ THV valve
23 mm - 26mm



Introducer Sheath

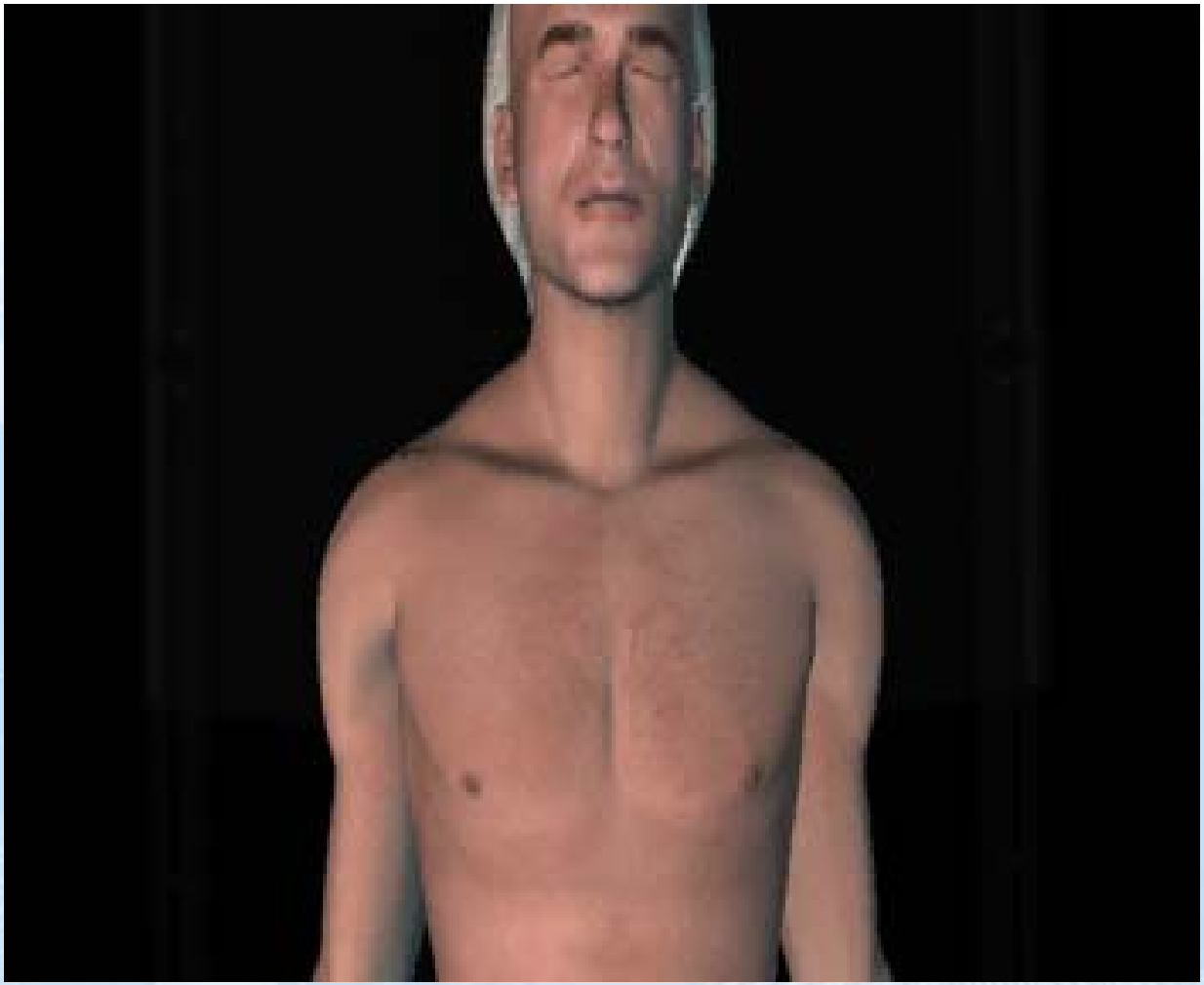


20mm BAVC



23mm & 26mm Balloon Catheters

Transapical Procedure with the Edwards SAPIEN™ THV



HYBRID OPERATING SUITE
Institut Jacques CARTIER – Massy

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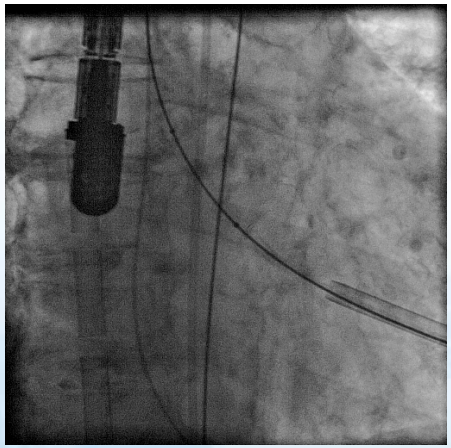
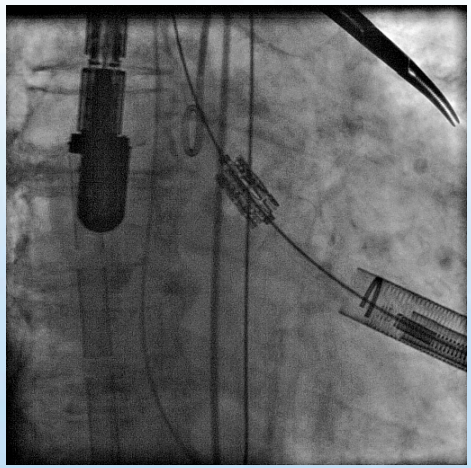
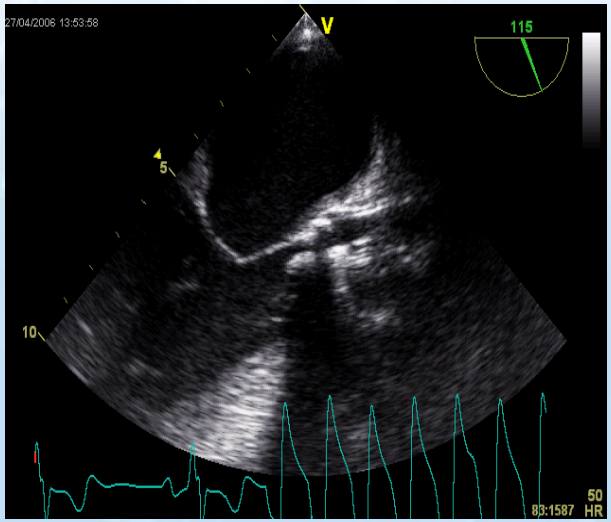
Edwards SAPIEN™ THV Transapical Procedure



Balloon Valvuloplasty

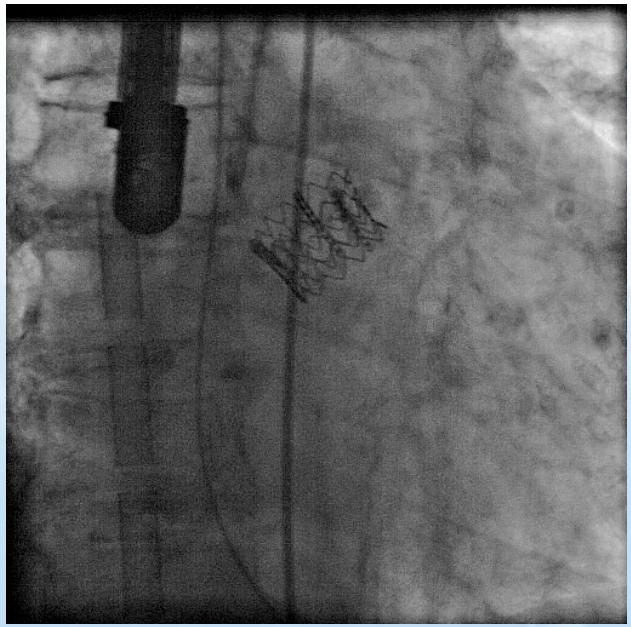


Valve Deployment - Fluoro

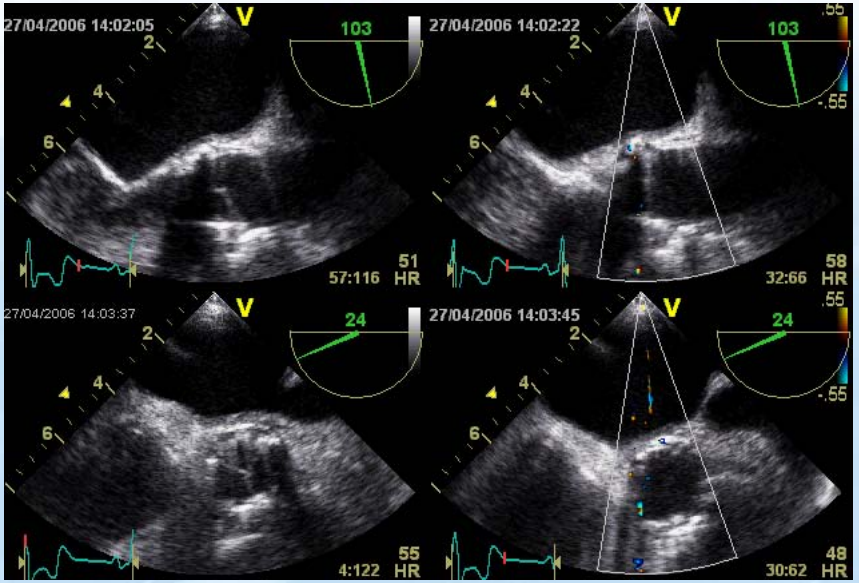


Valve deployment- Echo

Edwards SAPIEN™ THV Transapical Procedure



Deployment Confirmation - Fluoro



Deployment Confirmation - Echo

Current Indications

- The **Edwards SAPIEN transcatheter heart valve** is indicated for use in patients with **symptomatic** aortic stenosis (**aortic valve area <0.8 cm2**) requiring aortic valve replacement who have **high risk** for operative mortality, or are **"non-operable",** as determined by one of the following risk assessments:

  1) Logistic EuroSCORE >20%

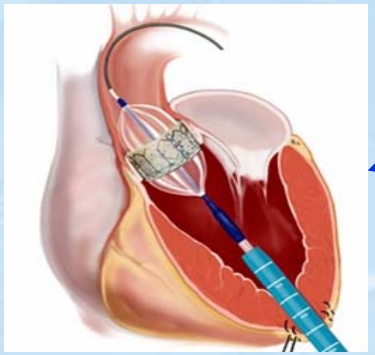
  or

  2) STS Score>10

- Implantation is intended to be performed via **transfemoral** or **transapical** access **without** cardiopulmonary bypass

