VI CONGRESSO NAZIONALE DI
ECOCARDIO CHIRURGIA

TAVI nelle mani del solo interventista. Pazienti eligibili alla procedura, indicazioni e timing, risultati alla dimissione, risultati ad un anno

Paolo Danna

Laboratorio di Emodinamica
Ospedale "Luigi Sacco" - Milano

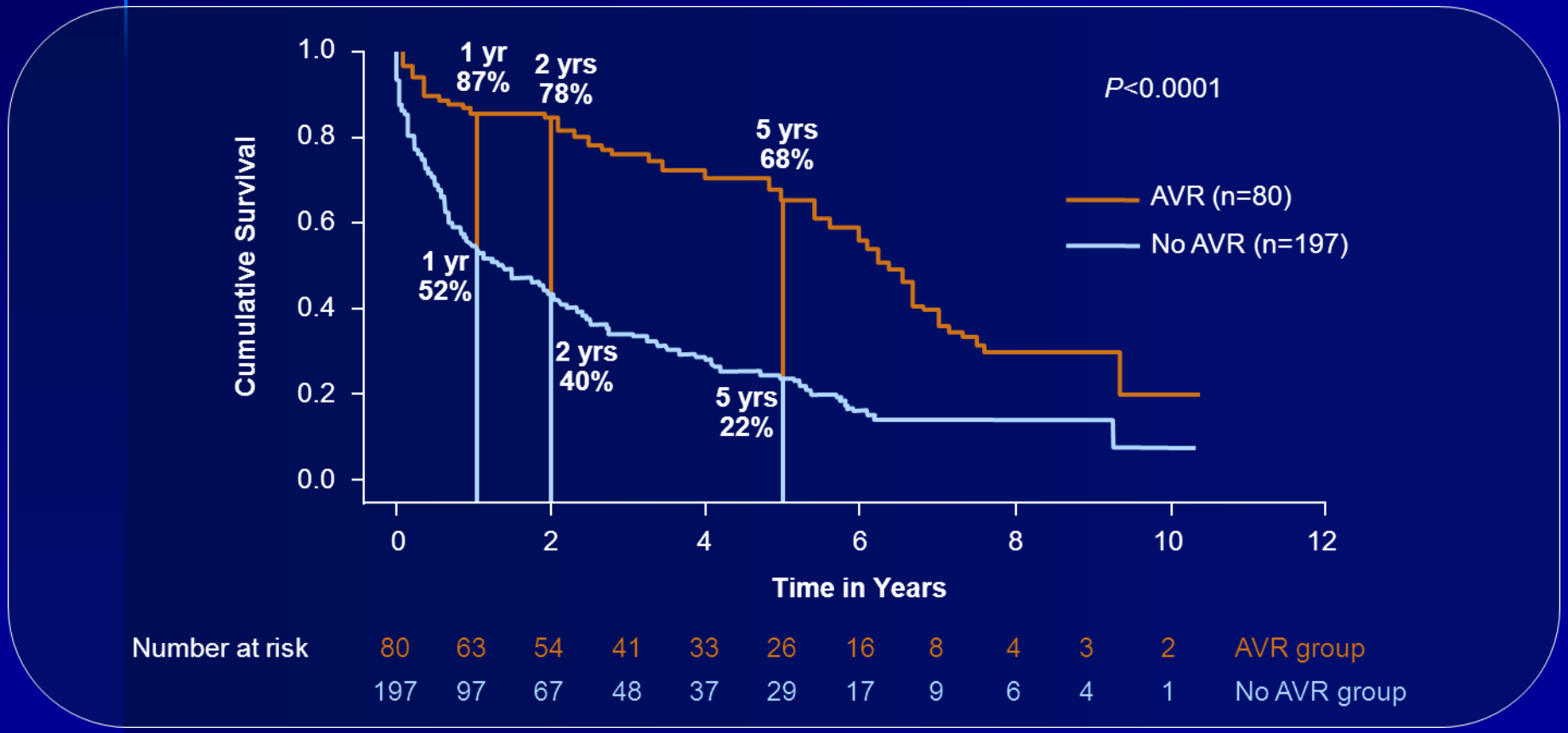
17 ottobre 2012

La Stenosi Aortica (SAo) Background

- La SAo è la più frequente fra le malattie delle valvole native[1]
- La prevalenza della SAo e le comorbidità che incrementano il rischio operatorio aumentano con l'aumentare dell'età[3]
- La mortalità della Sao grave, sintomatica, in terapia medica, è 50%-60% a 2 anni nei pazienti ad alto rischio[4]

1. Iung B, et al. *Eur Heart J*. 2003;24:1231-1243.
2. Backgrounder: Severe Aortic Stenosis. Detroit Medical Center Cardiovascular Institute Web site. http://www.dmccvi.org/aortic. Accessed 7/13/11.
3. Iung B, et al. *Eur Heart J*. 2005;26:2714-2720.
4. Spaccarotella C, et al. *Circ J*. 2010;75:11-19.

Sopravvivenza dei pazienti con SAo grave con o senza sostituzione valvolare aortica



AS=aortic stenosis; AVR=aortic valve replacement.

1. Varadarajan P, et al. *Eur J Cardiothorac Surg*. 2006;30:722-727.

Terapia chirurgica della stenosi aortica (SAo)

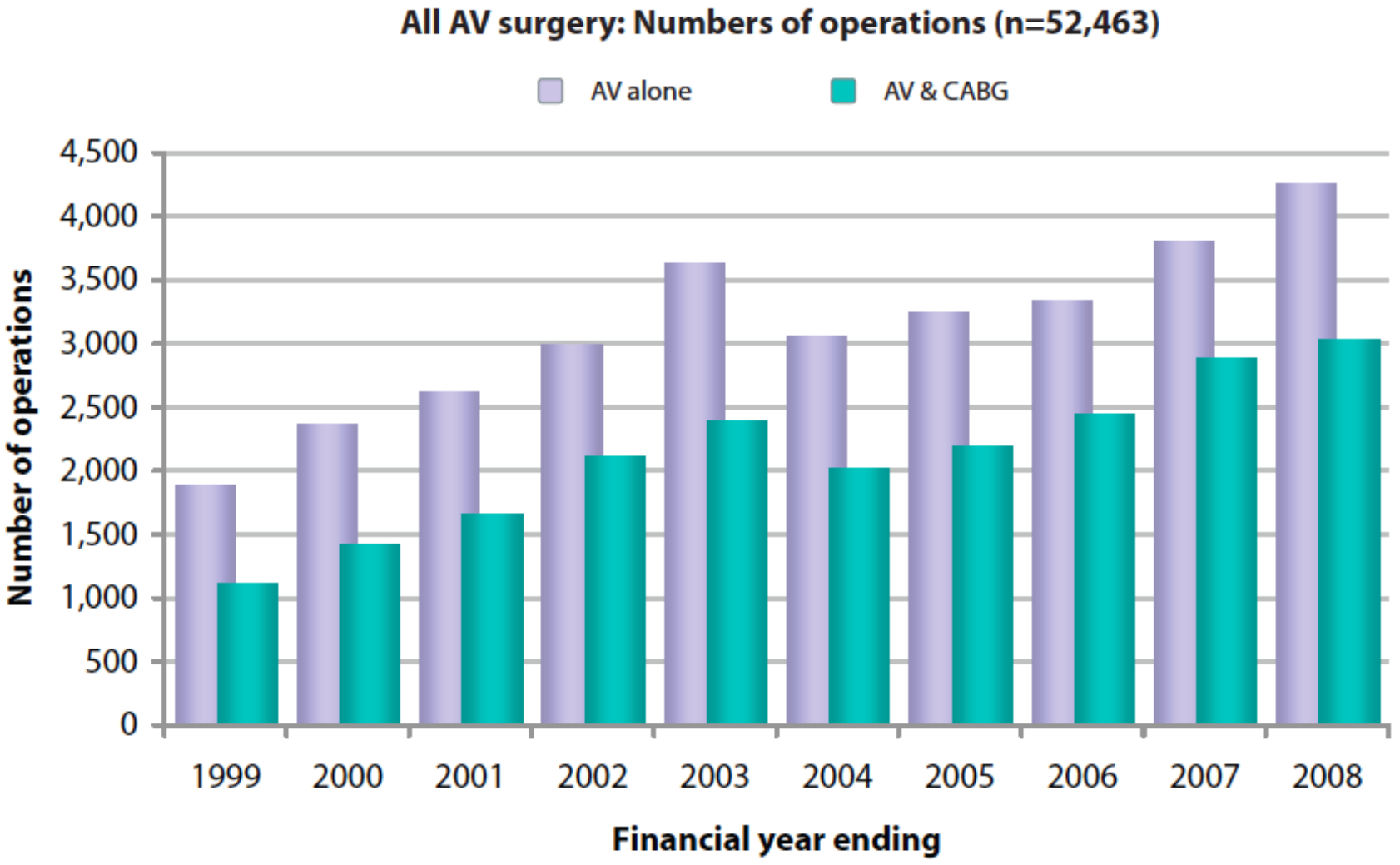
La sostituzione chirurgica della valvola aortica è il gold standard terapeutico.[1]

Il 33% dei pazienti di età≥75 della Euro Heart Survey non venivano avviati all'intervento.[2]

- **Molti pazienti avviati all'intervento presentavano alto rischio operatorio.**
- **La mortalità a 30 giorni dei pazienti operati in questo studio è stata pari a 5%.**

