6th APVALVES 2017
August 16-18, 2017
Grand Walkerhill Seoul, Korea

Aortic and mitral VIV: data and devices

Wei-Hsian Yin, MD, PhD, FESC, FAPSC.
Director, Division of Cardiology, Heart Center,
Cheng Hsin General Hospital and
Professor of Medicine, National Yang Ming University, Taipe
Taiwan

Potential conflicts of interest

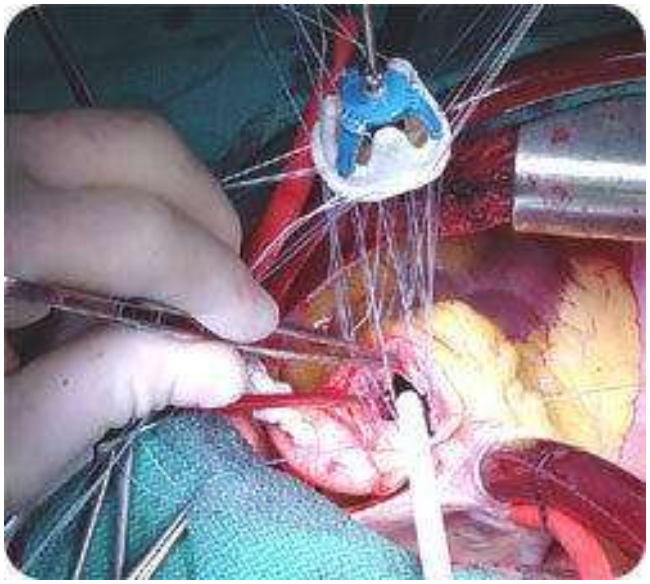
Speaker's name: Wei-Hsian Yin

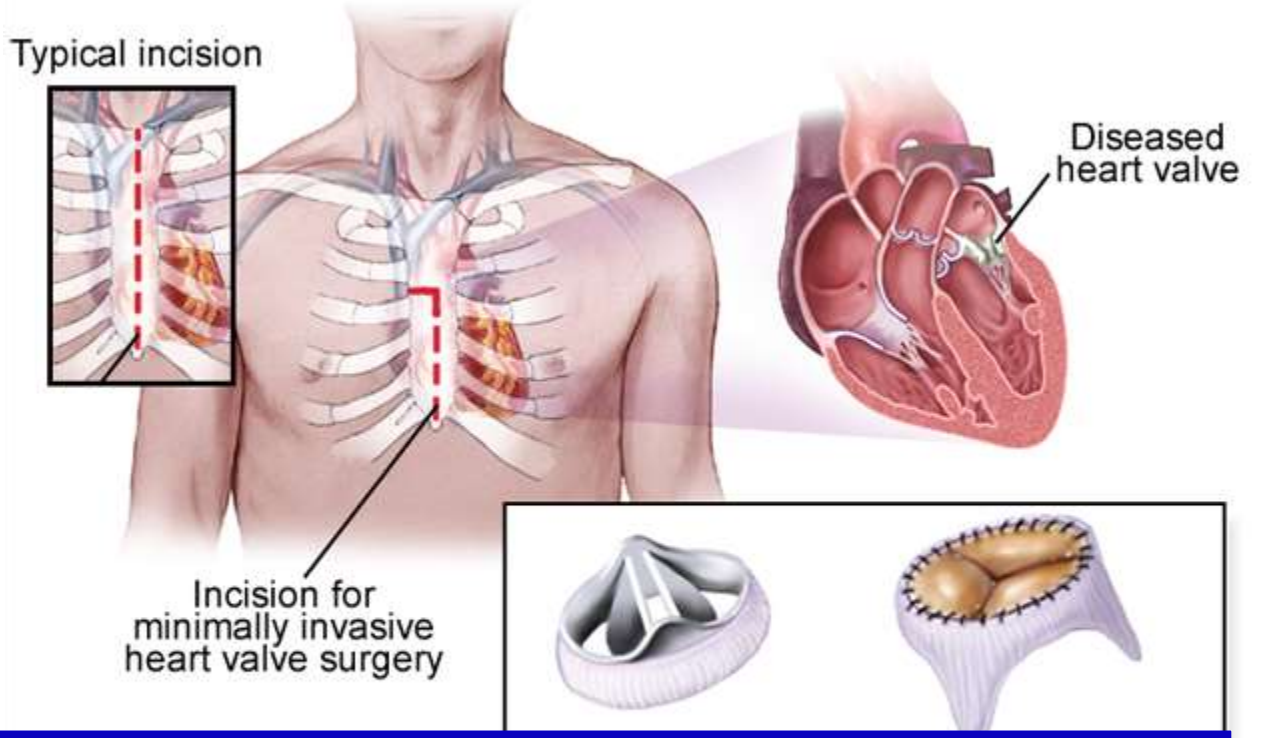
- ❑ **I have the following potential conflicts of interest to report:**

Honorarium: Edwards, Medtronic, Boston Scientific,

Proctor: Edwards (Sapien XT), Medtronic (CoreValve), Boston Scientific (Lotus valve)

