Role of Surgical AVR in TAVR era :

A Viewpoint from Korean Cardiac Surgeon

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Life expectancy at birth (years), UN World Population Prospects (2015)

Country	Overall rank	Overall life expectancy	Female rank	Female life expectancy	Male rank	Male life expectancy
Japan	1	84	1	87	6	80
Spain	2	83	2	86	6	80
Switzerland	2	83	4	85	2	81
Australia	2	83	4	85	6	80
Italy	2	83	4	85	6	80
France	9	82	4	85	16	79
Republic of Korea	9	82	4	85	27	78
Canada	9	82	11	84	6	80
Germany	20	81	25	83	16	79
United Kingdom	20	81	25	83	16	79
Chile	29	80	25	83	34	77
United States of America	34	79	36	81	39	76
Turkey	68	75	53	79	71	72
China	68	75	88	77	50	74

Aortic Stenosis in Korea

- Only national medical insurance
- Sometimes refuse operation due to medical cost
- Still low incidence of associated coronary disease
- Very few cases of AS surgery in previous CABG or AVR
- Relatively high incidence of bicuspid AS
- Combined rheumatic component with degenerative AS
- Higher medical cost of TAVI than surgical AVR
    (patient's burden: 24000 US$ vs 9000 US$)

Primary AVR for AS in SMC

- 1995 Jan. ~ 2013 Dec.
- 753 pts : severe AS referred for AVR
    AVR :   665 pts (88.3%)
    AVR+CABG: 88 pts (11.7%)
- Exclusion criteria
    main CAD with AS (58 pts)
    previous cardiac surgery (3 pts)
    rheumatic AS (22 pts)

Mechanical vs Tissue valve in AS
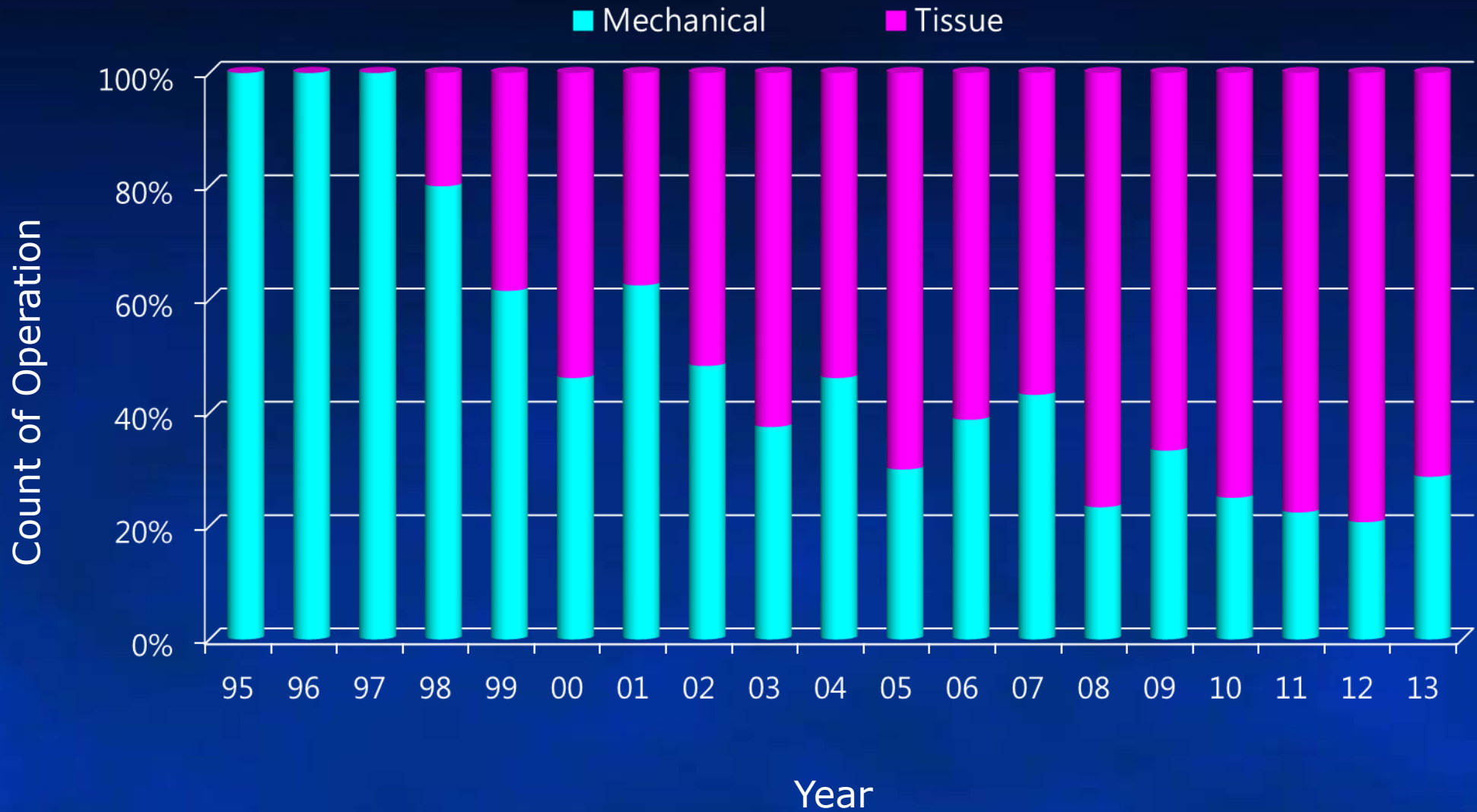
Incidence of Bicuspid Valve

■ **Tricuspid**　■ **Bicuspid**　(SMC, N=559)