Contraindications

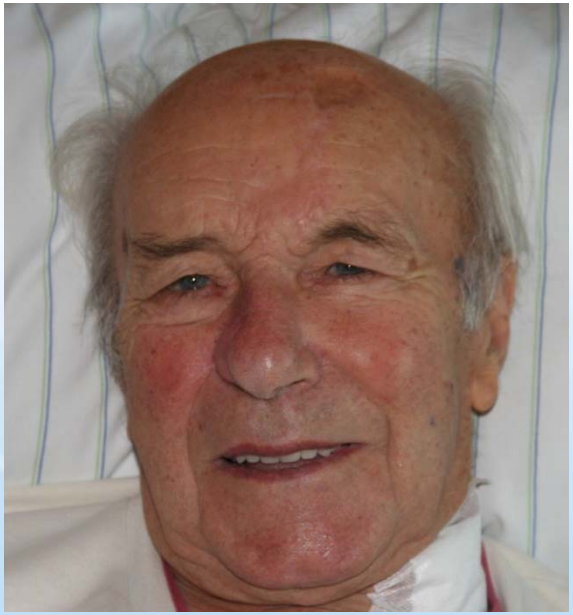
- Non-valvular aortic stenosis
- Congenital aortic stenosis, unicuspid, or bicuspid aortic valve
- Non-calcific acquired aortic stenosis
- Evidence of intracardiac mass, thrombus or vegetation
- Untreated clinically significant coronary artery disease requiring revascularization
- Severe deformation of the chest
- Severe coagulation problems
- Active bacterial endocarditis or other active infections
- Myocardial infarction (MI) within 1 month



Transapical

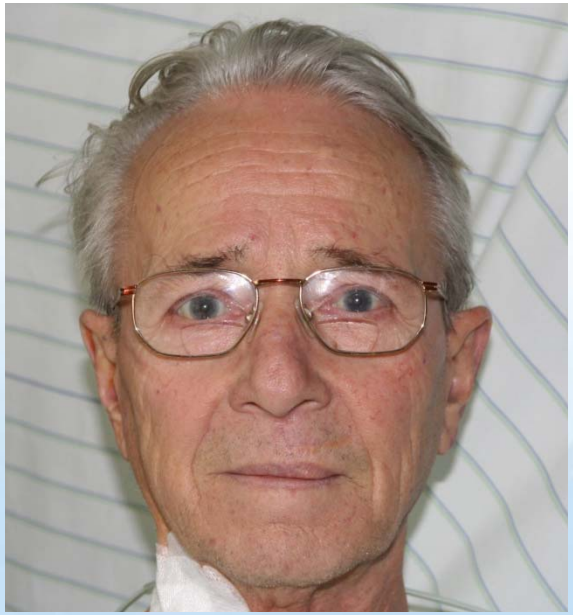
- Unstable angina during index hospitalization
- Recent pulmonary emboli
- Recent cerebrovascular accident (CVA)
- Patients unable to tolerate anticoagulation therapy
- Significant atheroma of the femoral and iliac vessels
- Severe tortuosities of the femoro-iliac vessels
- Femoro-iliac vessels < 7 mm
- Patients with bilateral iliofemoral bypass
- Hypertrophic cardiomyopathy with or without obstruction (HOCM)
- Severe ventricular dysfunction with ejection fraction < 20%

Patient Selection:Individual Assessment



annulus 27mm **=> conv. AVR**

92y s/p minor stroke,
***log.* Euroscore 24%** (12%)



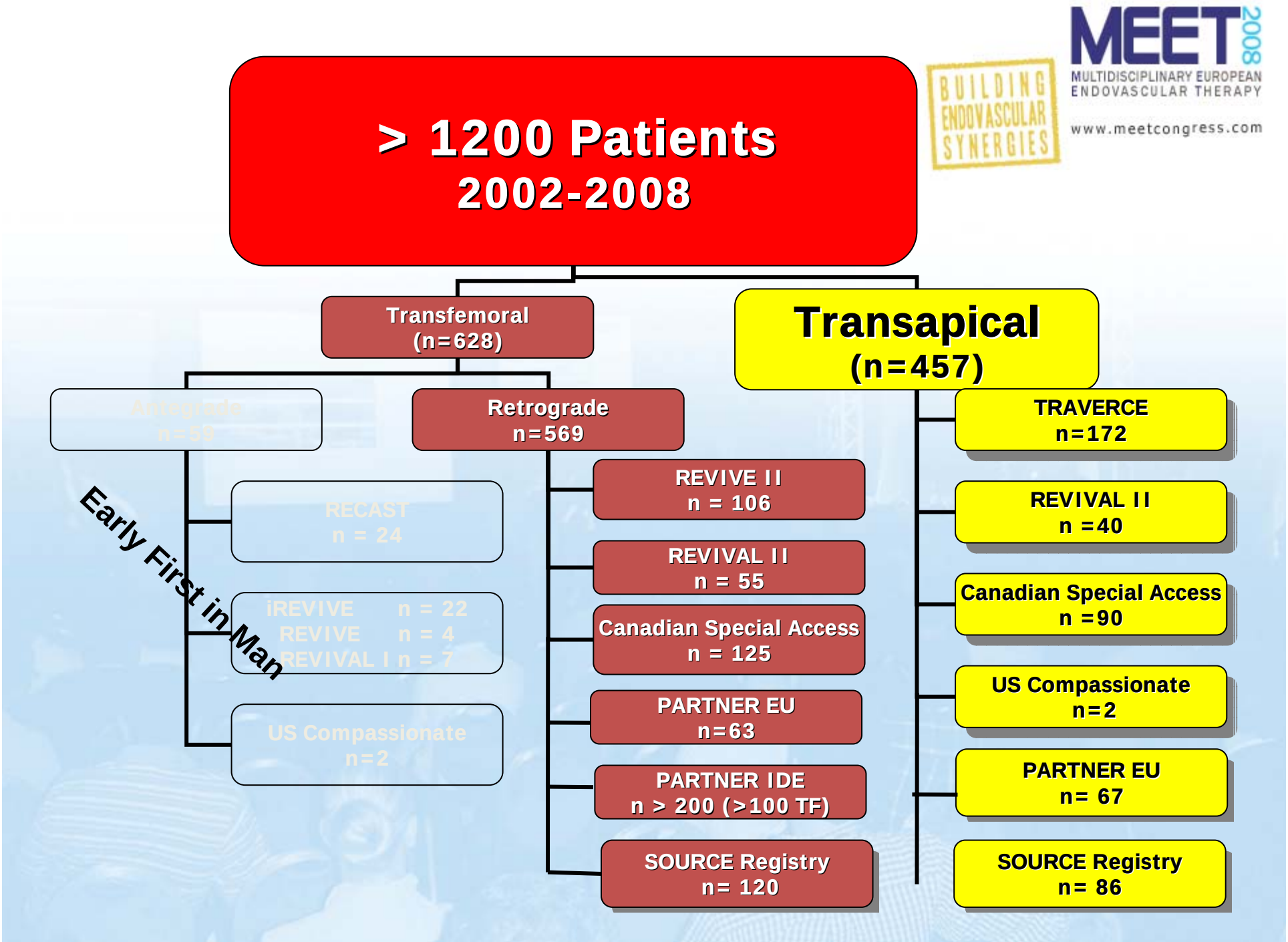
annulus 24mm **=> TA-AVI**

71y EF 20%, COPD,
s/p thoracotomy, porcelain aorta,
***log.* Euroscore 46%** (24%)

Patient selection

Team approach

- Cardiac surgeon
- Cardiologist
- Echocardiographist
- Interventional cardiologist
- Geriatrician
- Psychologist


> 1200 Patients
2002-2008
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Transfemoral (n=628)
Transapical (n=457)
Antegrade n=59
Retrograde n=569
Early First in Man
RECAST n = 24
iREVIVE n = 22
REVIVE n = 4
REVIVAL I n = 7
US Compassionate n=2
REVIVE II n = 106
REVIVAL II n = 55
Canadian Special Access n = 125
PARTNER EU n=63
PARTNER IDE n > 200 (>100 TF)
SOURCE Registry n= 120
TRAVERCE n=172
REVIVAL II n =40
Canadian Special Access n =90
US Compassionate n=2
PARTNER EU n= 67
SOURCE Registry n= 86

TRAVERCE Feasibility Study

Overview

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- **Purpose:** Prospective, multicenter, single arm Phase I pilot study evaluating the feasibility and safety of transapical delivery and implantation of the Edwards SAPIEN™ Transcatheter Heart Valve with the Ascendra™ delivery system.
  - symptomatic adult patients with severe, valvular aortic stenosis, and who are high risk candidates for routine open heart on-pump cardiac surgery
- **Enrollment:** n = 172; complete
- **Interim report:** n = 135 currently available with monitored, core lab reviewed, and adjudicated data
- **Primary safety endpoint:** Death, stroke, valve migration, severe AI, urgent cardiac surgery or device failure at discharge (< 30 d) and 6 months
- **Efficacy endpoints:** Numerous, including EOA by Echo, NYHA and perivalvular leak at discharge (≤ 30d) and 6 months

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Inclusion/Exclusion Criteria

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- **Inclusion Criteria**
- Age >70 yrs old
- Additive EuroSCORE risk ≥ 9
- AVR required
- EOA ≤ 1.2 cm2
- NYHA class III or IV

Exclusion Criteria

- **Native aortic annulus < 19 mm or> 24 mm, as estimated by TEE**
- Contraindication for aortic valvuloplasty or TEE
- Severe chest wall deformity
- Primary hypertrophic obstructive cardiomyopathy
- History of active endocarditis within last 3 months

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Baseline Demographics

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	Transapical **n = 135**
Age	**Mean 81.7 yrs ± 5.1** (Range 63 - 93)
Gender	**Female 77% (104)**
NYHA	**3.23 ± 0.4** (Range 1- 4)
Logistic EuroSCORE	**26.8 ± 12.9** (Range 7 – 59)
Aortic Valve Area n = 100	**Mean 0.55 cm^2 ± 0.22** (Range 0.24 - 1.4)
Mean Gradient n = 108	**Mean 44.76 ± 14.97** (Range 2.3 - 80)
Ejection Fraction n = 111	**Mean 50.75% ± 15.9%** (Range 15- 80.6)

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Baseline Co-Morbidities

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Co-morbidities	n	%
Systemic hypertension	112	83
Coronary artery disease	64	47.4
Pulmonary disease	48	35.6
Diabetes mellitus	43	31.9
Chronic renal disease	44	32.6
Peripheral vascular disease	35	25.2
Congestive heart failure	30	22.2
Myocardial infarction	27	20.0
Carotid disease	30	22.2
Prior PTCA	25	18.5
Prior CABG	19	14.0
Prior stroke	17	12.6