Valve-in-valve implantations: the new standard for degenerated bioprostheses





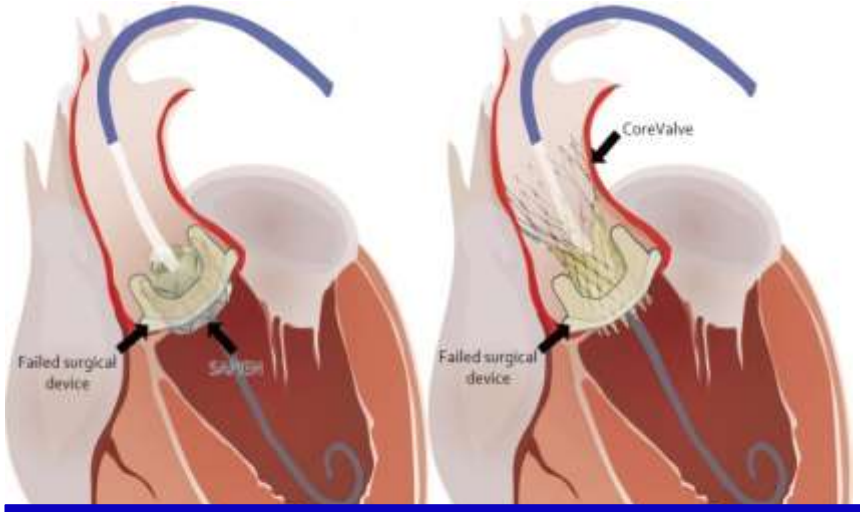
In the current context of increasing bioprosthetic valve implants and an ageing population with growing comorbidities,……

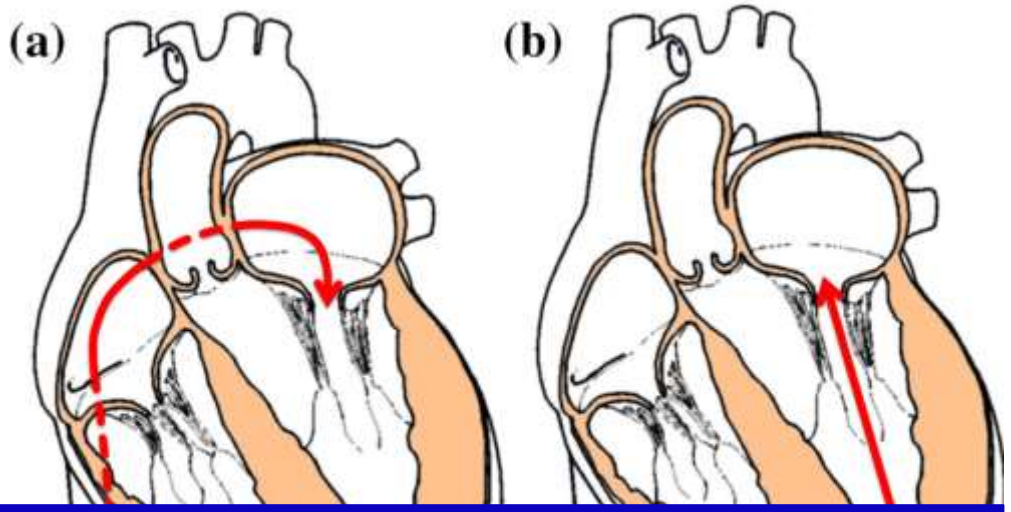
a less invasive approach to the treatment of bioprosthetic dysfunction would be an appealing alternative to the standard of care.

Transcatheter aortic & mitral VIV is feasible and safe in high-risk & inoperable patients for redo surgery.

Aortic Valve-in-valve

Mitral Valve-in-valve





It can be applied to dysfunctional aortic bioprosthetic valves and can also be used in the pulmonary and atrioventricular valve bioprosthesis.

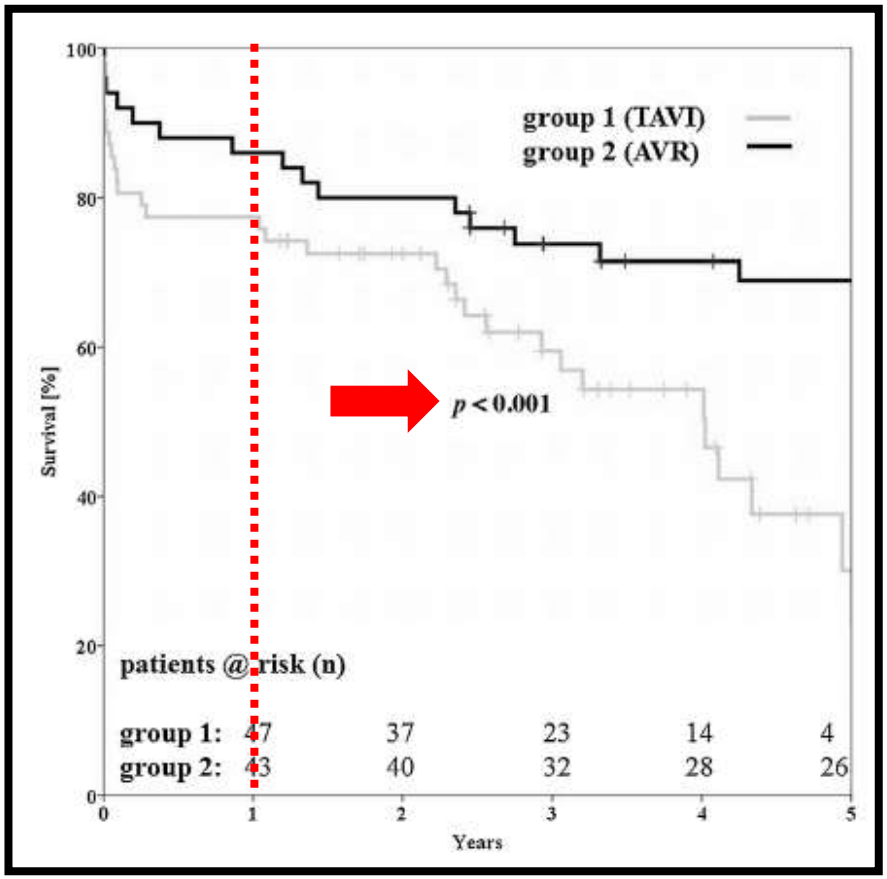
Journal of Cardiology 66 (2015) 292–297

Conventional aortic valve replacement or transcatheter aortic valve implantation in patients with previous cardiac surgery

Patient baseline characteristics.