Count of Operation

Age	Value
~49	83%
50~59	79%
60~69	60%
70~79	43%
80~	17%

Age
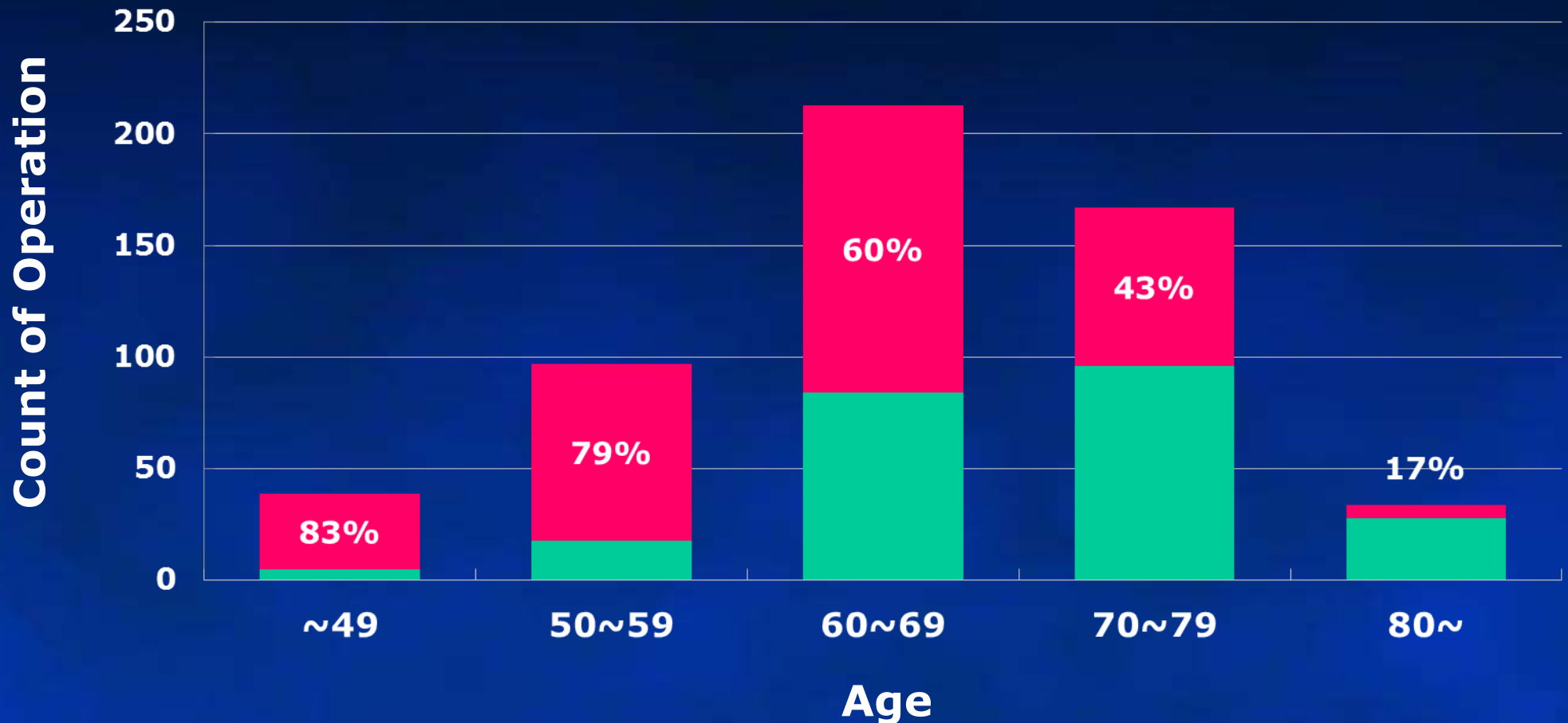
Aortic Valve Replacement With Carpentier-Edwards: Hemodynamic Outcomes for the 19-mm Valve

Ji Hoon You, MD, PhD,* Dong Seop Jeong, MD, PhD,* Kiick Sung, MD, PhD, Wook Sung Kim, MD, PhD, K. C. Carriere, PhD, Young Tak Lee, MD, PhD, and Pyo Won Park, MD, PhD

- 1998 Jan. ~ 2013 Dec.
- 447 pts CE AVR: severe AS referred for AVR
- Mean age : 71.9±6.5 (33-90 yr)
  - <60   1.3 % (n=6)
  - 60-70   35.8 % (n=160)
  - 70-80   49.9 % (n=223)
  - > 80   13.0 % (n=58)
- Implanted valve
  19mm (54), 21mm (154), >21mm (239)

Serial Changes of Echo data according to valve size

	19mm (n=54)	21mm (n=154)	23-27mm(n=239)	p
TMPG				
preoperative	64.3±20.6	60.7±20.1	57.2±18.8	0.032
At discharge	16.4±5.6	14.6±4.7	12.2±4.0	<0.001
At 1yr	14.8±5.0	13.1±4.1	10.6±3.4	<0.001
At 5yr	14.5±6.7	14.2±5.7	10.9±5.4	0.006
LVMI				
preoperative	143.6±41.6	143.1±37.4	148.1±45.1	0.477
At discharge	136.0±44.3	129.3±37.1	135.2±35.9	0.287
At 1yr	108.5±33.7	107.4±33.0	108.3±29.0	0.963
At 5yr	88.8±28.2	98.2±25.7	99.5±27.7	0.486
EOAI at 1yr	0.95±0.20	1.00±0.23	1.11±0.23	<0.001
PPM (EOAI<0.85)	14/35(40.0%)	30/113(26.5%)	18/183(9.8%)	<0.001
Moderate PPM	14	25	17	
Severe PPM	0	5	1	

Late Outcomes According to Implanted Valve Size
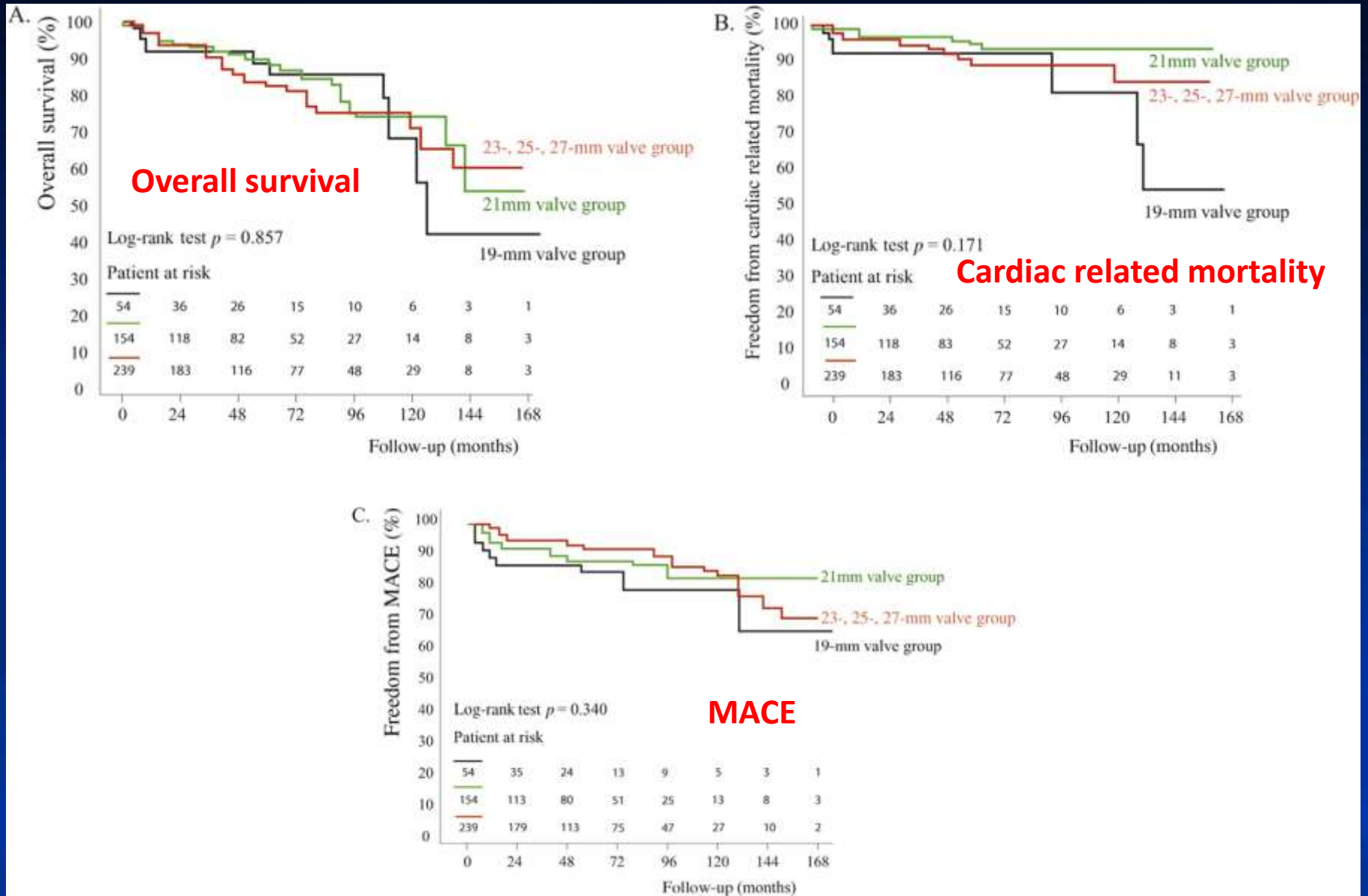
Serial Changes of TMPG & LVMI according to PPM