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Implant Success

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92 %
Implant Success

Patients Implanted
n = 135

Beating Heart Implants
n = 124

Implants requiring open conversion
n = 11

- malposition (n = 4)
- valve migration (n = 3)
- aortic insufficiency (n= 5)
- ascending aorta dissection (n = 1)
- mitral chordae entanglement (n = 1)

23 mm SAPIEN valve
n = 37

26mm SAPIEN valve
n = 87

Note: Patients can have more than one intraprocedural complication leading to open conversion

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Procedure Outcomes

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Procedural Outcomes (n = 135)	
Total Procedure Time (n = 131)	**127.6 ± 82.5 min** Range: 55 – 440 min
Deployment Time BAV to Valve deployment (n = 124)	**8.2 ± 5.6 min** Range: 2 – 38 min
Beating Heart Procedure (n = 97)	**71.9%**
Correct Valve Positioning (n = 126)	**93.3%**
Valve Area Increase[1]	**0.55 to 1.46 cm^2**
Mean Gradient decrease[1]	**44.5 to 7.4 mmHg**
Arrhythmias requiring a pacemaker[2]	**6.6%**

[1] Baseline to discharge

[2] **Pacemaker rate in conventional AVR, 3.2% - 8.5%;** Dawkins et al, *Ann Thorac Surg*, 2008, 85:108-12

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Intraprocedural Complications

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Complications	n = 25 (18.5%)
Vascular – descending aortic dissection	1
Apical bleeding/ventricular injury	8
Arrhythmias requiring intervention	4
Hemodynamic instability requiring intervention	3
Cardiac failure	4
Partial coronary occlusion	3
Coronary occlusion	2

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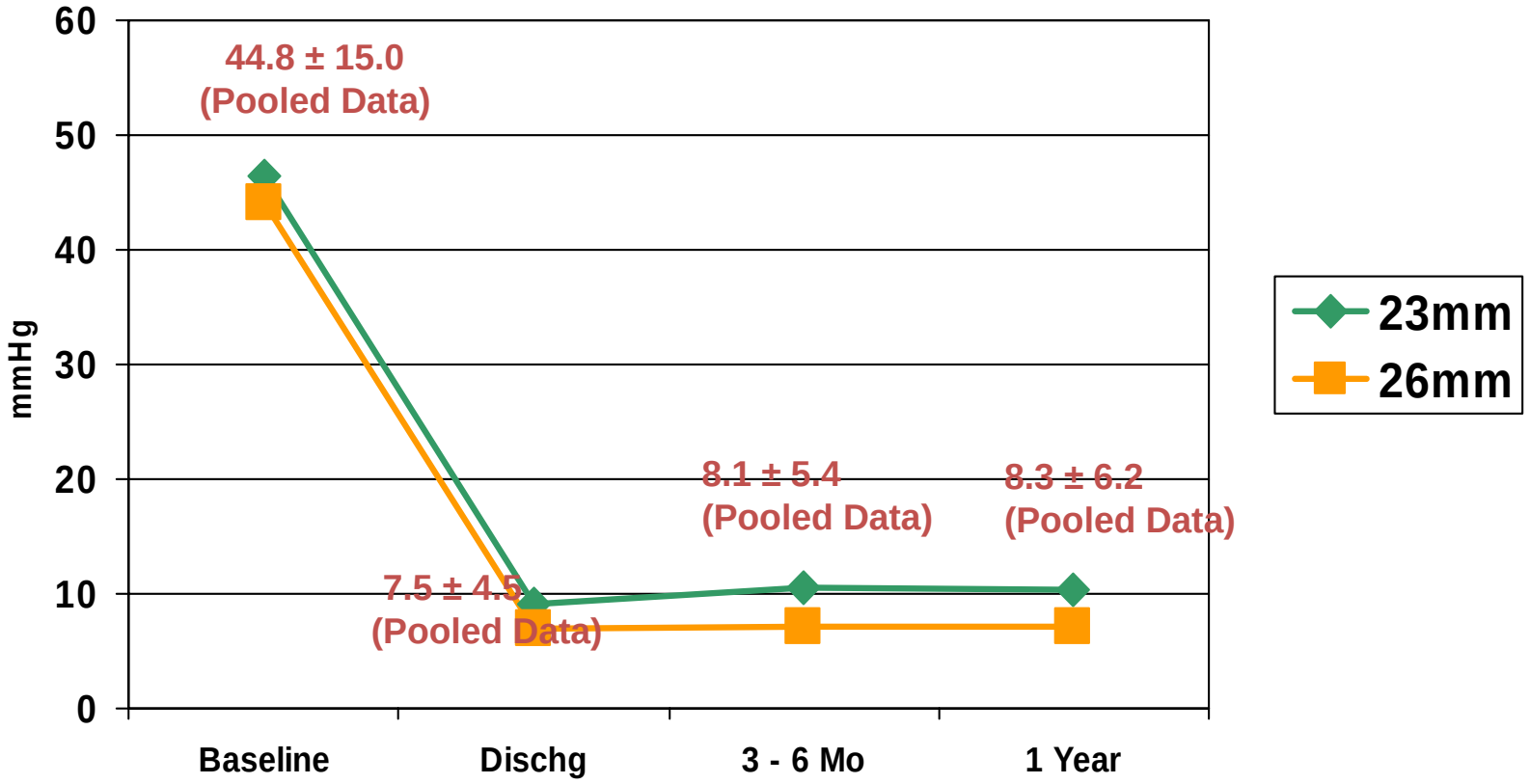
Mean Gradients (Core Lab)



23mm	n =	31	28	16	9
26mm	n =	77	70	39	15

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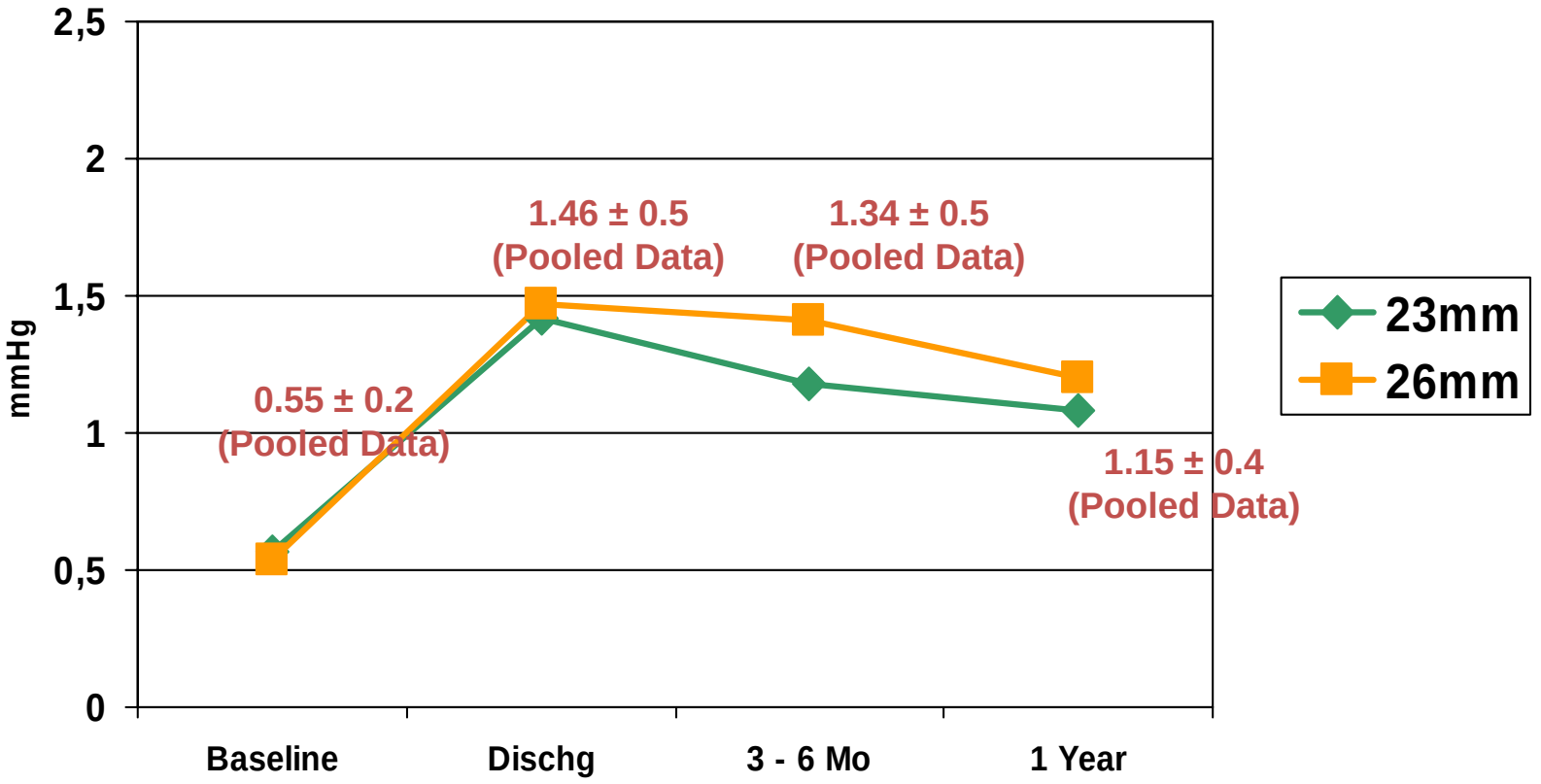
EOA (Core Lab)



23mm	n =	25	27	12	8
26mm	n =	75	57	29	14

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Aortic Regurgitation (Core Lab)