A-VIV **R-SVR**

Variable	Group 1 (n=62)	Group 2 (n=51)	p-Value
Demographics			
Age, years	78.7 ± 5.9	71.1 ± 10.8	<0.001
Gender, female	19 (30.6)	13 (25.5)	0.67
BMI, kg/m^2	27.1 ± 4.1	26.6 ± 3.7	0.53
Risk factors and comorbidities			
NYHA class (range)	3 (2–4)	3 (2–4)	–
Peripheral vascular disease	32 (52.4)	15 (29.4)	0.02
Systemic hypertension	57 (91.9)	45 (88.2)	0.54
COPD	16 (25.8)	17 (33.3)	0.42
Renal disease (serum creatinine >200 μmol/L)	12 (23.5)	13 (21.0)	0.82
Diabetes mellitus	24 (38.7)	22 (43.1)	0.71
Cardiac history			
LV-EF, %	48.1 ± 13.0	49.9 ± 12.3	0.44
LV-EF, <35%	14 (22.6)	6 (11.8)	0.15
Pulmonary hypertension	14 (22.6)	7 (13.7)	0.33
Atrial fibrillation	14 (22.6)	13 (25.5)	0.82
Previous cardiac surgery	62 (100.0)	51 (100.0)	1.00
Isolated CABG surgery	54 (87.1)	33 (64.7)	<0.01
CABG + mitral valve surgery	1 (1.6)	1 (1.9)	1.00
Isolated mitral valve surgery	1 (1.6)	5 (9.8)	0.09
Isolated aortic valve surgery	2 (3.2)	10 (19.6)	<0.01
Aortic valve + CABG	4 (6.5)	2 (3.9)	0.69
Patent IMA-graft	58 (93.5)	51 (100.0)	0.13
Risk scores			
STS-Score, %	12.1 ± 10.0	7.1 ± 5.2	<0.01
Logistic EuroSCORE-I, %	36.4 ± 17.4	22.2 ± 17.5	<0.01
Additive EuroSCORE-I, %	12.9 ± 2.9	10.1 ± 2.9	<0.01
EuroSCORE-II, %	13.0 ± 9.2	9.2 ± 7.2	<0.01
ACEF-Score, %	1.9 ± 0.8	1.6 ± 0.6	<0.01



Logistic EuroSCORE is associated with both 30-day and long-term mortality.

