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 - Impact of 19mm valve & PPM
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- TAVR for intermediate risk patients
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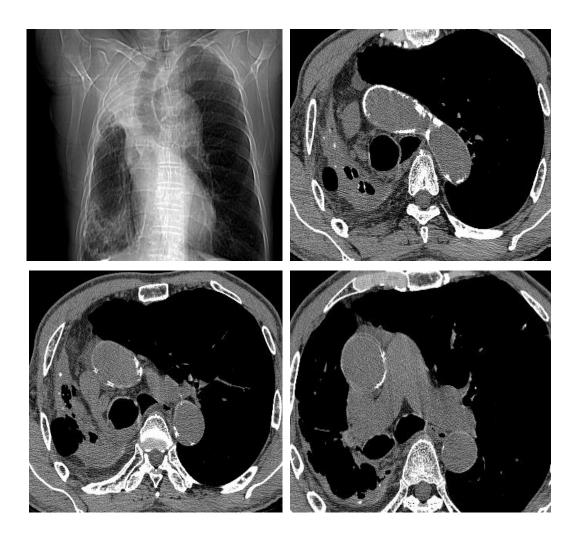
Are there any contraindications of Surgical AVR?

Too high mortality or morbidity (stroke) for surgical AVR compared with alternative procedure (TAVR) or medical treatment

Factors for surgical decision making in old patients with severe AS

- Age
- Frailty
- Comorbidity
- Support of family, economic status
- Anatomical findings
- Willingness of patients, family & surgeon
- Procedure information

Case



- 85 yrs, male
- AS with TB destroyed lung
- 2008

Rt axillary artery cannulation

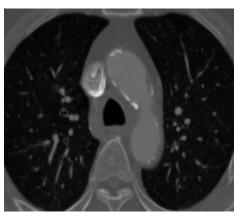
Distal aorta endartherectomy

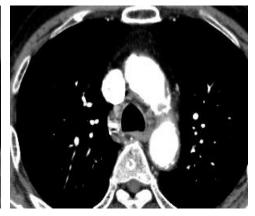
Aorta replacement + AVR

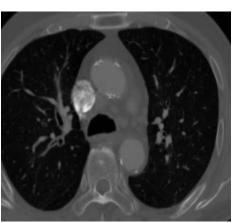
Uneventul hospital course

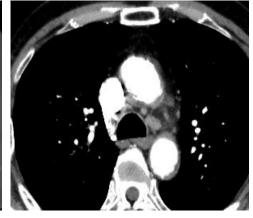
2016: still visiting clinic at 93 yrs

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
- 2012 Jan: Em op. for HF & no urine

results: no neurologic Cx, ARF recovered after CRRT, prolonged ICU stay (107days)

2014 Oct: die from pneumonia

SMC experience of AVR for AS

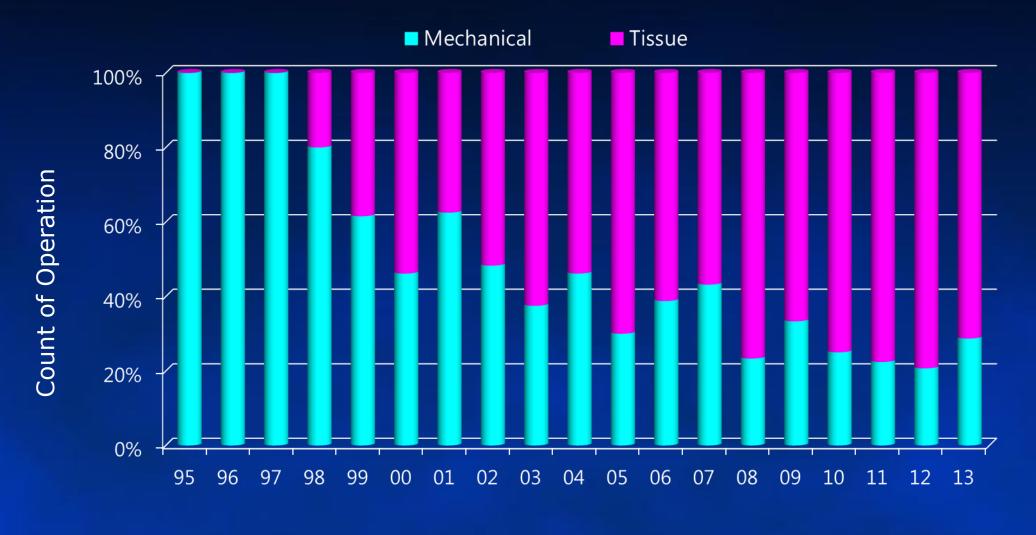
- 1995 Jan. ~ 2013 Dec.
- 753 pts : severe AS referred for AVR