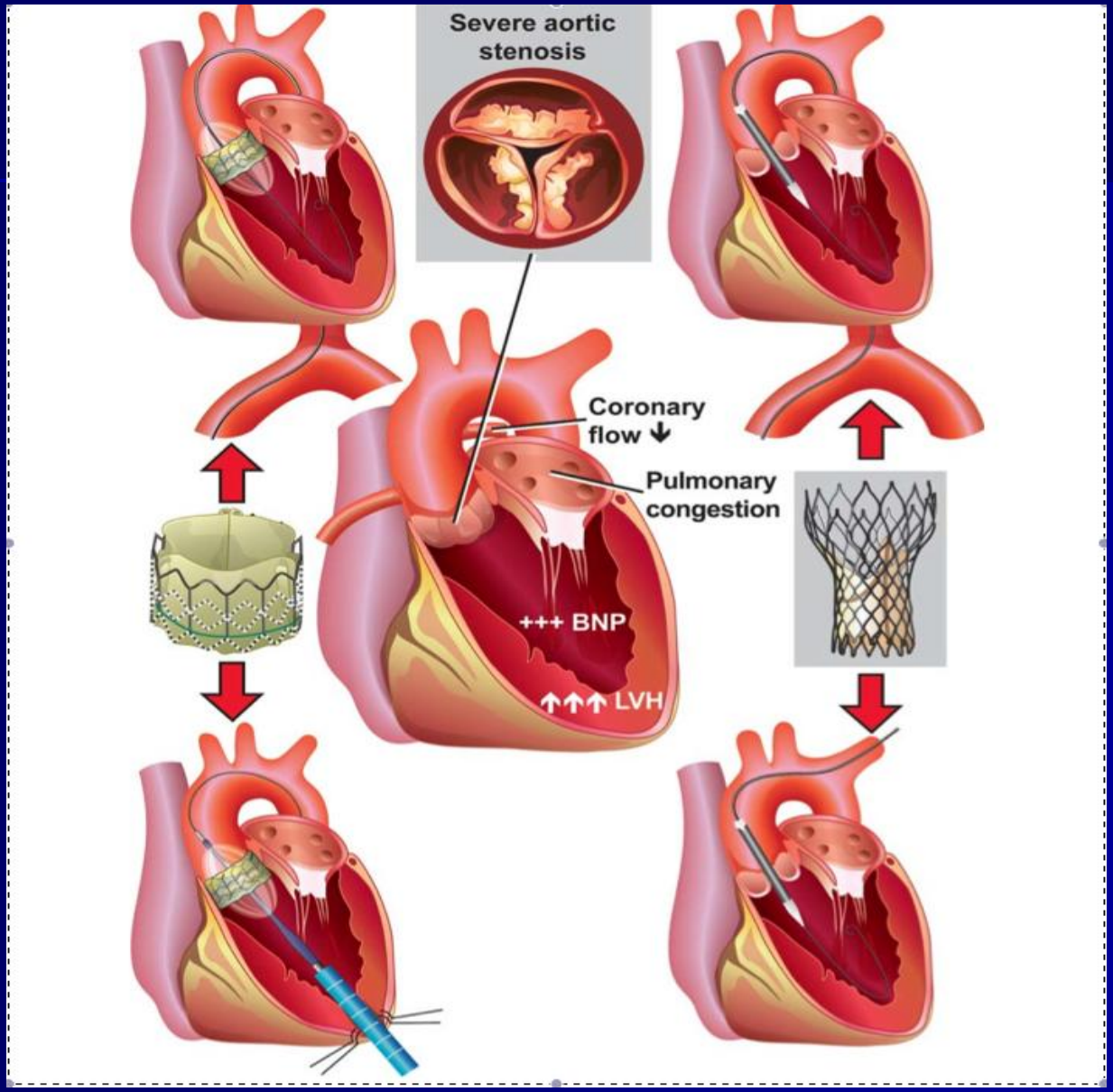
SAVR=surgical aortic valve replacement.

1. Bagur R, et al. *Eur Heart J.* 2010;31:865-874.
2. Iung B, et al. *Eur Heart J.* 2005;26:2714-2720.



Sixth
National Adult Cardiac
Surgical Database Report
2008

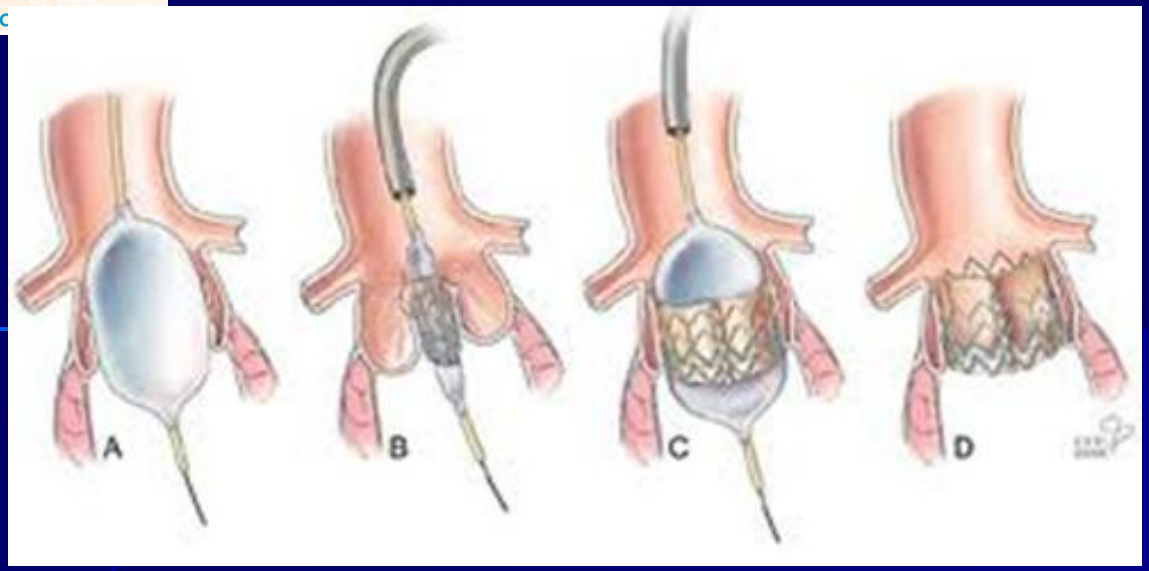
TAVI


Severe aortic stenosis
Coronary flow ↓
Pulmonary congestion
+++ BNP
↑↑↑ LVH

Sapien THV (22-24F)

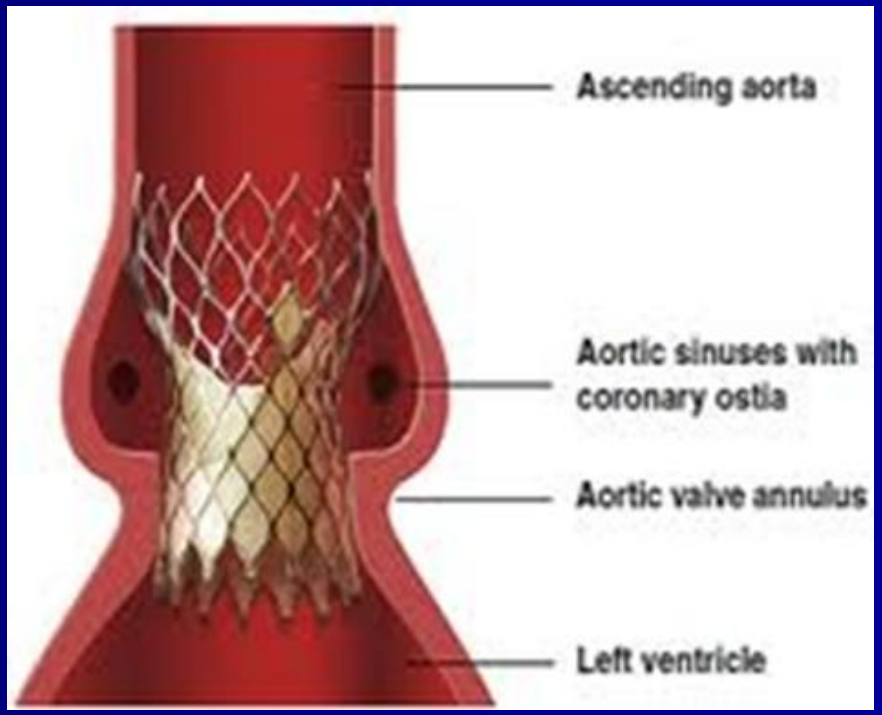
CoreValve (18F)

Sapien XT (18-19F)



Balloon-expandable (acciaio o cromo-cobalto)

Self-expandable (nitinolo)



SELEZIONE DEI PAZIENTI: I PAZIENTI ELIGIBILI ALLA PROCEDURA

La selezione dei pazienti: lo "heart team"

- Valutazione collegiale da parte di cardiochirurgo,cardiologo clinico, cardiologo intervenzionale, anestesista ("heart team")
- Decisione riguardo la terapia ottimale (medica, chirurgica, TAVI)
- Idealmente la procedura va eseguita da un team congiunto cardiologo-cardiochirugo.

Indicazioni attuali

1) Pazienti con stenosi aortica grave:
   - sintomatici
   - area valvolare <0.8 cm^2
   - V max > 4 cm/sec
   - Gradiente medio > 40 mmHg

2) Pazienti inoperabili o ad alto rischio chirurgico:
   - Punteggio di rischio elevato
      - Euroscore
      - STS score
   - Multiple comorbidità

Il paziente "ideale"