	No PPM (n=269)	PPM (n=62)	p
TMPG			
preoperative	59.5±20.0	57.5±18.7	0.480
At discharge	13.0±4.3	15.7±5.7	0.001
At 1yr	11.0±3.6	13.9±4.5	<0.001
At 5yr	11.5±6.1	13.2±4.7	0.204
LVMI			
preoperative	143.6±40.9	147.3±45.2	0.555
At discharge	131.9±35.7	134.7±43.1	0.369
At 1yr	105.3±28.0	110.8±35.4	0.256
At 5yr	97.6±26.5	88.5±18.0	0.143

PPM : moderate (15%) (EOAI < 0.85) , severe (2%) (EOAI < 0.65)
by measured EOAI at I year F-U (80% data available)

Late Outcomes According to PPM

A. **Overall Survival** — Overall survival (%) vs Follow-up (months). No patient–prosthesis mismatch. Patient–prosthesis mismatch. Log-rank test $p = 0.620$. Patient at risk: 269, 193, 108, 55, 22, 7 / 62, 54, 43, 24, 10, 1.

B. **Cardiac related mortality** — Freedom from cardiac related mortality (%) vs Follow-up (months). No patient–prosthesis mismatch. Patient–prosthesis mismatch. Log-rank test $p = 0.154$. Patient at risk: 269, 193, 108, 55, 22, 7 / 62, 54, 43, 24, 10, 1.

C. **MACE** — Freedom from MACE (%) vs Follow-up (months). Patient–prosthesis mismatch. No patient–prosthesis mismatch. Log-rank test $p = 0.840$. Patient at risk: 269, 187, 104, 53, 20, 7 / 62, 52, 40, 23, 10, 1.

Patient Characteristics According to Age group

Variables	Age 60-69 (n=160)	Age 70-79 (n=223)	Age 80-89 (n=58)	p value
Age, y	66.1±2.5	74.0±2.8	82.3±2.0	<0.001
Female gender, n (%)	59(36.9)	103(46.2)	30(51.7)	0.078
Hypertension, n (%)	71(44.4)	133(59.6)	40(69.0)	0.001
Diabetes mellitus, n (%)	36(22.5)	74(33.2)	19(32.8)	0.063
Coronary artery disease, n (%)	30(18.8)	44(19.7)	15(25.9)	0.498
Cerebrovascular disease, n (%)	12(7.5)	17(7.6)	7(12.1)	0.506
Chronic kidney disease, n (%)	25(15.6)	50(22.4)	25(43.1)	<0.001
Anemia	8(5.0)	20(9.0)	8(13.8)	0.092
Atrial fibrillation, n (%)	16(10.0)	26(11.7)	14(24.1)	0.017
NYHA class, *III- IV* n(%)	29(18.1)	66(29.6)	23(39.7)	0.003
LVEF <40%	14(8.8)	17(7.6)	10(17.2)	0.077
BSA	1.67±0.16	1.60±0.17	1.53±0.18	<0.001
Euro score	5.29±1.97	7.14±2.16	9.98±2.26	<0.001
Logistic mean EURO score(%)	5.20±5.31	8.99±9.54	18.74±13.44	<0.001
Aortic valve area	0.73±0.19	0.69±0.17	0.64±0.17	0.022

Unpublished data, SMC

Operative data According to Age Group

Concomitant surgery, n(%)	Age 60-69 (n=160)	Age 70-79 (n=223)	Age 80-89 (n=58)	p value
Ascending Ao wrapping	32(20.0)	29(13.0)	2(3.4)	0.006
Ascending Ao replacement	11(6.9)	21(9.4)	9(15.5)	0.151
Root widening	2(1.3)	3(1.3)	0(0)	0.679
MR repair	8(5.0)	9(4.0)	2(3.4)	0.848
TR repair	6(3.8)	12(5.4)	3(5.2)	0.752
Subaortic myectomy	21(13.1)	27(12.1)	5(8.6)	0.664
Maze	11(6.9)	17(7.6)	6(10.3)	0.696
CABG	24(15.0)	37(16.6)	10(17.2)	0.887

Unpublished data, SMC

Early Outcomes According to Age Group

Variables	Age 60-69 (n=160)	Age 70-79 (n=223)	Age 80-89 (n=58)	p value
Early mortality,%	0(0)	1(0.4)	2(3.4)	0.020
Early morbidity, n(%)				
Paravalvular leakage	1(0.6)	1(0.4)	0(0)	0.832
Bleeding (reoperation)	6(3.8)	2(0.9)	2(3.4)	0.146
New onset heart block	0(0)	3(1.3)	3(5.2)	0.014
Cerebral infarction	1(0.6)	7(3.1)	2(3.4)	0.215
Cerebral hemorrhage	0(0)	2(0.9)	1(1.7)	0.335
AKI requiring dialysis	2(1.3)	1(0.4)	2(3.4)	0.155