AVR: 665 pts (88.3%)

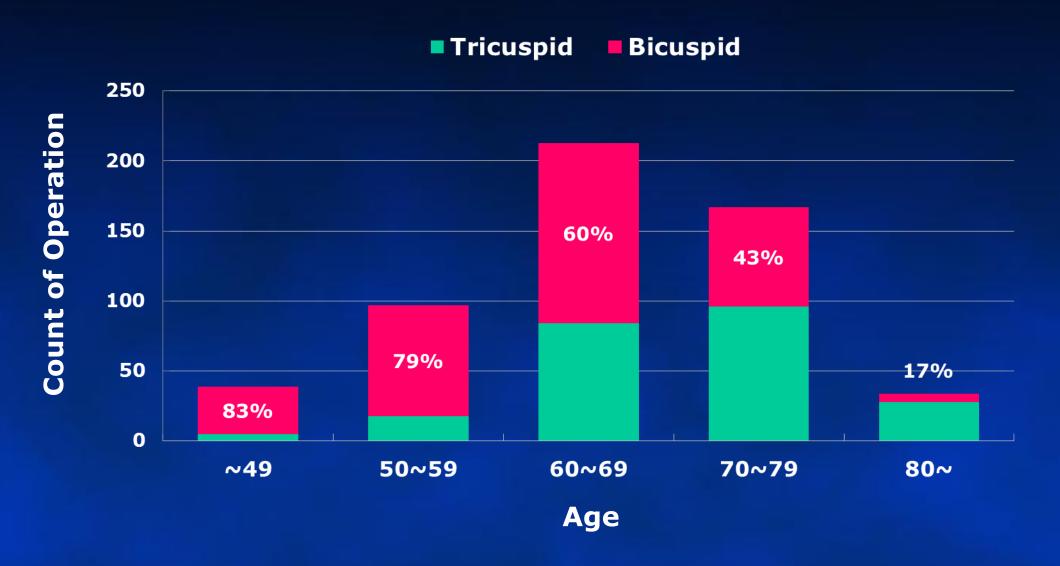
AVR+CABG: 88 pts (11.7%)

- Exclusion criteria
 main CAD with AS (58 pts)
 previous cardiac surgery (3 pts)
 rheumatic AS (22 pts)
- Mechanical valve 259 pts (34.4%)
 Tissue Valve 494 pts (65.6%)

Mechanical vs Tissue valve in AS



Incidence of Bicuspid Valve



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

Ann Thorac Surg, 2016 (In Press)

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 patients: AVR with Carpentier-Edwards valve
- 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)

Patient Characteristics According to Valve Size

Variables	19mm (n=54)	21mm (n=154)	23,25mm (n=239)	p value
Age	74.5±5.4	73.1±6.5	70.6±6.4	<0.001
Sex (Female)	50 (93%)	99 (64%)	47 (20%)	< 0.001
BSA (m ²)	1.45±0.12	1.56±0.15	1.70±0.15	< 0.001
Hypertension	33 (61%)	87 (56%)	126 (53%)	0.076
Diabetes	18 (33%)	47 (31%)	64 (27%)	0.439
CAD	13 (24%)	29 (19%)	48 (20%)	0.764
NYHA III - IV	21 (39%)	47 (31%)	51 (21%)	0.007
Atrial fibrillation	7 (13%)	18 (12%)	31 (13%)	0.980
Anemia (Hb < 10)	8 (18.5%)	20 (13%)	72 (2.9%)	0.019
Logistic Euroscore	14.0±15.5	9.6±9.3	7.2±7.9	< 0.001
Bicuspid	10 (19%)	62 (39%)	116 (49%)	0.002