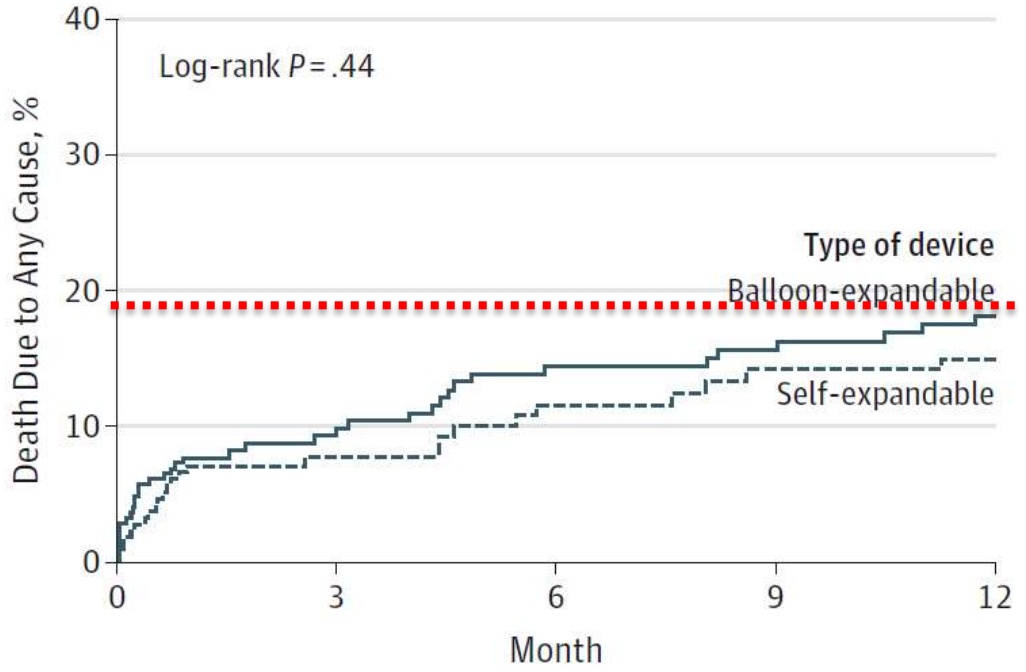
Original Investigation

JAMA. 2014;312(2):162-170. doi:10.1001/jama.2014.7246

Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

Between 2007 and 2013; 459 patients from 55 centers;
STS mortality score: 9.8%

C Device used during valve-in-valve implantation



No. at risk by type of device

Balloon-expandable	246	163	146	136	130
Self-expandable	213	126	112	101	98

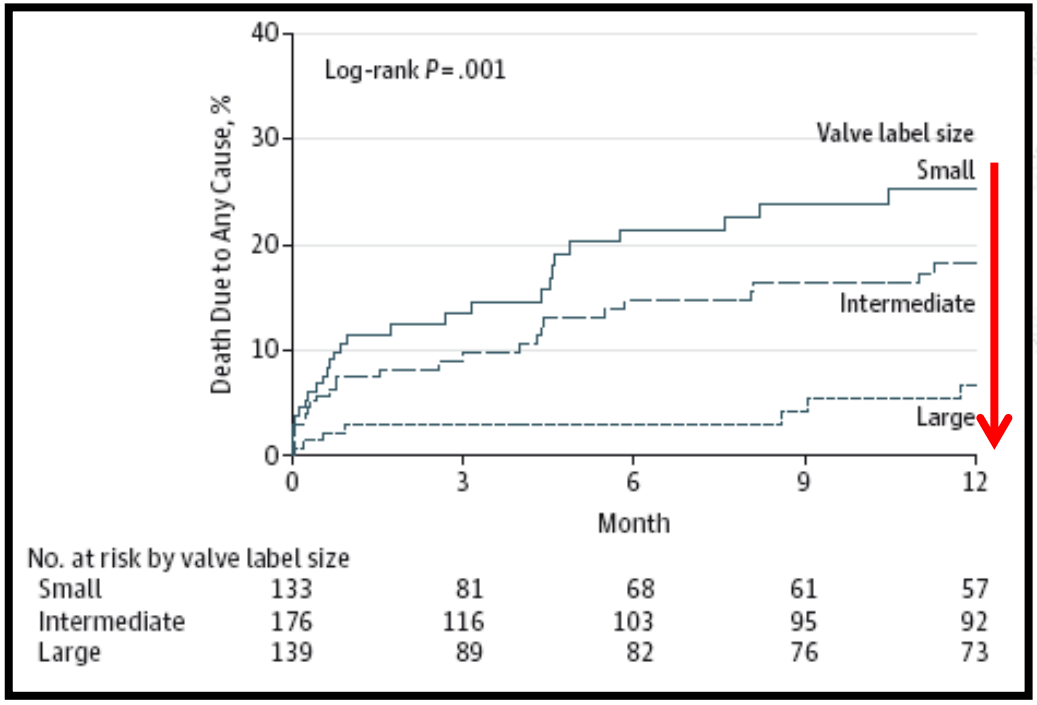
Original Investigation

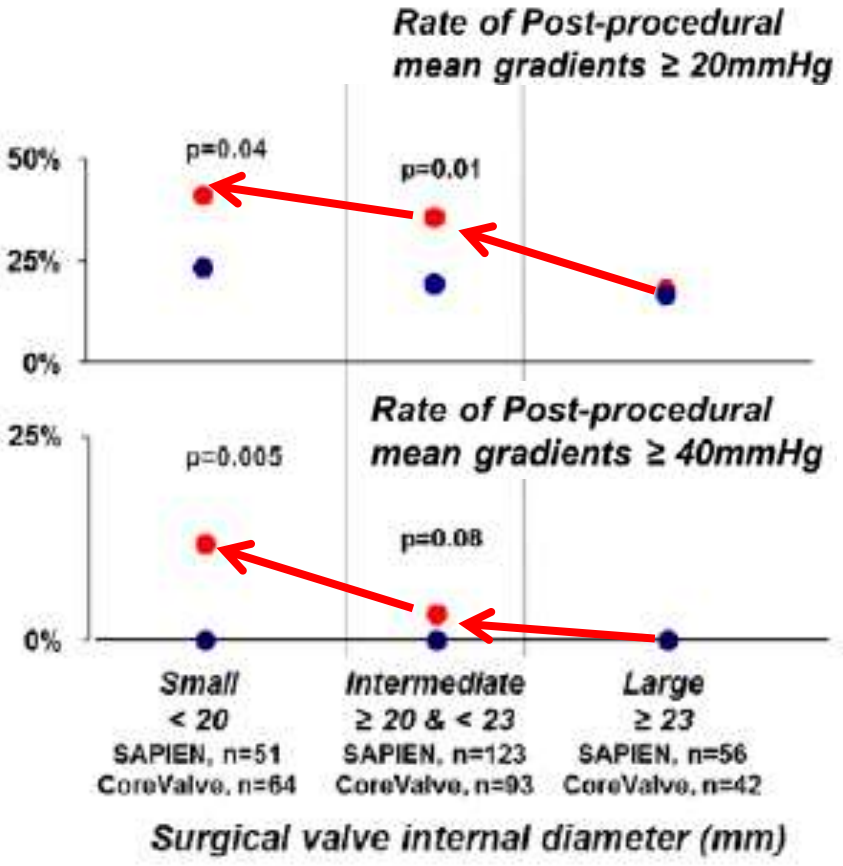
JAMA. 2014;312(2):162-170. doi:10.1001/jama.2014.7246

Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

In the Edwards SAPIEN group, there was a negative trend between the bioprosthesis size and high post-procedural gradients rates

