A case study: the TAVI (Transcatheter Aortic Valve Implantation) Procedure. Multicriteria Decision Analysis in Lombardy

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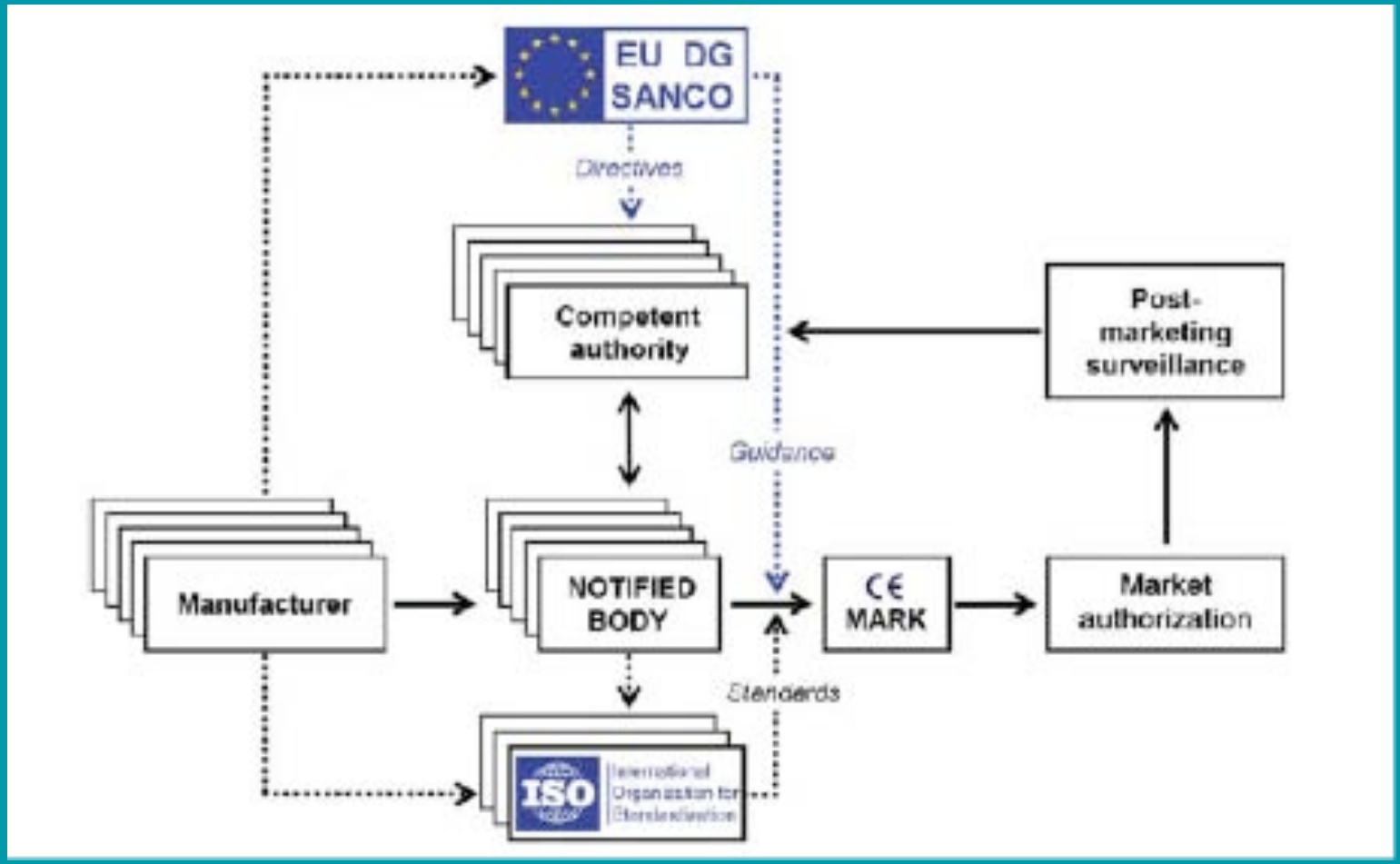
Medical Devices

The use and complexity of diagnostic and therapeutic devices is increasing, particularly in cardiovascular medicine, and expenditure on devices contributes significantly to the escalating costs of health care.

Estimates of the total number of medical devices in Europe range upwards from 200 000, with combined annual sales of more than 72 billion Euro.

Regulatory Framework for Approving Medical Devices in Europe



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Approval of Medical Devices in the United States and European Union

System Feature	United States	European Union	Potential Implications
Mandate	Oversight of public health	Device safety (overseen through Competent Authorities), device approval (through Notified Bodies), and facilitation of trade	May influence dealings with industry clients, and attention paid to balance between effectiveness and risk of safety concerns
Centralization	Oversight of all device regulation by the FDA	Directives outline processes carried out by Competent Authorities and Notified Bodies	Standardization and coordination of premarketing and postmarketing evaluation are theoretically simpler and easier to enforce in the United States
Data requirements	Reasonable assurance of safety and effectiveness for approval of high-risk devices, "substantial equivalence" for 510(k) clearance	Generally performance-based analysis, requiring proof that device works as intended	E.U. assessment made by manufacturers and Notified Bodies; provides less insight into clinical end points for high-risk devices
Transparency	Proprietary limits with public reporting of premarketing review of approved devices, recalls, and adverse events	Review of Notified Bodies not made public; postmarketing data shared among Competent Authorities but not with the public	Greater public access to evidence in the United States
Funding	Combination of federal appropriations (80%) and user fees (<20%)	Funding of Competent Authorities variable among countries; Notified Bodies paid directly by sponsors	Notified Bodies may be vulnerable to conflict of interest with industry client; the FDA may be influenced by changes in federal funding and political climate
Access	Clinical premarketing testing of high-risk devices delays patient access to these devices (no differences for low- and moderate-risk devices)	E.U. patients may have access to certain high-risk devices sooner than in the United States, subject to limitations by payers	E.U. patients have faster access to certain devices, but these products are marketed with less rigorous proof of effectiveness and may have a greater chance of later-identified adverse events

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ESC REPORT

Clinical evaluation of cardiovascular devices: principles, problems, and proposals for European regulatory reform

Report of a policy conference of the European Society of Cardiology†

Alan G. Fraser*, Jean-Claude Daubert, Frans Van de Werf, N.A. Mark Estes III, Sidney C. Smith Jr, Mitchell W. Krucoff, Panos E. Vardas, and Michel Komajda, on behalf of the participants‡

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EUROPEAN COMMISSION

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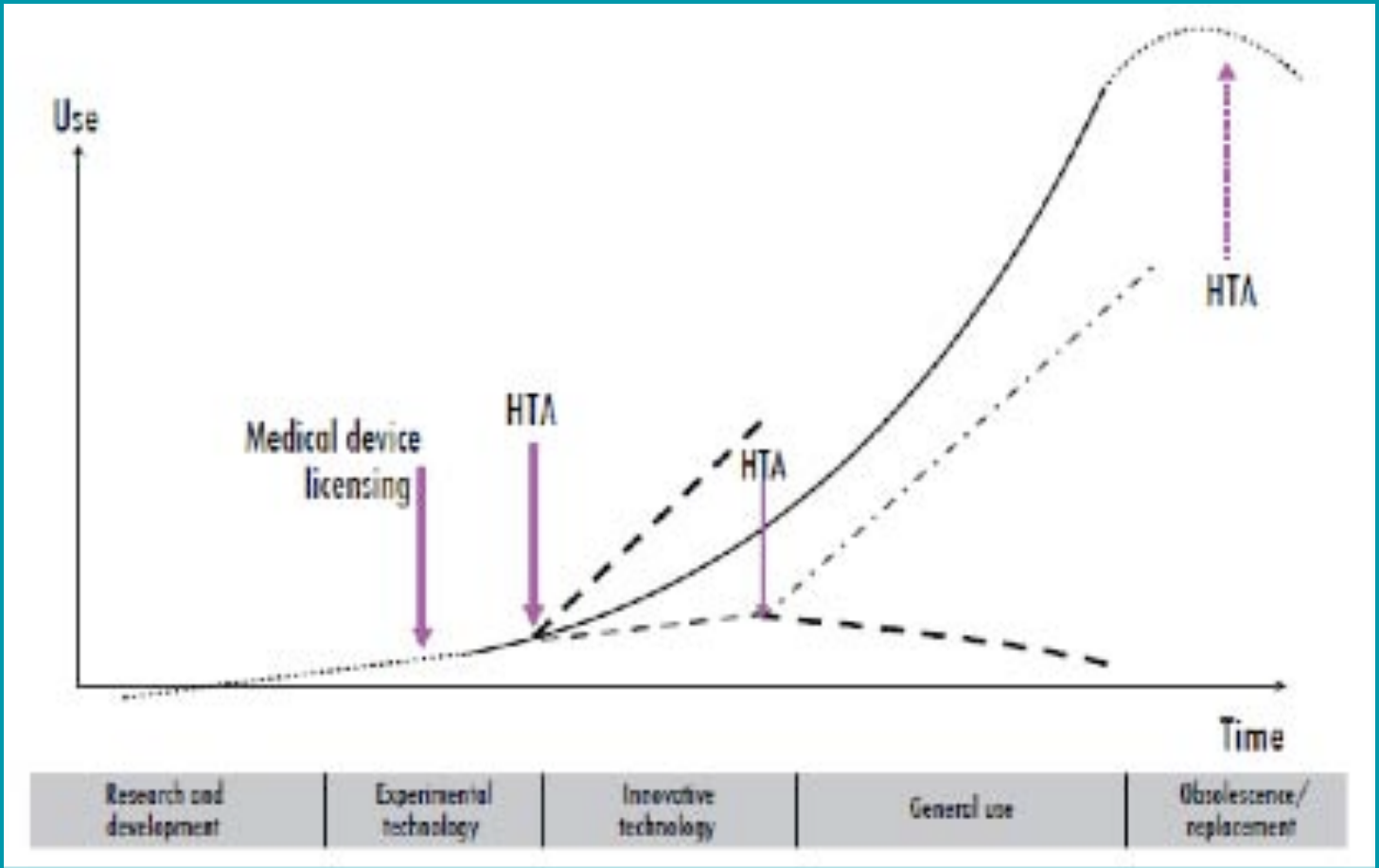
Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Health Technology Assessment



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The Main Phases of HTA

Scoping	**The scoping process consists of identifying the specific questions to be addressed. The scope defines the 'substrate' of the HTA, such as populations or groups of patients with specific conditions, and the comparators. The final scope defines the remit and boundaries of the appraisal.**
Assessment .	This consists of a systematic evaluation of the relevant evidence. It has quite separate components, namely a systematic review and an economic evaluation. These processes may be undertaken by an independent assessment group, particularly in the case of multiple technology appraisals.
Appraisal	The appraisal process consists of reviewing the reports and analyses gathered during the assessment phase in the background of the input provided by other experts, (consultants, commentators, clinical specialists), patient groups and the general public.

Multidimensional Assessment of Health Technology in Lombardy

General Relevance
Quality of scientific documentation Q1 + Q2 + Q3
Description and severity of illness D1
Size of population D2
General Healthcare Goals T1
Description of technology and benefits areas T2
Safety
Improvement of Safety and Tolerability I2
Effectiveness and Efficacy
Improvement of Effectiveness and Efficacy I1
Improvement of patient related outcomes I3
Guidelines and good practice recommendations C1
Limitations of alternative technologies in use C2
Economic and Financial Impact
Financial Impact on SSN E1
Cost-effectiveness E2
Impact on other spending E3
Impact on efficiency (cost-opportunity) Et2
Equity
Impact on equity and accessibility Et3
Social and Ethical Impact
Coherence with national and regional planning
Impact on healthcare needs Et1
Pressure of interest groups O2
Historical and political context O3
Organizational Impact
System capacity and appropriate technology use O1

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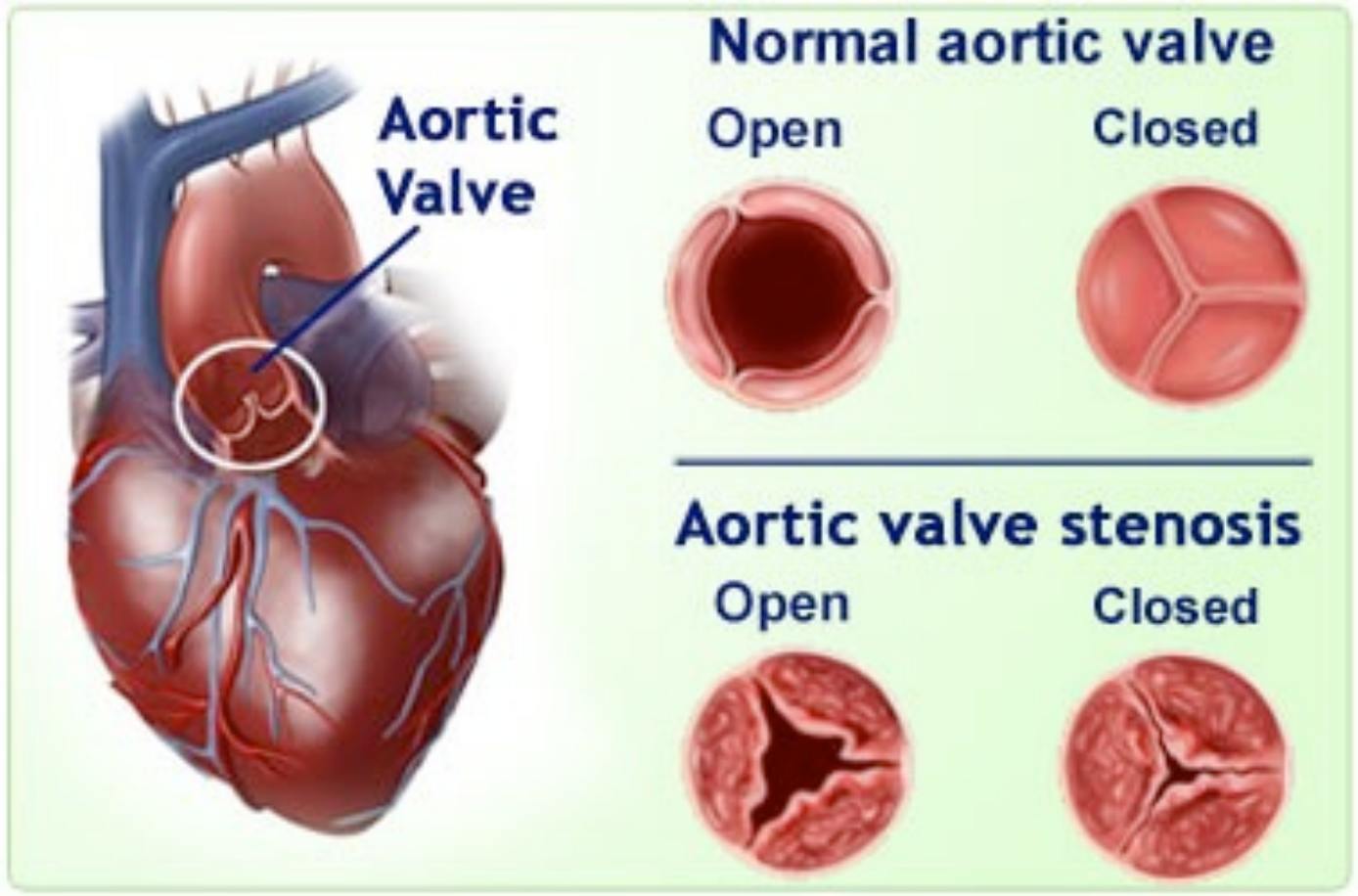
Multidimensional Assessment of Health Technology
General Relevance

Topic: TARGET CONDITION
A0001 - Which disease/health problem/potential health problem will the technology be used for?
A0002 - What, if any, is the precise definition/ characterization of the target disease? Which diagnosis is given to the condition and according to which classification system (e.g. ICD-10)?
A0003 - Which are the known risk factors for acquiring the condition?
A0004 - What is the natural course of the condition?
A0005 - What are the symptoms of the disease?
A0006 - What are the consequences of the condition?
A0008 - What is the burden of disease (mortality, disability, life years lost)?