Unpublished data, SMC

Late Clinical Outcomes of CE AVR

Overall Survival of according to age

		5yr	10yr
—	60-70	94.1±2.2	86.6±4.2
—	70-80	86.3±2.9	73.8±6.2
—	>80	74.7±11.3	

Freedom from SVD

5 yr   100%
10 yr 100%

Freedom from endocarditis

5 yr   99.7%
10 yr 97.4%
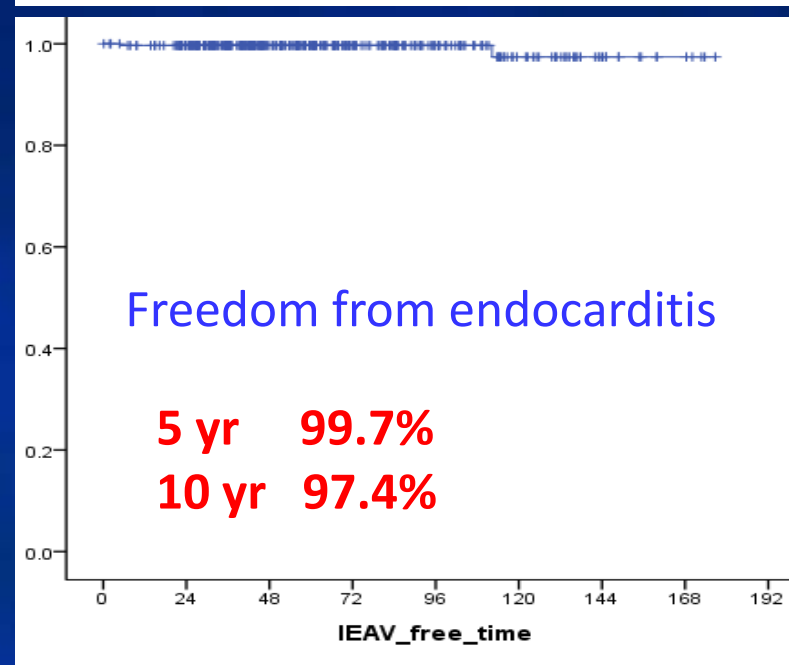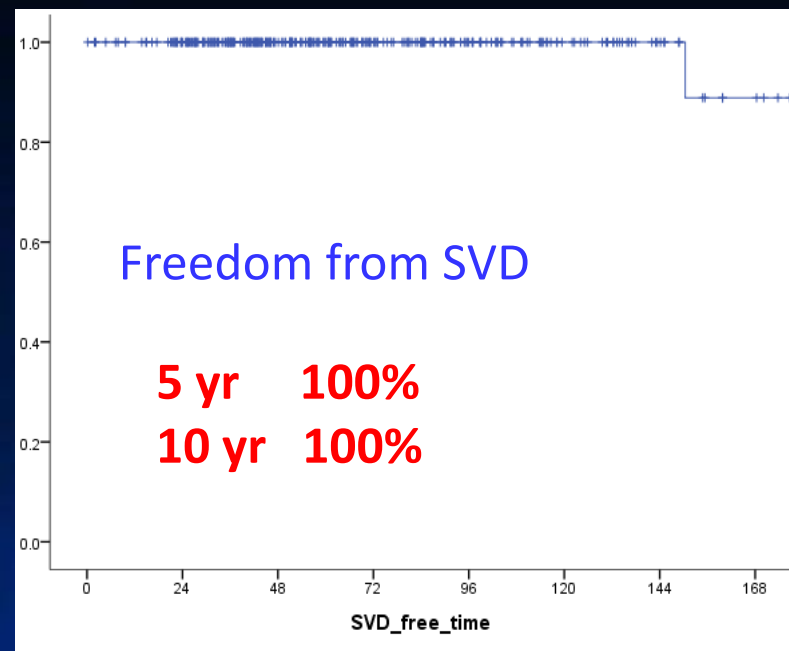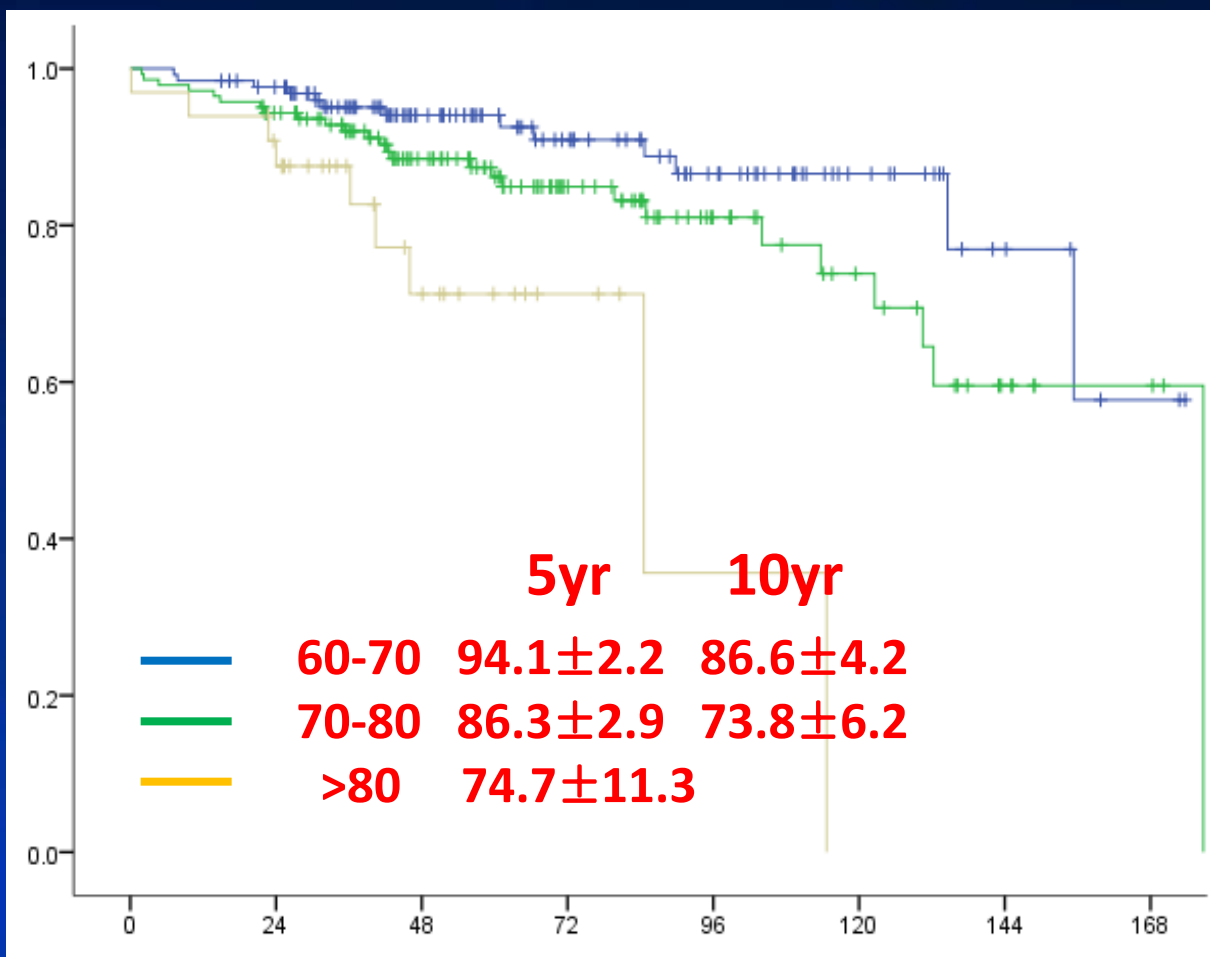
Ascending Aorta Replacement under Circulatory Arrest for Severe Aortic Calcification in Patients with AS

- Presented 2015 EACTS meeting
- 2004-2014, Samsung Medical center
- 32 patients underwent primary AVR with AAR under arrest
- Mean age: 74 years (59-87)
  Octogenarian (n=7,22%)
- Logistic EuroSCORE: 21+19%(3.3-68%)
- Results: no early mortality
   no paravavular leakage, 1 TIA
- 5 year survival
   AVR+AAR 83%
   AVR 86%
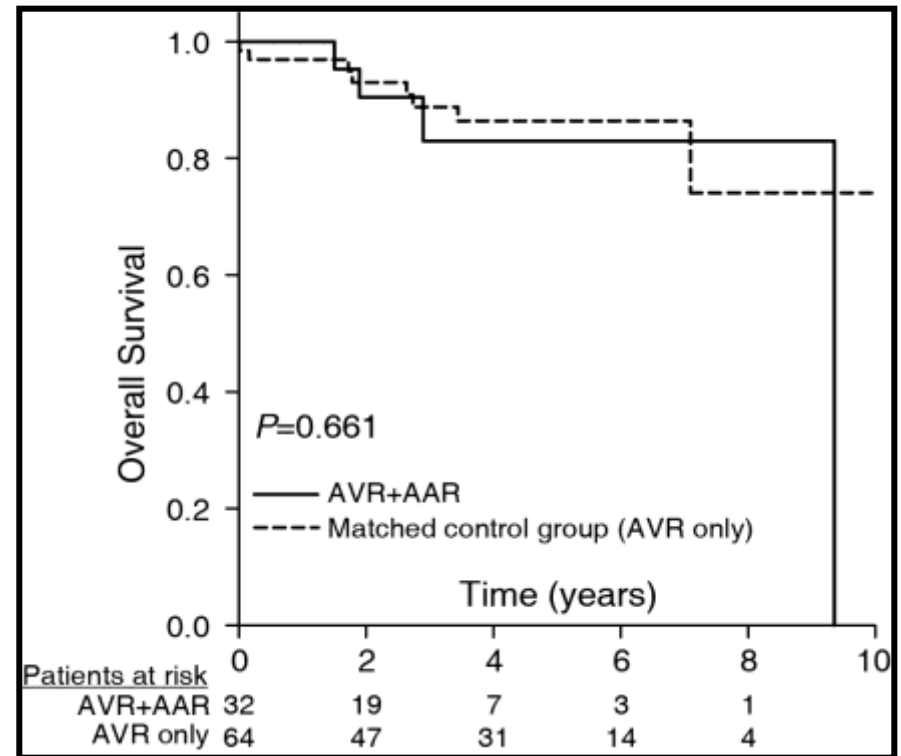
1:2 matching with age, sex, coronary disease, atrial fibrillation and NYHA Fc