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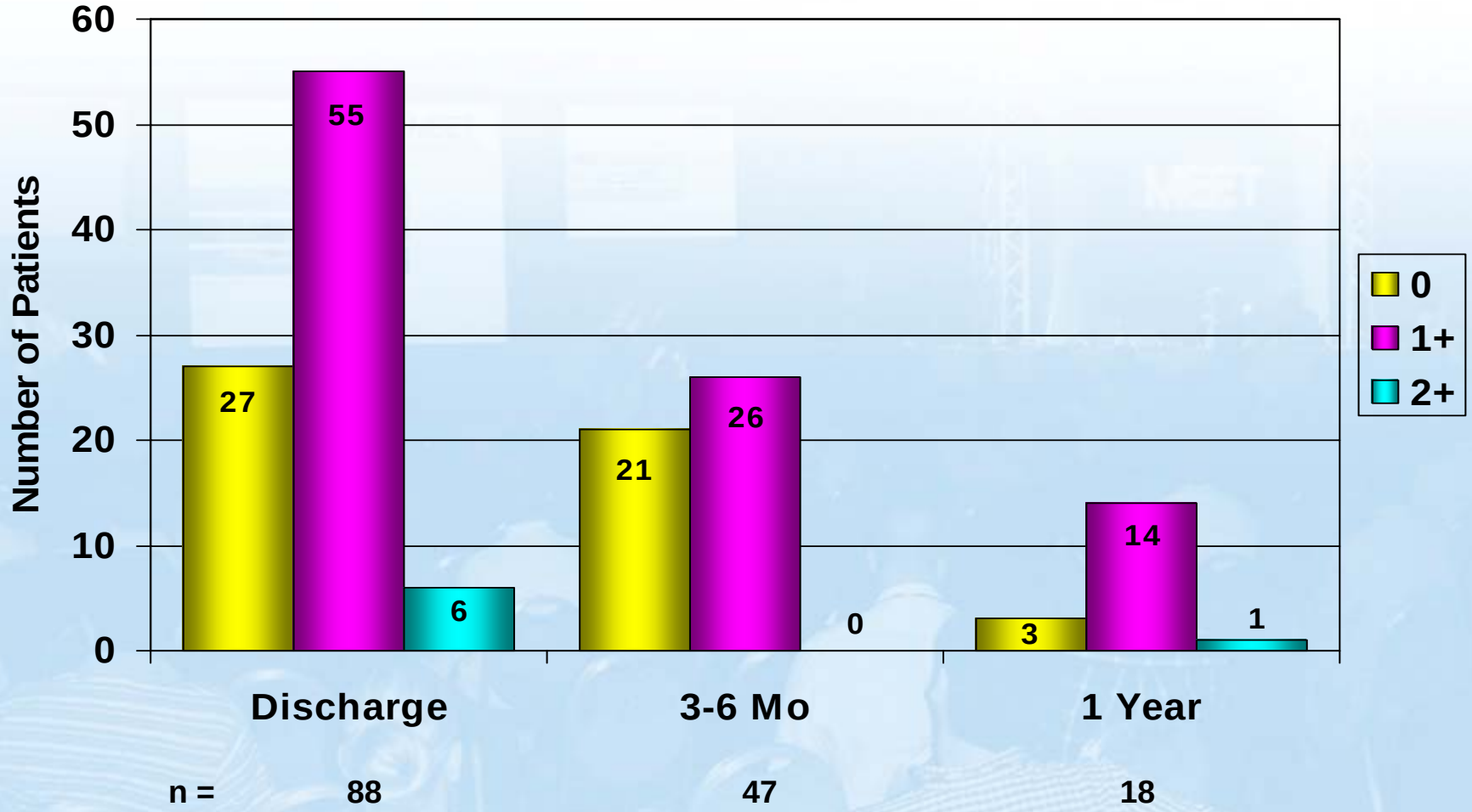
Pooled 23mm & 26mm valve



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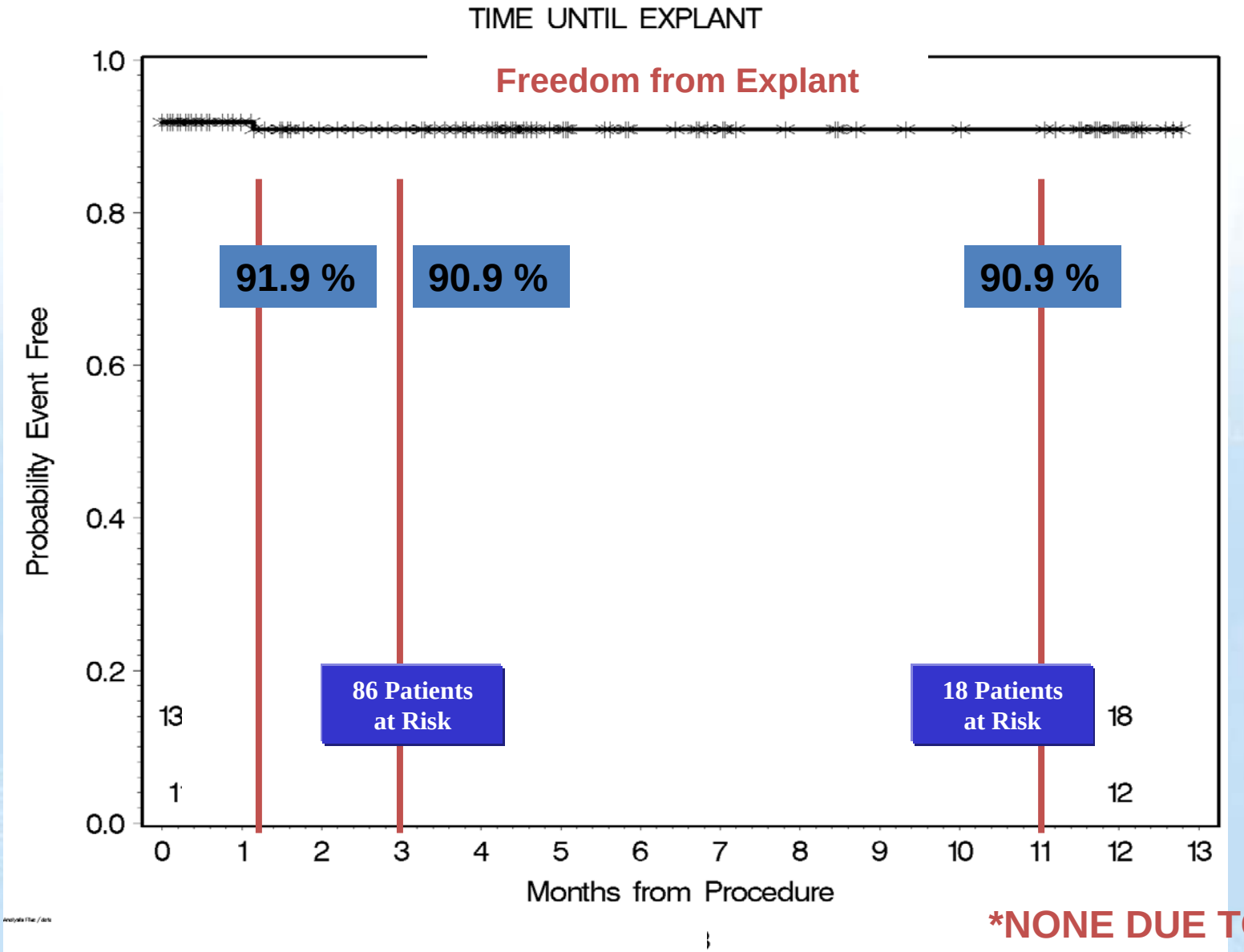
*Freedom from Explant**



*NONE DUE TO SVD

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Freedom from Death

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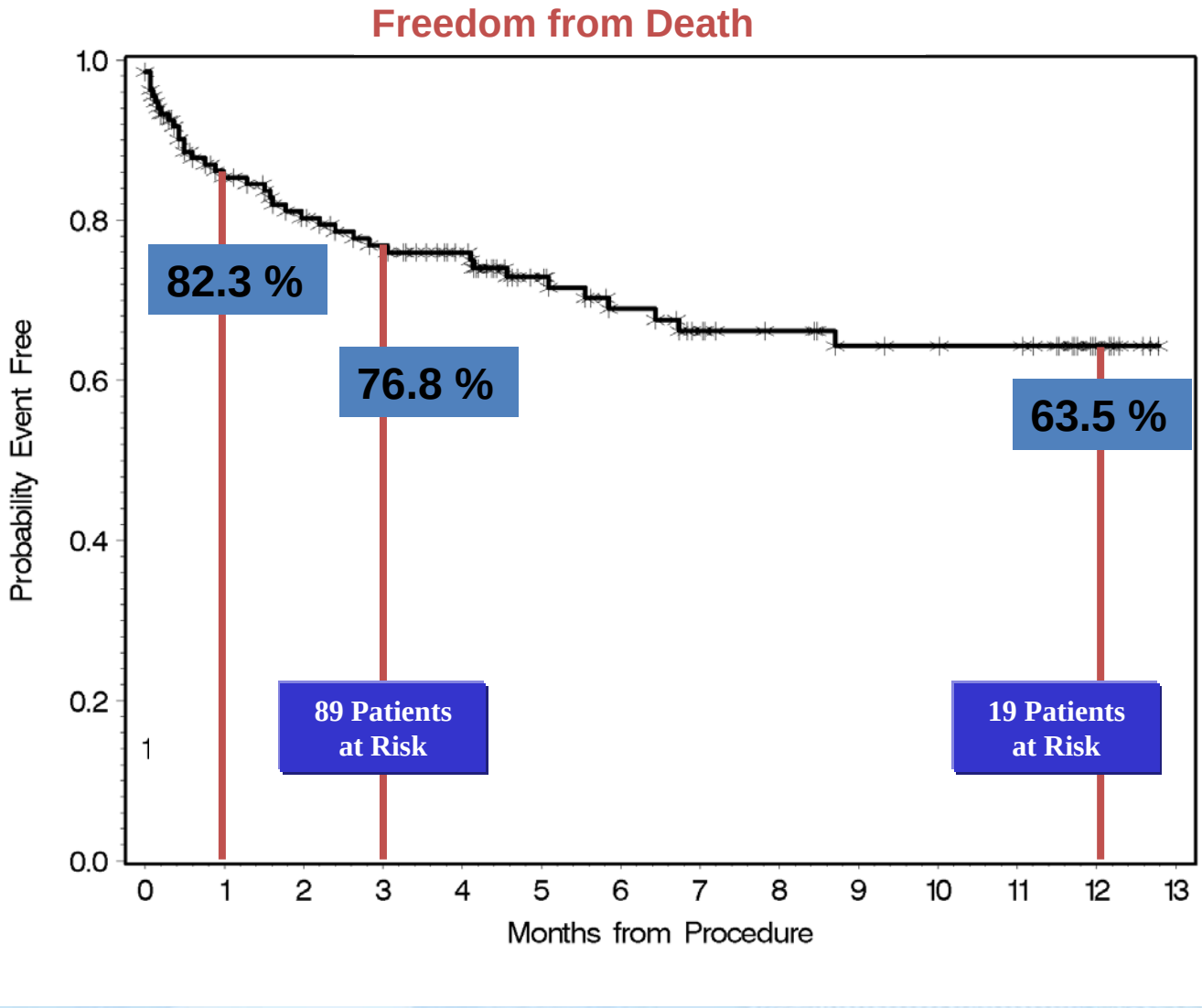