Aortic Valve Stenosis



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Prevalence of Moderate-Severe Aortic Stenosis

Population > 75 years	4.6%
Population > 85 years	8.1%

Mortality in Patients with Symptomatic Aortic Stenosis

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Mortality in Patients with Symptomatic Aortic Stenosis

1 year	25%

Mortality in Patients with Symptomatic Aortic Stenosis

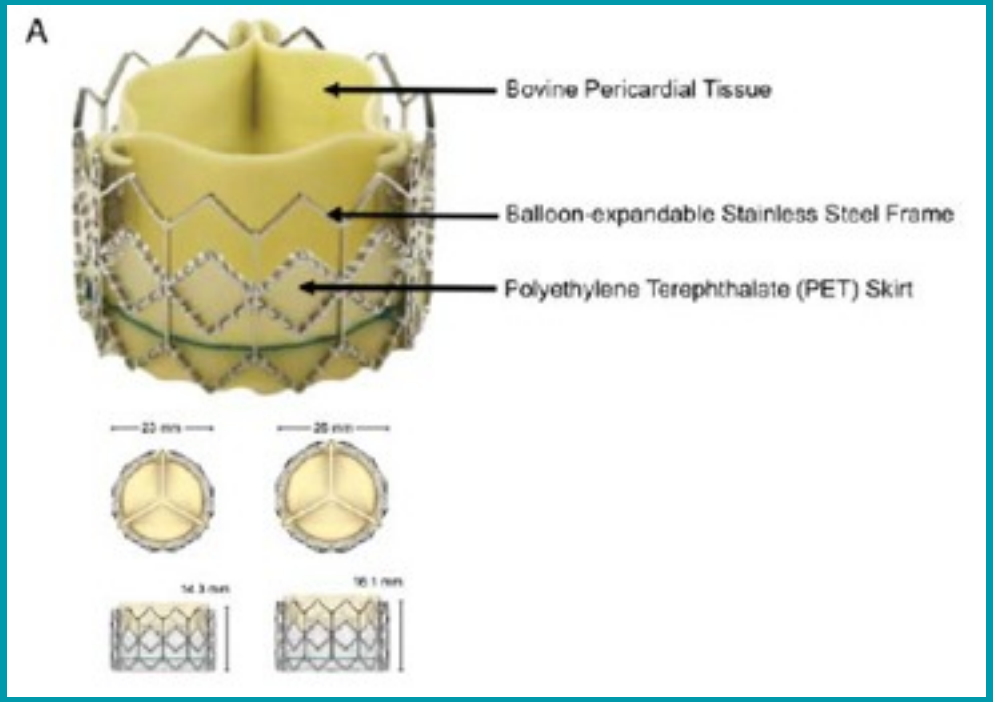
1 year	25%
2 years	50%

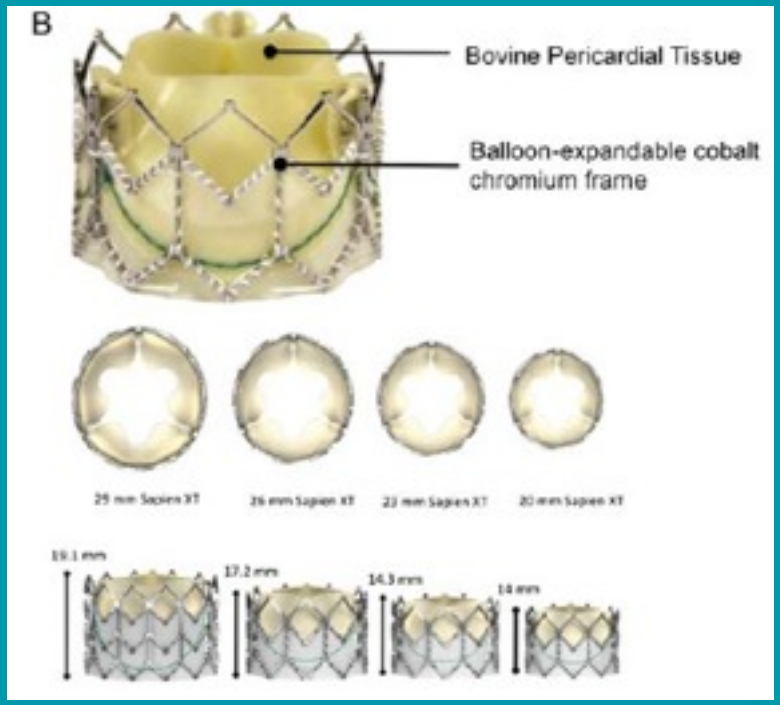
Multidimensional Assessment of Health Technology

General Relevance

Topic: Features of Technology
B0001 - What is this technology?
B0002 - Why is this technology used?
B0003 - Phase of the technology: When was it developed or introduced in health care?
B0004 - Who will apply this technology?
B0005 - What is the place and context for utilizing the technology
B0006 - Are there any special features relevant to this technology?
B0017 - Is the technology rapidly changing / improving? (life-cycle)
B0018 - Are the reference values or cut-off points clearly established?

Transcatheter Aortic Valve Implantation (TAVI)
Edward Sapien Valves





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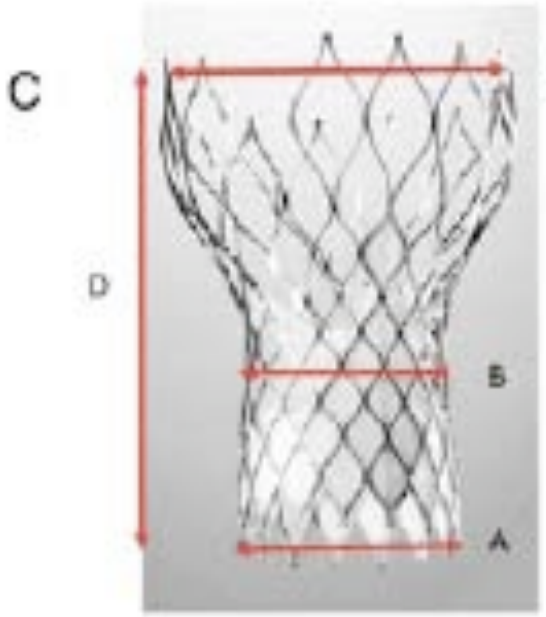
Transcatheter Aortic Valve Implantation (TAVI)
Medtronic CoreValve



Nitinol stent in diamond configuration

Porcine pericardium leaflets

	Valve Size (mm)	26	29	31
A	Inflow part diameter (mm)	26	29	31
B	Constrained part diameter (mm)	22	24	24
C	Outflow part diameter (mm)	40	43	43
D	High (mm)	55	53	53

Edwards Sapien Transcatheter Heart Valve Registries (Demographics)

Characteristic	REVIVE, REVIVAL, PARTNER EU N=222	SOURCE Registry (TF) N=920	France Registry N=1,137	Belgium Registry N=303	Canada Registry (TF) N=162
Demographics					
Age (y)	83	82	83	83	83
Female (%)	55	56	49	46	44
EuroSCORE (mean, %)	26	24	23	29	26
NYHA Class III/IV (%)	89	76	75	80	93
Aortic valve area (cm^2)	0.59	0.70	0.67	0.60	0.63
Mean gradient (mm Hg)	45	49	48	47	48
Prior CABG (%)	26	15	19	20	30
Ejection fraction (%)	51	52	53	50	55

Medtronic CoreValve Transcatheter Heart Valve Registries (Demographics)

Characteristic	Tamburino et al. (109) N=663	Milan (107) N=61	French (106) N=66	Spanish (97) N=108	UK/Ireland (108) N=288	UK (115) N=452	German (110) N=588	Buellesfeld et al. (105) N=126
Demographics								
Age (y)	82	79	82.5	78.6	81	81.3	81.4	81.9
Female (%)	56	47	51.5	54.6	NR	48	55.8	57.1
EuroSCORE (mean, %)	23	26.6	24.7	16	22	18.1	20.8	23.4
NYHA Class III/IV (%)	71.5	69	74.6	58.4	74	73.9	88.2	74.6
Mean gradient (mm Hg)	52	54	46	55	NR	NR	48.7	46.8

Multidimensional Assessment of Health Technology

Safety

Topic: PATIENT SAFETY
C0001 - What kind of harms can use of the technology cause to the patient and what is the incidence, severity and duration of harms?
C0002 - What is the dose relatedness of the harms to patients?
C0003 - What is timing of harms onset to patients: immediate/early/late?
C0004 - Is the incidence of harms to patients likely to change over time?
C0005 - Are there susceptible patient groups that are more likely to be harmed through use of the technology?
C0006 - What are the consequences of false positive, false negative and incidental findings brought about using the technology to the patients from the viewpoint of patient safety?
C0007 - What are the special features in using the technology that may increase the risk of patient safety?
C0008 - What is the safety of the technology in comparison to alternative technologies used for the same purpose?

Multidimensional Assessment of Health Technology
Efficacy and Effectiveness

Topic: MORTALITY
D0001 - What is the effect of intervention on overall mortality?
D0002 - What is the effect of intervention on the mortality caused by the target disease?
D0003 - What is the effect of intervention on mortality due to other causes than the target disease?
Topic: MORBIDITY
D0005 - How does the intervention modify the severity and frequency of symptoms and findings?
D0006 - How does the intervention modify the progression of disease?

Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard"**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or n-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, n-of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or n-of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non-randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

http://www.cebm.net/index.aspx?o=5653

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Edwards Sapien Transcatheter Heart Valve Registries (Outcomes)

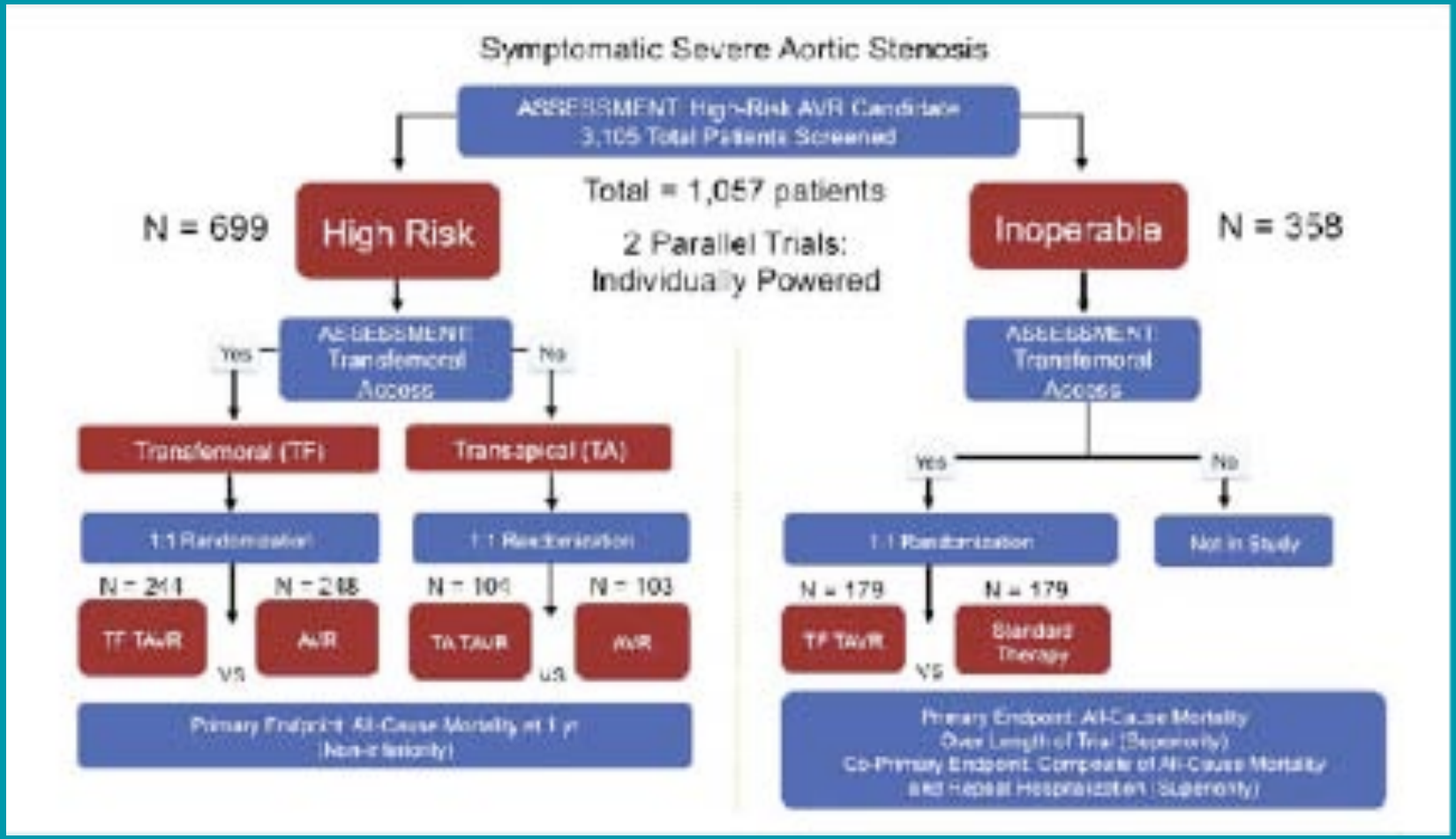
Characteristic	REVIVE, REVIVAL, PARTNER EU N=222	SOURCE Registry (TF) N=920	France Registry N=1,137	Belgium Registry N=303	Canada Registry (TF) N=162
30-day mortality (%)	10.4	7.5	7.8	8	9.5
1-y mortality (%)	24	18.9	NR	NR	NR
Stroke (%)	3.3	3.5	3.5	5.0	3.0
Major vascular complications (%)	27.9	11.3	11.3	NR	13.1
Permanent pacemaker (%)	1.8	6.7	8.5	4.0	3.6

Medtronic CoreValve Transcatheter Heart Valve Registries (Outcomes)

Procedural success (%)	98	98.4	92.6	98.1	97.5	98.2	NR	72.6
30-day mortality (%)	5.9	2.2	15.1	7.4	4.7	5.8	12.4	15.2
1-y mortality (%)	15	18.4*	NR	17.7	NR	21.7	NR	38.1**
Stroke (%)	2.5	2.2	4.5	0.0	4.2	4.0	2.8	NR
Major vascular complications (%)	2.0	21.3	7.5	5.6	9.0	6.2	4.0	NR
Permanent pacemaker (%)	19.1	26.1	25.7	35.2	26	24.4	42.5	26.2