Case
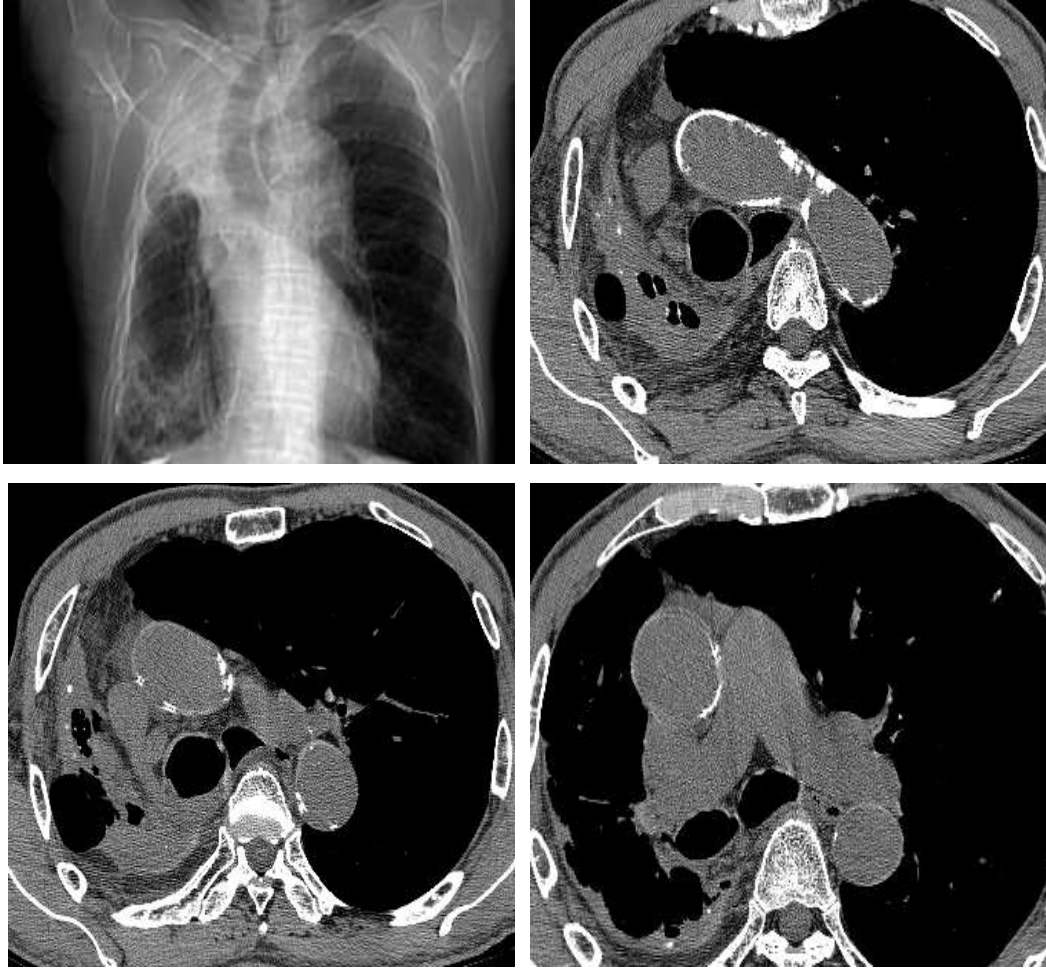
- **Rt destroyed lung due to tuberculosis**

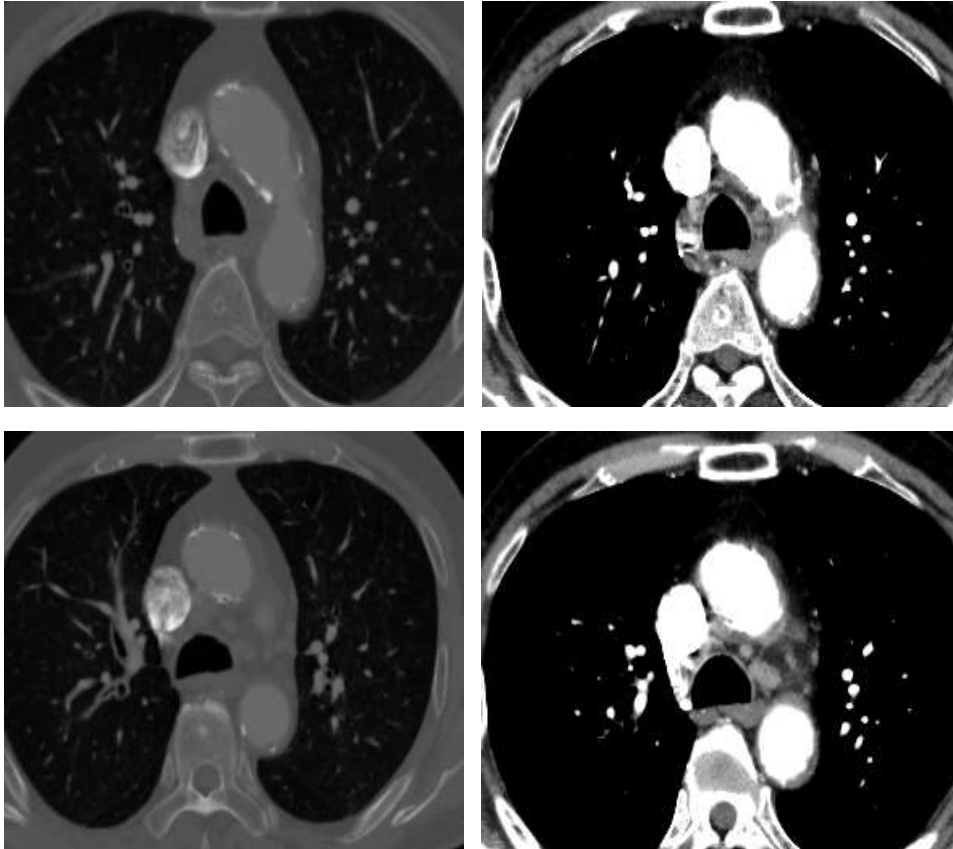- **85 yrs (2008)**

  Rt axillary artery cannulation

  Distal aorta endartherectomy

- **Uneventul hospital course**

  discharge (pop # 8)

- **92 yrs (2015) ; still visiting clinic**

Complicated case

- 87 yrs, male with severe AS, coronary HD, Af, DM, renal dysfunction, LVEF 25%, logistic EuroSCORE 68