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Deaths

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Early Deaths	
Early (< 30 days) {No intraprocedural deaths}	**19 (14.1%)**
Cardiac Failure	8
Multiple organ failure, respiratory complications, bleeding event	2 each
Leg Ischemia, GI complication, embolic event, arrhythmia, sudden death, calcium embolism	1 each

Late Deaths	
Late (> 30 days)	**20 (14.8%)**
Respiratory complications	5
Multi-organ failure and cardiac failure	3 each
Neurological complications	1 each
Sepsis, MI, GI complications, auto-immune vasculitis, arrhythmia, sudden death, cerebral bleed	1 each

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Freedom from Myocardial Infarction

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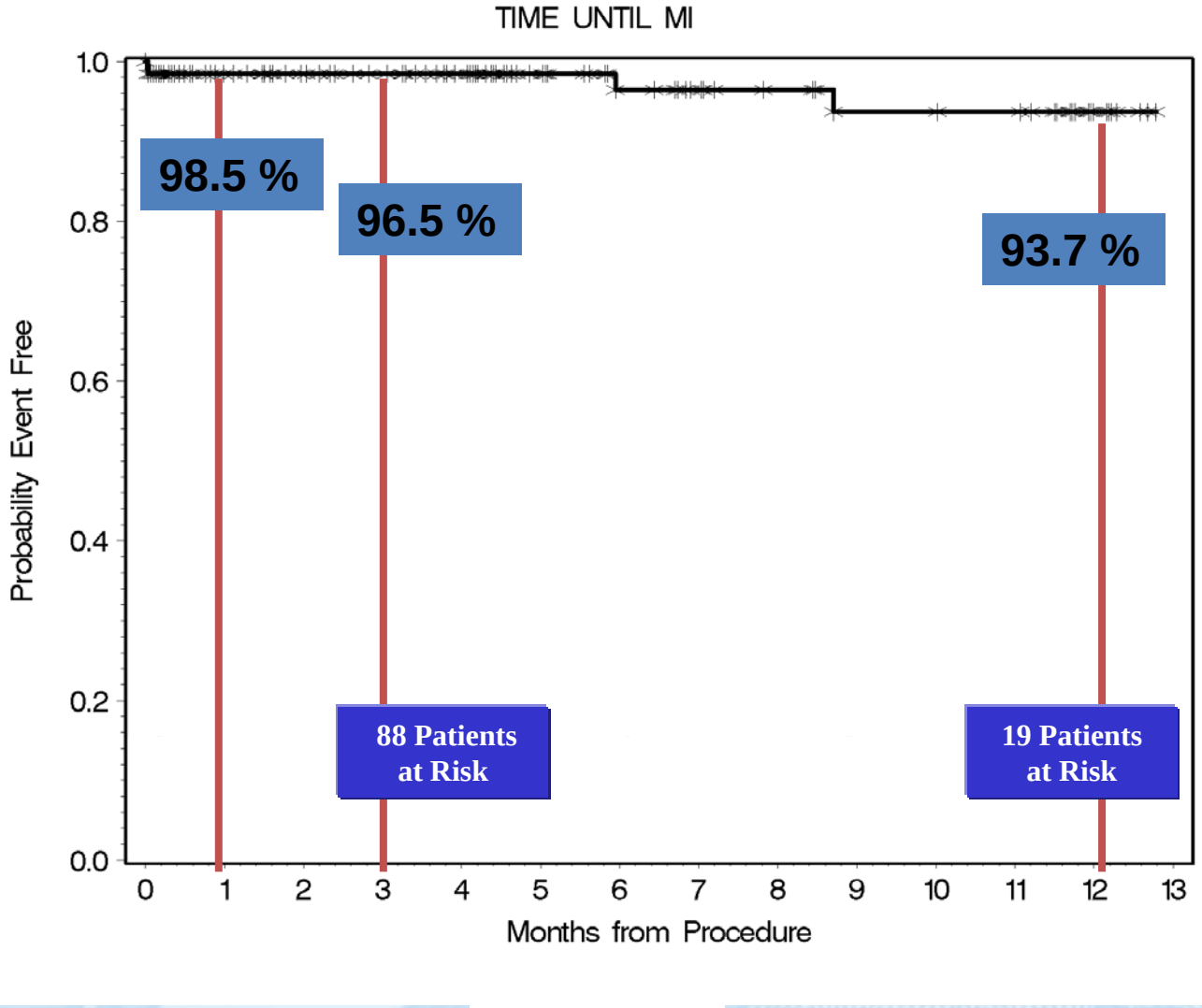
Freedom from Myocardial Infarction



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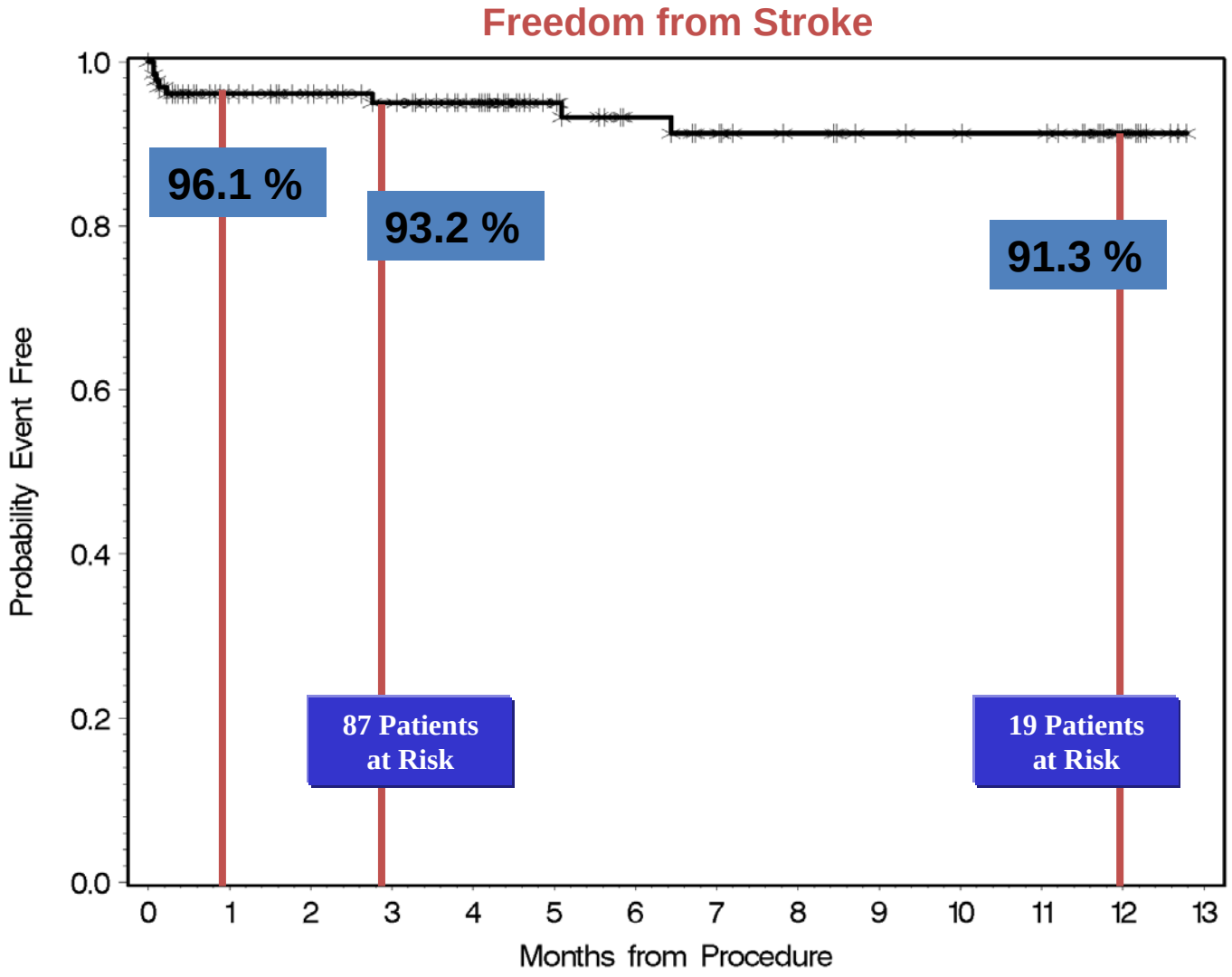
Freedom from Stroke



TRAVERCE Feasibility Study

Freedom from Structural Valve Deterioration

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	Kaplan – Meier Analysis		
	30 days	6 months	1 Year
Freedom from Structural Valve Deterioration	100%	100%	100%

TRAVERCE Feasibility Study

Interim Conclusions

- TRAVERCE study experience suggests that transapical AVR with the Edwards SAPIEN™THV is **feasible** and **reasonably safe** in high risk aortic stenosis patients
  - **No intraprocedural deaths**,
  - **No structural valve deterioration out to one year, and**
  - **Consistent valve gradients**.

- The transapical procedure with the Ascendra™ Delivery System is a unique procedure with different patient management and training requirements
  - **Cross-specialty case pre-planning**
  - **TEE and fixed, mounted fluoroscopy preferred**
  - **Experienced surgeon with interest in expanding catheter skills**
  - **Collaborative team**
  - **Intraprocedural hemodynamic monitoring**
  - **Proper coaxial positioning of delivery system**

- Further studies are required to compare this risk population to conventional procedures

Clinical Publications

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Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

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American Heart Association
Learn and Live

Transapical Transcatheter Aortic Valve Implantation in Hu
Experience
Samuel V. Lichtenstein, Anson Cheung, Jian Ye, Christopher I
G. Carere, Sanjeevan Pasupati and John G. W
Circulation 2006;114;591-596; originally published onli
DOI: 10.1161/CIRCULATIONAHA.106.632
Circulation is published by the American Heart Association. 7272 Greenv
72514
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Transapical Minimally Invasive Aortic Valve Implant
Experience
Thomas Walther, Paul Simon, Todd Dewey, Gerhard Wimme
Falk, Marie T. Kasimir, Mirko Doss, Michael A. Borger, Ge
Glogar, Wolfgang Fehske, Ernst Wolner, Friedrich W. Mol
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The Evolving Treatment of Aortic Stenosis: Do New Procedures Provide New Treatment Options for the Highest-Risk Patients?
John D. Carroll
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Transcatheter aortic valve implantation: time to expand?
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Current Opinion in Cardiology 2006, 21:111–116

Purpose of review
Transcatheter aortic valve implantation is a new, en
performed in elderly and higher-risk patients suffer
stenosis.
Recent findings
Initial clinical results are promising. Important techn
development of two stent-based aortic valve xenogr
a nitinol frame and the Edwards Sapien prosthesis w
achievements. Both prostheses can be crimped to
implantation by either a transfemoral or a transapic
approval has been obtained for both prostheses for
likely lead to an increased number of implantations.
prospective design with observational character. Ne
trials have been reported so far; however, one rand
Summary
Transcatheter aortic valve implantation has become
performed more frequently in the future. Patient sel
indications include only higher-risk patients sufferin
selecting the optimal therapy for individual patients,
of this novel approach must be carefully weighed ag
with conventional surgery.