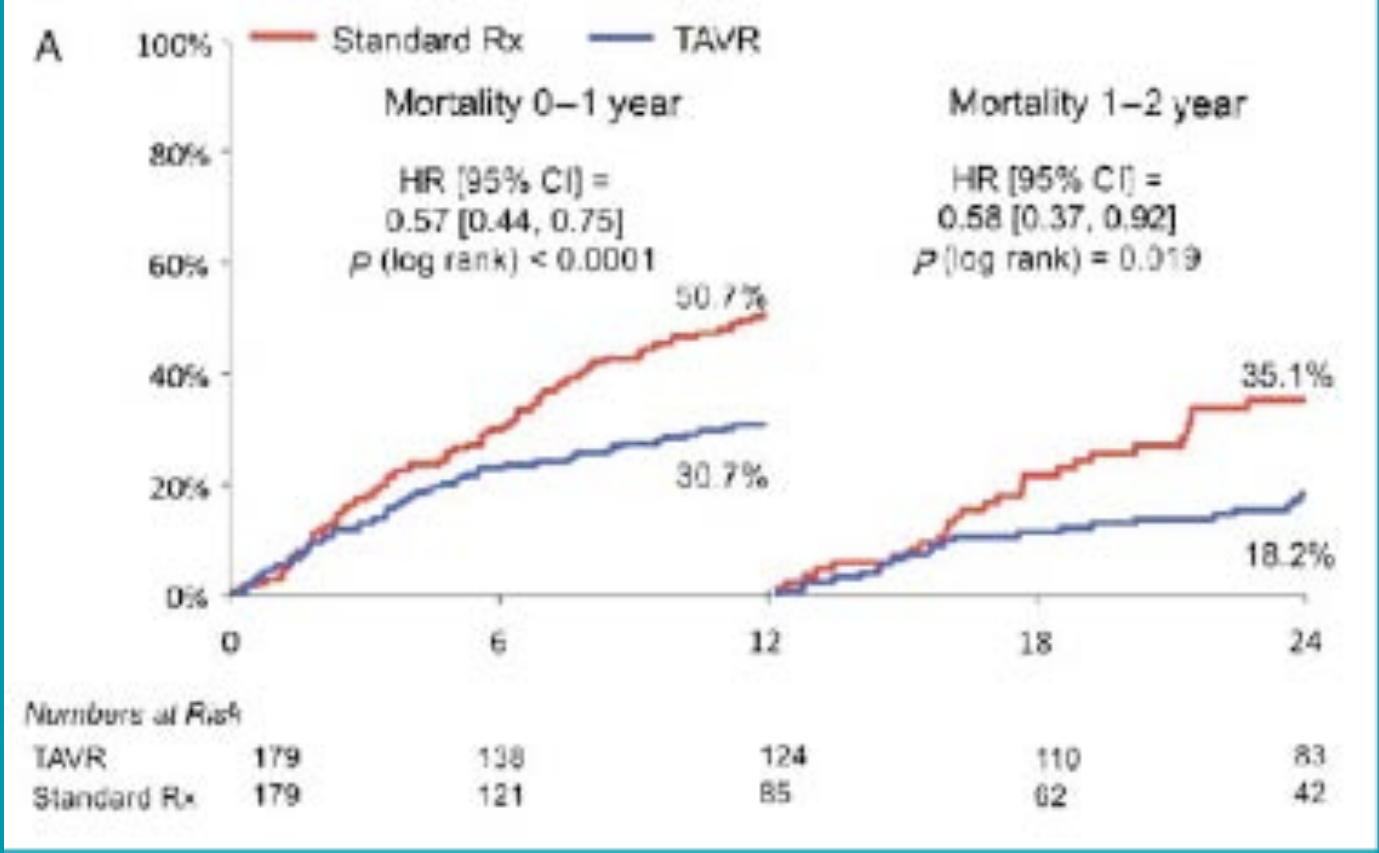
*6-month survival, **2-year survival.

Transcatheter Aortic Valve Implantation (TAVI)
PARTNER I Trial Design



Eur Heart J 2012; 33: 2388–2400

Effects of TAVI vs Standard Therapy on Mortality in Inoperable Patients PARTNER Trial



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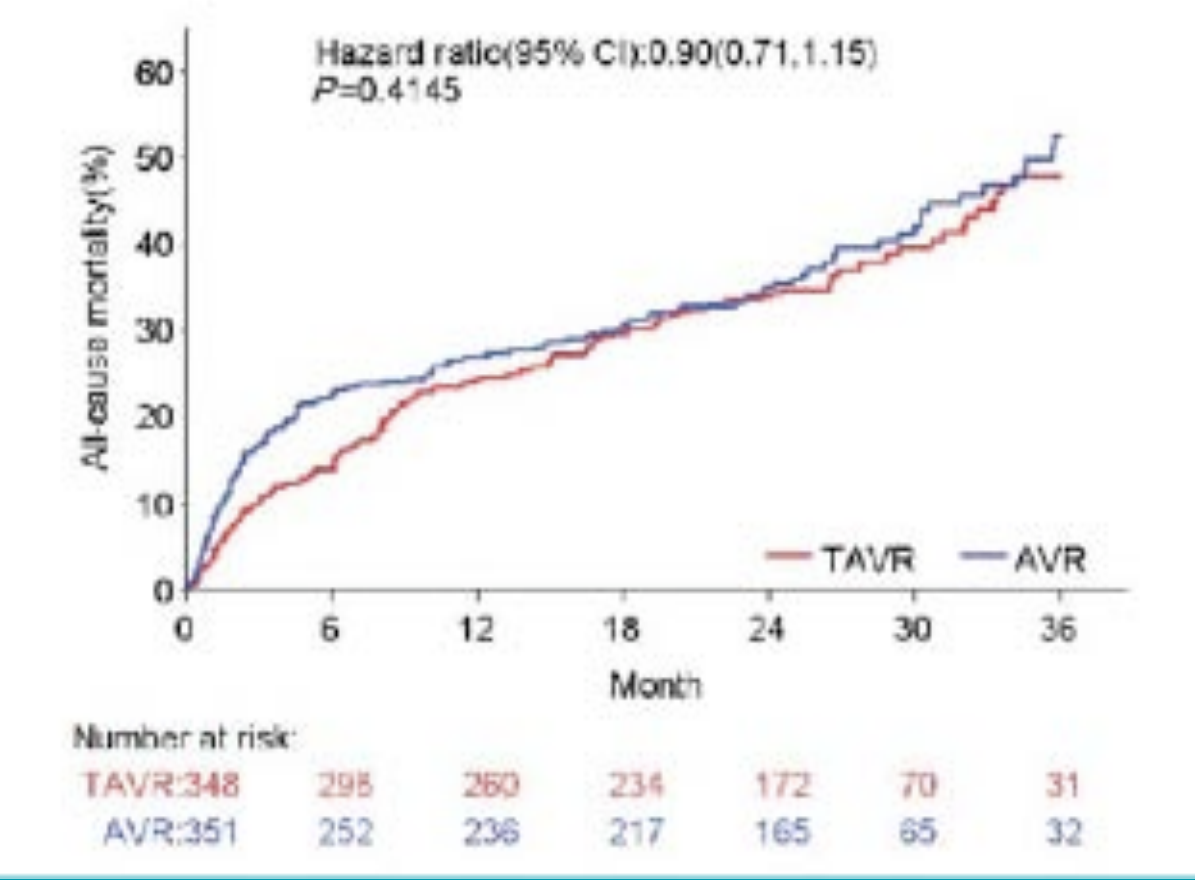
Effects of TAVI vs Surgery on Mortality in High Risk Patients PARTNER Trial



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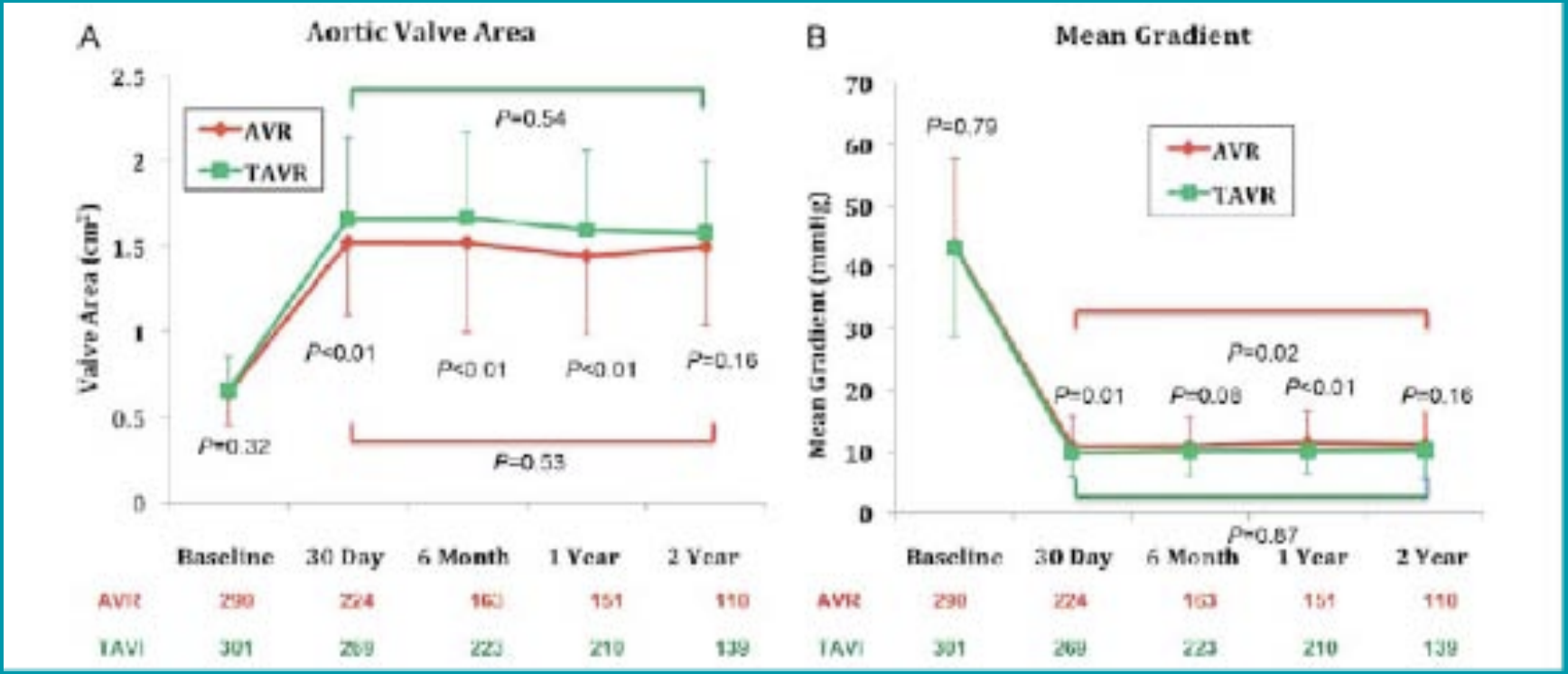
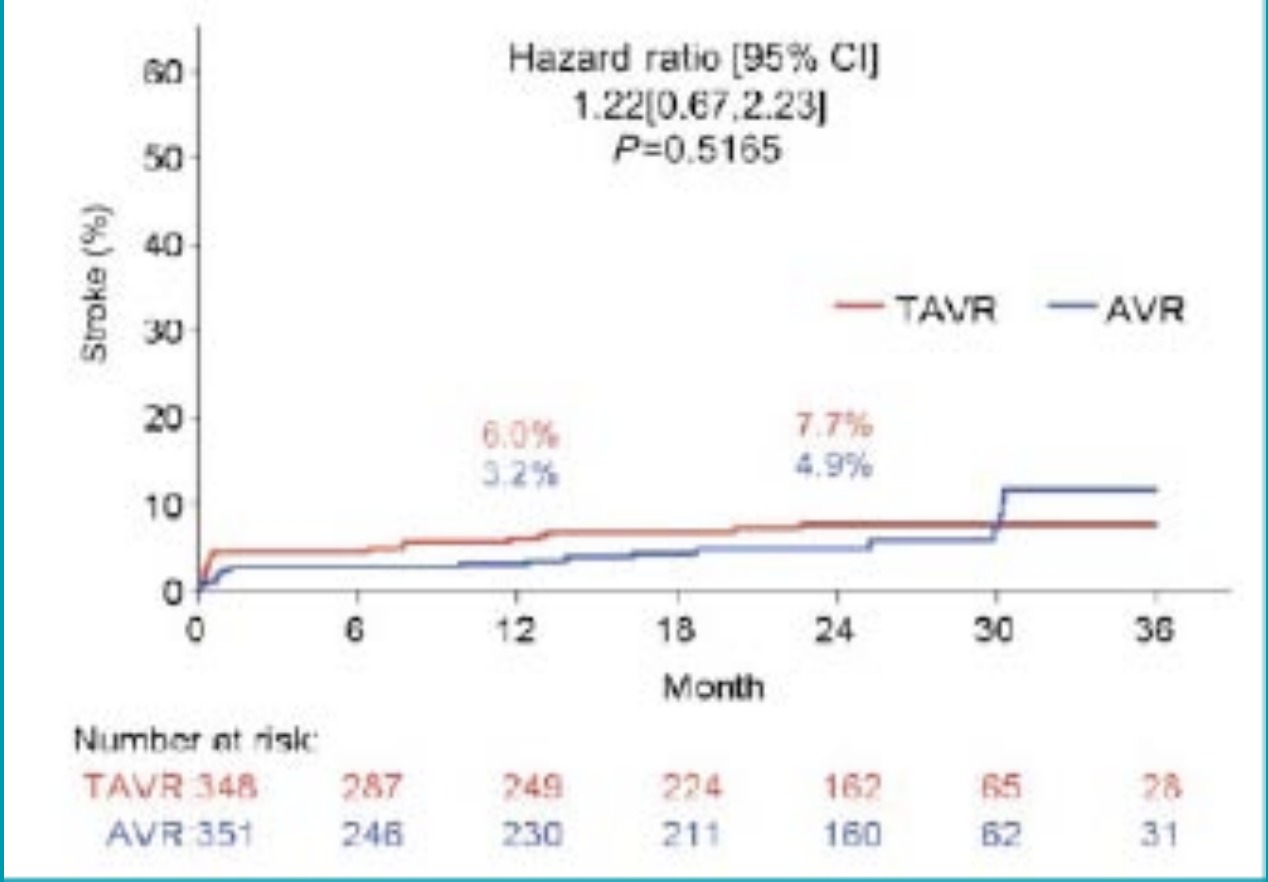
Valve Haemodinamic Performance PARTNER Trial



Eur Heart J 2012; 33: 2388–2400

Effects of TAVI vs Surgery on Stroke in High Risk Patients PARTNER Trial



Eur Heart J 2012; 33: 2388–2400

Quality of Life in TAVI Trials

Study Population	NYHA Class	6-Minute Walk	Questionnaire	Other
PARTNER B (Trial) TAVR vs. placebo (multicenter; N=358) (15,122)	More class I, II with TAVR at 1 year (74.8% vs. 42.0%)	TAVR improved walk time pre/post at 1 year; no change in no-TAVR group	KCCQ; Marked improvement with TAVR at 1 year; SF12; improvement in physical and mental HRQOL with TAVR	TAVR had fewer rehospitalizations at 1 year
PARTNER A (Trial) TAVR vs. SAVR (multicenter; N=699) (124)	More class I, II with TAVR at 30 days; No difference between TAVR and SAVR at 1 year	TAVR improved walk time at 30 days compared with SAVR; No difference between TAVR and SAVR at 1 year	NR	Shorter LOS with TAVR

European Heart Journal (2012) 33, 2451–2496
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Evaluation of Patients for Valvular Intervention

Table 3 Essential questions in the evaluation of a patient for valvular intervention

• Is valvular heart disease severe?
• Does the patient have symptoms?
• Are symptoms related to valvular disease?
• What are patient life expectancy* and expected quality of life?
• Do the expected benefits of intervention (vs. spontaneous outcome) outweigh its risks?
• What are the patient's wishes?
• Are local resources optimal for planned intervention?