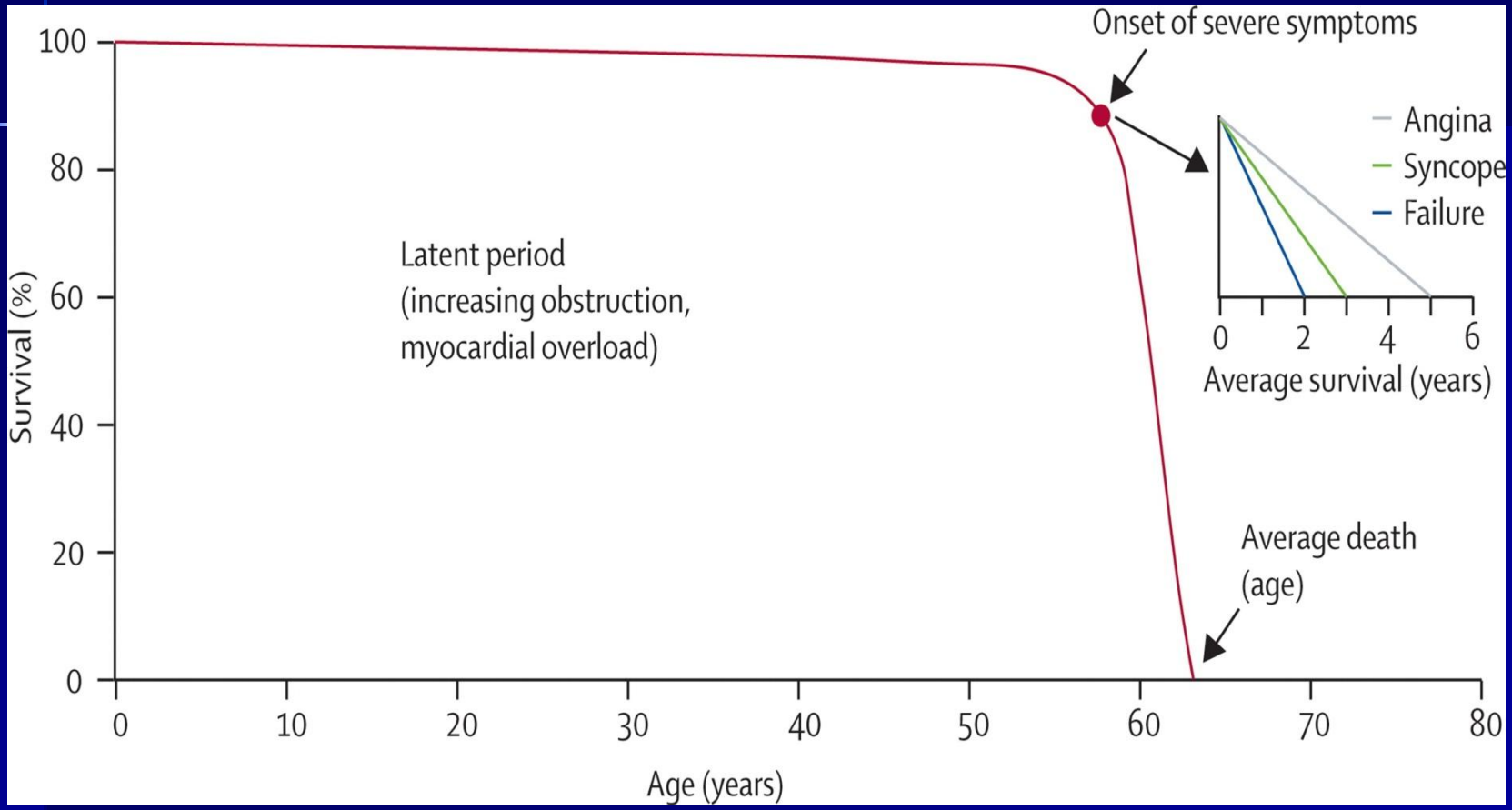
Il paziente ideale è l'anziano (>80 a) (?) sintomatico per stenosi aortica e altrimenti in buone condizioni generali o il paziente anche più giovane ma con elevato rischio chirurgico per comorbidità

Controindicazioni:

- Scompenso multi-organo
- Debilitazione generale multifattoriale
- Dipendenza fisica
- Decadimento mentale avanzato

TIMING
DELLA PROCEDURA

Storia naturale dei pazienti con SAo



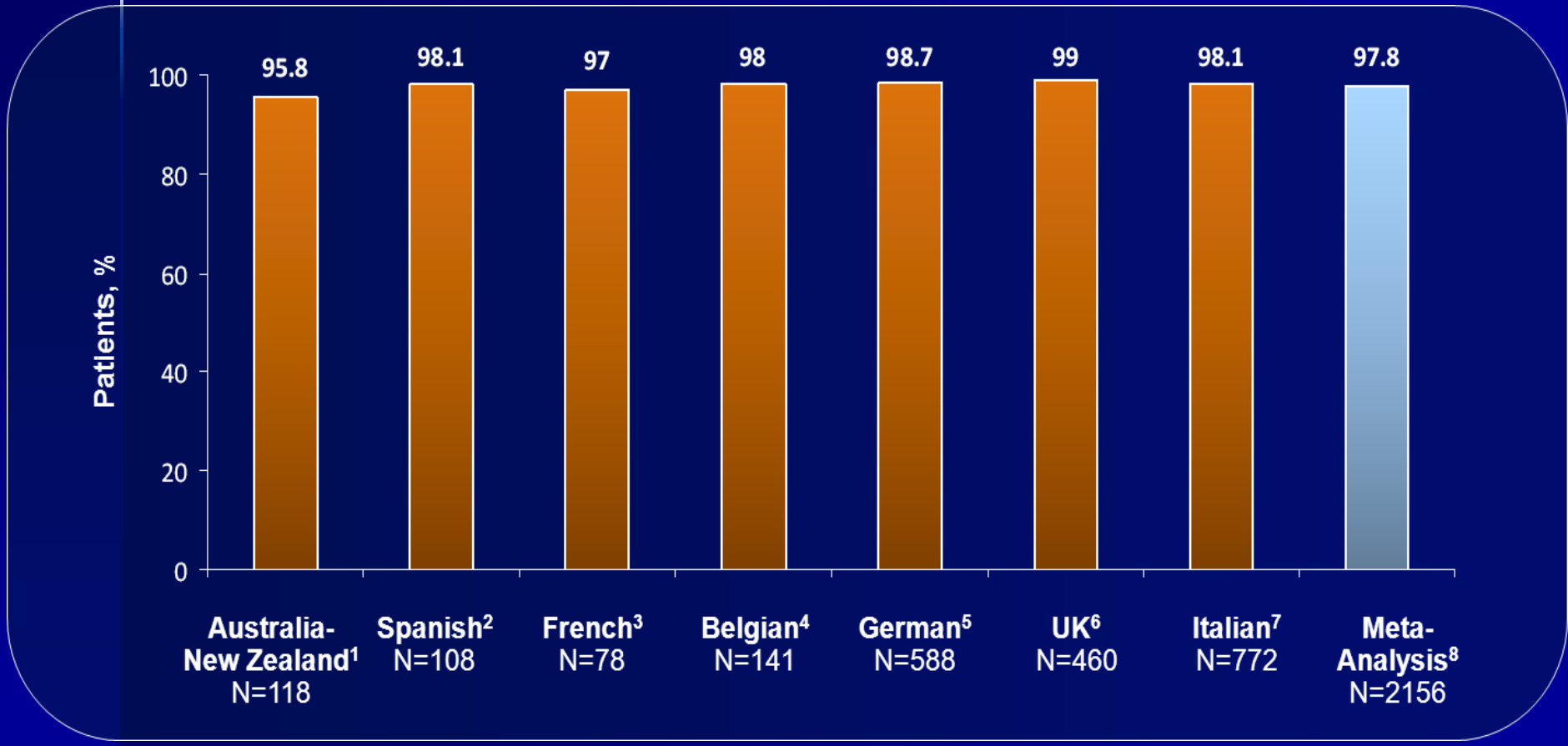
Stabilita l'indicazione, il timing ideale è: "il più presto possibile"!

RISULTATI ALLA DIMISSIONE, RISULTATI AD UN ANNO

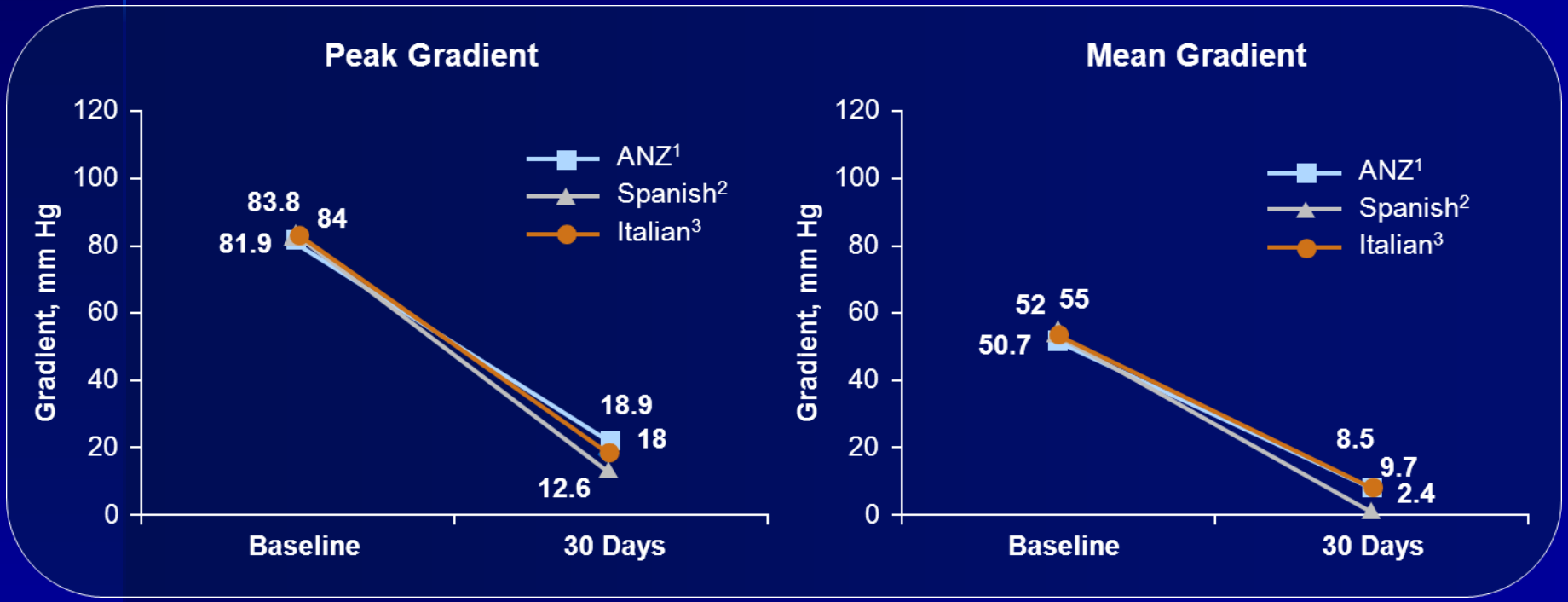
Caratteristiche dei pazienti: dati COREVALVE

	ANZ Registry[1]	Spanish Registry[2]	French Registry[3]	Belgian Registry[4]	German Registry[5]	UK Registry[6]	Italian Registry[7]
N	**118**	**108**	**78**	**141**	**588**	**460**	**772**
Age, years	82.3 ± 7.7	78.6 ± 6.7	82.5 ± 5.9	82 ± 6	81.4 ± 6.4	83	82 ± 6
Female, %	40.7	54.6	51.5	56	55.8	48	56
Logistic EuroSCORE, %	18.4 ± 11.9	16 ± 13.9	24.7 ± 11.2	25 ± 15	20.8 ± 13.3	20.3	22.9 ± 13.5
NYHA class III and IV, %	83.9	58.4	–	78	88.2	74	70.6
LVEF, %	57.8 ± 13.0	–	51 ± 15	59 ± 13	52.1 ± 15	–	51 ± 13
Mean pressure gradient, mm Hg	50.6 ± 16.2	55 ± 14.3	46 ± 15	49 ± 16	48.7 ± 17.2	–	52 ± 17
Aortic valve area, cm^2	0.71 ± 0.21	0.63 ± 0.2	0.71 ± 0.16	0.63 ± 0.13	0.64 ± 0.18	0.71	–