Ann Thorac Surg 2016

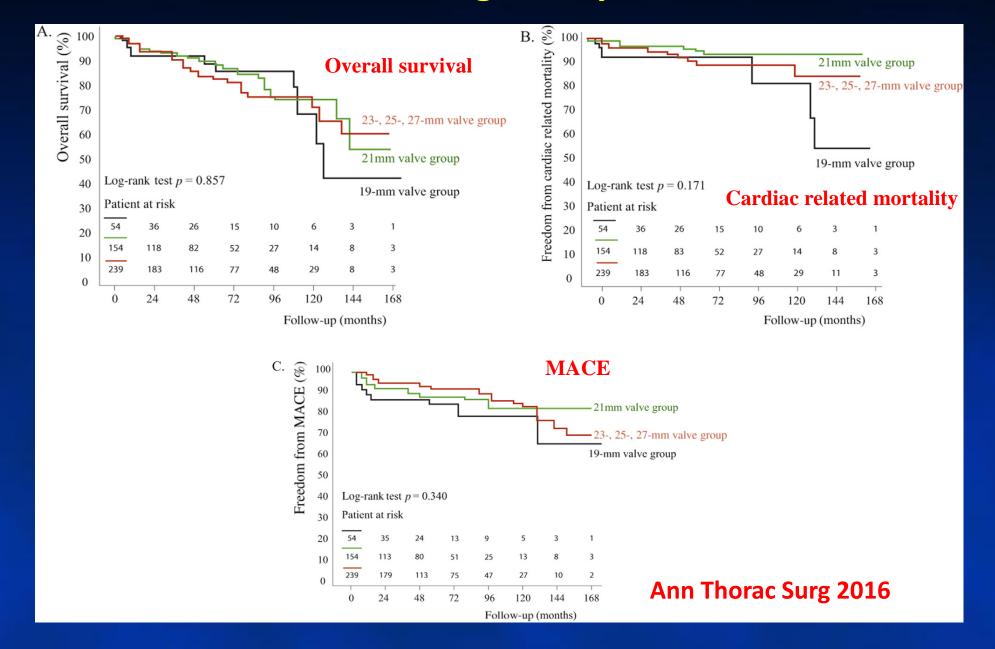
Early Outcomes after AVR According to Valve Size

Variables	19mm (n=54)	21mm (n=154)	23,25mm (n=239)	p value
Early mortality	0	2 (1.3)	1(0.4)	0.704
Cerebral infarction	2(3.7)	3 (1.9)	5 (2.1)	0.779
Cerebral hemorrhage	0	2 (1.3)	1(0.4)	0.704
Paravalvular leak	1 (1.9)	0	1(0.4)	0.345
Heart block	0	4(2.6)	2 (0.8)	0.318
Renal failure	1 (1.9)	1(0.6)	3 (1.3)	0.678
Bleeding reoperation	1 (1.9)	6 (3.9)	3 (1.3)	0.234

Serial Changes of Echo data according to valve size

	19mm (n=54)	21mm (n=154)	23-27mm(n=239	р
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	$14.8 \!\pm\! 5.0$	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