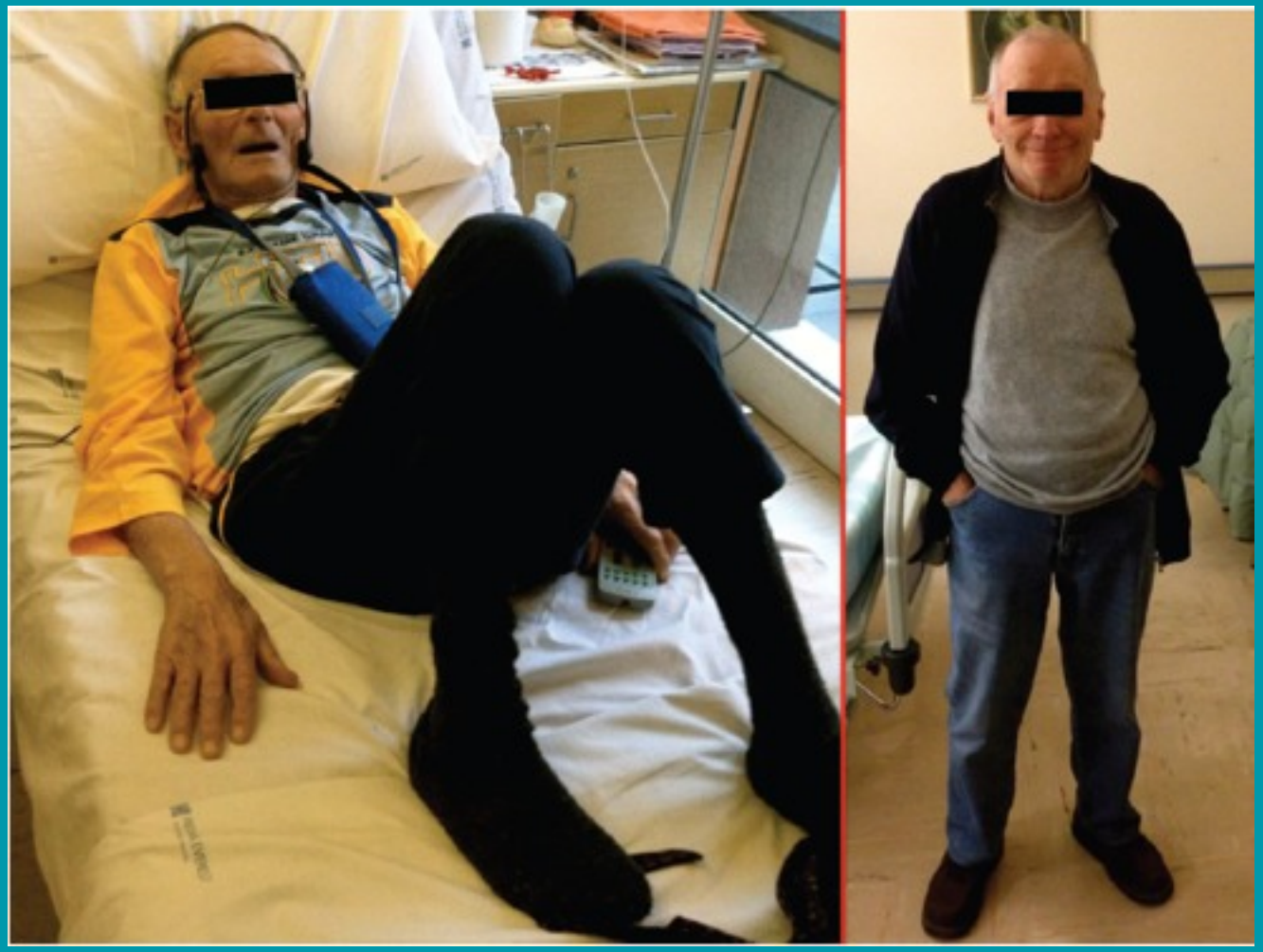
Clinical Predictors of Increased Risk for TAVI

- Severely reduced left ventricular function
- Very low transvalvular gradient (mean gradient <20 mm Hg)
- Low flow (low stroke volume index, <35 ml/m^2)
- Severe myocardial fibrosis
- Severe concomitant mitral and/or tricuspid valve disease
- Severe pulmonary hypertension (PASP ≥60 mm Hg)
- Severe lung disease, particularly oxygen-dependent
- Advanced renal impairment (stages 4 and 5)
- Liver disease
- Very high STS score (predicted risk of mortality >15%)

Absolute Contraindications for TAVI

Absolute contraindications
Absence of a 'heart team' and no cardiac surgery on the site
Appropriateness of TAVI, as an alternative to AVR, not confirmed by a 'heart team'
Clinical
Estimated life expectancy <1 year Improvement of quality of life by TAVI unlikely because of comorbidities Severe primary associated disease of other valves with major contribution to the patient's symptoms, that can be treated only by surgery
Anatomical
Inadequate annulus size (<18 mm, >29 mm²)
Thrombus in the left ventricle
Active endocarditis
Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuses)
Plaques with mobile thrombi in the ascending aorta, or arch
For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity)
Relative contraindications
Bicuspid or non-calcified valves
Untreated coronary artery disease requiring revascularization
Haemodynamic instability
LVEF <20%
For transapical approach: severe pulmonary disease, LV apex not accessible

Frailty



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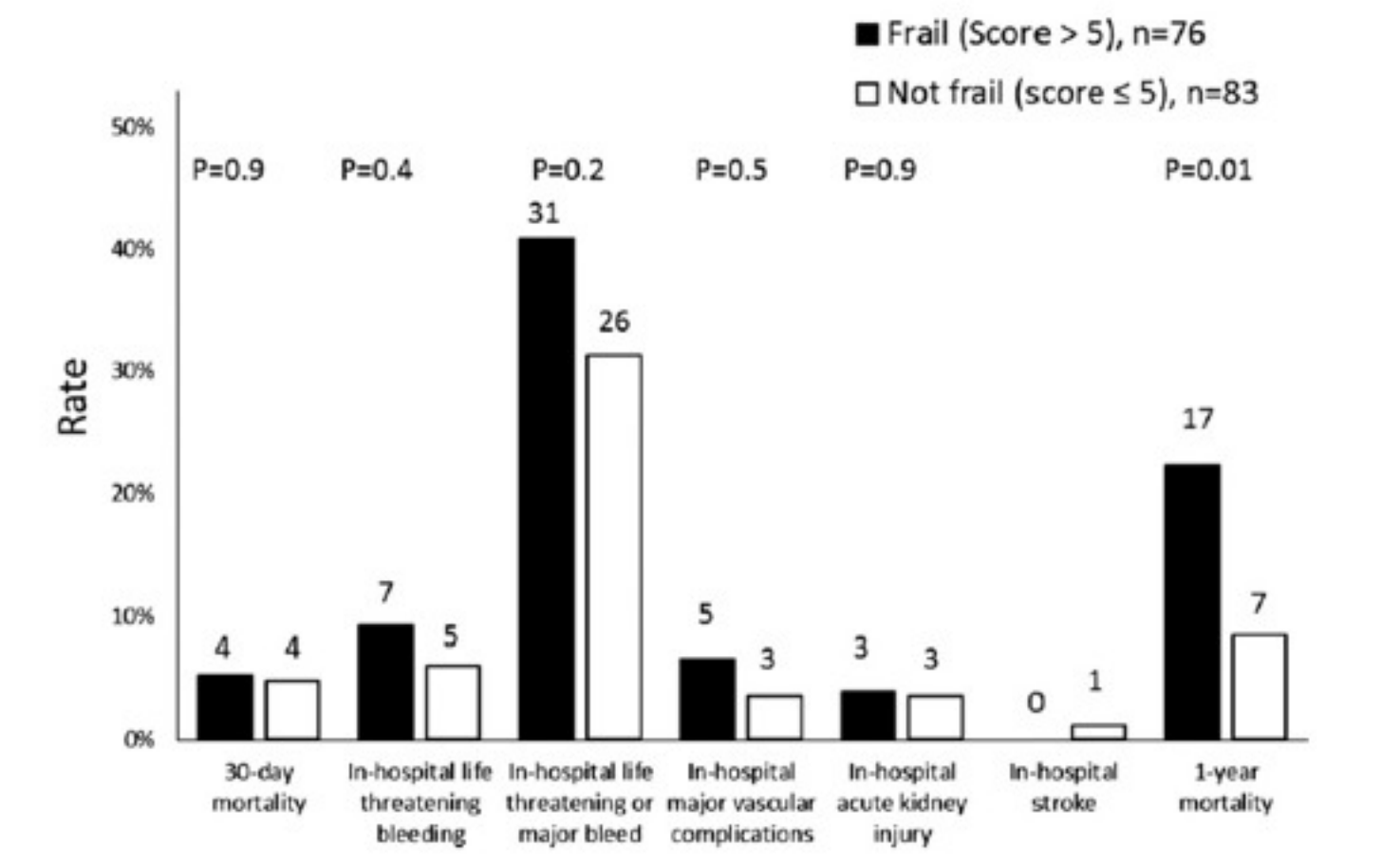
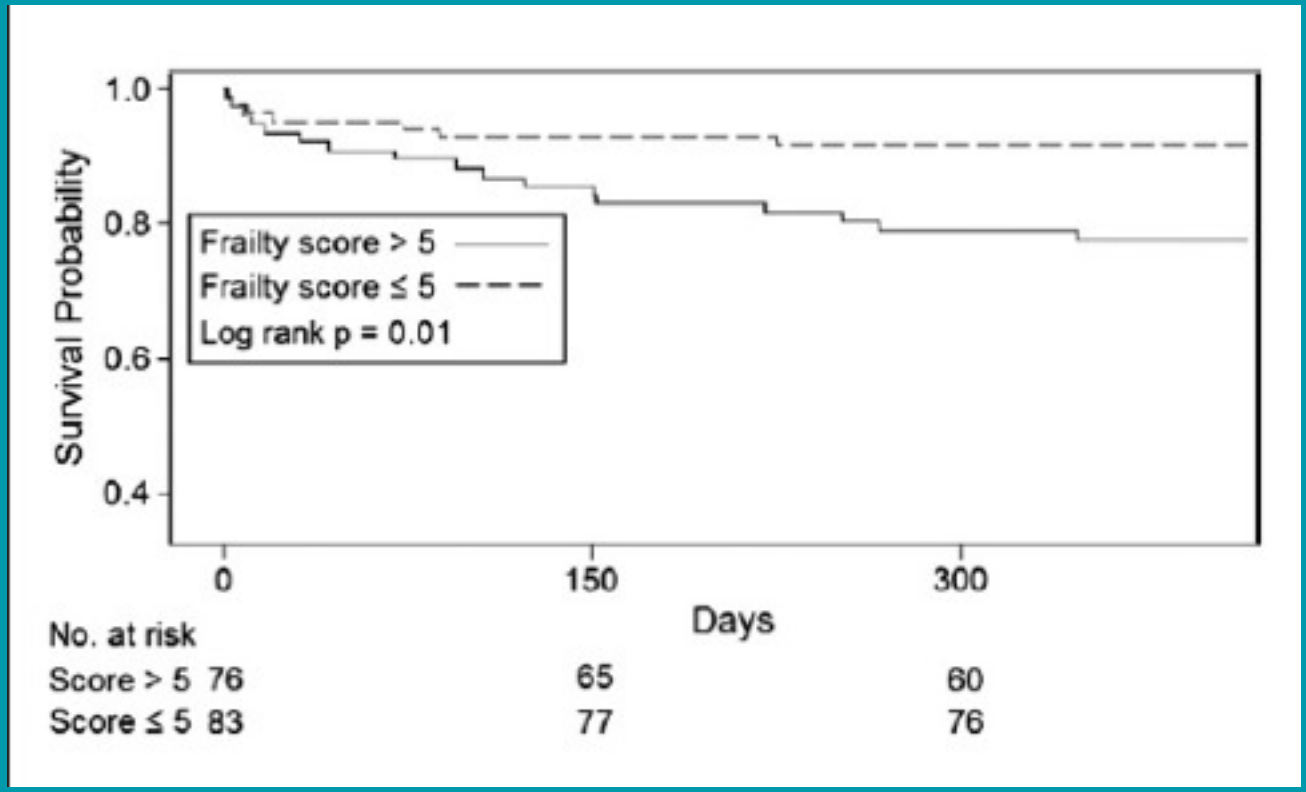
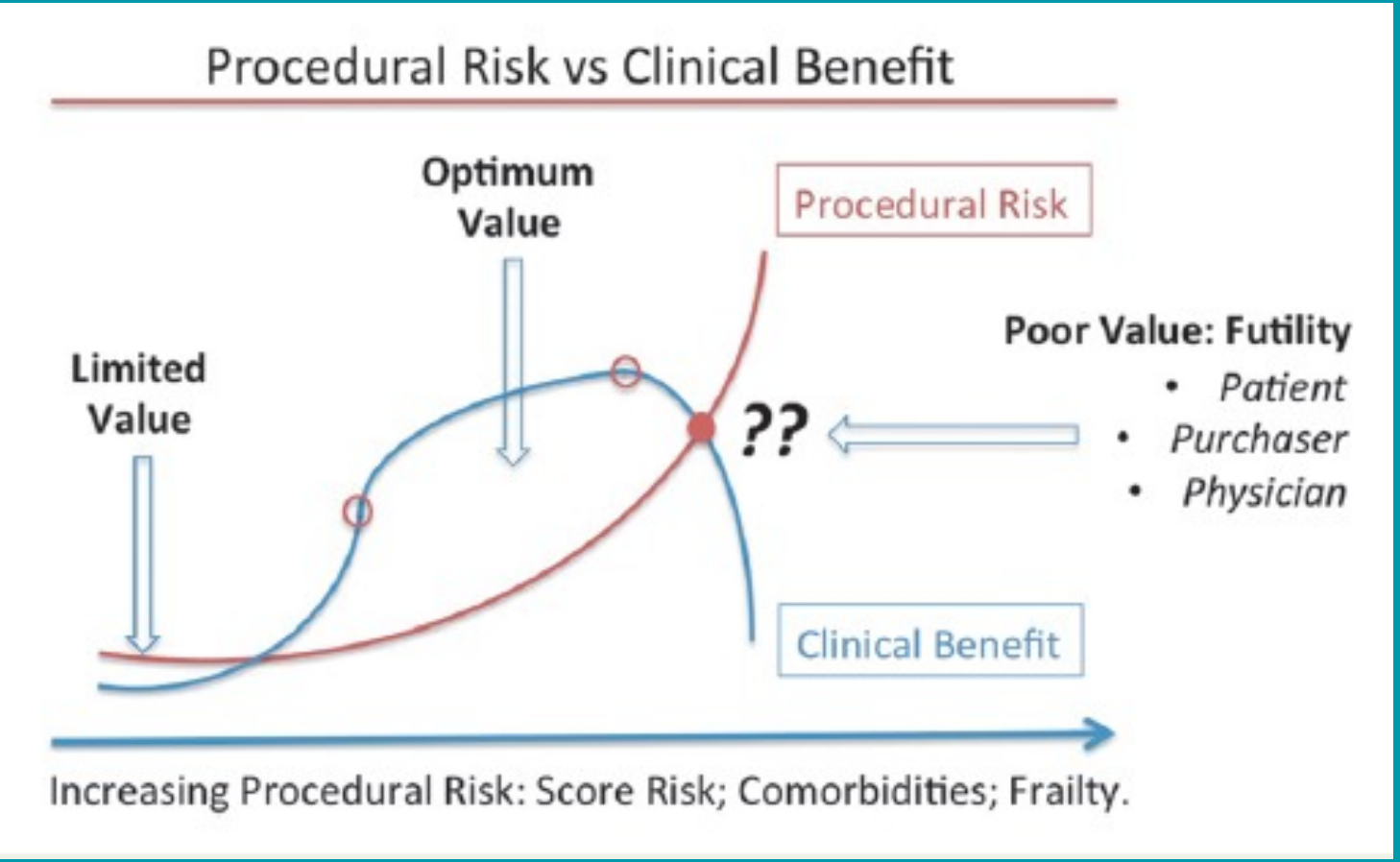
TAVI and Frailty