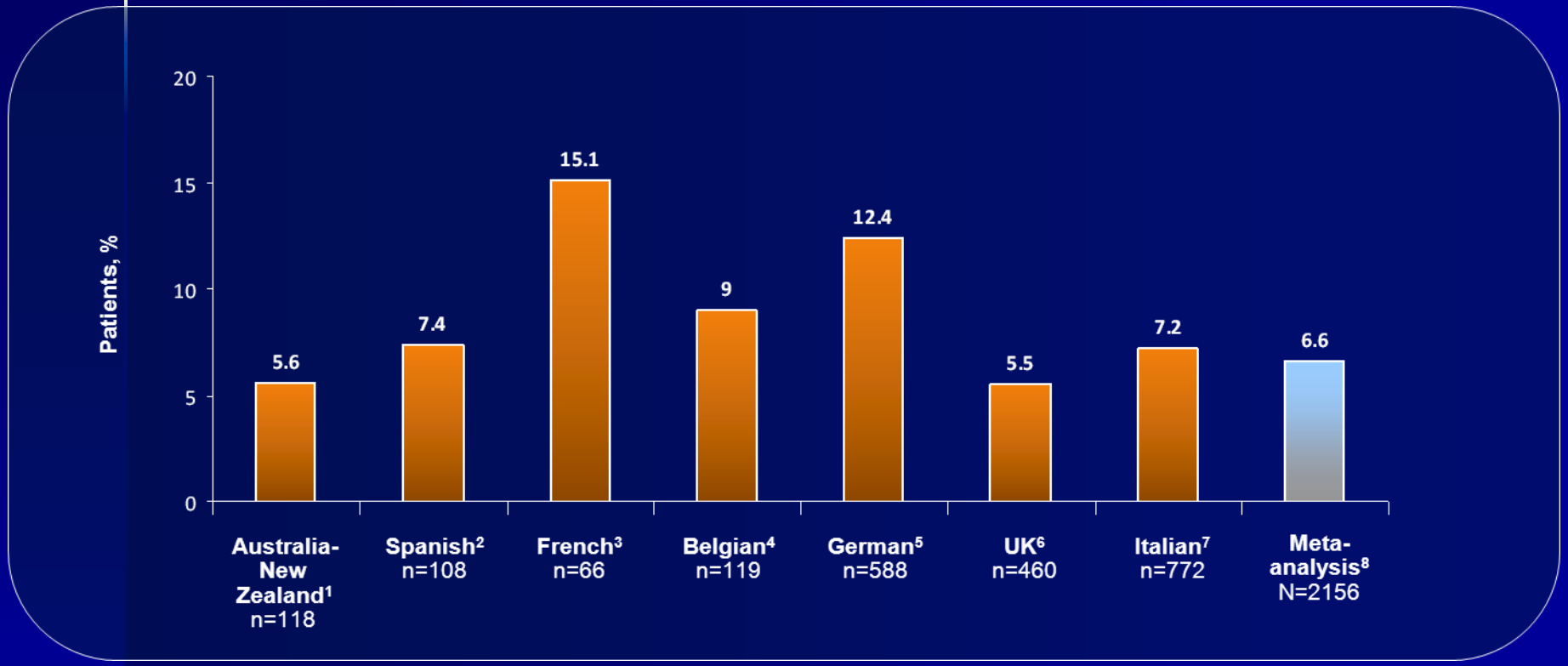
Successo Procedurale negli studi CoreValve



Effetto emodinamico dell'impianto negli studi CoreValve



Mortalità globale a 30 giorni negli studi Corevalve

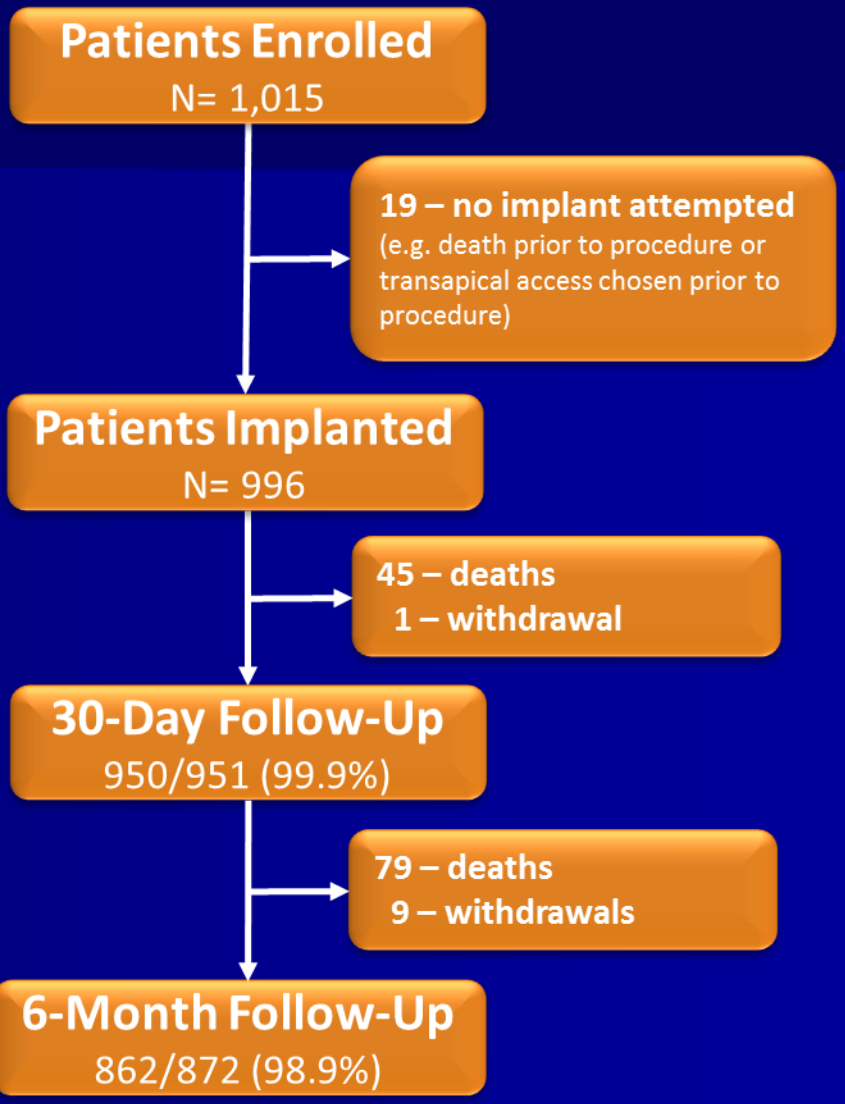


CoreValve ADVANCE
Caratteristiche dei pazienti

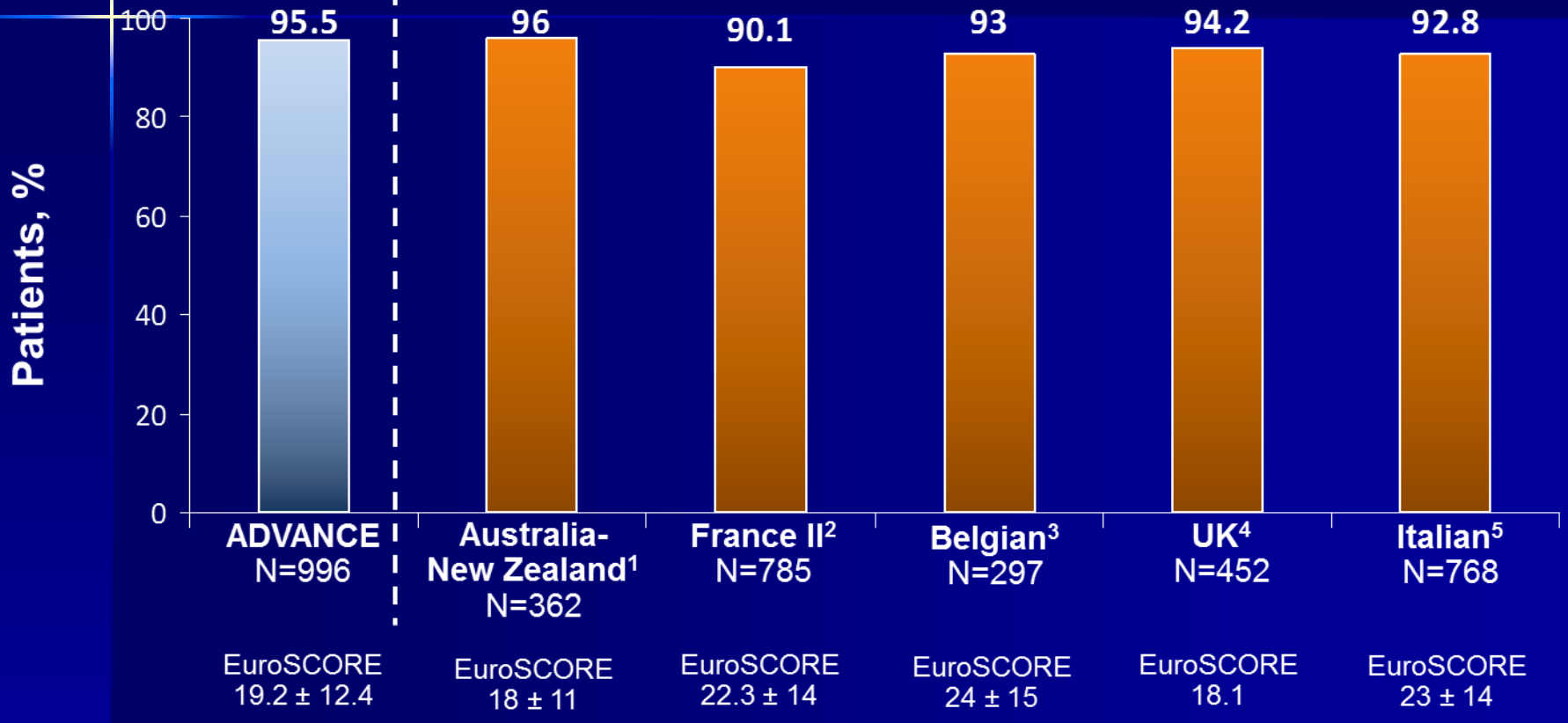
Characteristics	N=1015 %		%
Age (yrs.)	81 ± 6	Prior MI	16.0
Male	49.4	Prior PCI	31.1
Logistic EuroSCORE	19.2 ± 12.4	Permanent Pacemaker	12.8
NYHA		**EuroSCORE Relevant Factors**	
I or II	20.4	Prior CABG	21.4
III or IV	79.6	Cerebrovascular Disease	12.9
Diabetes	30.9	COPD	22.6
CAD	57.6	Pulmonary Hypertension	12.6
PVD	19.5	Prior median sternotomy	17.3
Atrial Fibrillation	32.8	Renal Failure	14.6