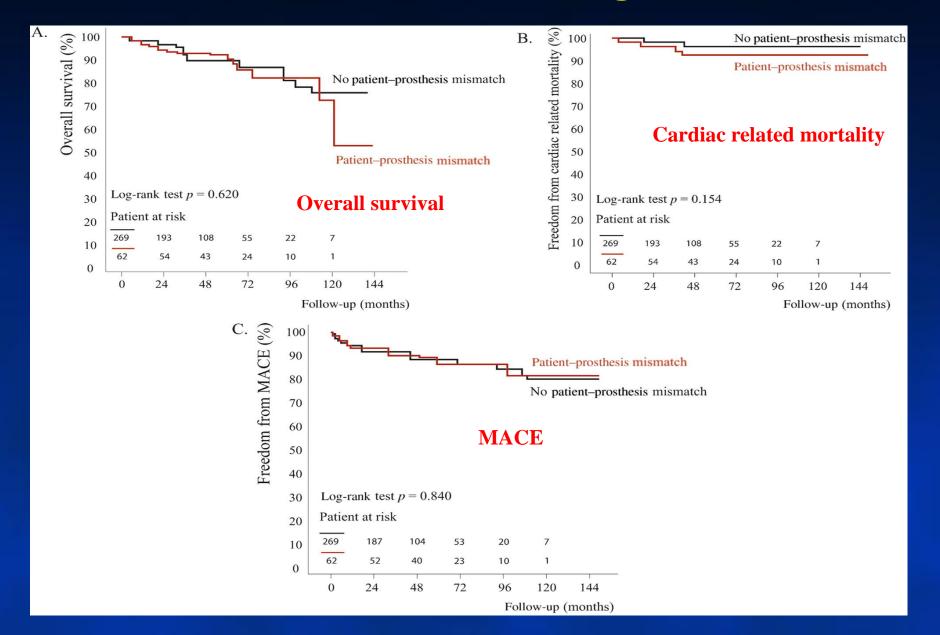


Serial Changes of TMPG & LVMI according to PPM

	No PPM (n=269)	PPM (n=62)	р
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



Patient Characteristics According to Age group

Variables	Age 60대 (n=160)	Age 70대 (n=223)	Age 80대 (n=58)	<i>p</i> 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
Logistric 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

Operative data According to Age Group

Concomitant surgery, n(%)	Age 60대 (n=160)	Age 70대 (n=223)	Age 80대 (n=58)	p value
Assonding As wronning	,	29(13.0)	\	0.006
Ascending Ao wrapping	32(20.0)	,	2(3.4)	0.008
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
CPB time (min)	120±41	142±226	136±45	0.182
ACC time (min)	90±31	97±51	96±29	0.172

Unpublished data

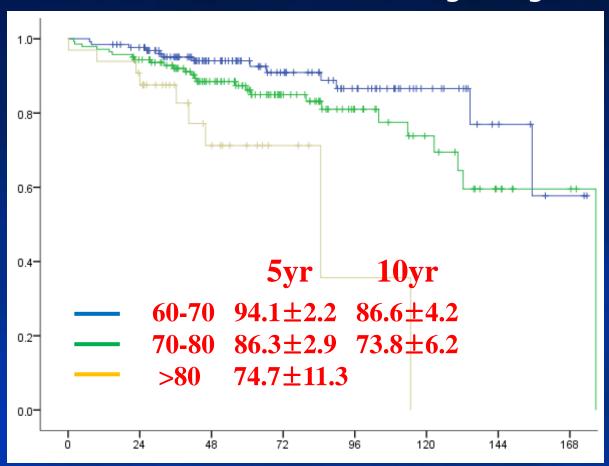
Early Outcomes According to Age Group

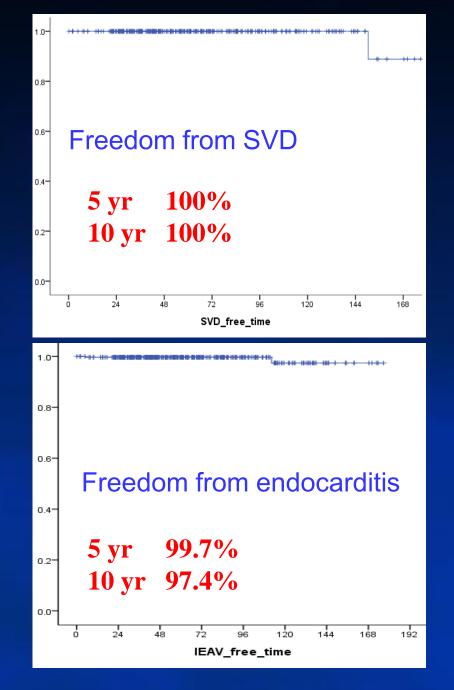
Variables	Age 60대	Age 70대	Age 80대	р
v ariables	(n=160)	(n=223)	(n=58)	value
Early mortality,%	0(0)	1(0.4)	2(3.4)	0.020
Early morbidity, n(%)				
Paravalvular leakage	1(0.6)	1(0.4)	0(0)	0.832
Bleeding (reoperation)	6(3.8)	2(0.9)	2(3.4)	0.146
New onset heart block	0(0)	3(1.3)	3(5.2)	0.014
Cerebral infarction	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