TAVI Survival and Frailty



Heart Valve Diseases



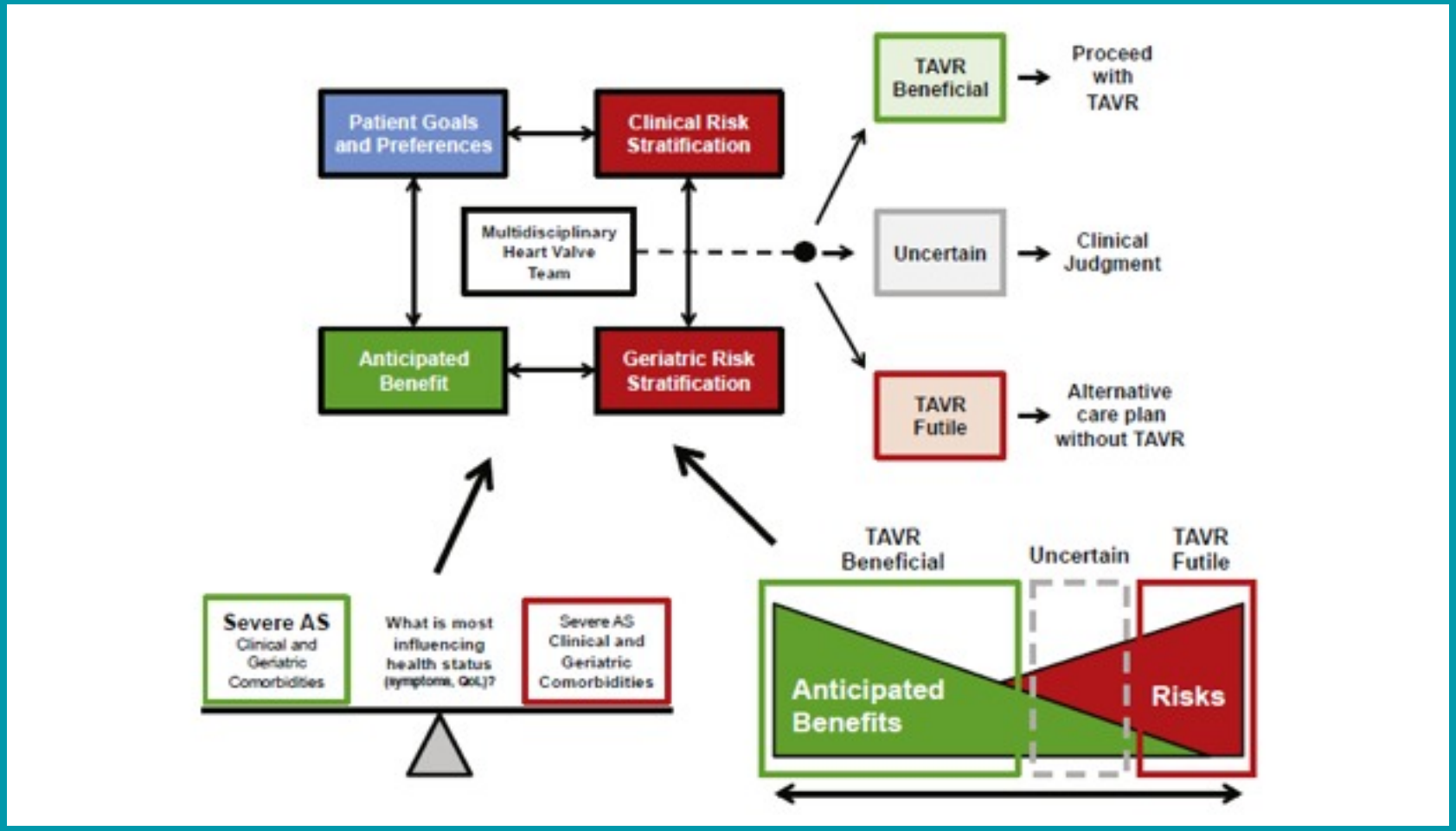
Geriatric Predictors of Increased Risk for TAVI

- Advanced frailty
- Disability in activities of daily living
- Malnutrition
- Mobility impairment
- Low muscle mass and strength ("sarcopenia")
- Cognitive impairment
- Mood disorders (depression, anxiety)

Selected Geriatric Assessment Tools

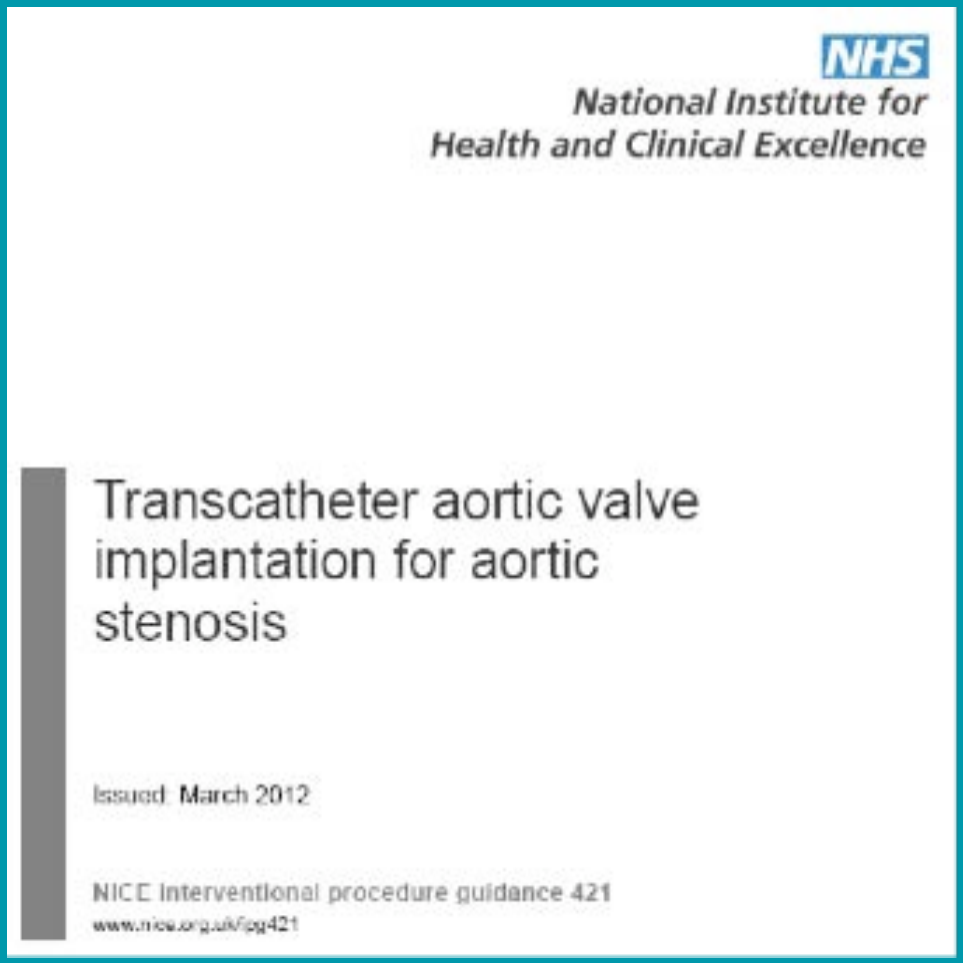
- Frailty
  - 5-m gait speed
  - Fried's frailty scale
  - Short physical performance battery
- Disability
  - Activities of daily living
  - Instrumental activities of daily living
- Cognitive impairment
  - Mini-Mental Status Examination
  - Montreal Cognitive Assessment
- Mood disturbance
  - Geriatric Depression Scale
  - Hospital Anxiety and Depression Scale
- Malnutrition
  - Albumin
  - Mininutritional assessment
- Polypharmacy
- Fall risk
- Social isolation

Decision Making by the Multidisciplinary Heart Valve Team on Patients Referred for TAVI



ESC/EASCT Reccommendations for TAVI

Recommendations	Class[a]	Level[b]	Ref[c]
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C	
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B	99
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.	IIa	B	97


NHS
National Institute for
Health and Clinical Excellence
Transcatheter aortic valve implantation for aortic stenosis
Issued: March 2012
NICE interventional procedure guidance 421

NICE Reccommendations for TAVI

1.1 Evidence on the safety of transcatheter aortic valve implantation (TAVI) for aortic stenosis shows the potential for serious but well-recognised complications.

1.2 For patients with aortic stenosis who are considered to be unsuitable for surgical aortic valve replacement (SAVR; see sections 1.6 and 2.1.3) the evidence on the efficacy of TAVI is adequate. For these patients, TAVI may be used with normal arrangements for clinical governance, consent and audit. Details of all patients should be entered into the UK Central Cardiac Audit Database.

1.3 For patients with aortic stenosis for whom SAVR is considered suitable but to pose a high risk (see sections 1.5, 1.6 and 2.1.3) the evidence on the efficacy of TAVI is inadequate. For these patients TAVI should only be used with special arrangements for clinical governance, consent and data collection or research. NICE encourages clinicians to enter suitable patients into the UK TAVI trial. In addition, details of all patients should be entered into the UK Central Cardiac Audit Database.

1.4 For patients with aortic stenosis for whom SAVR is considered suitable and not to pose a high risk (see sections 1.6 and 2.1.3) the evidence on the efficacy of TAVI is inadequate. For these patients TAVI should only be used in the context of research. NICE encourages clinicians to enter suitable patients into the UK TAVI trial. In addition, details of all patients should be entered into the UK Central Cardiac Audit Database.

NICE Reccommendations for TAVI

1.5 Clinicians wishing to undertake TAVI for patients with aortic stenosis for whom SAVR is considered suitable but to pose a high risk (see section 1.3) should take the following actions.

- Inform the clinical governance leads in their Trusts.

clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.

1.6 Patient selection should be carried out by a multidisciplinary team including interventional cardiologists, cardiac surgeons, a cardiac anaesthetist and an expert in cardiac imaging. The multidisciplinary team should determine the risk level for each patient.

1.7 TAVI is a technically challenging procedure that should be performed only by clinicians and teams with special training and experience in complex endovascular cardiac interventions. Units undertaking this procedure should have both cardiac and vascular surgical support for emergency treatment of complications.

1.8 NICE encourages further research into TAVI for aortic stenosis. In particular, NICE encourages clinicians to enter all suitable patients into the UK TAVI trial. Information from research trials that will be useful for future guidance includes patient selection criteria and comparisons between TAVI and SAVR in patients who would be suitable for either procedure. Outcomes should include incidence of stroke and other adverse events, symptom relief, quality of life, occurrence of aortic regurgitation, and valve durability in the short and long term.

Exploratory Analysis from the Lombardy Data Warehouse on Appropriateness of TAVI

SESSO	AS	AVR	TAVI	Total
F	1188 10.96 23.58 53.11	3013 27.80 59.81 42.29	837 7.72 16.61 56.75	5038 46.49
M	1049 9.68 18.09 46.89	4112 37.94 70.91 57.71	638 5.89 11.00 43.25	5799 53.51
Total	2237 20.64	7125 65.75	1475 13.61	10837 100.00

ELSEVIER

Journal of Clinical Epidemiology 64 (2011) 749–759

Journal of Clinical Epidemiology

A combined comorbidity score predicted mortality in elderly patients better than existing scores

Joshua J. Gagne*, Robert J. Glynn, Jerry Avorn, Raisa Levin, Sebastian Schneeweiss

Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital, Harvard Medical School, 1620 Tremont Street, Suite 3030, Boston, MA 02120, USA

Accepted 5 October 2010

Abstract

Objective: To develop and validate a single numerical comorbidity score for predicting short- and long-term mortality, by combining conditions in the Charlson and Elixhauser measures.

Study Design and Setting: In a cohort of 120,679 Pennsylvania Medicare enrollees with drug coverage through a pharmacy assistance program, we developed a single numerical comorbidity score for predicting 1-year mortality, by combining the conditions in the Charlson and Elixhauser measures. We externally validated the combined score in a cohort of New Jersey Medicare enrollees, by comparing its performance to that of both component scores in predicting 1-year mortality, as well as 180-, 90-, and 30-day mortality.

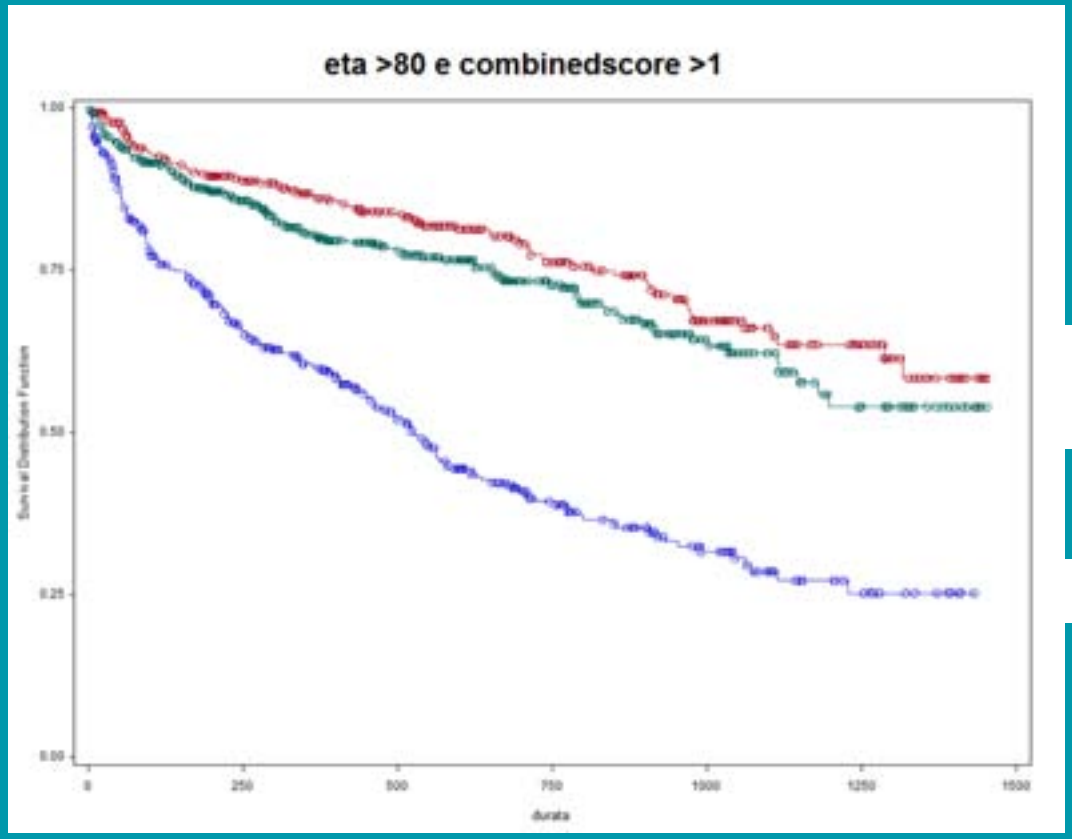
Results: C-statistics from logistic regression models including the combined score were higher than corresponding c-statistics from models including either the Romano implementation of the Charlson Index or the single numerical version of the Elixhauser system; c-statistics were 0.860 (95% confidence interval [CI]: 0.854, 0.866), 0.839 (95% CI: 0.836, 0.849), and 0.836 (95% CI: 0.834, 0.847), respectively, for the 30-day mortality outcome. The combined comorbidity score also yielded positive values for two recently proposed measures of reclassification.

Conclusion: In similar populations and data settings, the combined score may offer improvements in comorbidity summarization over existing scores.