Surgical valve label size



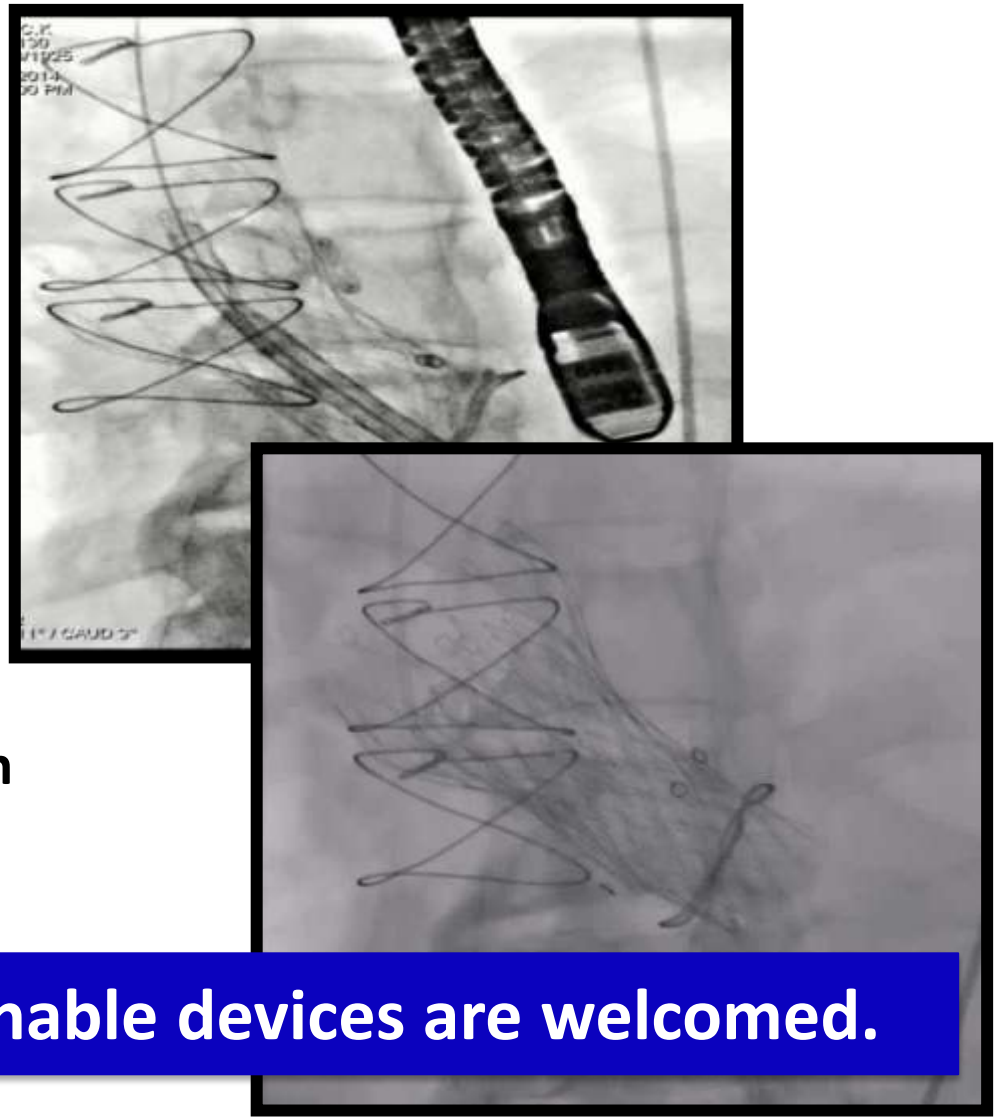


Original Investigation

JAMA. 2014;312(2):162-170. doi:10.1001/jama.2014.7246

Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

- Device retrieval was attempted in 10.3% of self-expandable procedures.
- A second transcatheter device was implanted in 5.7% of the total patients (self-expandable, 7.5% vs. balloon-expandable, 4.1%; P = .05), which is significantly higher than those in the CHOICE randomized trial (self-expandable, 5.8% vs.



Retrievable and repositionable devices are welcomed.

Transcatheter implantation of aortic valve prostheses into degenerated mitral valve bioprostheses and failed annuloplasty rings: outcomes according to access route and Mitral Valve Academic Research Consortium (MVARC) criteria

EuroIntervention 2016;12

Online Table 1. Haemodynamic variables before and after TMVIV/TMVIR.

	All patients (n=24)			TA access (n=13)			TS access (n=11)		
	Pre	Post	*p*-value	Pre	Post	*p*-value	Pre	Post	*p*-value
Pulmonary artery pressure, mmHg									
Systolic	56.4±17.7	53.3±11.6	0.60	54.1±17.1	53.6±12.6	0.78	57.9±18.9	53.7±11.0	0.66
Diastolic	26.6±10.2	23.2±9.4	0.24	27.1±10.0	25.1±10.5	0.62	26.2±10.9	21.2±8.1	0.21
Mean	38.5±12.2	34.4±9.6	0.14	37.6±12.1	35.2±11.1	0.53	39.5±12.8	33.6±8.2	0.11
Pulmonary capillary wedge pressure, mmHg	25.0±9.5	18.3±6.1	0.0047	25.4±10.5	18.7±6.2	0.0458	24.5±8.9	17.8±6.2	0.06
Right atrial pressure, mmHg	13.7±5.9	12.1±4.0	0.33	13.3±5.4	11.2±4.0	0.14	14.2±6.7	13.1±4.1	0.83
Left atrial pressure, mmHg	22.9±8.4	14.7±6.4	0.0006	22.3±10.5	15.7±5.5	0.07	23.5±6.0	13.7±7.6	0.0034
v-wave LA, mmHg	42.3±18.3	22.2±9.9	0.0004	37.4±15.9	22.8±8.1	0.0148	47.3±20.0	21.6±11.7	0.0090
Mean transmitral pressure gradient, mmHg	11.7±6.3	5.6±2.0	0.0024	13.7±6.0	5.5±2.1	0.0300	10.2±6.6	5.8±1.9	0.052
Cardiac output, l/min	4.1±1.0	4.6±1.2	0.0070	4.1±1.0	4.1±0.8	0.82	4.1±1.1	5.0±1.4	0.0015
Aortic pressure, mmHg									
Systolic								116±29	0.49
Diastolic								3.2±12.9	0.08
Mean								7.2±11.0	0.52

LA: left atrium; PVR: pulmonary vascular resistance; SVR: systemic vascular resistance; TA: transapical; TMVIR: transcatheter mitral valve-in-ring; TMVIV: transcatheter mitral valve-in-valve; TS: transseptal

No acute improvement in cardiac output was noted in patients underwent TA acess.