- 2011 Mar: Waiting list on transapical TAVI family refused TAVI after accident in other patient with transapical TAVI

- 2012 Jan: Em op. for HF & no urine results: no neurologic Cx, ARF recovered after CRRT, prolonged ICU stay (107days)

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients
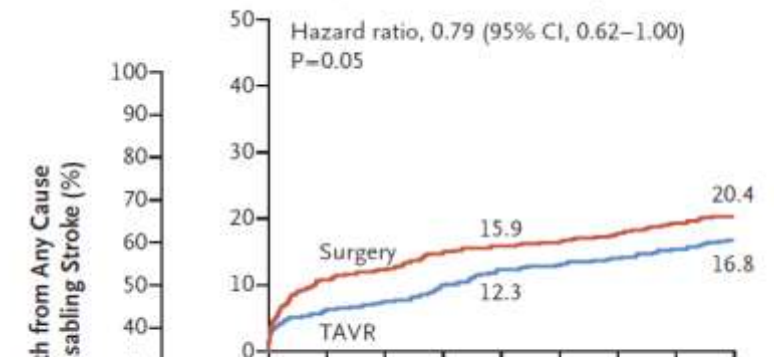
BACKGROUND

Previous trials have shown that among high-risk patients with aortic stenosis, survival rates are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. We evaluated the two procedures in a randomized trial involving intermediate-risk patients.

METHODS

We randomly assigned 2032 intermediate-risk patients with severe aortic stenosis, at 57 centers, to undergo either TAVR or surgical replacement. The primary end point was death from any cause or disabling stroke at 2 years. The primary hypothesis was that TAVR would

C Transfemoral-Access Cohort, Intention-to-Treat Analysis

Hazard ratio, 0.79 (95% CI, 0.62–1.00)
P=0.05

20.4
15.9
Surgery
16.8
12.3
TAVR

Months since Procedure

No. at Risk

TAVR	775	718	709	685	663	652	644	634	612
Surgery	775	643	628	604	595	577	569	557	538

> **In the transfemoral access cohort, TAVR results in a lower rate of death or disablling stroke than surgery (hazard ratio, 0.79: P=0.05)**

the surgery group (P=0.001 for noninferiority). At 2 years, the Kaplan–Meier event rates were 19.3% in the TAVR group and 21.1% in the surgery group (hazard ratio in the TAVR group, 0.89; 95% confidence interval [CI], 0.73 to 1.09; P=0.25). In the transfemoral-access cohort, TAVR resulted in a lower rate of death or disabling stroke than surgery (hazard ratio, 0.79; 95% CI, 0.62 to 1.00; P=0.05), whereas in the transthoracic-access cohort, outcomes were similar in the two groups. TAVR resulted in larger aortic-valve areas than did surgery and also resulted in lower rates of acute kidney injury, severe bleeding, and new-onset atrial fibrillation; surgery resulted in fewer major vascular complications and less paravalvular aortic regurgitation.

CONCLUSIONS

In intermediate-risk patients, TAVR was similar to surgical aortic-valve replacement with respect to the primary end point of death or disabling stroke. (Funded by Edwards Life-sciences; PARTNER 2 ClinicalTrials.gov number, NCT01314313.)

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Table S3. Baseline characteristics of the patients (transfemoral cohort and transthoracic cohort)

Supplement data

Characteristic	TAVR	Surgery
Transfemoral Cohort	**(N = 775)**	**(N = 775)**
Age – years	81.8 ± 6.7	82.1 ± 6.6
Male sex – no./total no. (%)	426/775 (55.0)	431/775 (55.6)
Body mass index – kg/m² *	28.9 ± 6.3	28.3 ± 6.4
Society of Thoracic Surgeons score†	5.8 ± 2.1	5.7 ± 1.8
New York Heart Association class III or IV – no./total no. (%)	601/775 (77.5)	577/774 (74.5)
Coronary artery disease – no./total no. (%)	531/775 (68.5)	509/775 (65.7)
Previous myocardial infarction – no./total no. (%)	137/775 (17.7)	123/775 (15.9)
Previous CABG – no./total no. (%)	179/775 (23.1)	171/775 (22.1)
Previous PCI – no./total no. (%)	202/775 (26.1)	193/775 (24.9)
Previous balloon aortic valvuloplasty – no./total no. (%)	35/775 (4.5)	30/775 (3.9)
Cerebral vascular disease – no./total no. (%)	167/775 (21.5)	202/775 (26.1)
Peripheral vascular disease – no./total no. (%)*	221/775 (28.5)	215/775 (27.7)
Diabetes mellitus – no./total no. (%)	282/775 (36.4)	258/775 (33.3)
COPD – no./total no. (%)		
Any	228/775 (29.4)	195/775 (25.2)
Oxygen-dependent	20/228 (8.8)	21/195 (10.8)
Creatinine level >2 mg/dL (177 µmol/L) – no./total no. (%)	39/775 (5.0)	40/775 (5.2)
Atrial fibrillation – no./total no. (%)*	245/775 (31.6)	291/775 (37.5)
Permanent pacemaker – no./total no. (%)	91/775 (11.7)	98/775 (12.6)
Frail condition – no./total no. (%)		
15 ft walk test time > 7 secs	325/718 (45.3)	321/686 (46.8)
Serum albumin < 3.5 g/dL	112/754 (14.9)	108/725 (14.9)
Liver disease – no./total no. (%)	14/775 (1.8)	23/775 (3.0)

Table S7. Multivariable predictors of death

	TAVR	
Previous CABG	0.55 (0.37, 0.83)	0.005
Previous MI	2.11 (1.49, 2.99)	<0.001
STS Risk Score	1.09 (1.03, 1.16)	0.005
Atrial Fibrillation	1.57 (1.15, 2.14)	0.005
Not Transfemoral	1.87 (1.36, 2.58)	<0.001
BMI at Baseline (kg/m2)	0.97 (0.94, 1.00)	0.03
Renal insufficiency (Cr greater than or equal to 2.0)	1.92 (1.13, 3.25)	0.02
SURGERY		
Albumin < 3.5 g/dL	1.87 (1.31, 2.67)	<0.001
Atrial Fibrillation	1.61 (1.19, 2.17)	0.002
STS Risk Score	1.11 (1.03, 1.19)	0.005

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Baseline Characteristics of Transfemoral TAVR and SAVR

Characteristics	TF TAVR(n=775)	Surgery(n=775)	p
Age	81.8±6.7	82.1±6.6	NA
Body mass index	28.9±6.3	28.3±6.4	**< 0.05**
STS score	5.8±2.1	5.7±1.8	NA
Previous MI	137/775(17.7)	123/775(15.9)	0.341
Previous CABG	179/775(23.1)	171/775(22.1)	0.627
Cerebral vascular disease	167/775(21.5)	202/775(26.1)	**0.037**
Creatinine>2 mg/dL	39/775(5.0)	40/775(5.2)	0.908
Atrial fibrillation	245/775(31.6)	291/775(37.5)	**0.014**
Liver disease	14/775(1.8)	23/775(3.0)	0.134

P value was calculated by SMC statistician

Interpretation of TF TAVR vs SAVR with CoreValve in intermediate risks

- Different risk factors even RCT

- Higher incidence of risk factor in SAVR

- No description on screening test (CT) & concomitant CABG or PCI

- Study design include previous CABG (23%)