Keywords
aortic valve implantation, transapical, transcatheter,

Curr Opin Cardiol 21:111–116
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Introduction
Aortic stenosis is the most frequent acquired heart valve lesion in the Western world. Therapeutic intervention is based upon standardized guidelines, which have resulted in excellent outcomes using conventional surgical valve replacement, especially in younger patients with a relatively low-risk profile [1–8]. Even in octogenarians, however, recently published literature indicates good patient outcomes [9–12]. In addition to advanced age, other significant comorbidities may lead to an increased risk and a 'nonreferral' pattern for surgery [13], yet conservative treatment of aortic stenosis carries a grave prognosis [14]. Therefore, alternative, minimally invasive techniques need to be further developed to treat these very high-risk patients safely.

Transcatheter aortic valve prostheses
During the past few years, two devices have been introduced into clinical practice for sutureless transcatheter aortic valve implantation (AVI), i.e. the CoreValve and the Edwards Sapien prostheses (Figs 1 and 2). Both have

some similar fundament
xenogenic pericardial val
stent suspending these cu
delivery. There are, ho
The CoreValve prosthesi
long self-expanding nitin
glass' shape that can depl
level of the coronary atter
ing for unabated coronar
prosthesis has a 14–16m
tube steel stent, mimickii
thetic valve. It is sutied
annulus and sits in a subs
regard to the leaflet cu
constructed of porcine per
Sapien device utilizes bov
fix anticalcification treatm

Three generations of
been implanted, the 24F
generation) and 18F (thir
inflow diameters, 26 and 2
sufficient oversizing. Initia

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ELSEVIER

European Journal of Cardio-Thoracic Surgery 31 (2007) 9–15

Minimally invasive transapical beating heart aortic valve implantation — proof of concept

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Abstract

Objective: To evaluate the feasibility of minimally invasive transapical beating heart aortic valve implantation (TAP-AVI) for high-risk patients with aortic stenosis. Methods: TAP-AVI was performed via a small anterolateral minithoracotomy with or without femoral extracorporeal circulation (ECC) on the beating heart. A pericardial xenograft fixed within a stainless steel, balloon expandable stent (Edwards Lifesciences, Irvine, CA, USA) was used. Thirty consecutive patients (82 ± 5.1 years, 21 (70%) females) were operated from 02/06 until 04/06 at one center using fluoroscopic and echocardiographic visualization. Average EuroSCORE predicted risk for mortality was 27 ± 12%. Results: Valve positioning was successful in 29 patients and one required early conversion to full sternotomy. Implantation (8 mm × 22 mm and 22 mm × 26 mm valves) was performed on the beating heart during brief periods of rapid ventricular pacing. ECC was applied in 13 patients. Neither coronary artery obstruction nor migration of the prosthesis was observed and all valves displayed good hemodynamic function. Echocardiography revealed minor paravalvular leakage in 14 patients (trace in three, mild in nine and moderate in two). Three patients (10%) died, one on postoperative day (POD) three secondary to preoperative global myocardial failure and two on POD 18 and 35 due to abdominal complications. Conclusions: Minimally invasive beating heart TAP-AVI is feasible. Initial results are encouraging in view of the high-risk profile of the patients. Long-term studies as well as randomized protocols are required.
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Keywords: Aortic valve replacement; Transapical aortic valve implantation; Minimally invasive cardiac surgery; Beating heart cardiac surgery; Transcatheter valve implantation

1. Introduction

Aortic valve replacement is a standard procedure performed for more than five decades with excellent short and long-term outcomes. More than 50,000 patients are being operated in the USA and more than 11,000 patients in Germany annually [1,2]. Surgical valve replacement is the only definitive therapeutic strategy, indicated in presence of severe symptomatic disease with a valve orifice area of ≤1 cm² [3]. Current conventional surgical techniques consist of partial or complete sternotomy with extracorporeal circulation (ECC) and cardioplegic cardiac arrest.

In parallel with an overall increasing life expectancy more and more elderly patients are being diagnosed with AS. Besides older age additional perioperative risk factors may be present such as low ejection fraction, pulmonary hypertension, respiratory dysfunction, renal failure or peripheral arterial occlusive disease. Such co-morbidities are associated with an increased perioperative risk, particularly for mortality. Truly minimally invasive strategies may be an important treatment option for such high-risk patients. Important areas of development include minimizing the overall surgical trauma by potentially avoiding a sternotomy, avoiding the use of ECC and implanting the prostheses on the beating heart thereby avoiding cardiac arrest.

The aim of our study was to evaluate the feasibility of minimally invasive transapical aortic valve implantation (TAP-AVI) on the beating heart in high-risk patients.

2. Methods

Before performing a clinical study, extensive experimental evaluation of the transapical approach as well as transcatheter valve implantation techniques was performed

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g to Facilitate Transcatheter Prosthetic Heart Valve Implantation

Vebb,* MD, Sanjeevan Pasupati, MD, Leslie Achtem, RN, and Christopher R. Thompson, MD

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ECLINICAL STUDIES

Valve-in-a-Valve Concept for Transcatheter Minimally Invasive Repeat Xenograft Implantation

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Transapical Approach:

The Initial 50 Patients in Leipzig

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Patient demographics

	Mean	Range
Total (*n*)	50	
Female	39	78%
Age (years)	82.4 ± 4.6	65–93
Body weight (kg)	68 ± 13	43–120
Body surface area (m^2)	1.7 ± 0.2	1.4–2
NYHA class	3.3 ± 0.5	3–4
Ejection fraction (%)	53 ± 14	15–75
Aortic incompetence[a]	28	56%
EuroSCORE (points)	11.3 ± 1.6	9–15
Logistic EuroSCORE (%)	27.6 ± 12.2	11–61
STS score (%)	15.8 ± 9.1	5.6–40

NYHA: New York Heart Association; STS: Society of Thoracic Surgeons.
[a] Mild-to-moderate aortic valve incompetence at preoperative echocardiography in conjunction with severe aortic valve stenosis.

Additional risk factors present in the initial 50 patients

	n	(%)
Chronic pulmonary disease	21	42
Pulmonary hypertension	16	32
Neurological dysfunction	12	24
Peripheral vascular disease	8	16
Renal dysfunction (creatinine > 200 μmol/l)	7	14
Previous cardiac surgery[a]	5	10
Critical preoperative state	4	8

[a] With patent bypass grafts.

Mortality observed at 30 days: 8%

Transapical

Walther et al., Transapical miminally invasive aortic valve implantation; the initial 50 patients. EJCTS 2008. In press

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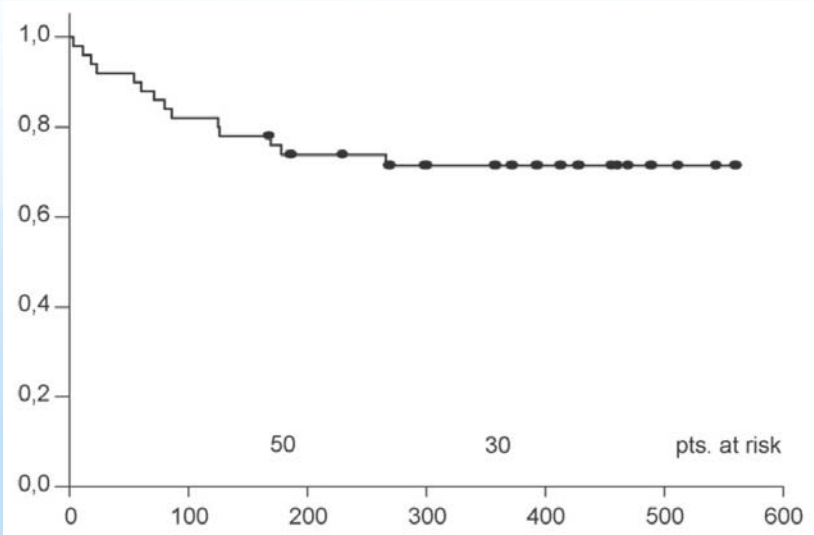

Fig. 2. Survival analysis for the 50 patients. Follow-up duration is shown in days on the *x*-axis.

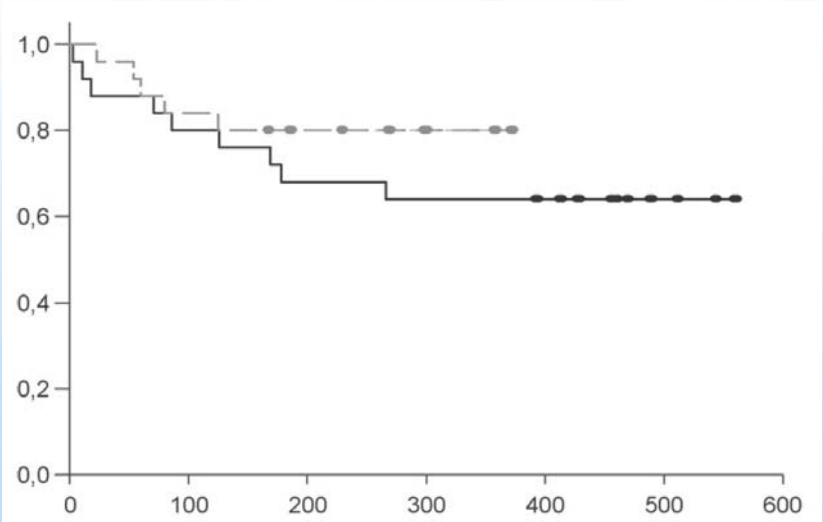

Fig. 3. Survival analysis for the initial 25 (lower curve, solid line) versus the more recent (upper curve, dashed line) patients. Follow-up duration is shown in days on the *x*-axis.