Transcatheter implantation of aortic valve prostheses into degenerated mitral valve bioprostheses and failed annuloplasty rings: outcomes according to access route and Mitral Valve Academic Research Consortium (MVARC) criteria

EuroIntervention 2016;12

In the long term, TA access had a significant adverse impactd on survival.

- **TA approach with its direct, shortest, and co-axial access to the mitral valve has advantages with respect to positioning and implantation of the new bioprosthesis.**
- **The less invasive TS approach is technically more challenging in order to achieve coaxial alignment of the new prosthesis with the degenerated surgical bioprosthesis or ring.**

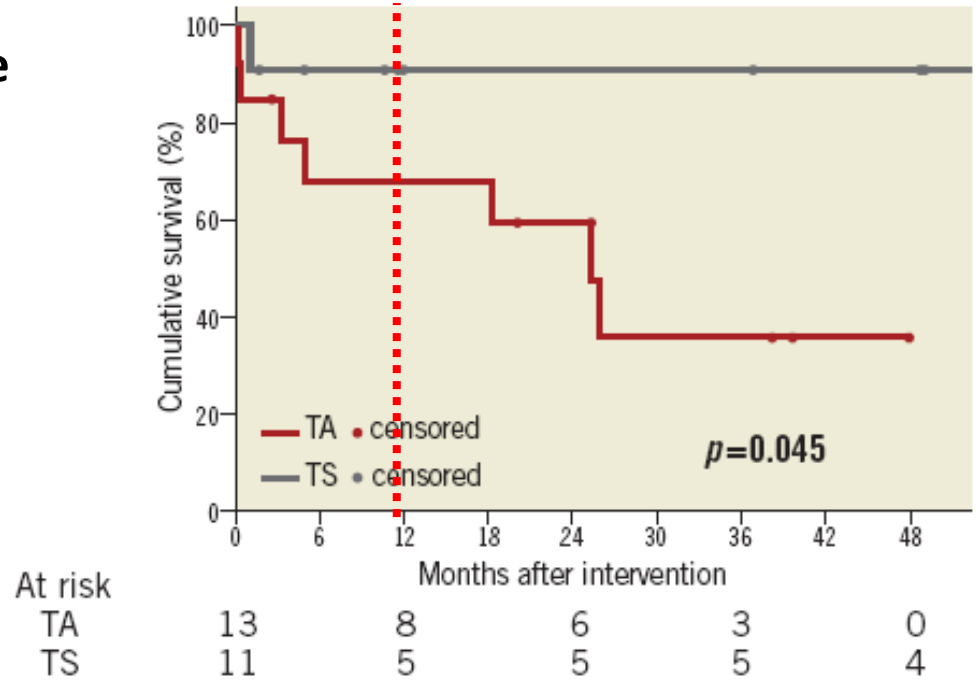


Figure 2. *Cumulative survival according to vascular access route.*

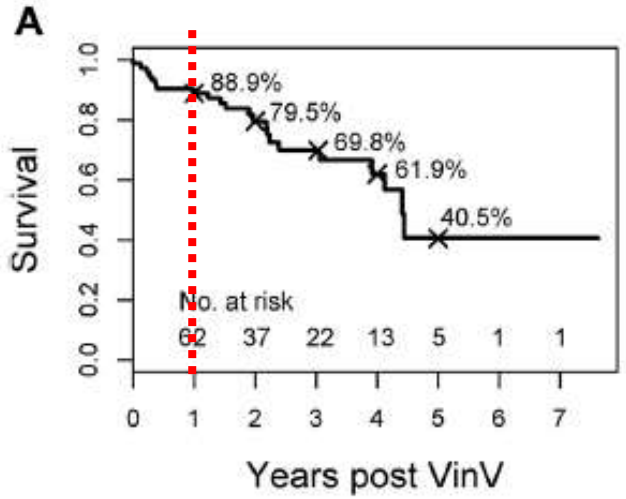
Mitral VIV: Access selection based on patient and anatomical characteristics

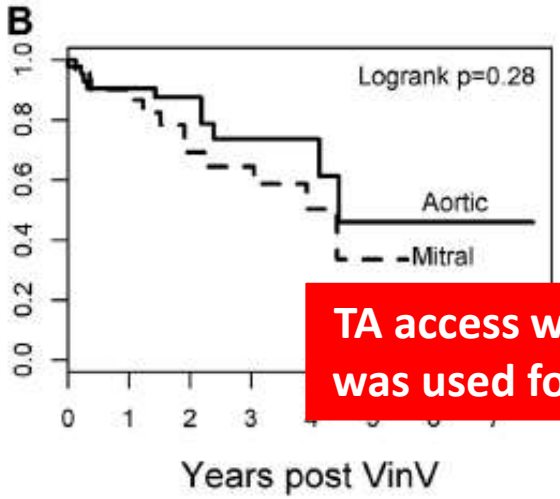
Favors transapical	Base on the experiences of the operators and the heart team
Combined mitral and aortic valve implantation	Combined mitral and pulmonary/tricuspid valve implantation
Need for very precise positioning	Aiming for a shorter hospital stay
Crossing the surgical valve with a transcatheter heart valve is predicted to be challenging	Chest wall deformity or when aiming for avoid thoracotomy
Future transseptal procedure is planned	Clinical need to avoid general anesthesia
Peripheral venous system abnormality	Apical scar
Atrial septal anatomy is challenging	Left ventricular systolic dysfunction
Thrombus in left atrial cavity or appendage	