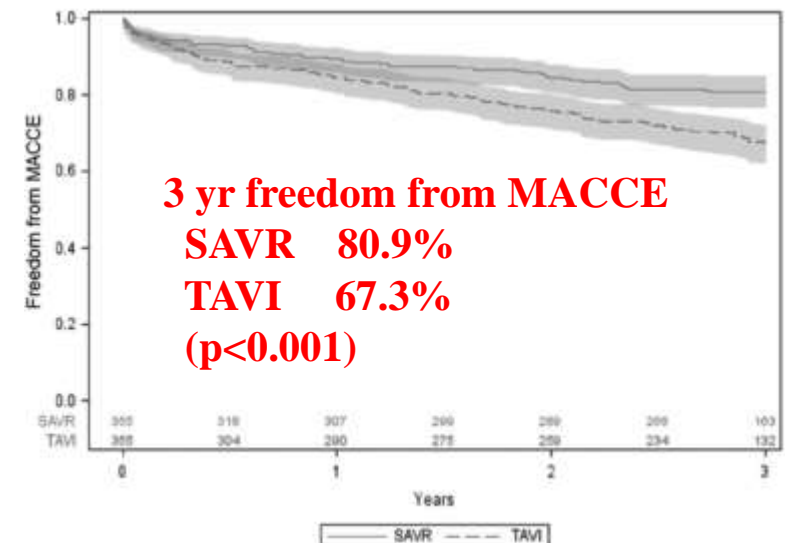# Transcatheter Aortic Valve Implantation Compared With Surgical Aortic Valve Replacement in Low-Risk Patients
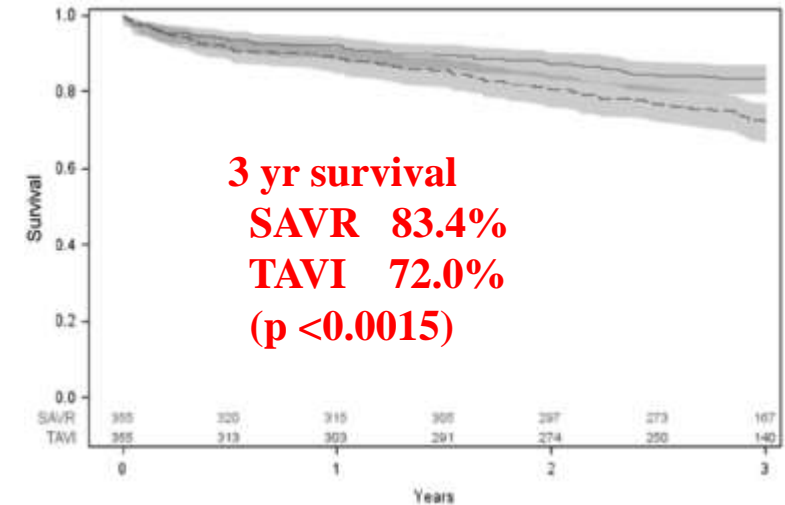
- Italian OBSERVANT research group
- Fund from Italian Ministry of Health
- From Dec. 2010 to Jun 2012
- Low risk pts (EuroSCORE II <4%)
- 355 pairs of TAVI or SAVR after matching
- Mean age: 80.1 years
- Previous cardiac surgery: 1.9%
- Exclusion: porcelain aorta, endocarditis, O2 therapy, combined procedure (coronary or other valve), emergency op.
- Results

  3 yr survival: 83.4% SAVR 72.o% TAVI (p=0.0015)

  3 yr freedom from major adverse cardiac & cerebrovascular events 80.9% vs 67.3% (p <0.001)

3 yr survival
SAVR   83.4%
TAVI   72.0%
(p <0.0015)

3 yr freedom from MACCE
SAVR   80.9%
TAVI   67.3%
(p<0.001)

SAVR ———   TAVI - - - -

Early and Midterm Outcome of Propensity-Matched Intermediate-Risk Patients Aged ≥80 Years With Aortic Stenosis Undergoing Surgical or Transcatheter Aortic Valve Replacement (from the Italian Multicenter OBSERVANT Study)

CrossMark

Fraccaro C, Am J Cardiol 2016;117:1494

- Italian OBSERVANT research group
- From Dec. 2010 to Jun 2012
- Intermediate risk pts
- 415 pairs of TAVI or SAVR after matching
- Mean age: 83.7 years
- Previous cardiac surgery: 5.1%
- Exclusion: porcelain aorta, hostile thorax, need for coronary artery bypass, emergency op.
- No differences in survival & MACE
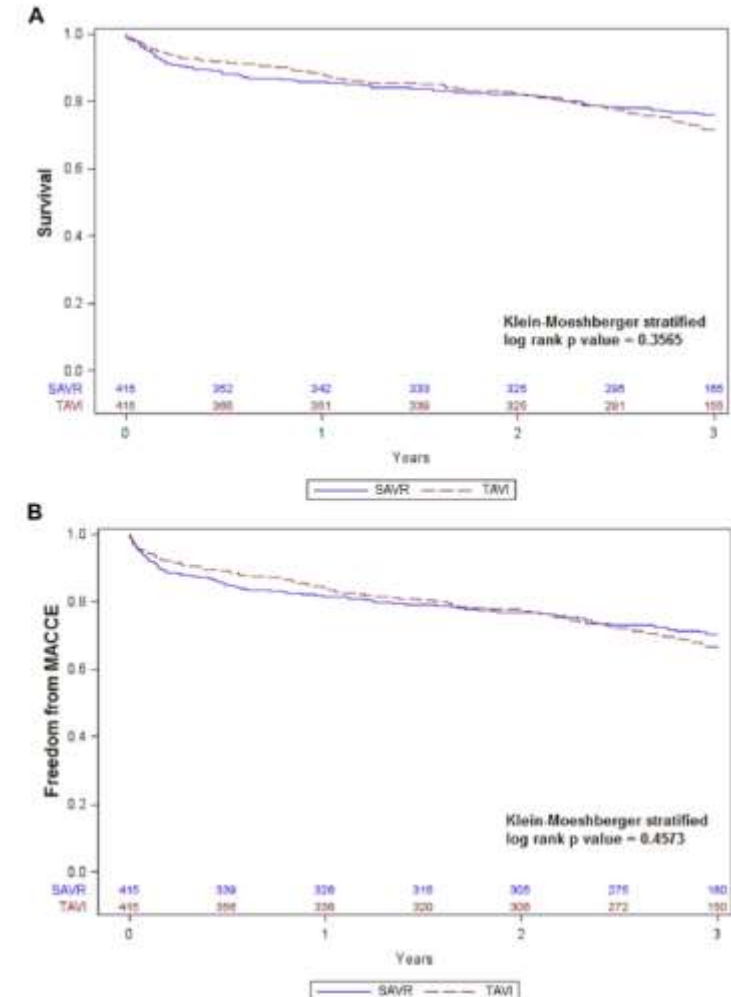
5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

- Lancet 2015;385:2477
- PARTNER I RCT study
- 348 TAVR vs 351 SAVR
- Mean STS score: 11.7%
- 5 yr survival: TAVR 67.8% SAVR 62.4%(P=0.76)
- No SVD requiring reoperation in either group