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Massy experience

Dec. 2007- June 2008

14 patients

Mean age		**82 (69-93)**
M / F		**10 / 4**
Euroscore (%)		**28**
Valve area	**(mean)**	**0.58**
Aortic annulus size	**(mean)**	**22**
LV- Ao gradient	**(mean)**	**47**
E F	**(mean)**	**52 (25-75)**
COPD		**5**
Previous CABG		**4**
Porcelain Aorta		**2**
Morbid Obesity		**2**

Massy experience

operative data and results

- **23 mm** **3**
- **26 mm** **11**
- **Procedure time** **55-120**
- **Positioning to deployment** **16 +/- 9 min.**

- **Hospital deaths** **2**

THV: Conclusions

"It's What You Leave Behind That Matters"

Key success factors:

- Optimal visualization equipment
- Rigorous patient selection / screening process
- Procedure planning
- In-depth training and shared-learning

<u>The most successful results come from multidisciplinary, collaborative teams</u>!

Selection criteria

Euroscore

STS score

Others

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TRAVERCE Feasibility Study
Interim Conclusions

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While Surgery is The Gold Standard, Patient Profiles Have Changed over Time

	1990	1995	2000	2002	p
Patients	126	230	269	146	
Operative mortality (%)	9.5	14.8	7.1	8,9	NS
Age	82.2	82.3	82.9	82	<0.001
Comorbidities (%)	34.9	37.8	39.4	63.7	<0.001
Coronary disease (%)	4	27	31.4	34.9	<0.001
Concomittant CABG (%)	2.4	16.5	15.6	19.9	<0.001
Left heart failure (%)	59.5	50	34.6	25.3	<0.001
NYHA III/IV	72.2	81.3	66.8	45.1	<0.001

Courtesy of T.Langanay: JHVD 2004;13 : 545 - 553

Transapical Procedural Steps Using The Ascendra™ Delivery System

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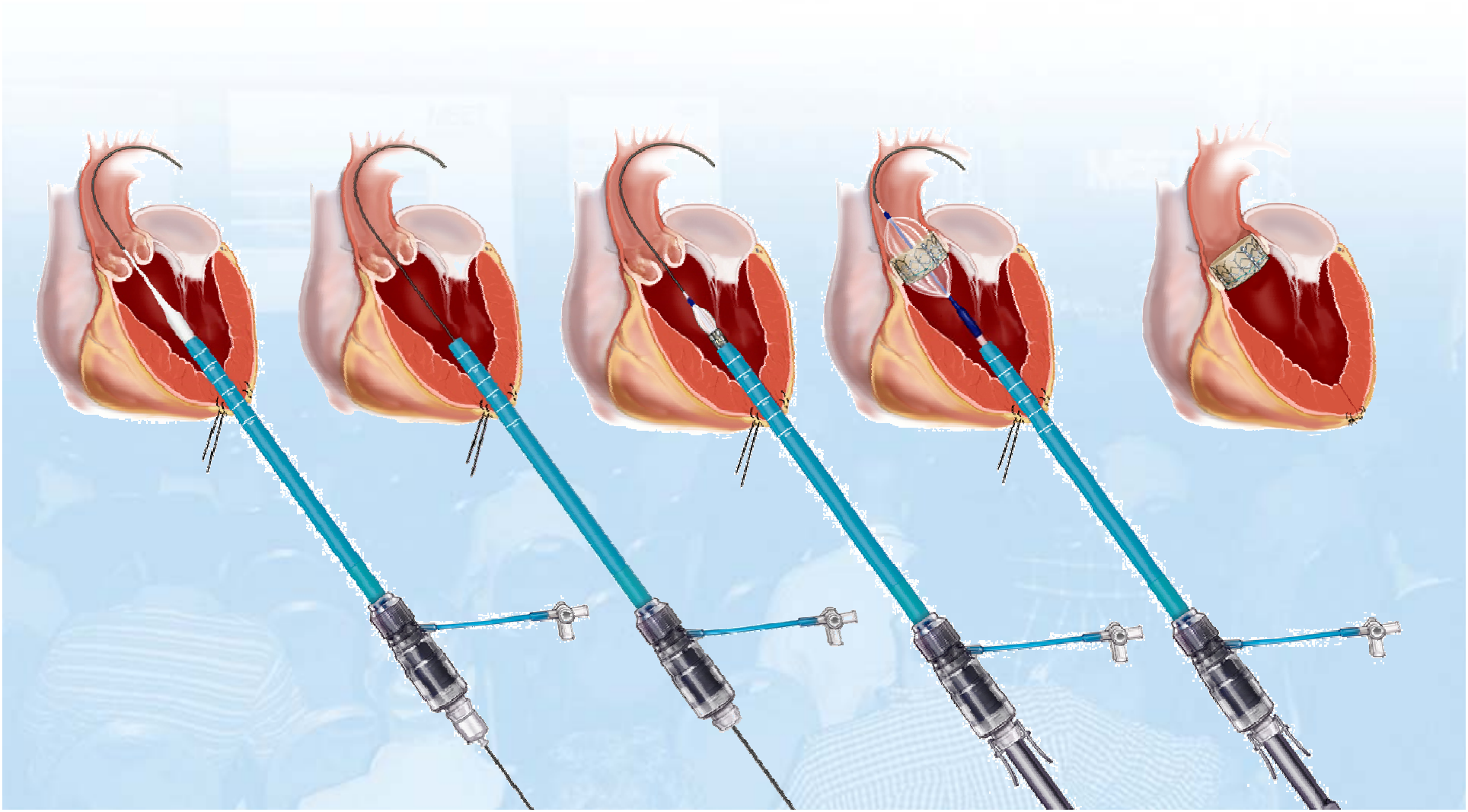
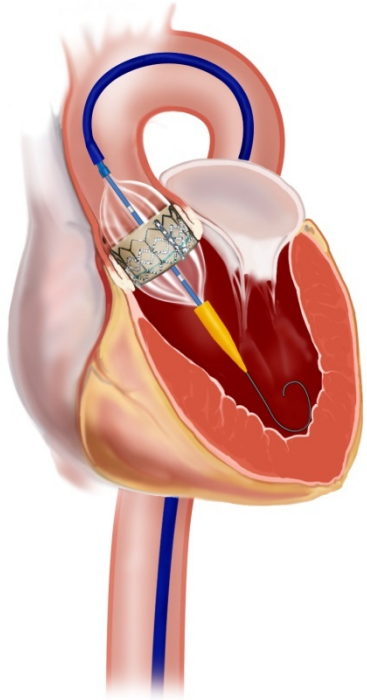
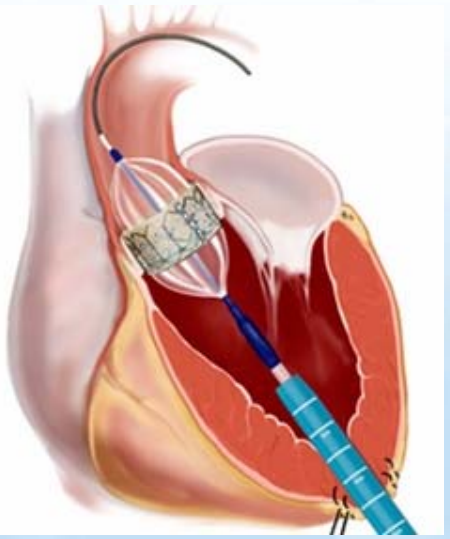


Edwards SAPIEN™ Transcatheter Two Approaches

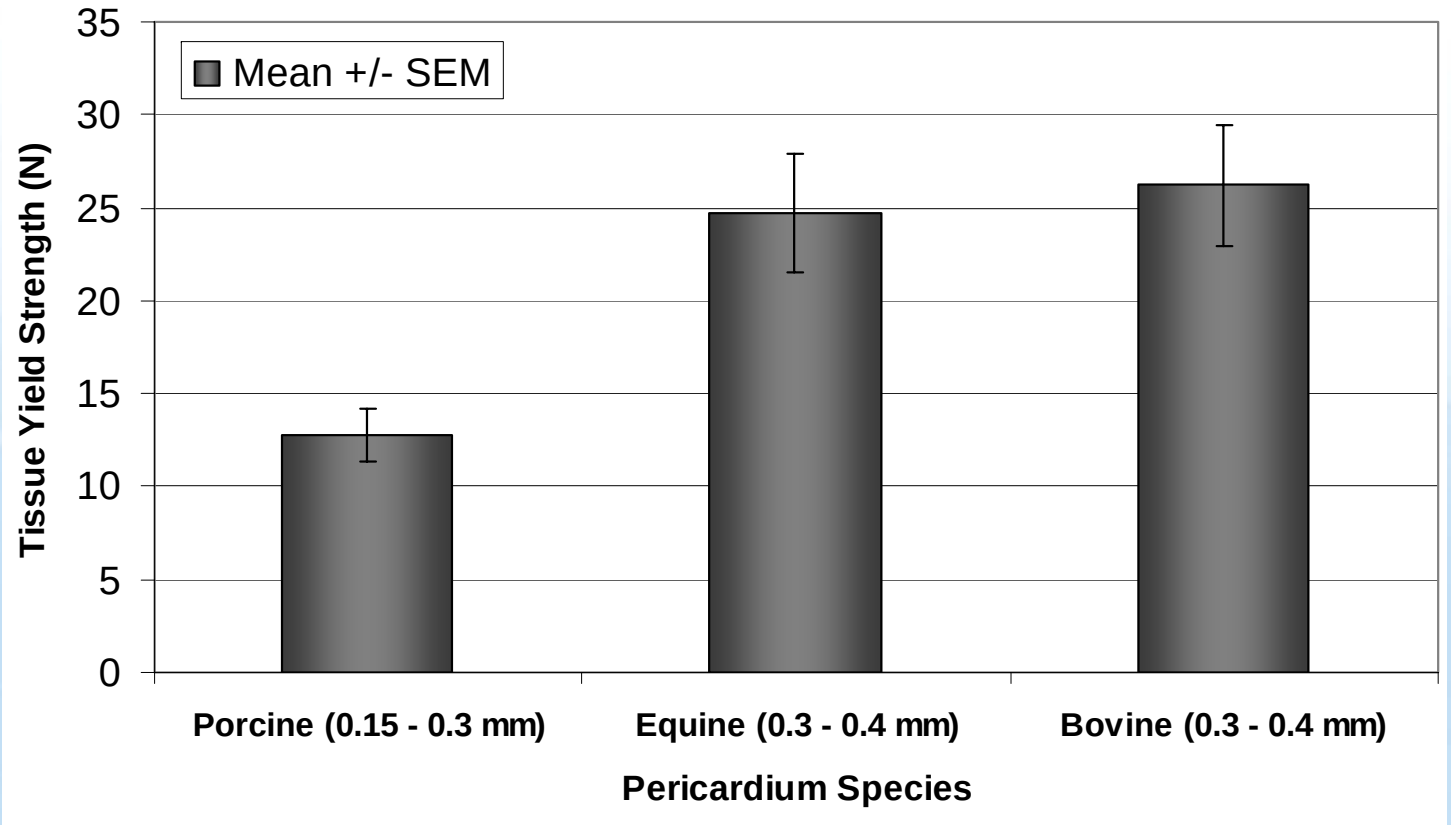


Transfemoral



Transapical

Edwards SAPIEN™ Bovine Pericardial THV



- Tissue selection has a significant influence on valve durability

[1]Data on file with Edwards Lifesciences. RD1208 and LN1223.

