Current Status of Balloon-Expandable TAVR in Korea

Jung-Min Ahn, MD.

University of Ulsan College of Medicine, Heart Institute, Asan Medical Center, Seoul, Korea







First-In-Man TAVR was done in 2002



Cribier A, et al. Circulation. 2002;106:3006-3008





Clinical Trials

Trial Name	STS Score	Age
Inoperable Population		
PARTNER IB Trial (2010)	11.6	83
High Risk Population (>8)		
PARTNER IA Trial (2011)	11.8	84
CoreValve US Pivotal Trial (2014)	7.4	83
Intermediate Risk Population (4-8)		
PARTNER II Trial (2016)	5.8	82
Low Risk Population (<4)		
NOTION Trial (2015)	3.0	79
PARTNER III (<mark>2019</mark>)	1.9	73
Evolut Low Risk Trial (2019)	1.9	74



Adoption of TAVR in Asian Pacific



The Asian TAVR Registry 12 centers, 6 Countries

Sponsored by CVRF



HongKong	Queen Elizabeth Hospital
Singapore	National University Heart Centre
Taiwan	National Taiwan University
	Cheng-Hsin Hospital
Korea	Seoul National University Hospital
	Asan Medical Center
Japan	Shonan Kamakura General Hospital
	Keio University Hospital
	Teikyo University Hospital
	Saiseikai Yokohama Eastern Hospital
	Kokura Memorial Hospital
Australia	Royal Perth Hospital

ClinicalTrials.gov:

NCT02308150



Asian vs Caucasian

	Asian	Caucasian	
	N=202	N=106	P value
Age, year	81 ± 6	81±6	0.45
Height, cm	153 ± 9	160 ± 9	<0.001
Weight, kg	56 ± 10	70 ± 13	<0.001
Annulus Area, mm²	406 ±70	430 ± 77	0.007
Annulus Perimeter, mm	73 ± 6	75 ± 7	0.008
Mean Diameter, mm	23 ± 2	24 ± 2	0.009
LCA height, mm	12 ± 3	13 ± 3	< 0.001
RCA height, mm	17 ± 3	17 ± 4	0.82
Calcification at Aortic Root	376 ± 332	416±329	0.33

Yoon et al., AJC 2015; 116: 1566-73

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Baseline Characteristics (n=940)

	N=940
Age	82.1 ± 6.5
Female	52.9%
STS score	7.0 ± 5.6
BMI, kg/m ²	23.0 ± 3.8
Diabetes mellitus	28.3%
NYHA class III/IV	74.1%
CAD	50.9%
Previous stroke	14.4%
Peripheral vascular disease	17.0%
COPD	1.9%
Sapien	615 (65%)
CoreValve	325 (35%)



Asian TAVR Registry, 2015



Procedural Outcomes

	N=940
Access site	
Transfemoral	85.8%
Transapical	12.0%
Transsubclavian, Tranaortic	0.4%, 1.6%
Device success	86.2%
Conversion to surgery	1.6%
Coronary obstruction	1.3%
Implantation of two valves	4.3%
New permanent pacemaker	10.2%
Paravalvular leakage (PVL) ≥ moderate to severe	9.5%

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Asian TAVR Registry, 2015



30 Days Outcomes

Mortality	
Any cause	3.4%
Cardiovascular cause	1.7%
Stroke	
All	3.0%
Disabling	1.2%
Bleeding	
Life-threatening	7.6%
Major	6.2%
Vascular complications	
Major	5.2%
Minor	4.6%



Asian TAVR Registry, 2015





Increasing TAVI Experiences in Korea (2010-2017: 1209 Patients)



K-TAVI Registry Korean Circ J. 2018 May;48(5):382-394



Case Number by Year

	2010	2011	2012	2013	2014	2015	2016	2017	2018
Balloon Expandable Valve	13	28	14	33	65	73	140	256	368







K-TAVI registry (N=17 sites)

From June 2015 to June 2017



Hospital

ASAN medical center

Seoul National University Hospital

The Catholic University of Korea Seoul St. Mary's Hospital

Severance Hospital

Samsung Medical Center

Korea University Anam Hospital

CHONNAM National University Hospital

Sejong Hospital

YEUNGNAM University Medical Center

Pusan National University YANGSAN Hospital

CHUNGNAM National University Hospital

Seoul National University Bundang Hospital

CHA Bundang Medical Center

Gangnam Severance Hospital

AJOO University Medical Center

Gachon University Gil Medical Center

Pusan National University Hospital



Baseline Characteristics (n=576)

	N=576
Age (Years)	79.0 (75-83)
Female	51.4 %
STS score	5.2 (3.0-9.0)
DM	35.4 %
HTN	78.3 %
Stroke or TIA	15.3 %
PAOD	13.9 %
CKD on dialysis	6.4 %
Bicuspid AV	8.5%
Hospitalization period (Days)	11.9±7.5
TAVR to discharge (Days)	7.5±6.1

K-TAVI Registry Korean Circ J. 2018 May;48(5):382-394







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Procedural Characteristics

	N=576
Approach	
Femoral	566 (98.3%)
Apical	10 (1.7%)
Operation room	
Hybrid room	358 (62.2%)
Cath room	218 (37.8%)
Anesthesia duration (mins)	127.2±39.3
General anesthesia	481 (83.5%)
Conscious sedation	95 (16.5%)

K-TAVI Registry Korean Circ J. 2018 May;48(5):382-394



30 Days Outcomes

Procedural Success	99.7%
PVL, moderate to severe	4.2%
Permanent Pacemaker Rate	6.1%
Cardiac tamponade	0.7%
Coronary obstruction	0.2%
Access site complications	6.8%
Aortic dissection	0.2%
Aortic rupture	0.2%
All cause death	2.6%
Cardiac death	1.2%
Stroke, disabling	1.2%
Bleeding, major	3.1%