Mean valve area

LVMI

Mean gradients
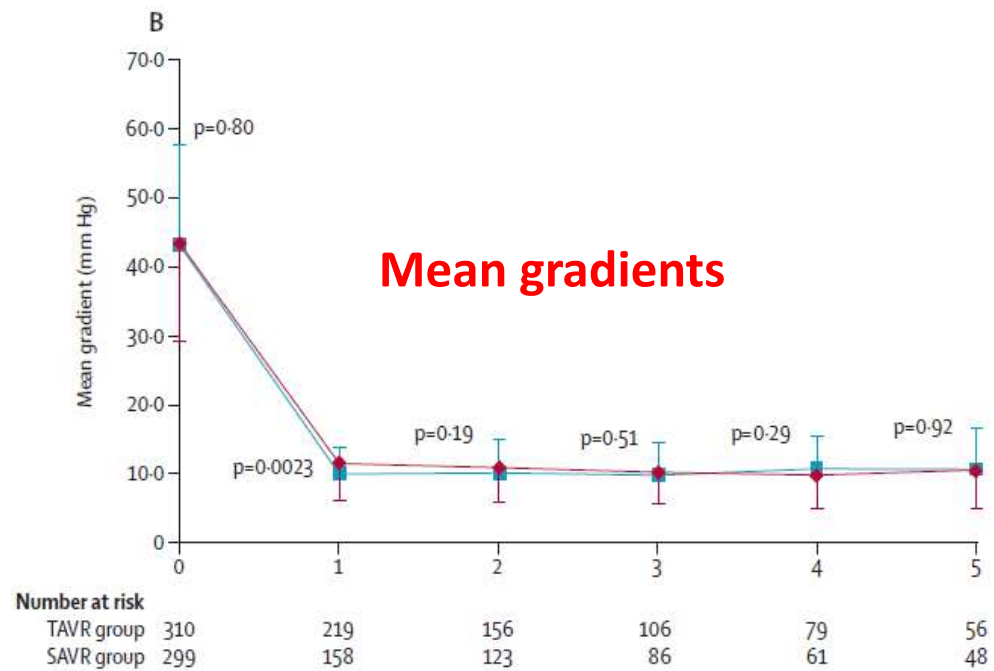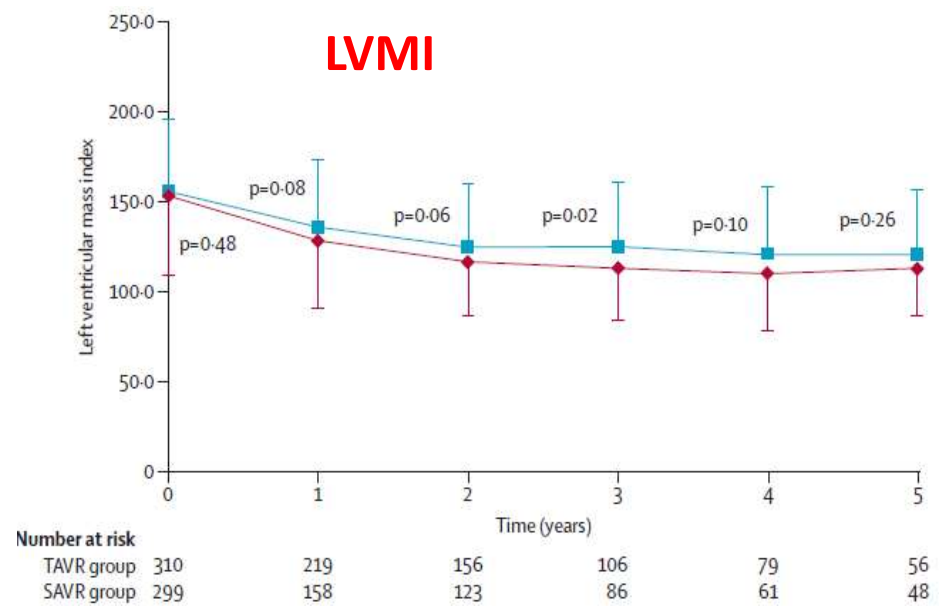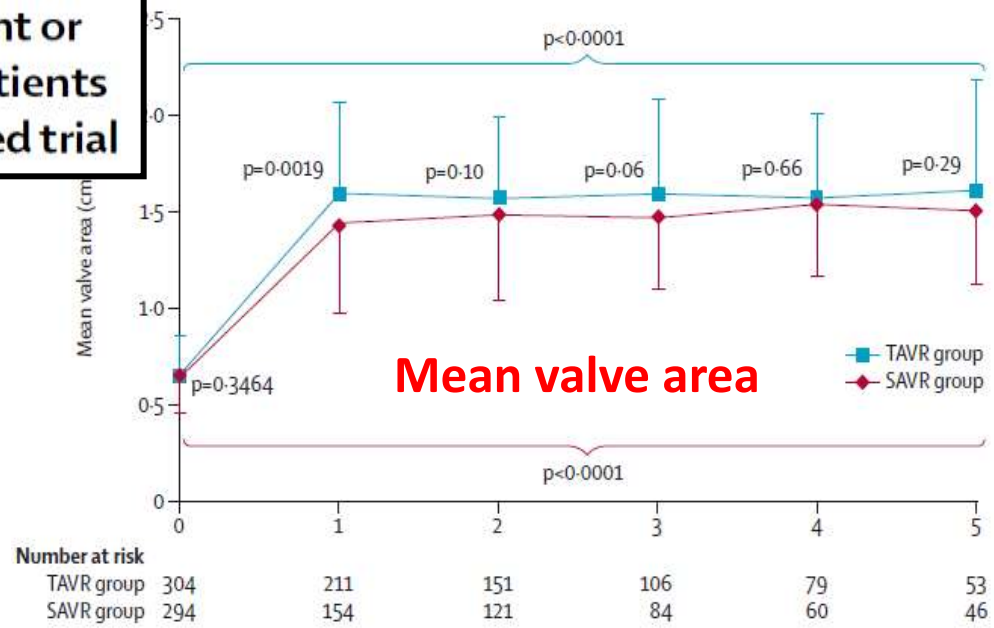
5-Year Outcomes After Transcatheter Aortic Valve Implantation With CoreValve Prosthesis

- Italian multicenter study (2007-2009)
- 3rd generation 18-Fr Core-Valve
- 353 pts with 5 year F-U data
- Mean age: 81.5 years, Logistic Euroscore: 21.5%
- 5 year survival: 45%
- Prosthesis performance
  10.3+6.5 mmHg at discharge
  12.8+10.0 mmHg at 5 years
  Late prosthetic failure: 5 cases (1.4%) including 2 redo TAVI
  mild to moderate stenosis (20-40mmHg): 10 cases (2.8%)
  No valve thrombosis

Risk factors for Late outcomes after AVR or TAVR

- Age, Anemia, Low LVEF, Coronary disease
- **Atrial fibrillation**
- **Significant MR**
- **Significant TR**
- **Postoperative significant AR**
- **Complete Heart block**
- **PPM**
- **Structural valve degeneration**

Concern of TAVR for intermediate or low risk with severe AS

- Long-term durability ? (esp. small delivery system)
- Possible repeated procedure for prolonged survival in relatively young patients
- Residual AR
- High incidence of heart block
- Uncertain efficacy in bicuspid valve
- No concomitant procedure

Surgical Role in TAVR Era

- TAVR has important role in Octogenarian.

- Surgical AVR is still standard procedure in patients less than 80 year old until firm evidence of long-term durability of TAVR.

- Severe ascending aorta calcification is not absolute contraindication for surgical AVR.