COREVALVE ADVANCE

- 1,015 patients enrolled from March 2010 to July 2011
  - 5 year follow-up
- 44 centers - 12 countries in Western Europe, Asia and South America
- All centers had conducted at least 40 TAVI procedures prior to the study and had Heart Team in place
- Clinical endpoints reported according to Valve Academic Research Consortium (VARC)



COREVALVE ADVANCE: SOPRAVVIVIENZA A 30 GIORNI



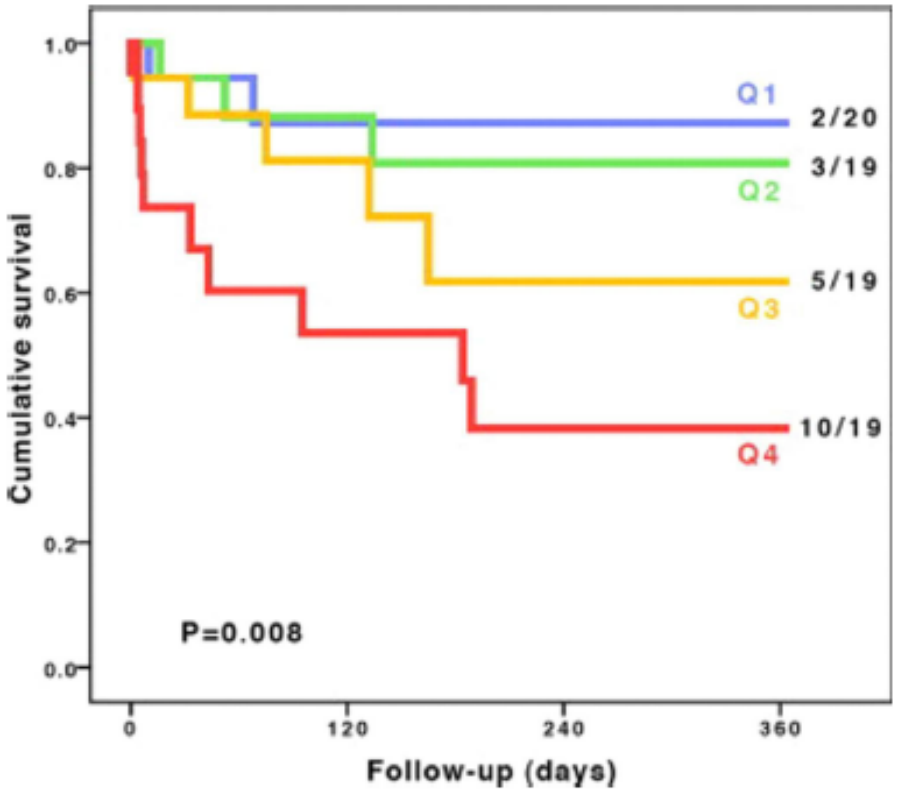
1. Meredith I.T. 12 Month Results from ANZ CoreValve TAV Study. Presented at: TCT 2011. 2. Cribier A. FRANCE II Multicenter TAVR Registry. Presented at: TCT 2011. 3. Bosmans J. Belgian TAVI Registry. Presented at: London Valves 2011. 4. Moat N.E., et al. *JACC*. 2011;58. 5. Petronio AS. Italian Registry. Presented at: EuroPCR 2010.

COREVALVE:SICUREZZA ED EFFICACIA A 2 E 4 ANNI

	18Fr[1] 2 Years, n (n=62)	21Fr[2] 4 Years, n (n=20)
Valve migrations	0 (0)	0 (0)
Reported frame fractures	0 (0)	0 (0)
Structural valve deterioration[a]	0 (0)	0 (0)
Aortic regurgitation (grade >2)	0 (0)	0 (0)

Renal Function and Mortality after TAVI

Sinning et al. (Bonn). JACC Interv 2010;3:1141-9



77 patients with CoreValve

Baseline Creatinine

<1.08 mg/dl

1.08 to 1.24 mg/dl

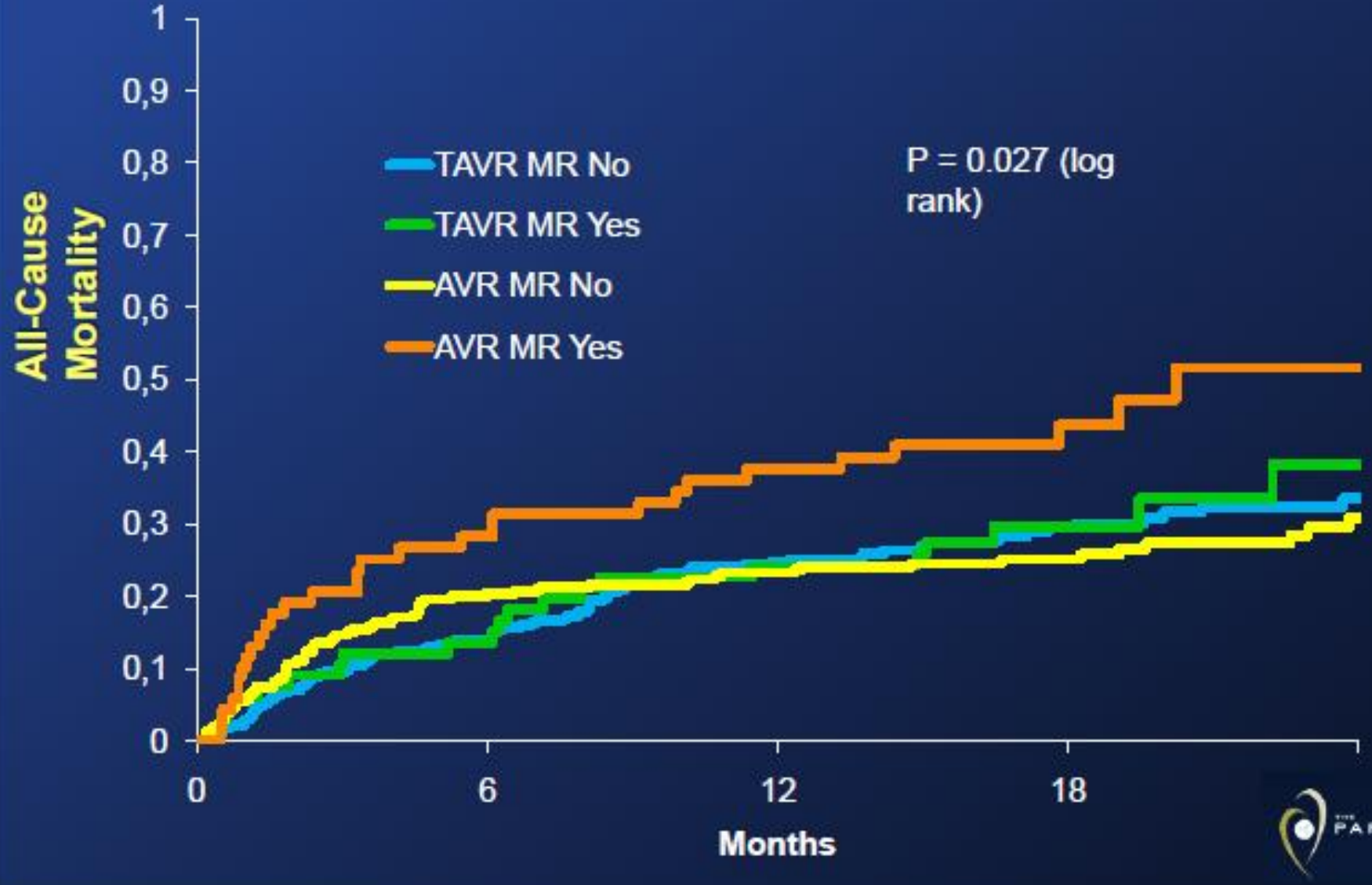
1.25 to 1.57 mg/dl

>1.58 mg/dl

Moderate/Severe MR and Mortality

THE PARTNER TRIAL

1A



THE PARTNER TRIAL

LO STUDIO PARTNER

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 9, 2011 VOL. 364 NO. 23

Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

CONCLUSIONS

In high-risk patients with severe aortic stenosis, transcatheter and surgical procedures for aortic-valve replacement were associated with similar rates of survival at 1 year, although there were important differences in periprocedural risks. (Funded by Edwards Lifesciences; Clinical Trials.gov number, NCT00530894.)