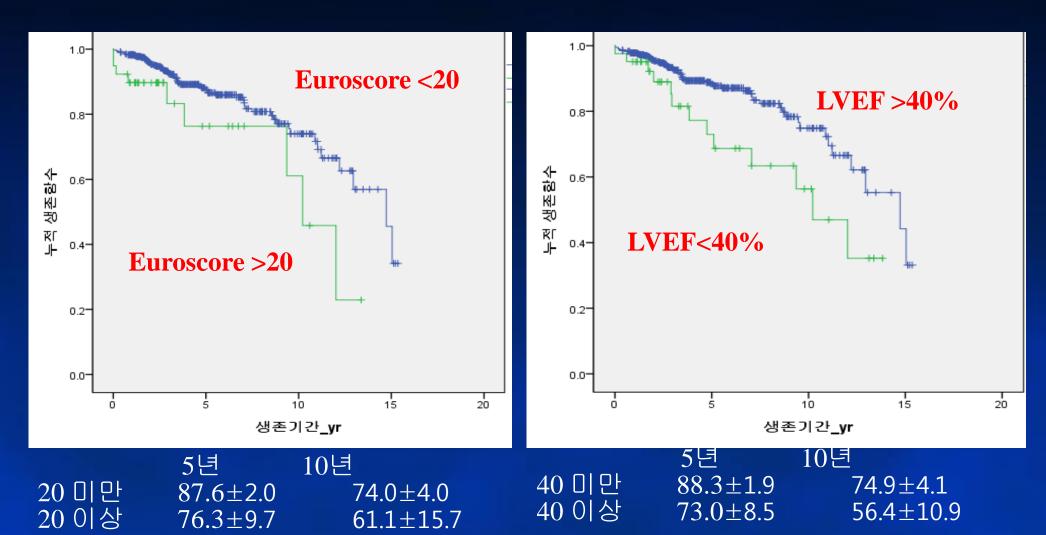
Late Clinical Outcomes of CE valve AVR

Overall Survival of according to age





Survival According to Euroscore(>20) and LVEF (<40%)



Clinical studies on concomitant procedure with AVR for AS

Long-Term Clinical Impact of Functional Mitral Regurgitation After Aortic Valve Replacement

Dong Seop Jeong, MD, PhD, Pyo Won Park, MD, PhD, Kiick Sung, MD, PhD, Wook Sung Kim, MD, PhD, Ji-Hyuk Yang, MD, PhD, Tae-Gook Jun, MD, PhD, and Young Tak Lee, MD, PhD

Ann Thorac Surg 2011

Fate of functional tricuspid regurgitation in aortic stenosis after aortic valve replacement J Thorac Cardiovasc Surg 2014

Dong Seop Jeong, MD, PhD, Kiick Sung, MD, PhD, Wook Sung Kim, MD, PhD, Young Tak Lee, MD, PhD, Ji-Hyuk Yang, MD, PhD, Tae-Gook Jun, MD, PhD, and Pyo Won Park, MD, PhD

Aortic Wrapping for a Dilated Ascending Aorta in Bicuspid Aortic Stenosis Circ J 2015

Min Suk Choi, MD; Dong Seop Jeong, MD, PhD; Hae Young Lee, MD; Kiick Sung, MD, PhD; Wook Sung Kim, MD, PhD; Young Tak Lee, MD, PhD; Pyo Won Park, MD, PhD

Ascending Aorta Replacement under Circulatory Arrest for Severe Aortic Calcification in Patients with AS

- From 2004- December 2014
- 32 patients underwent primary AVR with AAR under circulatory arrest
- Mean age: 74±7 years (59-87), Octogenarian (n=7, 22%)
- Diabetes mellitus (53%), Stroke history (6%),
 Chronic kidney disease (22%), Atrial fibrillation (22%),
 Coronary disease (28%), NYHA III or IV (28%)
- Logistic EuroSCORE: mean 21 ± 19% (3.3-68.2%)