K-TAVI Registry Korean Circ J. 2018 May;48(5):382-394

Annual Volume of TAVR in AMC





TAVR 2019 in AMC

TAVR Team



Minimalist



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CT based sizing





10%





Device in AMC



Sapien
Sapien XT
S3
Core
Evolut R
Lotus







TAVR Team AP Valves 2018 Live Demo



Active Involvement of Surgeon



S3 Area Oversizing Based on the CT 15%, Cutoff

Mild Calcification (Ca volume < 400 mm³) Moderate Calcification (Ca volume 400-1000 mm³) Severe Calcification (Ca volume < 400 mm³) Bicuspid AS and Heavy Calcification

10~15%, then Overfill
5~10%, then Overfill
0~5%, then Overfill
0%, then Overfill



"Minimalist Approach" TAVR in AMC





"Minimalist Approach" TAVR in AMC

- Conscious Sedation, No General Anesthesia
- No TEE, but TTE
- No central venous catheter (i.e. jugular)
- No Foley
- <1 hour Procedure</p>
- Early assessment of neurologic status
- Early recovery, shorter length of stay, discharge on Day #3
- Less Complications, Better Outcomes







Proportion of TAVR for Bicuspid AS



Heart Valve for Bicuspid AS





ASAN TAVR Registry



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Procedural Outcomes Sapien 3 Cohort

	Bicuspid AS (N = 34)	Tricuspid AS (N = 184)	Р
Valve Oversizing to annulus, %	106.4±7.2	113.4±6.1	<0.001
Pre-Balloon Valvuloplasty	33 (97.1%)	151 (82.1%)	0.036
Conversion To Surgery	1 (3.6%)	0%	0.20
	Valve migration: 1		
Coronary Obstruction	0%	3 (1.6%)	0.45
Annular Rupture	0%	1 (0.5%)	0.67
Second Valve Implantation	0%	0%	NA
New Permanent Pacemaker	3 (8.8%)	8 (4.3%)	0.27
PVL ≥ Moderate	3 (8.8%)	2 (1.1%)	0.006
	Valve migration: 1 Raphe calcification: 2		
Post-dilation	16 (47.1%)	56 (27.7%)	0.03

Moderate PVR











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Hemodynamic Outcomes





Para-Valvular Leakage





ASAN Medical Center

Death and Stroke*



TAVR with S3 in AMC

	N = 173
Age, years	79.7 ± 4.8
Male sex	87 (50.3%)
BMI, kg/m²	23.8 ± 3.1
Logistic Euroscore (%)	11.1 ± 8.2
STS risk score (%)	3.7 ± 2.2
DM	51 (29.5%)
Hypertension	141 (81.5%)
Atrial fibrillation	28 (16.2%)
Previous PCI	51 (29.5%)
Previous MI	7 (4.0%)
Previous stroke	15 (8.7%)
Permanent pacemaker	4 (2.3%)
Chronic Kidney Disease	51 (29.5%)
COPD	19 (11.0%)
LV Ejection fraction, %	59.6 ± 9.9





TAVR with S3 in AMC Procedural Characteristics

	N = 173
Prosthesis size	
20mm	2 (1.2%)
23mm	55 (31.8%)
26mm	101 (58.4%)
29mm	15 (8.7%)
Conscious sedation	157 (90.8%)
Transfemoral approach	172 (99.4%)
Pre-dilation	97 (56.1%)
Post-dilation	47 (27.2%)
Underfilled valve at the end of procedure	43 (24.9%)
Overfilled valve at the end of procedure	58 (33.5%)
Prosthesis to annulus area oversizing, %	13.0 ± 6.0
Depth of implantation, mm	5.9 ± 1.9



TAVR with S3 in AMC Procedural and Clinical Outcomes

	Overall (N = 173)
Device success	172 (99.4%)
Conversion to surgery	1 (0.6%)
Coronary obstruction	1 (0.6%)
Implantation of two valves	0
New permanent pacemaker	7 (4.0%)
PVL ≥ moderate	0
Major vascular complication	1 (0.6%)
Death, all	3 (1.7%)
Cardiac death	1 (0.6%)
Non-cardiac death	2 (1.2%)
Disabling stroke	1 (0.6%)
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Outcomes after TAVR in AMC

Outcomes of PARTNER II Low-Risk AS patients (@ 30	l for days)	AMC Total (n=533)	S3 <i>Tricuspid</i> (n=211)	S3 <i>Bicuspid</i> (n=34)
 All-cause mortality 	0.4%	2.6%	1.9%	2.9%
 Major (disabling) strokes 	0.0%	1.5%	0.5%	0%
 Major vascular complications 	2.2%	4.5%	1.9%	2.9%
 New permanent pacemakers 	6.6%	8.4%	5.7%	8.8%
 Mod-severe PVR 	0.8%	8.6%	1.4%	8.8%
STS 1.9%		4.3%	3.7%	2.7%

Medical Center



2017 AHA/ACC Guideline for TAVR



ACC 2019 presented

Inoperable

- High Surgical Risk
- Intermediate Surgical Risk
- Lower Surgical Risk Younger Patients
- Bicuspid AV Stenosis







Dr. Alain Cribier at TCTAP 2016

My prediction on the future of TAVR



TAVI is indicated in patients who are not optimal candidates to surgery



2020 SAVR is indicated in patients who are not optimal candidates to TAVR !