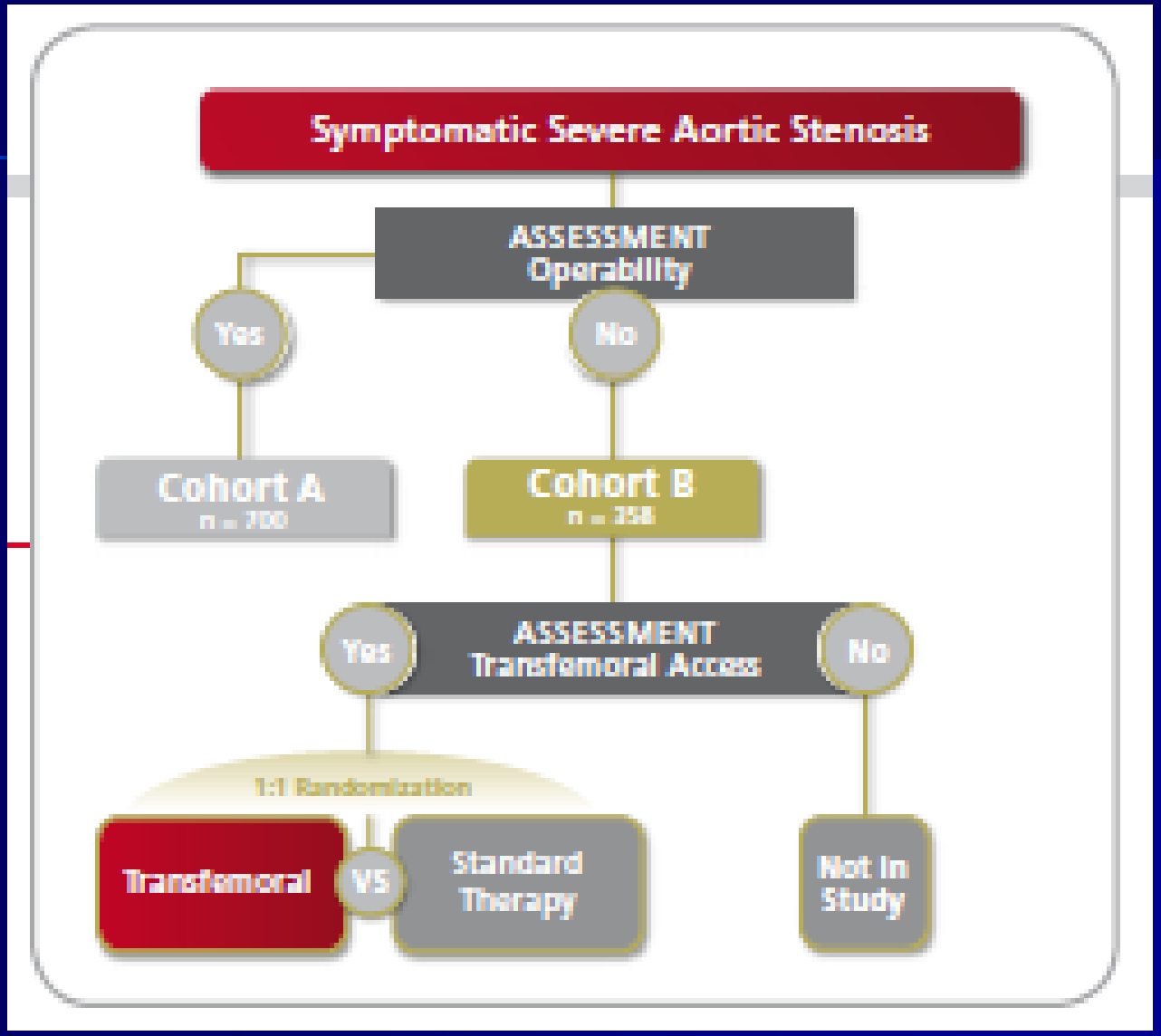

Symptomatic Severe Aortic Stenosis
ASSESSMENT
Operability
Yes
No
Cohort A
n = 700
Cohort B
n = 358
Yes
ASSESSMENT
Transfemoral Access
No
1:1 Randomization
Transfemoral
VS
Standard
Therapy
Not In
Study

Table 2. Clinical Outcomes at 30 Days and 1 Year in the Intention-to-Treat Population.*

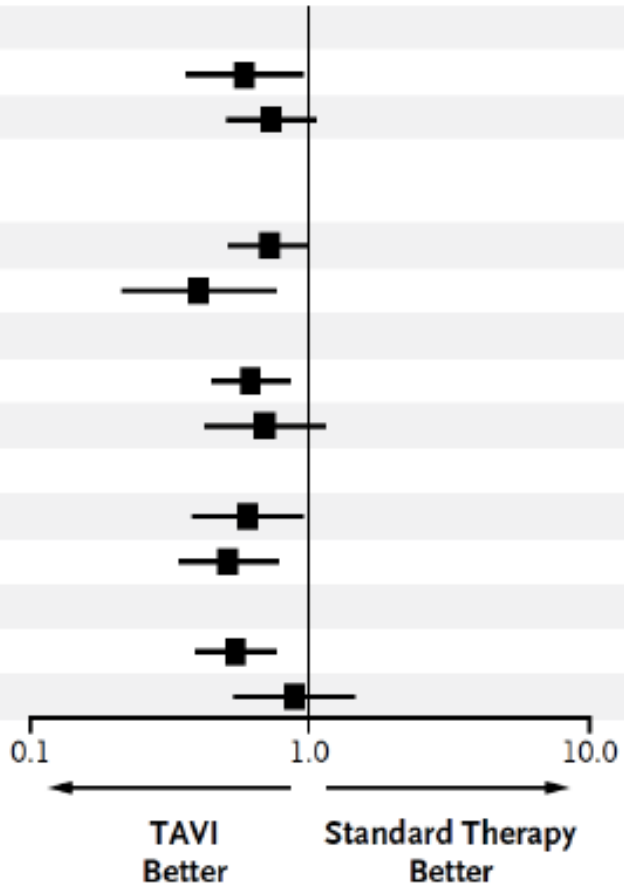
Outcome	30 Days			1 Year		
	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value
	no. of patients (%)			*no. of patients (%)*		
Death						
From any cause	12 (3.4)	22 (6.5)	0.07	84 (24.2)	89 (26.8)	0.44
From cardiac causes	11 (3.2)	10 (3.0)	0.90	47 (14.3)	40 (13.0)	0.63
Repeat hospitalization	15 (4.4)	12 (3.7)	0.64	58 (18.2)	45 (15.5)	0.38
Death or repeat hospitalization	25 (7.2)	33 (9.7)	0.24	120 (34.6)	119 (35.9)	0.73
Stroke or transient ischemic attack						
Either	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
Transient ischemic attack	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
Stroke						
Minor	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84
Major	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07
Death from any cause or major stroke	24 (6.9)	28 (8.2)	0.52	92 (26.5)	93 (28.0)	0.68
Myocardial infarction	0	2 (0.6)	0.16	1 (0.4)	2 (0.6)	0.69
Vascular complication						
Any	59 (17.0)	13 (3.8)	<0.001	62 (18.0)	16 (4.8)	<0.001
Major	38 (11.0)	11 (3.2)	<0.001	39 (11.3)	12 (3.5)	<0.001
Acute kidney injury						
Creatinine >3 mg/dl (265 μmol/liter)	4 (1.2)	4 (1.2)	0.95	12 (3.9)	8 (2.7)	0.41
Renal-replacement therapy	10 (2.9)	10 (3.0)	0.95	18 (5.4)	20 (6.5)	0.56
Major bleeding	32 (9.3)	67 (19.5)	<0.001	49 (14.7)	85 (25.7)	<0.001
Endocarditis	0	1 (0.3)	0.32	2 (0.6)	3 (1.0)	0.63
New-onset atrial fibrillation†	30 (8.6)	56 (16.0)	0.006	42 (12.1)	60 (17.1)	0.07
New pacemaker	13 (3.8)	12 (3.6)	0.89	19 (5.7)	16 (5.0)	0.68

* All percentages are Kaplan–Meier estimates at the specific time point and thus do not equal the number of patients divided by the total number in the study group.
† The presence of new-onset atrial fibrillation was determined in an electrocardiography core laboratory.

Comorbidities and Outcome

Partner 1, Cohort B

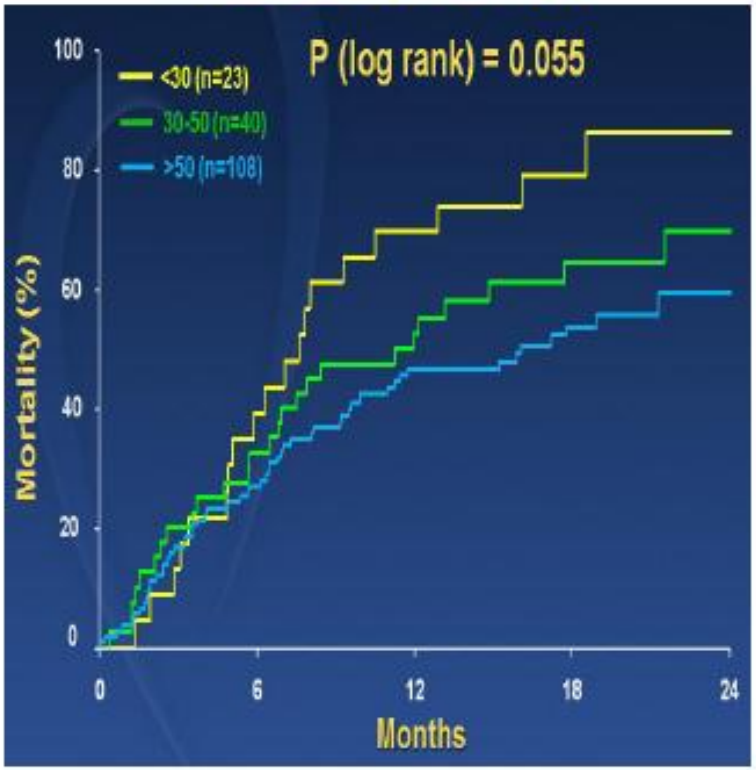
Pulmonary hypertension		
No	18/69 (26.1)	30/66 (45.5)
Yes	29/82 (35.4)	42/85 (49.4)
Moderate or severe mitral regurgitation		
No	43/133 (32.3)	59/127 (46.5)
Yes	9/38 (23.7)	23/38 (60.5)
COPD (oxygen-dependent)		
No	41/141 (29.1)	64/133 (48.1)
Yes	14/38 (36.8)	25/46 (54.3)
Prior CABG or PCI		
No	20/72 (27.8)	32/68 (47.1)
Yes	23/84 (27.4)	50/92 (54.3)
Peripheral vascular disease		
No	35/124 (28.2)	70/134 (52.2)
Yes	20/54 (37.0)	19/45 (42.2)