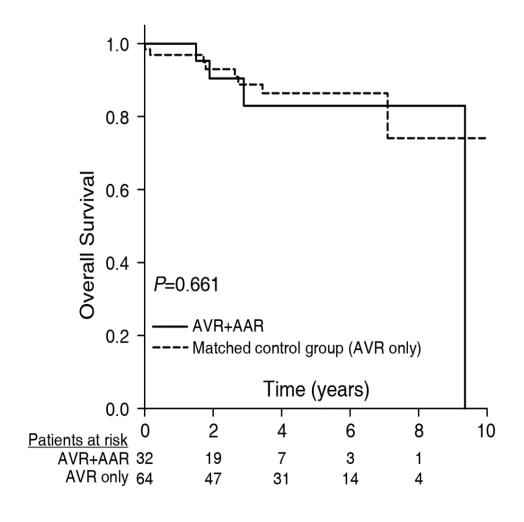
Early Outcomes

Early outcomes	Total (N=32)
ICU stay (days)	2.7±1.3*
Early mortality	0 (0%)
Paravalvular leakage	0 (0%)
Bleeding requiring re-exploration	1 (3%)
Transient ischemic attack	1 (3%)
Minor stroke without sequelae	1 (3%)
Pacemaker insertion	2 (6%:1 CHB, 1 SSS)
Acute renal failure	1 (3%)

^{*} exclude one patient with emergency operation

Overall Survival:

AVR + AAR vs AVR without AAR



- 1:2 matching with age, sex, coronary disease, atrial fibrillation and NYHA Fc
- 5 year survivalAVR+AAR 83%AVR 86%

TAVR Patient Demographics

- Most common patients is > 80 years old
- Some have low STS scores but have severe comorbidities

 Technical challenging for surgical AVR previous cardiac surgery (CABG, redo AVR) radiation therapy aorta calcification

Advantages of TAVR vs SAVR

TAVR

- Less invasive
- Short ICU & hospital stay
- Less pain & transfusion
- Feasible in porcelain aorta & chest deformity (inoperable)
- Possible valve in valve procedure
- Possible initial low gradients
- Comparable early results in high & intermediate risk

SAVR

- Possible combined procedure
 MR & TR repair, CABG, Aorta
 surgery, LVOT muscle resection
- Low incidence of early Cx stroke, residual AR, heart block
- Low cost in Korea
- Less exclusion criteria
- Proved long- term durability of current tissue valve

Age Distribution of TAVR patients in SMC

(2010 Jul- 2016 Jan)

Age	Patient Number
< 75 yr	2 (1:s/p CABG+Ao Calc 1:s/pPCI+Calc
75-80 yr	9
80-90 yr	18
> 90 yr	2

TAVR in US

Year	No of TAVR	Age (ye Med M	ear) lean	30 day mortality
2012	4601	84	32	7.05
2013	9128			
2014	16314			6.69
2015 (1 st part)	23002	83 8	31	

Grover F presented ATS meeting (Jan 2016)

Transcatheter or Surgical Aortic-Valve Replacement in 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 not be inferior to surgical replacement. Before randomization, patients were entered into one of two cohorts on the basis of clinical and imaging findings; 76.3% of the patients were included in the transfemoral-access cohort and 23.7% in the transthoracic-access cohort.

RESULTS

The rate of death from any cause or disabling stroke was similar in the TAVR group and 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 Lifesciences; PARTNER 2 ClinicalTrials.gov number, NCT01314313.)

Patients Characteristic (I)

Characteristic	TAVR (N=1011)	Surgery (N = 1021)
Age — yr	81.5±6.7	81.7±6.7
Male sex — no. (%)	548 (54.2)	560 (54.8)
Body-mass index†	28.6±6.2	28.3±6.2
STS risk score‡	5.8±2.1	5.8±1.9
NYHA class III or IV — no./total no. (%)	782/1011 (77.3)	776/1020 (76.1)
Coronary artery disease — no. (%)	700 (69.2)	679 (66.5)
Previous myocardial infarction — no. (%)	185 (18.3)	179 (17.5)
Previous CABG — no. (%)	239 (23.6)	261 (25.6)
Previous PCI — no. (%)	274 (27.1)	282 (27.6)
Previous balloon aortic valvuloplasty — no. (%)	51 (5.0)	50 (4.9)
Cerebral vascular disease — no. (%)	325 (32.1)	317 (31.0)
Peripheral vascular disease — no. (%)	282 (27.9)	336 (32.9)
Diabetes mellitus — no. (%)	381 (37.7)	349 (34.2)

Patients Characteristic (II)