Exploratory Analysis from the Lombardy Data Warehouse on Appropriateness of TAVI

Age (yrs)	Comorbidity	TAVI	AVR	Med Tx
≤ 80	≤1	259 17,6%	4730 66,4%	818 36,6%
≤ 80	>1	331 22,4%	1375 19,3%	423 18,9%
> 80	≤1	350 23,7%	676 9,5%	510 22,8%
> 80	>1	535 36,3%	344 4,8%	486 21,7%
	TOT	1475	7125	2237

Survival in Patients > 80 Years and Comorbities > 1

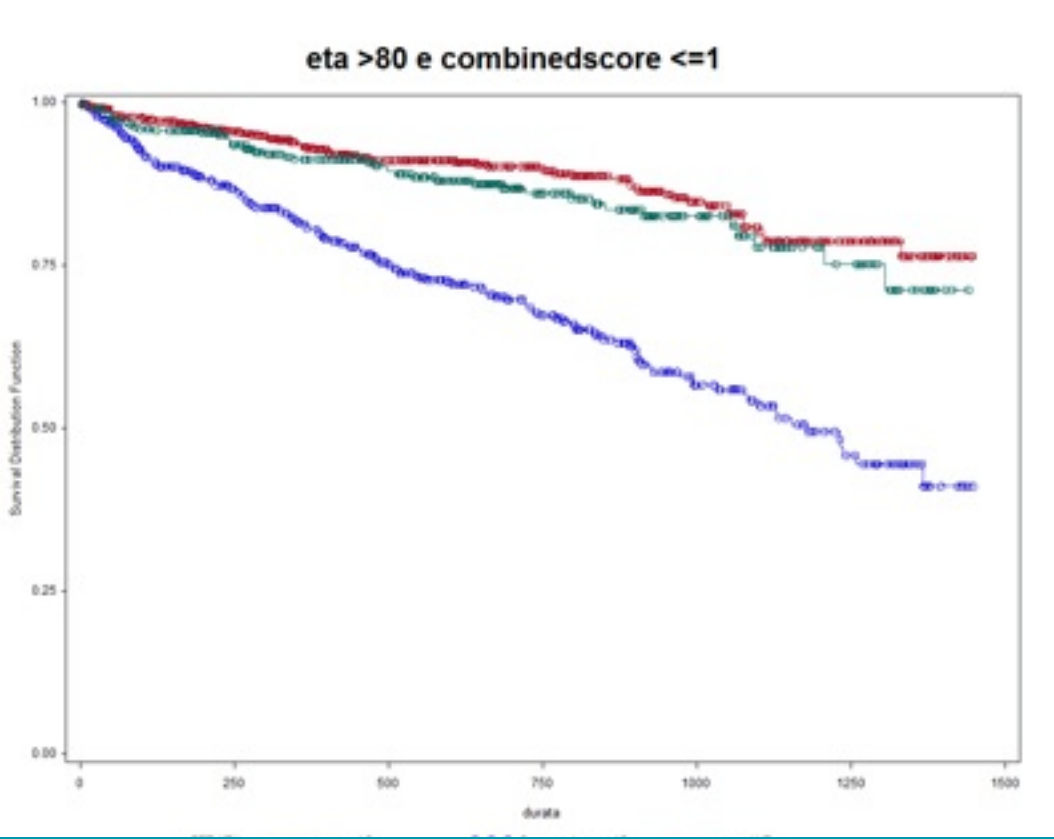


AVR

TAVI

Med Tx

Survival in Patients > 80 Years and Comorbities ≤ 1

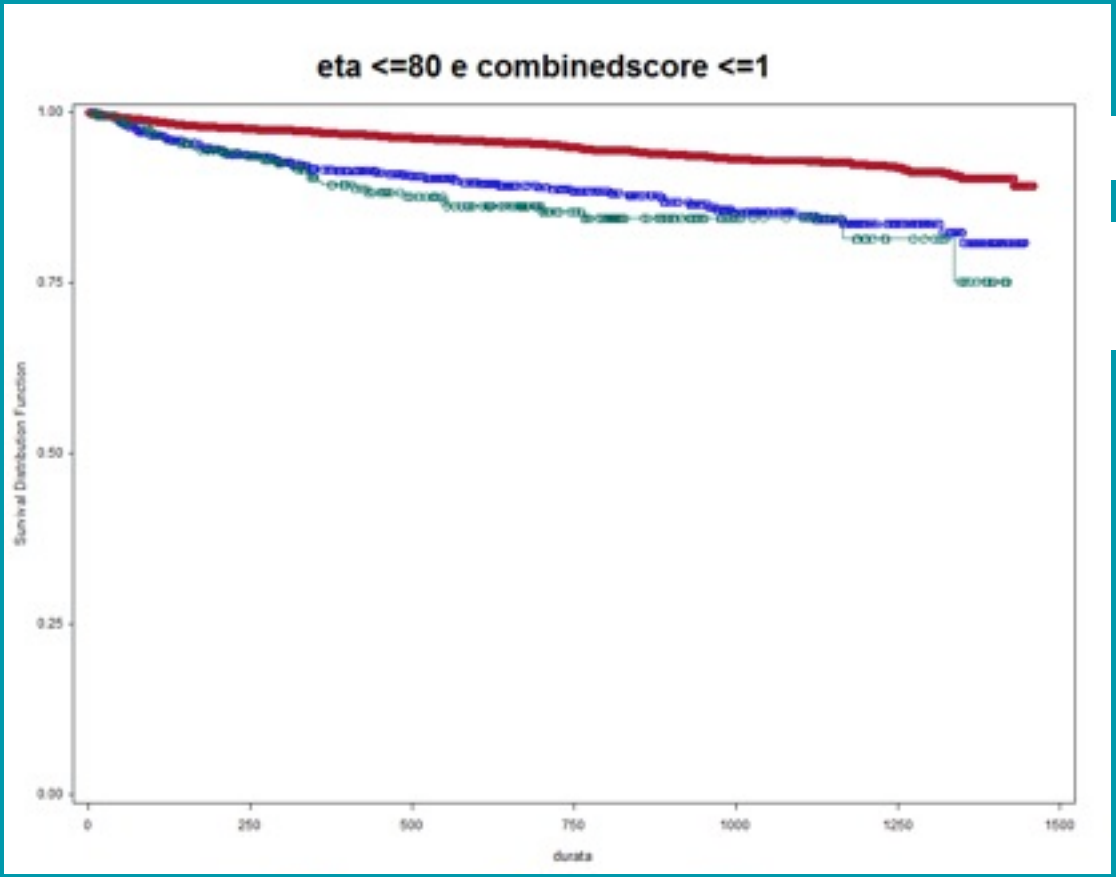


AVR

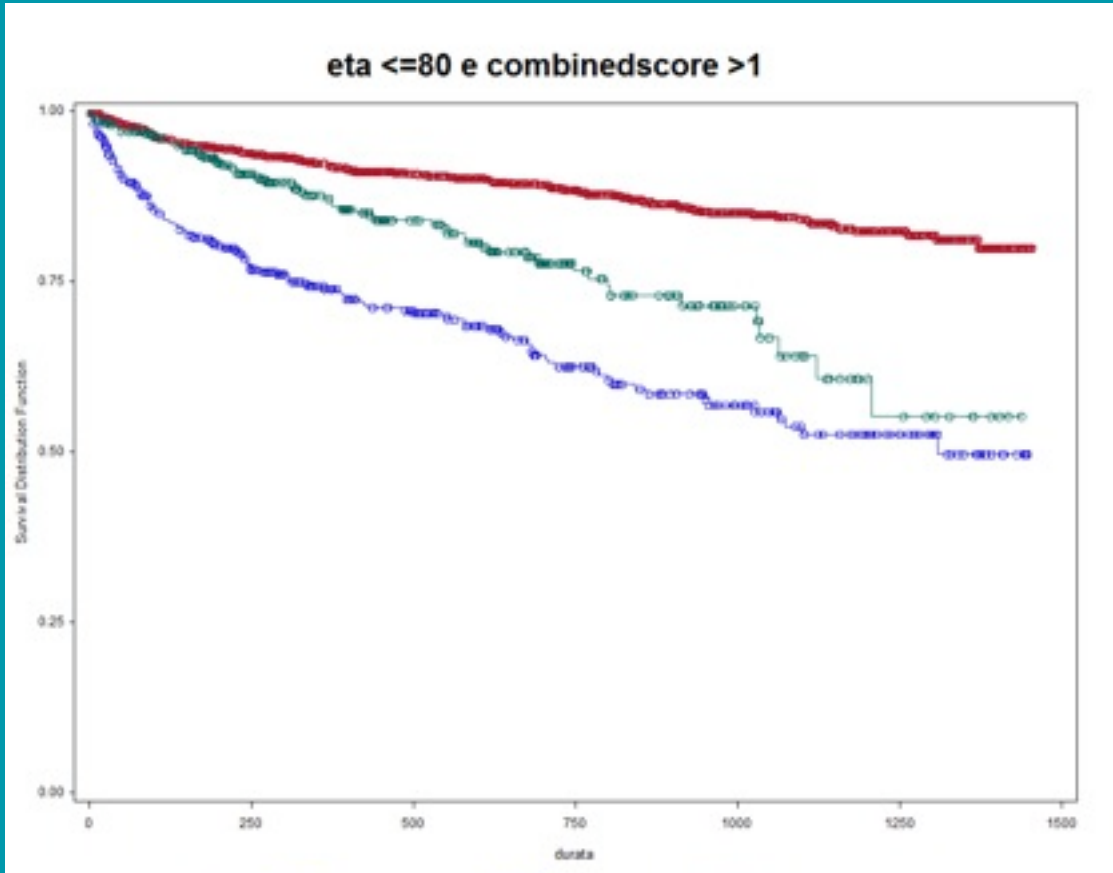
TAVI

Med Tx

Survival in Patients ≤ 80 Years and Comorbities ≤ 1



Survival in Patients ≤ 80 Years and Comorbities >1



AVR

TAVI

Med Tx

The NEW ENGLAND JOURNAL of MEDICINE

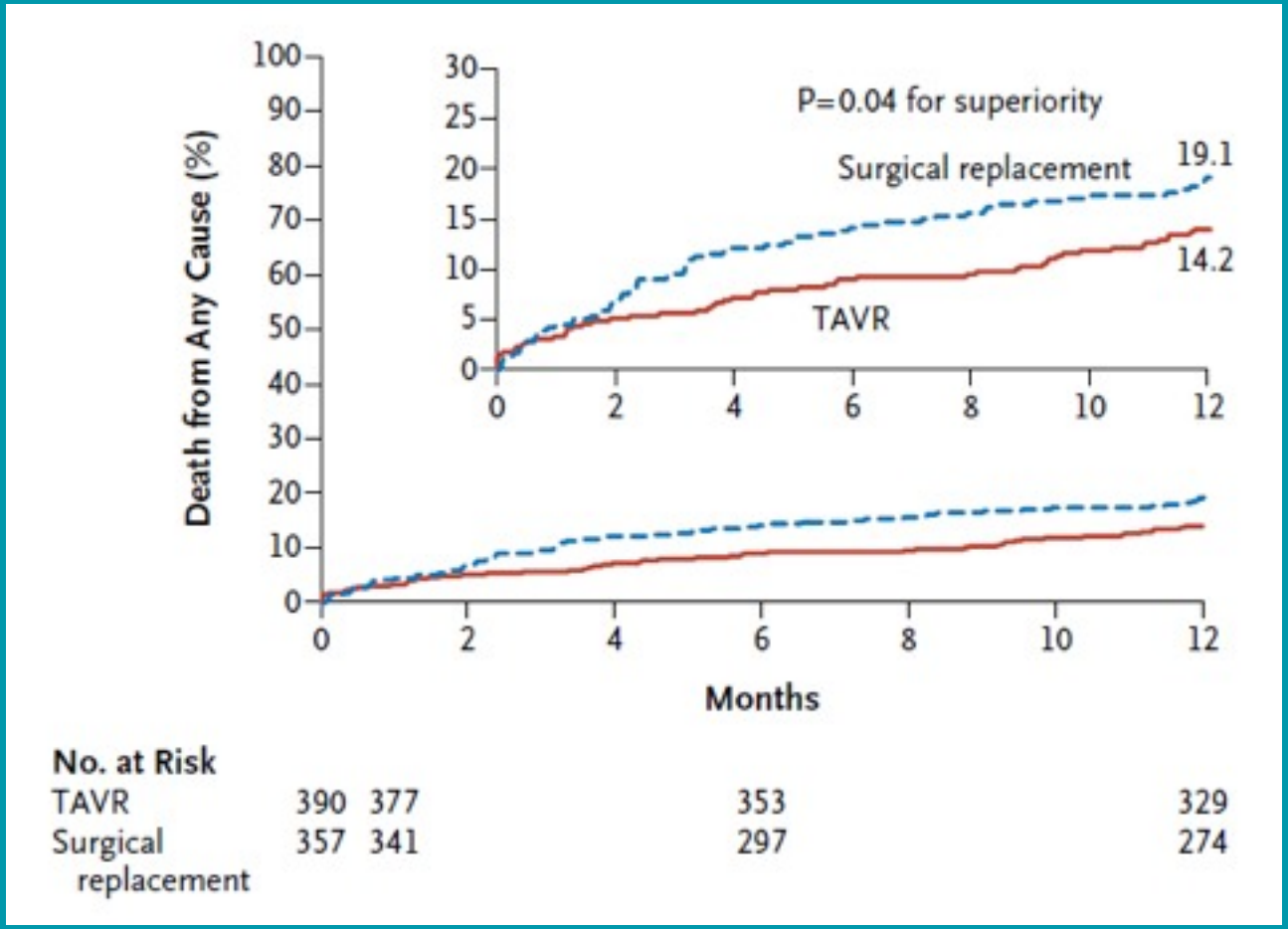
ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D., Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D., Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D., Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O., George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D., George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D., John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D., Sharla Chenoweth, M.S., and Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators*