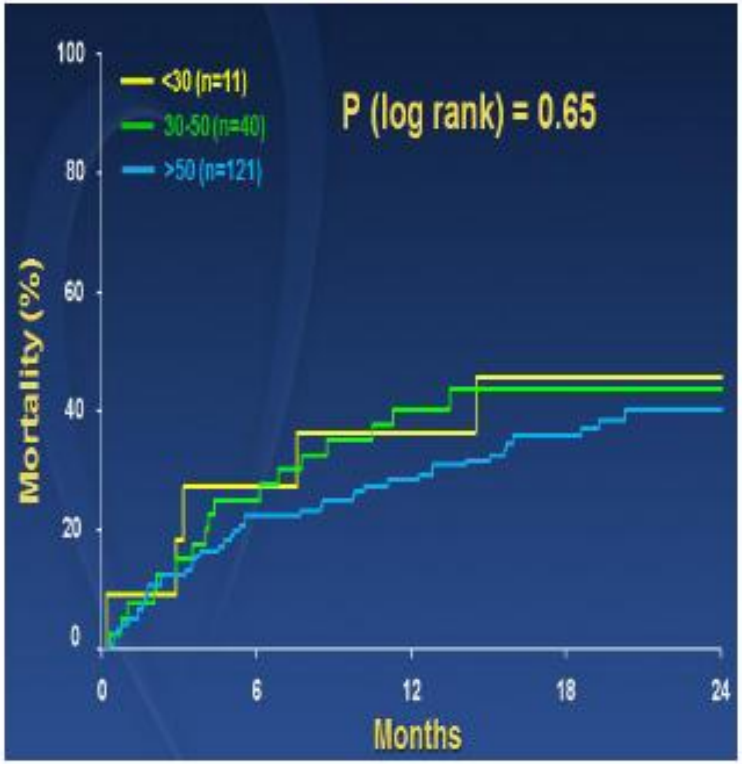
Low EF Patients

Partner 1, Cohort B

Medical Therapy



TAVR



Incidence and Predictors of Early and Late Mortality After Transcatheter Aortic Valve Implantation in 663 Patients With Severe Aortic Stenosis

Corrado Tamburino, MD, PhD; Davide Capodanno, MD; Angelo Ramondo, MD; Anna Sonia Petronio, MD; Federica Ettori, MD; Gennaro Santoro, MD; Silvio Klugmann, MD; Francesco Bedogni, MD; Francesco Maisano, MD; Antonio Marzocchi, MD; Arnaldo Poli, MD; David Antoniucci, MD; Massimo Napodano, MD; Marco De Carlo, MD, PhD; Claudia Fiorina, MD; Gian Paolo Ussia, MD

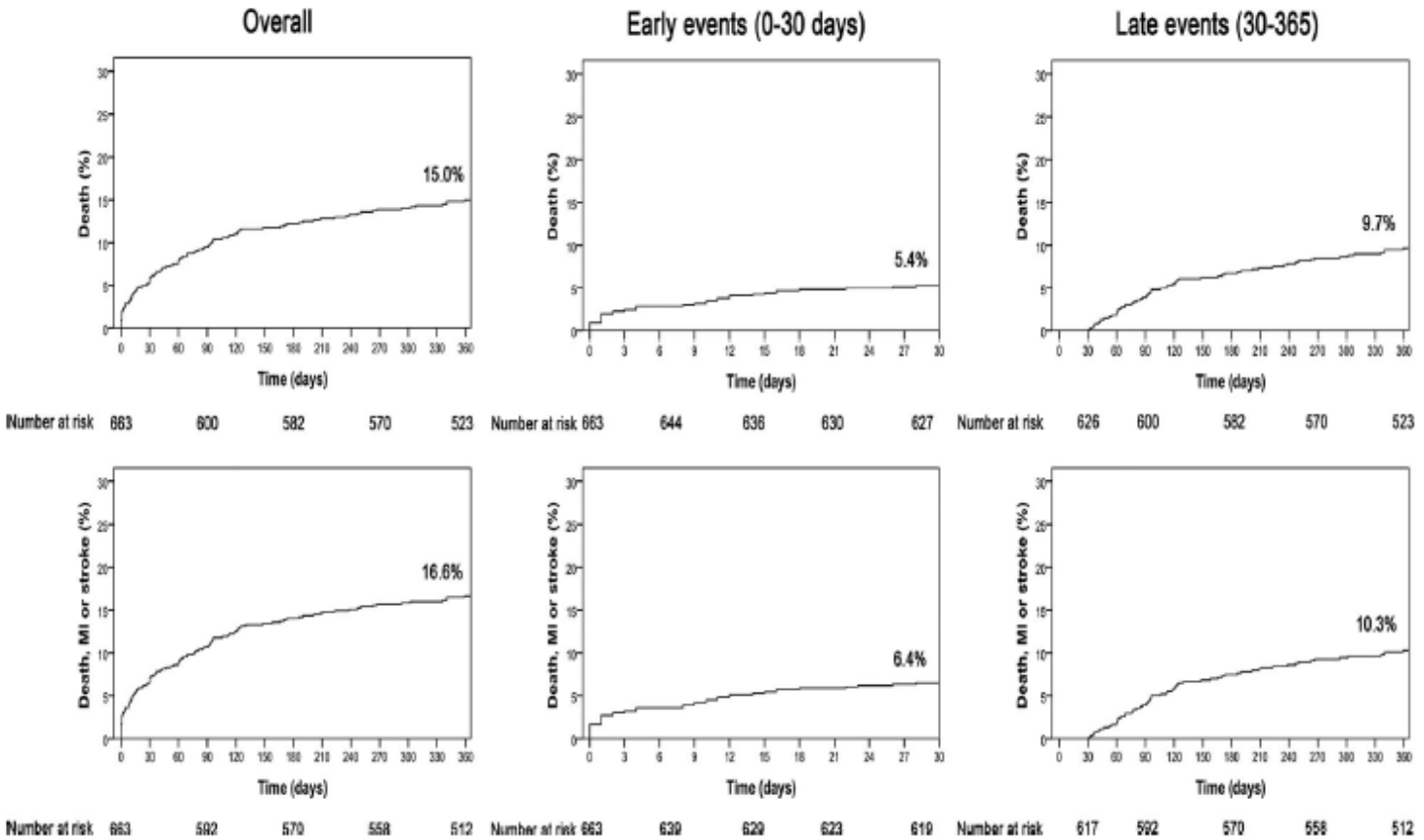


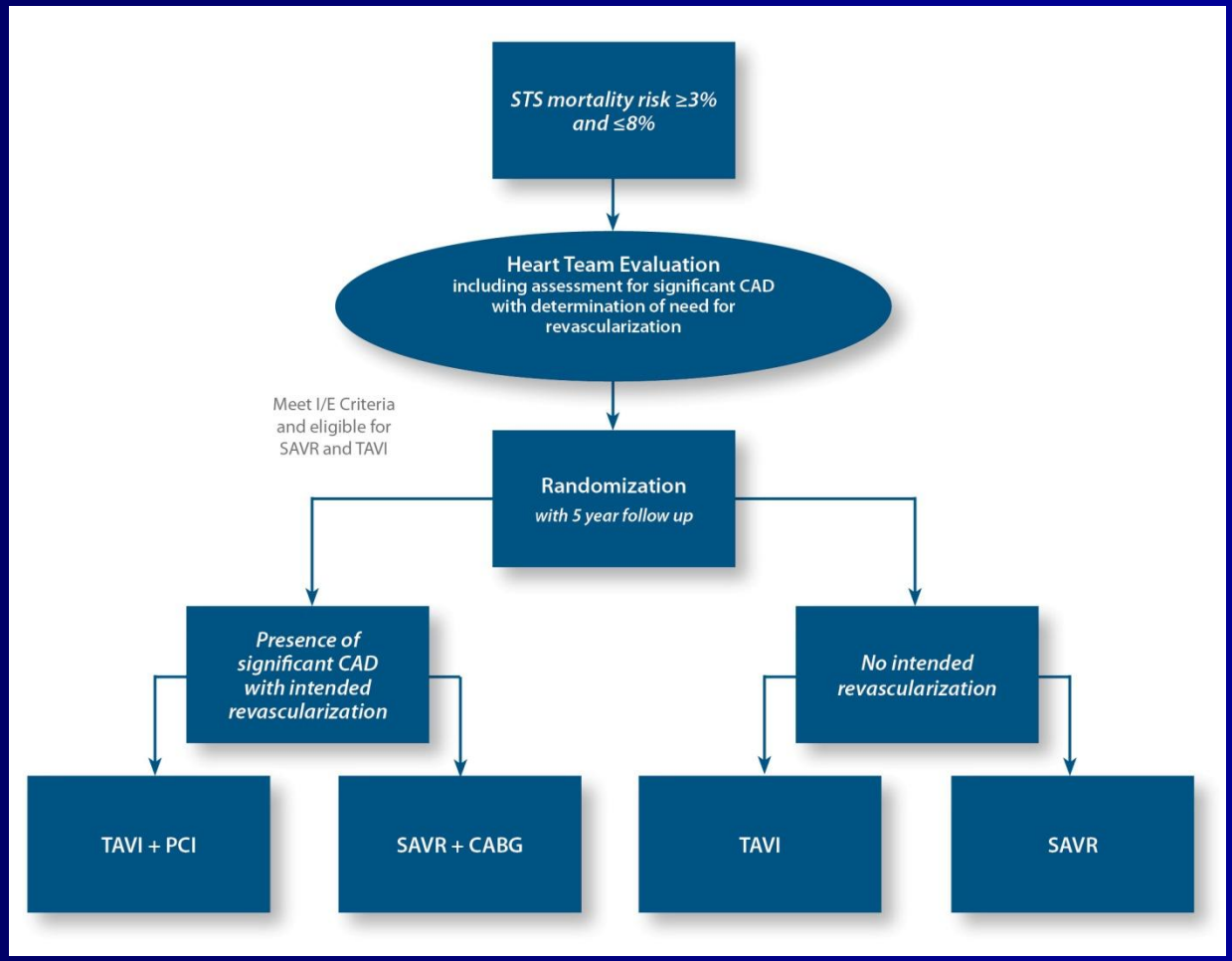
Figure 1. Cumulative incidence of death (upper row) and death, myocardial infarction or stroke (lower row) in the total study population and subdivided into early and late events.

COMPLICANZE POTENZIALI DELLA TAVI

- Morte (da ogni causa o cardiovascolare)
- Infarto miocardicco
- Ictus /TIA
- Necessità di re-intervento (chirurgico o transcatetere)
- Insufficienza aortica
- Necessità di impianto di pacemaker definitivo
- Tamponamento pericaridico
- Complicanze vascolari e sanguinamento
- Migrazione o frattura della valvola

SIAMO PRONTI PER ESTENDERE LE INDICAZIONI? ("TO PUSH THE ENVELOPE?")

LO STUDIO SURTAVI (1800 *PAZIENTI A RISCHIO INTERMEDIO* SEGUITI 5 ANNI)



NON CON LA TECNOLOGIA ATTUALE.