Transcatheter Aortic and Mitral Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

(J Am Coll Cardiol Intv 2015;8:1735–44)

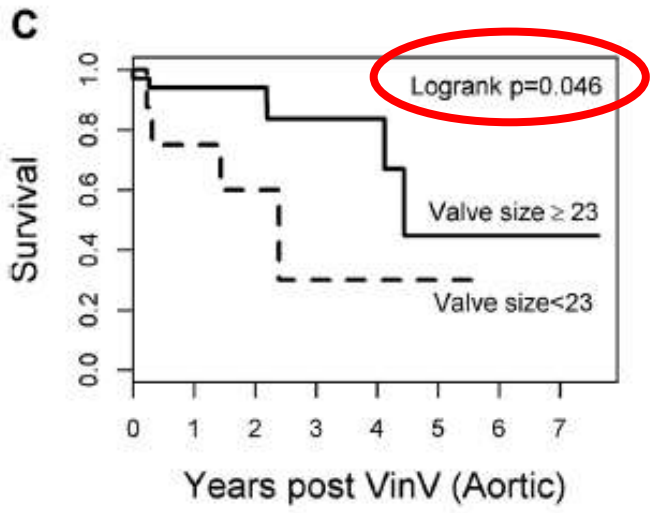
An 8-Year Single-Center Experience





D,† Defen Peng, PhD,‡
R. Moss, MD,†
, MD†

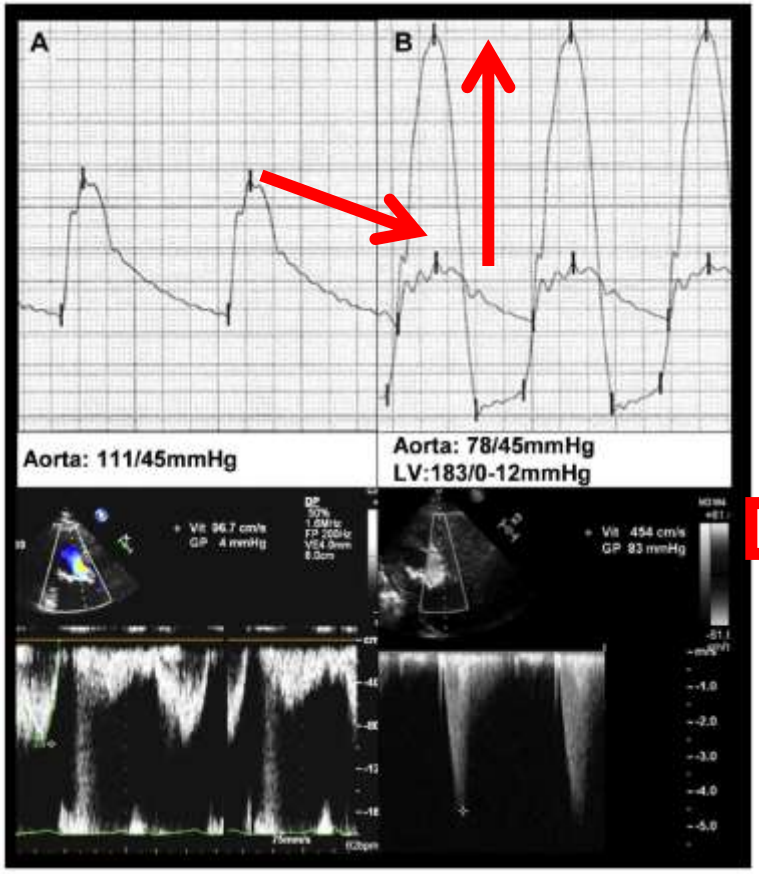
TA access was the only approach that was used for mitral VIV implantation.



WHAT IS NEW?

- Transcatheter VIV implantation provides encouraging mid-term clinical and hemodynamic outcomes in this high-risk elderly cohort of patients.
- The **small surgical valve size (19 and 21 mm)** was an independent risk factor for reduced survival in **aortic VIV** patients.