New Eng J Med 2014; March online

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis



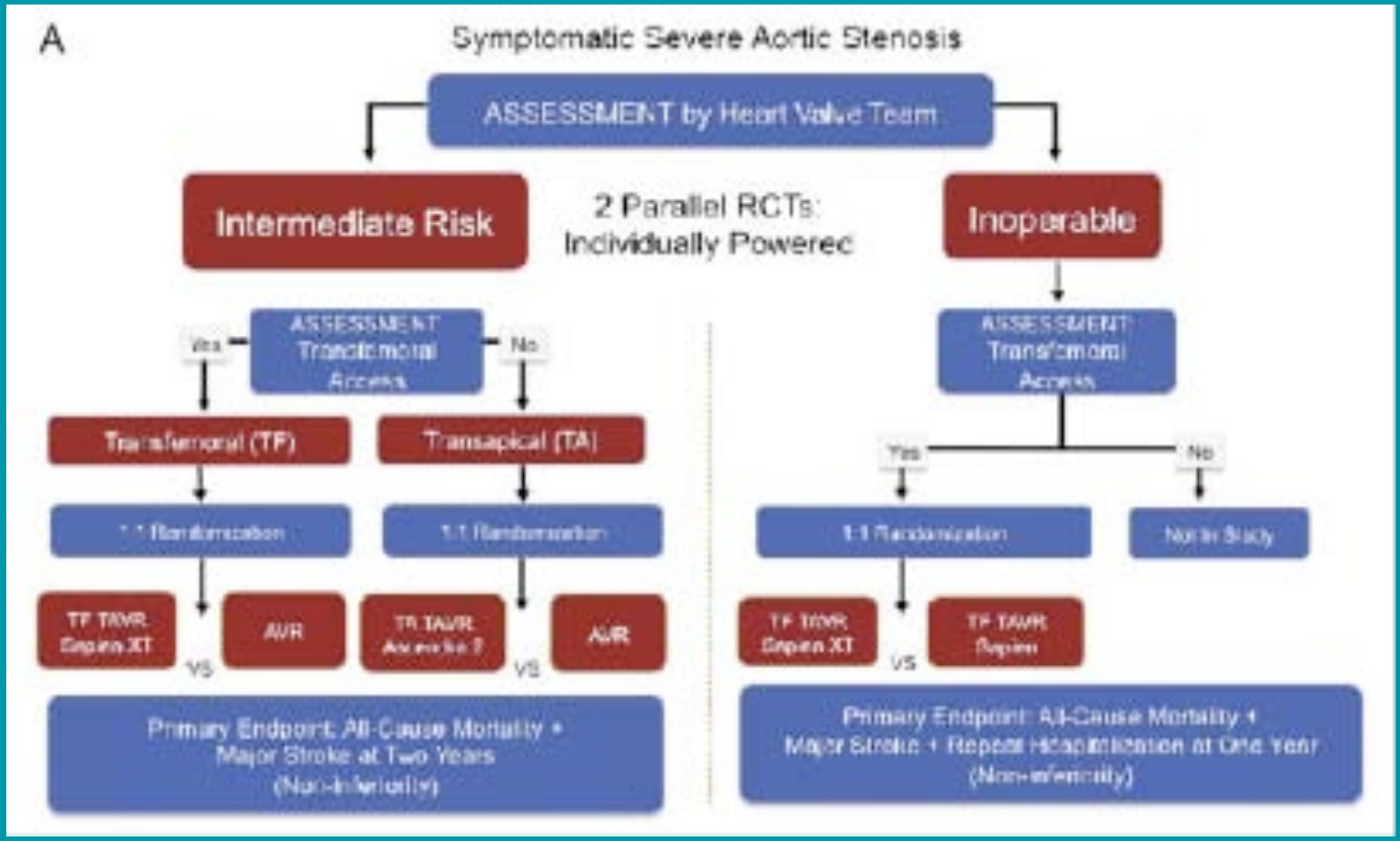
New Eng J Med 2014; March online

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

Outcome	30 Days			1 Year		
	TAVR Group (N = 390)	Surgical Group (N = 357)	P Value	TAVR Group (N = 390)	Surgical Group (N = 357)	P Value
	number (percent)			*number (percent)*		
Major vascular complication	23 (5.9)	6 (1.7)	0.003	24 (6.2)	7 (2.0)	0.004
Bleeding event†						
Life-threatening or disabling bleeding	53 (13.6)	125 (35.0)	<0.001	64 (16.6)	136 (38.4)	<0.001
Major bleeding	109 (28.1)	123 (34.5)	0.05	114 (29.5)	130 (36.7)	0.03
Acute kidney injury	23 (6.0)	54 (15.1)	<0.001	23 (6.0)	54 (15.1)	<0.001
Cardiogenic shock	9 (2.3)	11 (3.1)	0.51	9 (2.3)	11 (3.1)	0.51
Cardiac perforation	5 (1.3)	0	0.03	5 (1.3)	0	0.03
Permanent pacemaker implantation	76 (19.8)	25 (7.1)	<0.001	85 (22.3)	38 (11.3)	<0.001
New-onset or worsening atrial fibrillation	45 (11.7)	108 (30.5)	<0.001	60 (15.9)	115 (32.7)	<0.001

New Eng J Med 2014; March online

Transcatheter Aortic Valve Implantation (TAVI)
PARTNER II Trial Design

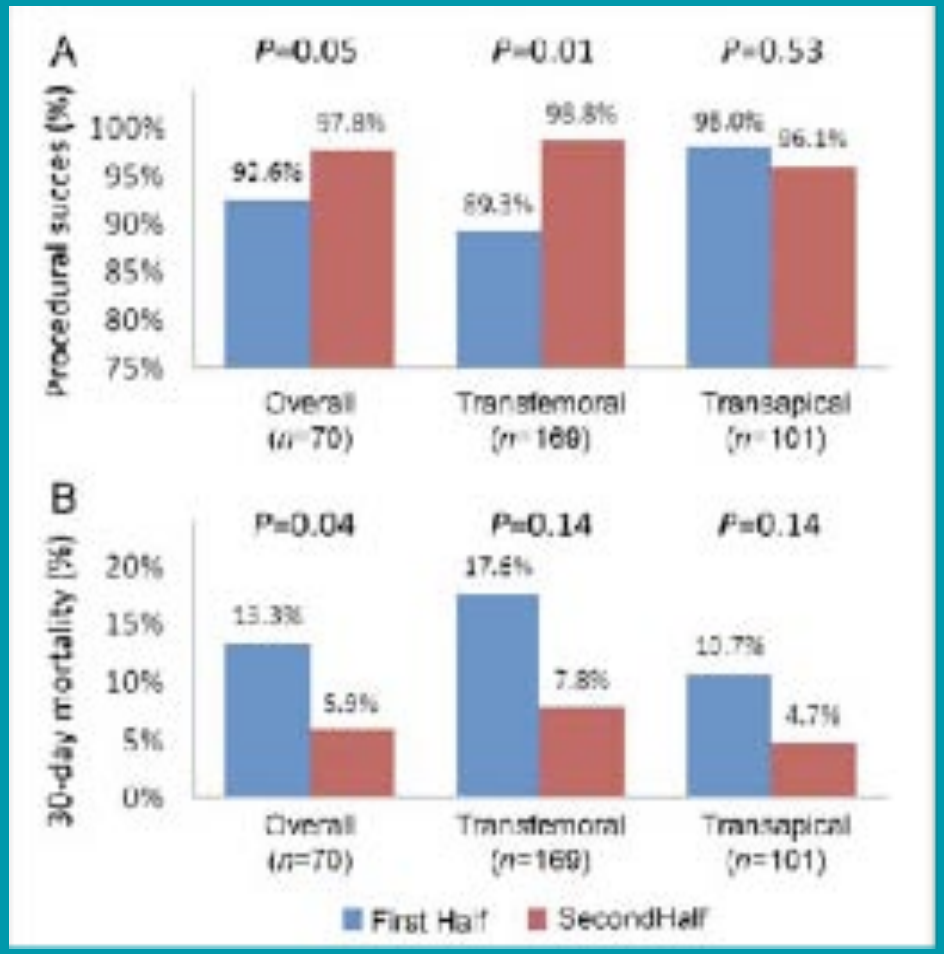


Eur Heart J 2012; 33: 2388–2400

Multidimensional Assessment of Health Technology

Topic: INVESTMENTS AND TOOLS REQUIRED TO USE THE TECHNOLOGY
B0008 - What kind of special premises are needed to use the technology?
Topic: TRAINING AND INFORMATION NEEDED FOR UTILIZING THE TECHNOLOGY
B0013 - What kind of training is needed for the personnel treating or investigating patients using this technology?
B0014 - What kind of training and information are needed for the patients receiving or using this technology & their families?
B0015 - What information do patients outside the target group and the general public need on the technology?
Topic: CHANGE-IN MANAGEMENT
D0023 - How does the technology modify the need for other technologies and use of resources?
D0020 - Does the use of technology lead to improved detection of disease?
D0021 - Does the use of the technology lead to a change in the physicians' management decisions?
D0022 - Does the use of technology detect other health conditions which have impact on the treatment decisions concerning the target condition?

Effects of the Learning Curve after TAVI



Eur Heart J 2012; 33: 2388–2400

COMPETENCE STATEMENT

Multisociety (AATS, ACCF, SCAI, and STS) Expert Consensus Statement: Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part 1: Transcatheter Aortic Valve Replacement

TAVI: Criteria for New and Existing Programs

Table 1. Transcatheter Aortic Valve Replacement: Criteria for New and Existing Programs

New Programs	
Institutional Interventional Program	1,000 cath/400 PCI per year*
TAVR Interventionalist	100 Structural procedures lifetime or 30 left sided structural per year of which 60% should be balloon aortic valvuloplasty (Left sided procedures include EVAR, TEVAR, BALLOON AORTIC VALVE (BAV), aortic valve (AV) and mitral valve (MV) prosthetic leak closures and ventricular septal defect [VSD] closures). (atrial septal defect/patent foramen ovale [ASD/PFO] closure are not considered left sided procedures)
	Suitable training on devices to be used
Institutional Surgical Program	50 Total AVR per year of which at least 10 aortic valve replacement (AVR) should be high-risk (STS score ≥6)
	Minimum of 2 institutionally-based cardiac surgeons in program (more than 50% time at hospital with surgical program)
TAVR Surgeon	100 AVR career, at least 10 of which are "high-risk" (STS score ≥8) or 25 AVR per year or 50 AVR in 2 years and at least 20 AVR in last year prior to TAVR initiation
	Experience with, and management of, peripherally inserted cardiopulmonary bypass
	Experience with open retroperitoneal exposure of, and surgical intervention on, the iliac arteries
	Suitable training on devices to be used
Training	Cardiologists must be board certified/eligible in interventional cardiology
	Surgeons must be board certified/eligible in thoracic surgery
	Additional operators who are trained or experienced in structural heart disease, and have unrestricted hospital privileges in structural procedures, may also be part of the interventional operating team with the interventional cardiologist and cardiovascular surgeon
Existing Programs	
Institutional	Programs in existence >18 months: 30 TAVR (total experience)
	Programs in existence <18 months: 2 per month
Training	Cardiologists must be board certified/eligible in interventional cardiology
	Surgeons must be board certified/eligible in thoracic surgery
	Additional operators who are trained or experienced in structural heart disease, and have unrestricted hospital privileges in structural procedures, may also be part of the interventional operating team with the interventional cardiologist and cardiovascular surgeon

TAVI: Criteria for New and Existing Programs

Table 2. Volume and Outcomes for Continued Certification for Both New and Existing TAVR Programs Applies to "Inoperable" (PARTNER Cohort B) TAVR Patients

Program volume of 20 TAVR per year or 40 per 2 years
30 day all-cause mortality <15%
30 day all-cause neurologic events including transient ischemic attack (TIAs) <15%
Major vascular complication <15%[a]
<90% Institutional follow-up
60% 1-year survival rate for nonoperable patients (cohort b)—after the program has been running for 2 years (2-year average)
Ongoing continuing medical education (CME) (or nursing/technologist equivalent) of 10 hr per year of relevant material
All cases must be submitted to a single national database

Number of TAVI/year (80% of cases in 7 Centers)

	2012	2011	2010	2009	Total
030935	110	170	148	71	499
030934	49	90	75	73	287
030906	73	53	52	50	228
030112	64	55	56	49	224
030943	54	69	56	28	207
030913	23	43	36	37	139
030281	49	31	25	21	126

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Number of TAVI/year (20% of cases in 13 Centers)

	2012	2011	2010	2009	Total
030905	31	22	18	11	82
030947	17	23	15	16	71
030140	19	25	18	0	62
030143	7	11	12	10	40
030907	15	14	6	0	35
030916	15	8	7	4	34
030924	14	12	8	0	34
030903	8	8	0	0	16
030909	8	3	5	0	16
030295	5	10	0	0	15
030106	0	6	3	2	11
030004	0	0	6	0	6
030097	0	1	0	0	1
Total	561	654	546	372	2133

Marco Stramba-Badiale, Italy

Multidimensional Assessment of Health Technology
Economic and Financial Impact

Topic: INVESTMENTS AND TOOLS REQUIRED TO USE THE TECHNOLOGY
B0007 - What material investments are needed to use the technology?
B0009 - What equipment and supplies are needed to use the technology?
B0010 - What kind of data and records are needed to monitor the use the technology?
B0011 - What kind of registers is needed to monitor the use the technology?
Topic: RESOURCE UTILIZATION
E0001 - What types of resources are used when delivering the assessed technology and its comparators (resource use identification)?
E0002 - What amounts of resources are used when delivering the assessed technology and its comparators (resource use measurement)?
Topic: UNIT COSTS
E0003 - What are the unit costs of the resources used when delivering the assessed technology and its comparators?
Topic: STRUCTURE
G0007 - What is the likely budget impact of the implementation of the technology for the payers (e.g. government)?
Topic: OUTCOMES
E0005 - What are the incremental effects of the technology relative to its comparator(s)?
Topic: COST-EFFECTIVENESS
E0006 - What is the incremental cost- effectiveness ratio?

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Cost Categories and Resources of Economic Evaluation

Cost category	Considered resources
Direct medical costs .	- outpatient visits - physicians and other services within the primary care sector - medication use, diagnostic tests, materials or medical equipment - inpatient care - rehabilitation
Direct non-medical costs	- social care - patient transportation - help at home - other resources used by patients - diets
Informal care costs	- unpaid time spent by family members and friends to care and supervise the patient
Productivity costs	- absence from work or reduced working capacity due to illness or premature

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart Association®

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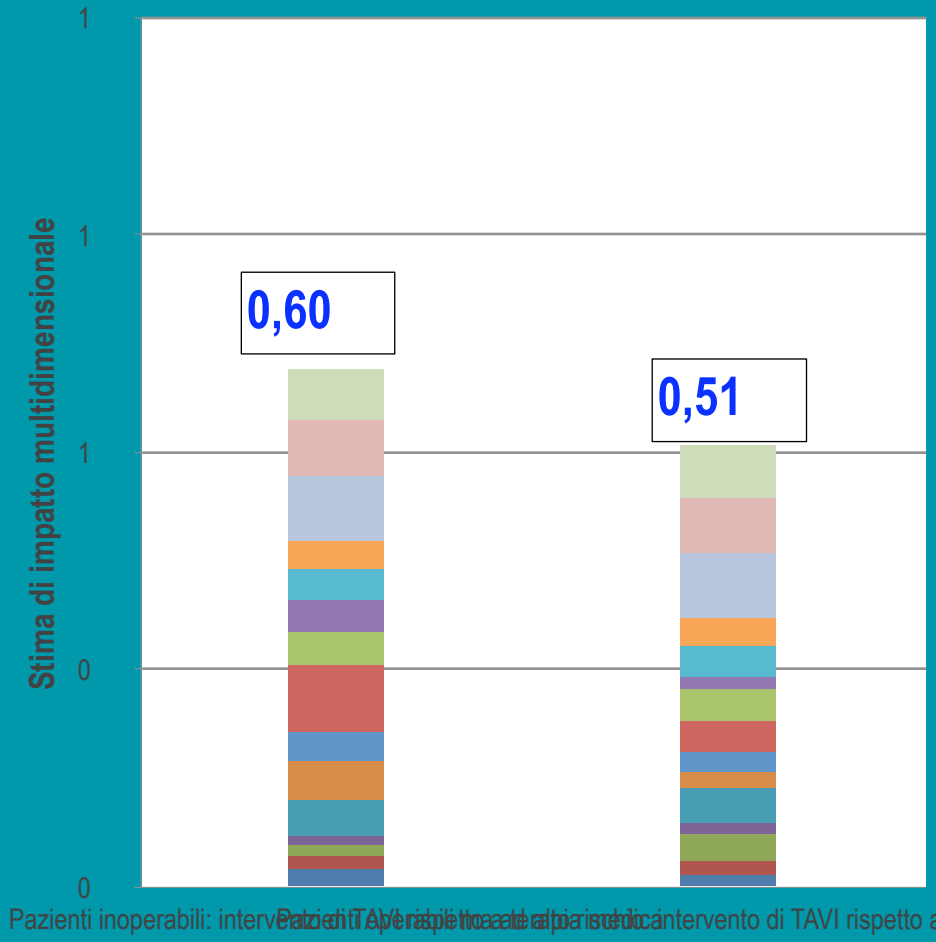
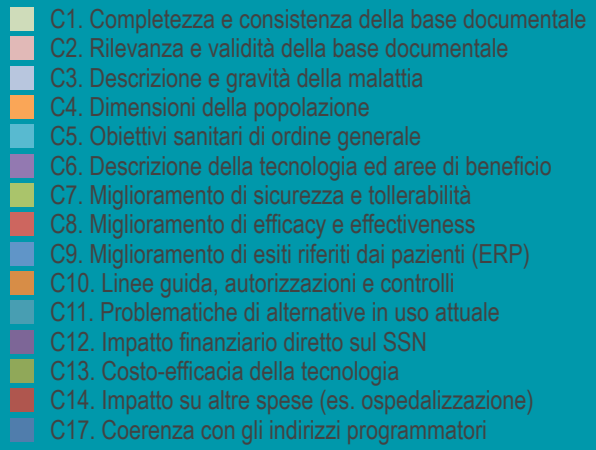
Cost Effectiveness of Transcatheter Aortic Valve Replacement Compared with Standard Care Among Inoperable Patients with Severe Aortic Stenosis: Results from The PARTNER Trial (Cohort B)