Characteristic	TAVR (N=1011)	Surgery (N=1021)
Creatinine >2 mg/dl — no. (%)∫	51 (5.0)	53 (5.2)
Atrial fibrillation — no. (%)	313 (31.0)	359 (35.2)
Permanent pacemaker — no. (%)	118 (11.7)	123 (12.0)
Frail condition — no./total no. (%)		
5-Meter walk-test time >7 sec	416/936 (44.4)	418/901 (46.4)
Serum albumin <3.5 g/dl	150/988 (15.2)	140/951 (14.7)
Liver disease — no. (%)	19 (1.9)	26 (2.5)
Aortic-valve area — cm²	0.7±0.2	0.7±0.2
Mean gradient — mm Hg	44.9±13.4	44.6±12.5
Left ventricular ejection fraction — %	56.2±10.8	55.3±11.9
Left ventricular mass index — g/m²	119.8±31.5	120.6±32.6
Moderate or severe mitral regurgitation — no./total no. (%)	151/899 (16.8)	171/894 (19.1)

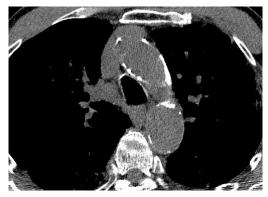
Concern of TAVR for intermediate or low risk with severe AS

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

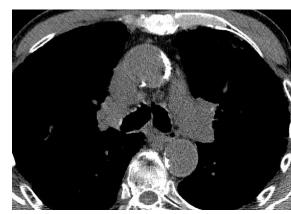
Case

- 82 year, Male
- 1993 FA- PA bypass op.
- 2004 FA- TA bypass op.
- 2016 scheduled femoral artery endatherectomy
- Severe AS
- Refuse TAVR
- Op plan; ascending aorta replacement + AVR





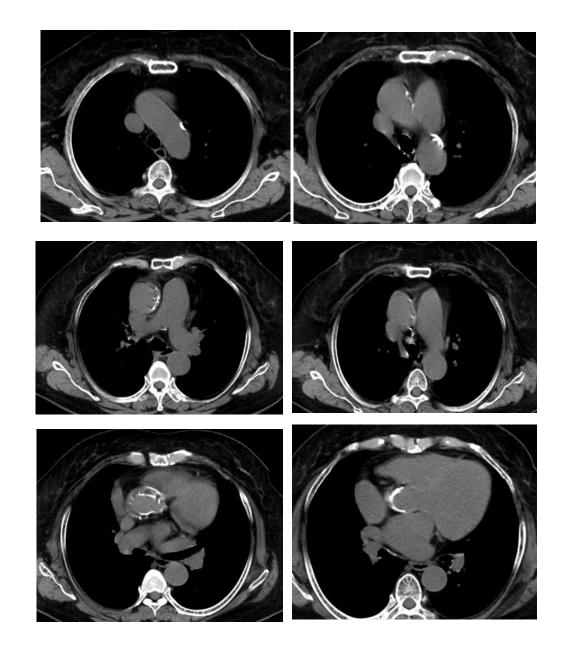






Case

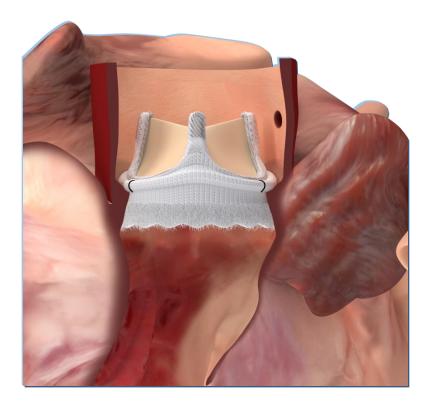
- 72 yr, female
- Severe AR
- Moderate AS
- RCA total occlusion
- Atrial fibrillation
- Severe proximal ascending aorta calcification
- No TAVR indication



Operation

- High oblique aortotomy
- Rapid deployment AVR with Intuity valve
- CABG to RCA with right IMA
- Uneventful hospital course





Aortic Stenosis in Korea

- Still low incidence of associated coronary disease
- Very few cases of AS surgery in previous CABG or redo AVR
- Relatively high incidence of bicuspid AS
- Combined rheumatic component with degenerative AS
- Higher medical cost of TAVI than surgical AVR
- Excellent early & late survival rate after AVR in Korea

Relative Contraindications of Surgical AVR

- Old age more than 80 years
 - severe ascending aorta calcification previous sternotomy (CABG, AVR) severe comorbidity
- Age less than 80 years
 comcomitant anatomical & clinical risk factors
- Severe aortic annular calcification with circular mitral annular calcification