FRAME:

- Consistency & durability with non-conformable, symmetrical, discreet frame
  - **Radial strength for concentric shape that creates uniform stress on leaflets and limits contact with frame**
- Skirt height optimized for maximum landing zone and reduced paravalvular leak

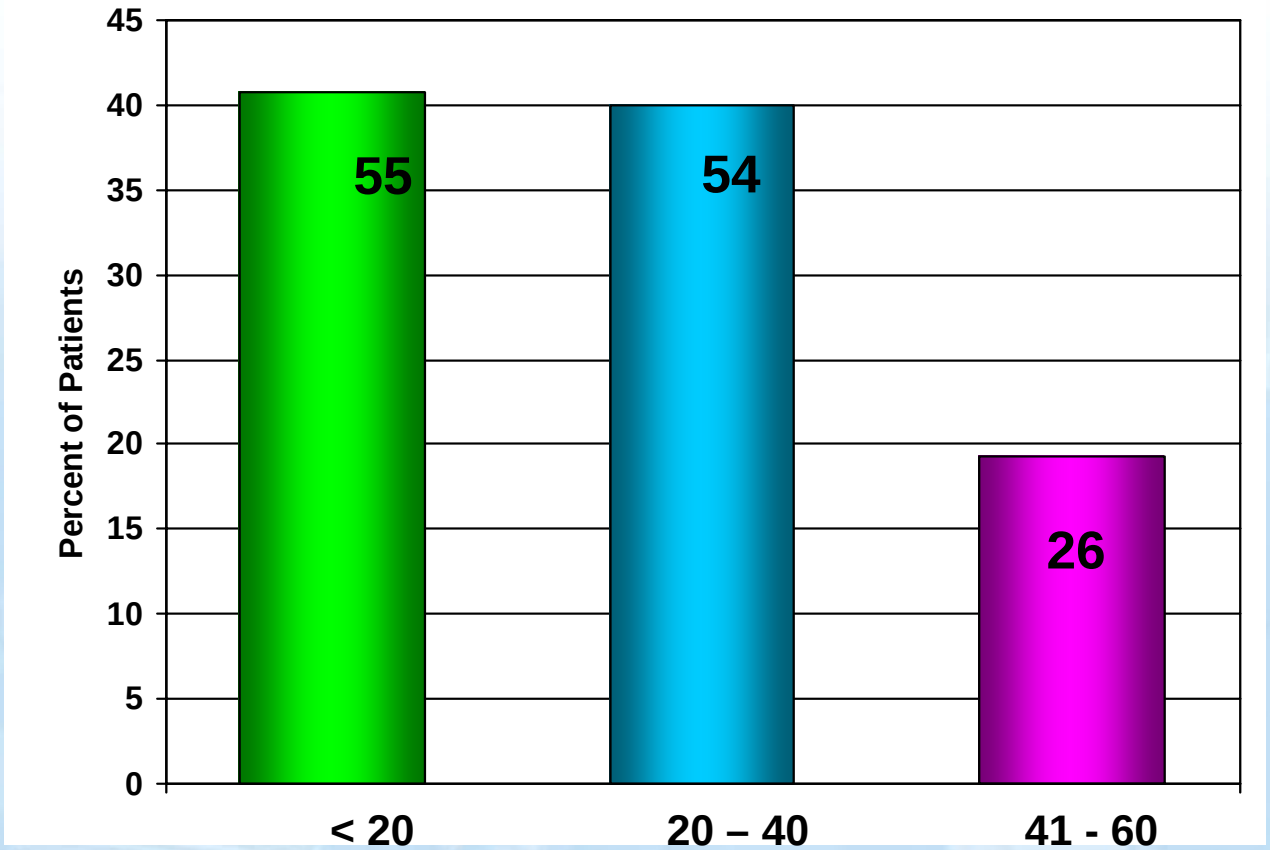
TISSUE:

- Bovine pericardial tissue
- ThermaFix[1] anti-calcification technology

[1]No clinical data are available which evaluate the long-term impact of the Edwards Lifesciences tissue treatment in patients.

TRAVERCE Feasibility Study

Baseline Demographics



n = 135

Mean = 26.8%

Range = 7- 59

TRAVERCE Feasibility Study

Baseline Demographics

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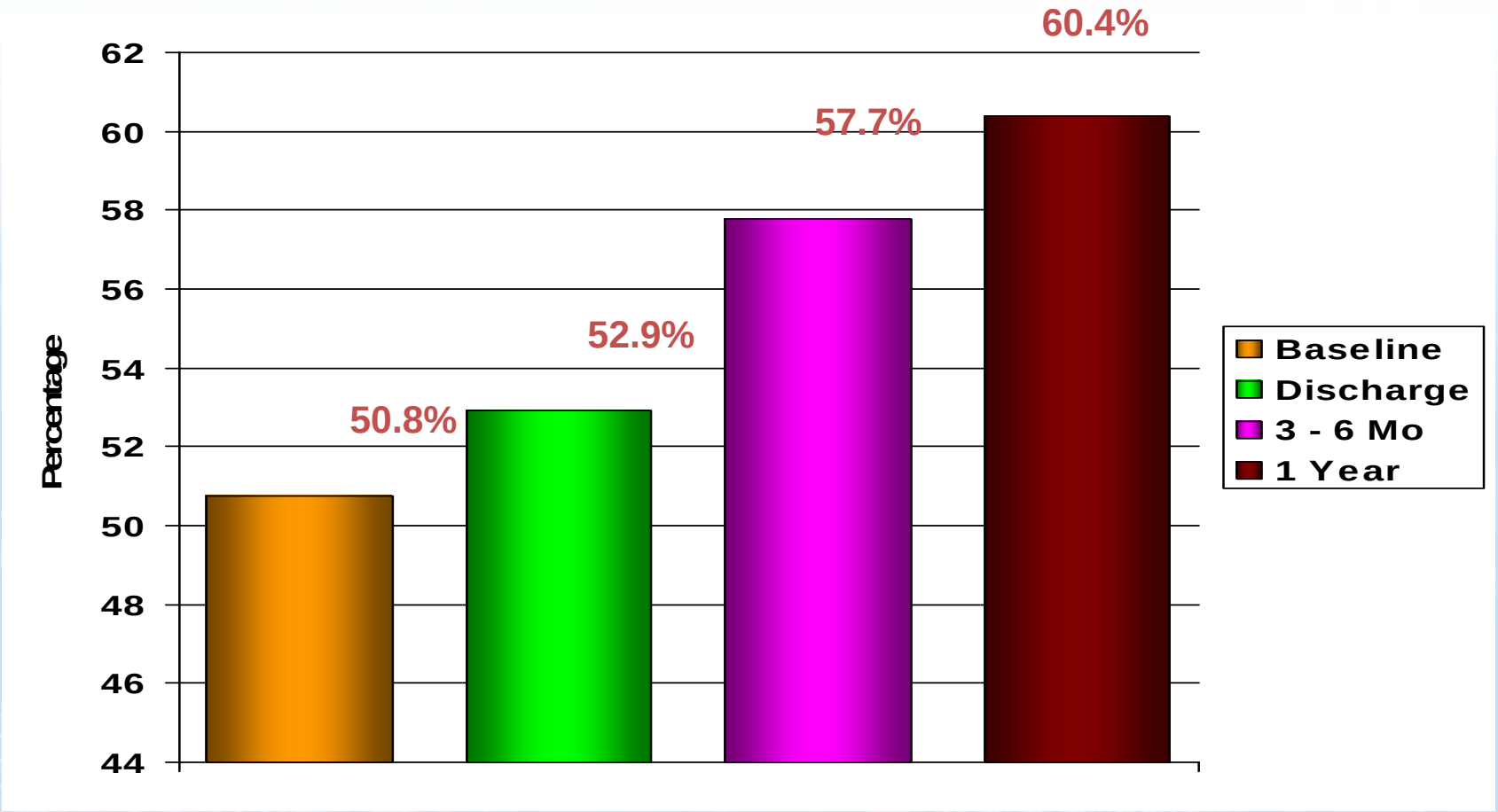
Echocardiography Core Lab Data (n = 135)	
Aortic Valve Area n=100	**Mean 0.55 cm^2 ± 0.22** (Range 0.24 - 1.4)
Mean Gradient n = 108	**Mean 44.76 ± 14.97** (Range 2.3 - 80)
Ejection Fraction n = 111	**Mean 50.75% ± 15.9%** (Range 15-80.6)

VERCE Feasibility Study

LV Ejection Fraction (Core Lab)

Pooled 23mm & 26mm valve



n =	111	98	56	24

Transapical Minimally Invasive Aortic Valve Implantation: The Initial 50 Patients

Abstract

Objective: To evaluate the feasibility of minimally invasive transapical beating heart aortic valve implantation (TAP-AVI) for high-risk patients with aortic stenosis. **Methods:** TAP-AVI was performed via a small anterolateral minithoracotomy in 50 patients from February 2006 to March 2007. A balloon expandable transcatheter xenograft (Edwards SAPIEN™ THV, Edwards Lifesciences, Irvine, CA, USA) was used. Mean age was 82.4 ± 5 years and 39 (78%) were female. Implantation was performed in a hybrid operative theatre using fluoroscopic and echocardiographic visualization. Average EuroSCORE predicted risk for mortality was 27.6 ± 12%. Seven (14%) patients were re-operations with patent bypass grafts. **Results:** TAP-AVI (13 patients 23 mm and 37 patients 26 mm) was successfully performed on the beating heart under temporary rapid ventricular pacing in 47 (94%) patients, and implantation was performed completely off-pump in 34 (68%) patients. Three patients required early conversion; two of them were successfully discharged. There was no prosthesis migration or embolization observed. Echocardiography revealed good hemodynamic function in all and minor incompetence in 23 patients, mostly paravalvular, without any signs of hemolysis. Mortality was due to the overall health condition and non-valve related in all patients. Actuarial survival at 1 month, 6 months and 1 year was 92 ± 3.8%, 73.9 ± 6.2% and 71.4 ± 6.5%, respectively. **Conclusions:** Transapical minimally invasive aortic valve implantation is feasible using an off-pump technique. Good results have been achieved in the initial 50 patients, especially when considering the overall high-risk profile of these patients.

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