NEL 2012, UN PAZIENTE CHE BIOLOGICAMENTE "SI POSSA PERMETTERE LA CHIRURGIA" HA UNA CHIARA INDICAZIONE ALLA SOSTITUZIONE VALVOLARE AORTICA CHIRURGICA.

LA TAVI PER IL MOMENTO AFFIANCA LA CHIRURGIA CON OTTIMI RISULTATI NEI PAZIENTI AD ALTO RISCHIO.

LA TAVI HA IL VALORE AGGIUNTO DI NON "SOTTRARRE TEMPO" PER IL POST-INTERVENTO E LA RIABILITAZIONE, TEMPO CHE NELL'ANZIANO HA UN "VALORE SPECIFICO"MOLTO ELEVATO.

MA…

…LE NUOVE TECNOLOGIE SONO LETTERALMENTE “DIETRO L’ANGOLO”.

L’INTERVENTISTICA STRUTTURALE CARDIACA NEL CAMPO DELLE VALVULOPATIE PREVEDIBILMENTE AFFIANCHERA’ PRESTO LA CHIRURGIA TRADIZIONALE;

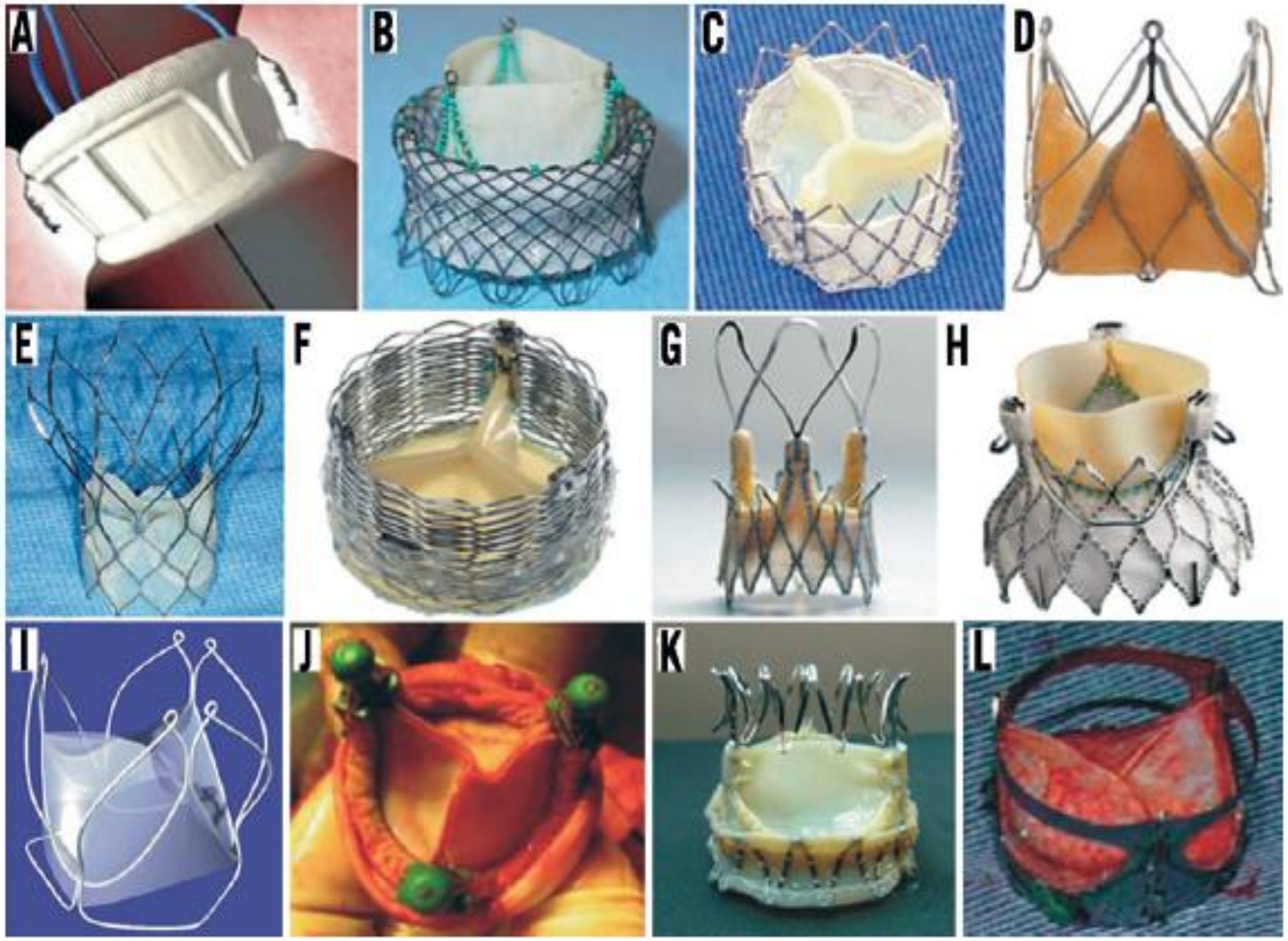
SARA’ “NELLE MANI” DI SPECIALISTI IN TERAPIA TRANSCATETERE (DI DERIVAZIONE CARDIOLOGICA O CARDIOCHIRURGICA) CHE AVRANNO LA CAPACITA’ E LA TECNICA PER POTERLA REALIZZARE.

LA DICOTOMIA CARDIOLOGO/CARDIOCHIRURGO E’ DESTINATA A PERDERE PRESTO LA SUA CARATTERISTICA ANTITETICA.

CARATTERISTICHE DESIDERABILI DELLE NUOVE VALVOLE

- Accuratezza del posizionamento
- Piccole dimensioni del delivery
- Riposizionabilità
- Minimizzazione della insufficienza aortica
- Posizione annulare (pacemaker)
- Durabilità

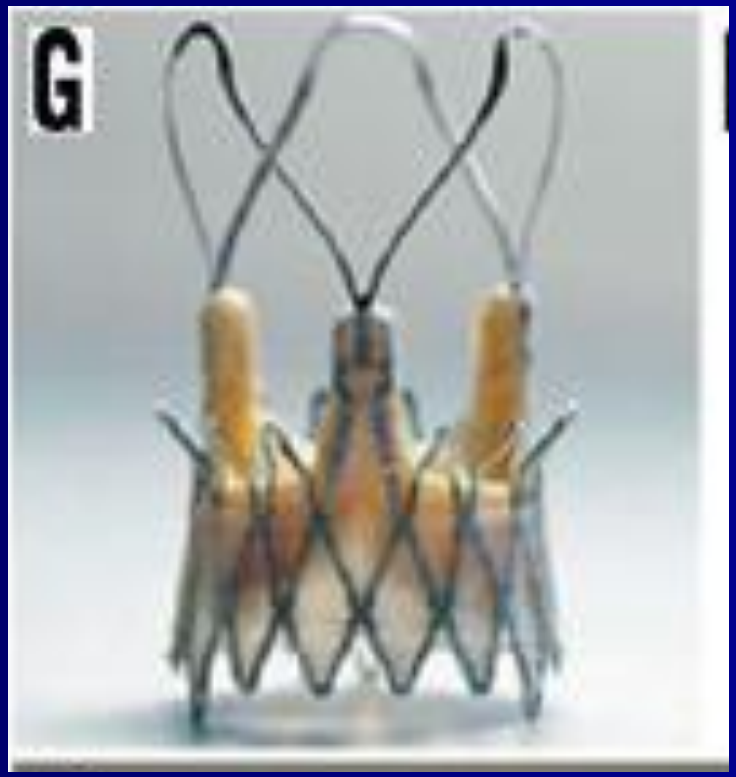
VALVOLE IN VALUTAZIONE CLINICA NELL'UOMO



SADRA LOTUS VALVE

DIRECT FLOW VALVE

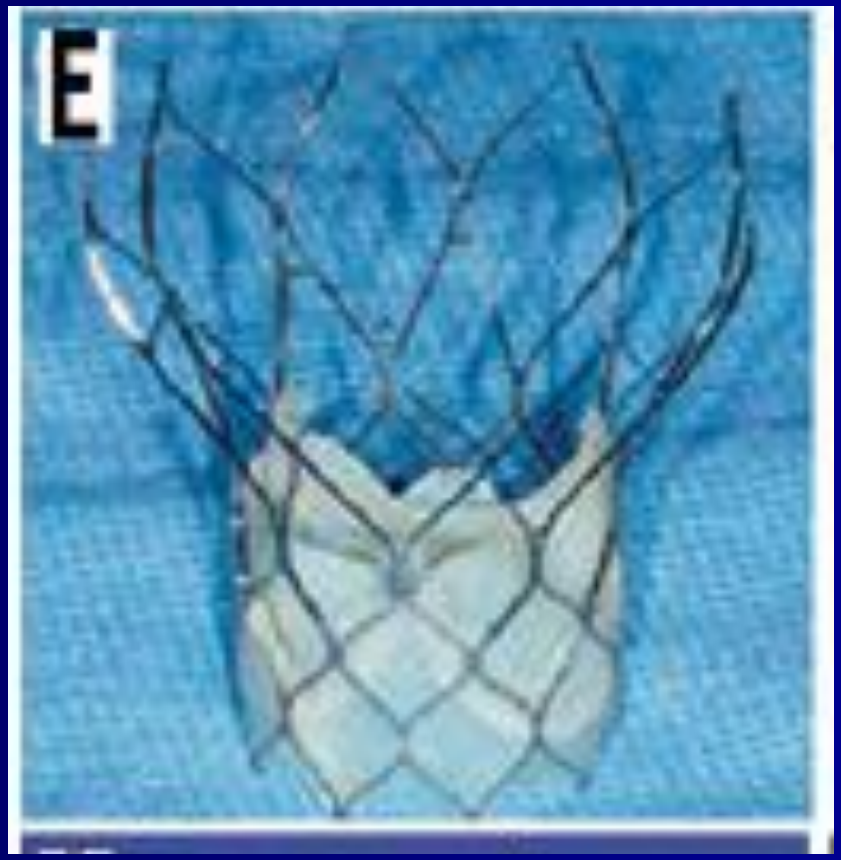
ACURATE VALVE



JENA VALVE

ENGAGER VALVE

PORTICO VALVE



DISPOSITIVI DI PROTEZIONE EMBOLICA

GRAZIE PER L'ATTENZIONE!