Matthew R. Reynolds, Elizabeth A. Magnuson, Kaijun Wang, Yang Lei, Katherine Vilain, Joshua Walczak, Susheel K. Kodali, John M. Lasala, William W. O'Neill, Charles J. Davidson, Craig R. Smith, Martin B. Leon and David J. Cohen

Marco Stramba-Badiale, Italy

TAVI - Indice di appropriatezza d'uso

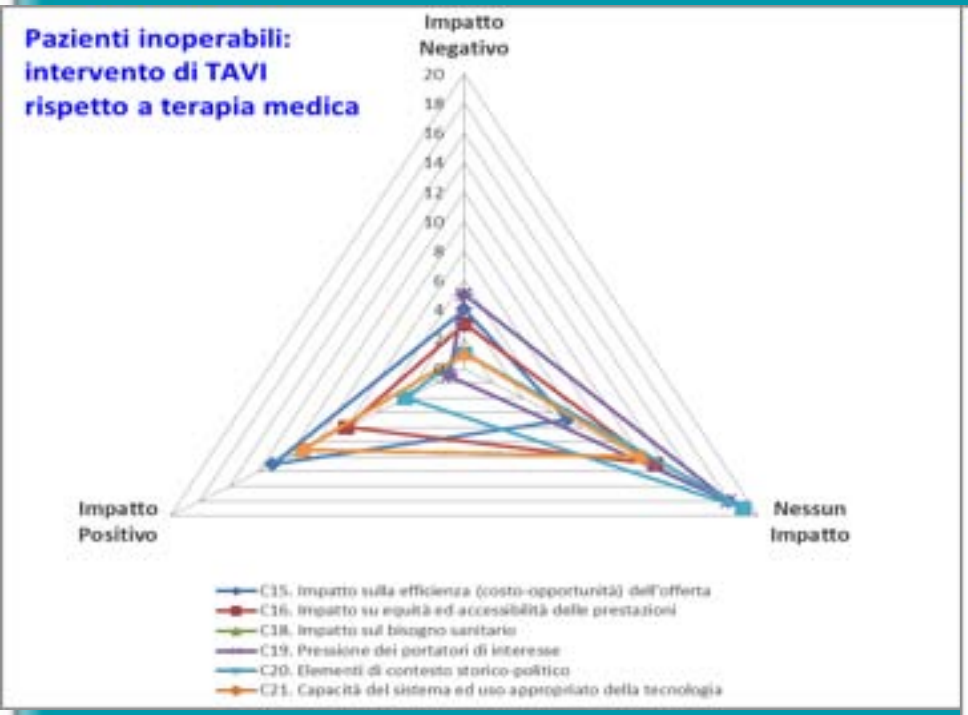




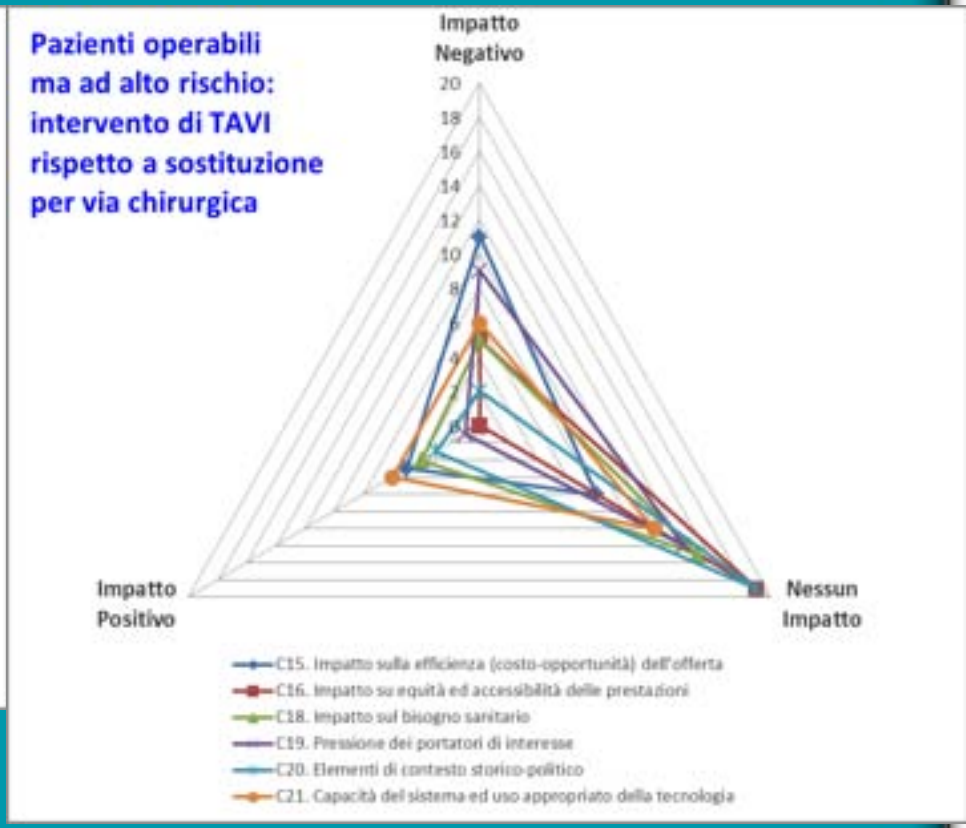
Analisi Decisionale a Criteri Multipli: GIUDIZI QUALITATIVI

Impatto finanziario: impatto sulla efficienza dell'offerta (costo-opportunità)
Equità d'accesso alle prestazioni equità e accessibilità prestazioni
Impatto sociale ed etico: bisogno, pressione portatori interesse, contesto storico-politico
Impatto organizzativo: capacità del sistema ed uso appropriato della tecnologia

Pazienti inoperabili: intervento di TAVI rispetto a terapia medica



Pazienti operabili ma ad alto rischio: intervento di TAVI rispetto a sostituzione per via chirurgica



Raccomandazioni per l'applicazione nel SSR approvate dal Nucleo di Valutazione per l'Appropriatezza in Medicina

Cod	Principali	Secondarie	
1	Proposta di modifica del PSR	-	No
2	Introduzione della nuova tecnologia	-	No
3	Revisione di tecnologia già in uso, per cui sono rilevate aree di inefficienza o spreco	**Revisione dei centri autorizzati** **Revisione dei criteri per uso appropriato (selezione pazienti)**	Sì
5	Modifica di procedure e sistemi di finanziamento	**Valorizzazione tariffa**	Sì
6	Modifica di un percorso assistenziale	Modifica di un PDTA di riferimento	Sì
8	Sviluppo o modifica di un sistema informativo	**Registro clinico regionale**	Sì
9	Attivazione processo di formazione	Formazione operatori; Coaching	Sì
10	Attivazione processo di informazione	Informazione pazienti e caregivers	?

* Valori possibili: Sì, No. Ove Sì, segue dettaglio in forma di testo esteso in calce alla tabella.

Analisi Decisionale a Criteri Multipli: Discussione per Atto Regionale

1. Revisione dei criteri per uso appropriato:
   pazienti appropriati e pazienti da non candidare alla TAVI
2. Revisione dei criteri per l'autorizzazione dei centri:
   requisiti strutturali, organizzativi, di esito clinico
3. Pubblicazione di un PDT di riferimento che preveda la valutazione geriatrico-riabilitativa specialistica della fragilità, oltre alla valutazione della comorbidità clinica
4. Strutturazione di un registro clinico regionale di patologia collegato alla procedura di rimborso
5. Rimborso condizionale: per indicazione appropriata e/o esito (es. pay-back collegato all'esito a 2 anni)
6. Pubblicazione di informazioni appropriate per pazienti e caregivers

Revisione dei criteri per uso appropriato: pazienti appropriati per TAVI

La TAVI è indicata in pazienti con stenosi aortica severa sintomatici per dispnea e/o sincope e/o angina oppure con disfunzione ventricolare sinistra (frazione di eiezione <50%) quando, in base alla valutazione delle caratteristiche anatomiche, delle comorbidità e della fragilità da parte dell'Heart team vi sia:

1. **controindicazione o alto rischio per intervento cardiochirurgico di sostituzione valvolare aortica;**
2. **probabile miglioramento della qualità della vita;**
3. **spettanza di vita di almeno un anno;**
4. **idoneità alla procedura transcatetere di sostituzione valvolare aortica.**

Revisione dei criteri per l'autorizzazione dei centri: requisiti strutturali, organizzativi, di

La TAVI può essere effettuata solo in Centri autorizzati che abbiano i seguenti requisiti (in aggiunta a quelli per l'accreditamento):

1. presenza di un Heart team multidisciplinare composto da cardiologo, cardiochirurgo, cardiologo emodinamista, anestesista, radiologo esperto in cardiologia e geriatra;
2. presenza di cardiochirurgia nella struttura;
3. esperienza in chirurgia valvolare;
4. esecuzione di almeno 20 procedure di TAVI l'anno;
5. mortalità a 30 giorni < 15%*;
6. incidenza di ictus o TIA a 30 giorni < 15%*;
7. capacità di eseguire follow-up a 1 anno > 90%;
8. mortalità a 1 anno < 60%*;
9. adesione al Registro clinico regionale.

*per i pazienti in cui sia controindicato l'intervento chirurgico

Delibera delle Regole 2013

1.a. Impianto di valvola aortica trans-catetere (TAVI)

In riferimento ai disposti della DGR n. VIII/7612 del 07.02.2008, con la quale sono state date le prime indicazioni sulle corrette modalità clinico-organizzative per il trattamento percutaneo della patologia valvolare cardiaca, si definisce di integrare i contenuti di cui alla norma citata, come di seguito specificato:

con particolare riferimento alla procedura di impianto di valvola aortica trans-catetere (TAVI, *Transcatheter Aortic Heart Valve*), al fine di garantire che la stessa venga effettuata secondo criteri di appropriatezza, si stabilisce di procedere ad una chiara individuazione delle indicazioni al trattamento.

A questo proposito, come da linee guida delle principali società scientifiche di riferimento nel settore della cardiologia interventistica (ESC, 2012 - EACTS, 2012 - SICCH, 2010), si chiarisce che l'indicazione alla TAVI è da circoscrivere a pazienti affetti da stenosi aortica severa sintomatica, non candidabili alla cardiochirurgia, con aspettativa di vita superiore ad un anno (in base alla valutazione delle comorbosità) e per i quali è atteso un miglioramento della qualità di vita.
Si ricorda altresì che questa tipologia di interventi deve essere eseguita solo in centri con un reparto di cardiochirurgia stabilmente presente ed autorizzato e con un volume di interventi riferito ad almeno 300 casi/anno.

Al fine di verificare il corretto rispetto delle indicazioni descritte, si stabilisce di istituire un meccanismo di controllo tra pari, che coinvolga quindi il livello del professionista; a questo scopo si è proceduto innanzitutto ad istituire un tavolo di lavoro regionale (che ha visto coinvolti i referenti delle principali società scientifiche di riferimento), al quale è stato dato mandato di predisporre una check-list, da utilizzare quale elemento di valutazione circa il rispetto delle corrette indicazioni al trattamento: la compilazione della citata check-list (di seguito riportata al Punto 1.a.1.) è obbligatoria a decorrere dalle prestazioni effettuate dal 1° gennaio 2014, garantendo che la stessa sia sempre presente in cartella clinica.
Successivamente verranno date indicazioni in merito alla metodologia di controllo della documentazione clinica, così integrata, della suddetta tipologia di ricoveri, da realizzarsi in sinergia tra gli organi di controllo delle ASL ed un pool di professionisti clinici esperti nella materia, cui si richiede di condurre una valutazione in cieco.
Gli esiti delle suddette valutazioni saranno ritenuti vincolanti ai fini del riconoscimento economico dei relativi episodi di ricovero.

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Gli esiti delle suddette valutazioni saranno ritenuti vincolanti ai fini del riconoscimento economico dei relativi episodi di ricovero.

1.a.i. Fac-simile di Scheda da inserire in cartella

Spazio per l'etichetta identificativa del Paziente

Premesse:
In base alle recenti linee guida sul trattamento della stenosi valvolare aortica[1] che noi sottoscritti dichiariamo di conoscere ed accettiamo, è stato presentato e discusso collegialmente nella riunione dell'"Heart Team" di questo Centro, svoltasi in data _____. Il caso della/del paziente Signora/Signor _____ n° nosologico_____ nata/o il _____ ricoverata/o il _____.

Si sottoscrive che in base alle linee guida ESC (2012), EACTS (2012) e SICCH (2010), l'intervento deve essere eseguito solo in centri con un reparto di cardiochirurgia stabilmente presente il loco ad autorizzato, con un volume di interventi riferito ad almeno 300 casi/anno.

Durante la riunione sono stati considerati, oltre agli elementi anamnestici ed alla sintomatologia riferita, i seguenti dati strumentali, i cui referti devono essere presenti in cartella:

1. I parametri ECOCARDIOGRAFICI

Parametri Stenosi aortica	Valori di riferimento	Valori rilevati
Area valvolare [cm^2]	<1.0	
Area valvolare indicizzata [cm^2/m^2/BSA]	<0.6	
Gradiente medio [mmHg]	>40*	
Velocità jet massima [m/s]	>4.0	
Frazione di eiezione del ventricolo sinistro		
Insufficienza valvolare	Trivalvolare o bivalvolare	

Note:

2. **Le Immagini CT Scan total body o angio-RM toraco-addominale** con eventuale ricostruzione 3D eseguita in data _____ presso questo centro/ospedale ovvero presso _____.
Note:

3. **La coronarografia e/o angio-TC coronarica eseguita** in data _____ presso questo centro/ospedale ovvero presso _____.
Note:

4. **I parametri utili per valutare lo score di rischio chirurgico e gli score di rischio derivati** (in cartella devono essere presenti tutti i parametri necessari per ricalcolarlo):
   a. STS Score = _____ (se < 10 specificare meglio il motivo di indicazione a TAVI): _____
   b. Frailty Index:
      - Test del cammino (miglior tempo misurato in tre prove su 4 metri): _____
      - Altro: _____
Note:

5. **Motivo di controindicazione all'intervento standard:**
   - Età
   - Reintervento con graft pervi

[1] Vahanian, A., Alfieri, O., Andreotti, F., Antunes, M. J., Baron-Esquivias, G., et al. (2012, October). Guidelines on the management of valvular heart disease (version 2012): The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *European Heart Journal*. Doi: 10.1093/eurheartj/ehs109.

- Aorta calcifica
- Malattia polmonare
- Epatopatia grave o malattia ematologica
- Altro _____

Conclusioni:
_____
_____
_____
_____

FIRME:
Nome e Cognome _____ Firma _____
*Cardiologo emodinamista

Nome e Cognome _____ Firma _____
*Cardiologo ecocardiografista

Nome e Cognome _____ Firma _____
*Cardiochirurgo

Nome e Cognome _____ Firma _____
*Anestesista

*Firme obbligatorie

Nome e Cognome _____ Firma _____
Altro specialista (neurologo, geriatra ecc.)

Importance of HTA

- Optimization of decision making processes – balance access, quality and sustainability
- Inform practice and governance
  - contextualization of global knowledge
  - transparent decision-making
  - overall vision of equity and accountability
- Legitimate decisions, policy and practice
- Diffusion of innovation