Life-threatemog complication of transcatheter mitral VIV/VIR – LVOT obstruction



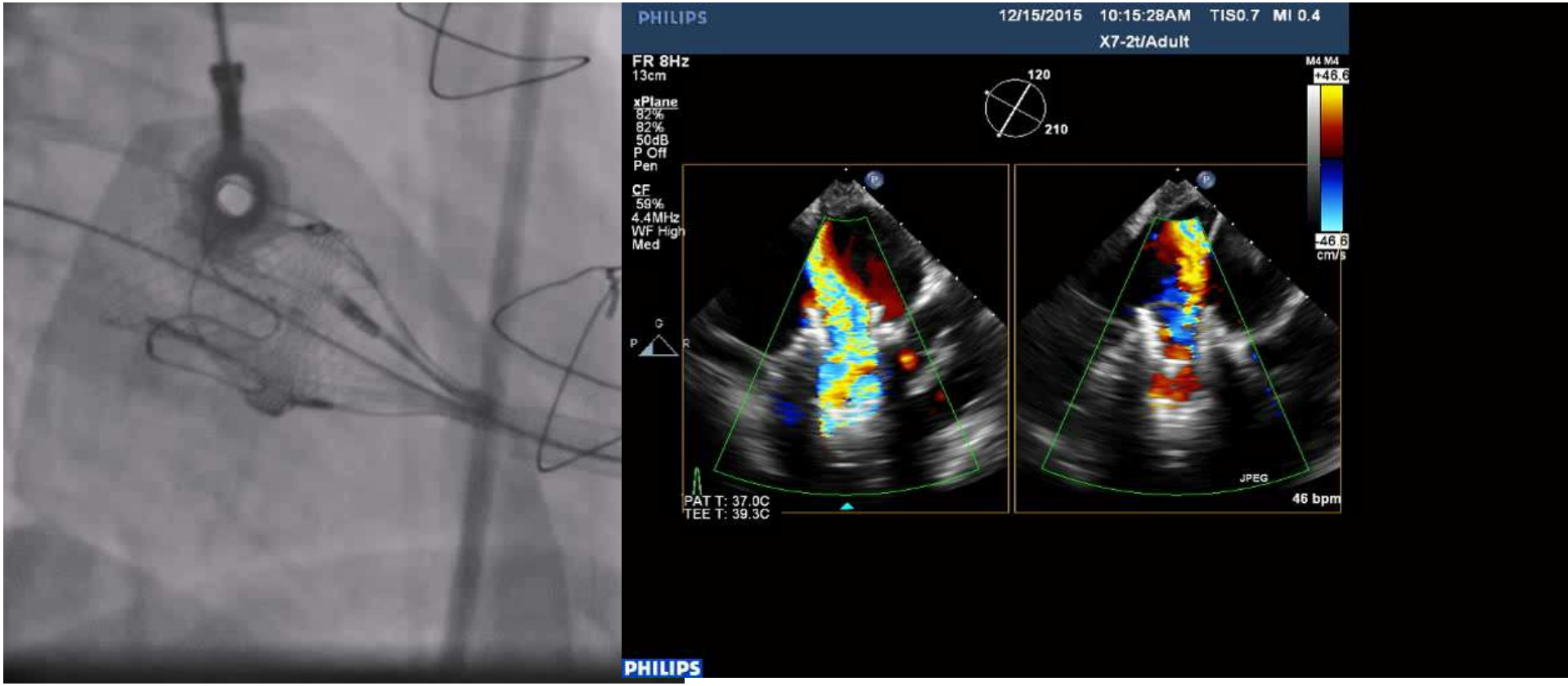
Bail-Out Alcohol Septal Ablation for Left Ventricular Outflow Tract Obstruction After Transcatheter Mitral Valve Replacement

FIGURE 3 Fluoroscopy Images Showing the Different Steps of the Septal Alcohol Ablation Procedure and Hemodynamic Curves and Echocardiographic Images Showing Acute Results

(A) A coronary angiogram confirmed the presence of a septal artery suitable for alcohol ablation. Two milliliters of pure ethanol were injected in the first septal branch (B), with complete occlusion of the artery (C, white arrows). (D) Immediately after injecting the ethanol, a normalization of the shape of the aorta pressure curve and recovery of the pressure were observed. (E) Echocardiographic assessment confirmed the maximal left ventricular outflow gradient of 24 mm Hg (Online Video 4). LV = left ventricle.

Advantage of transcatheter mitral VIV with the repositionable and retrievable Lotus valve

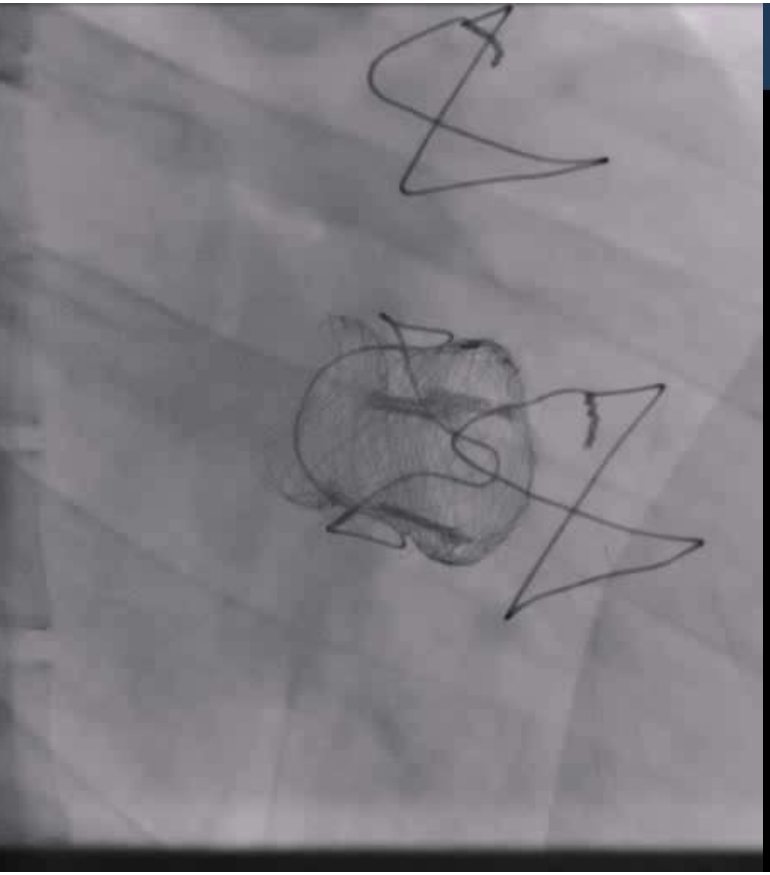
Positioned a little high in LA

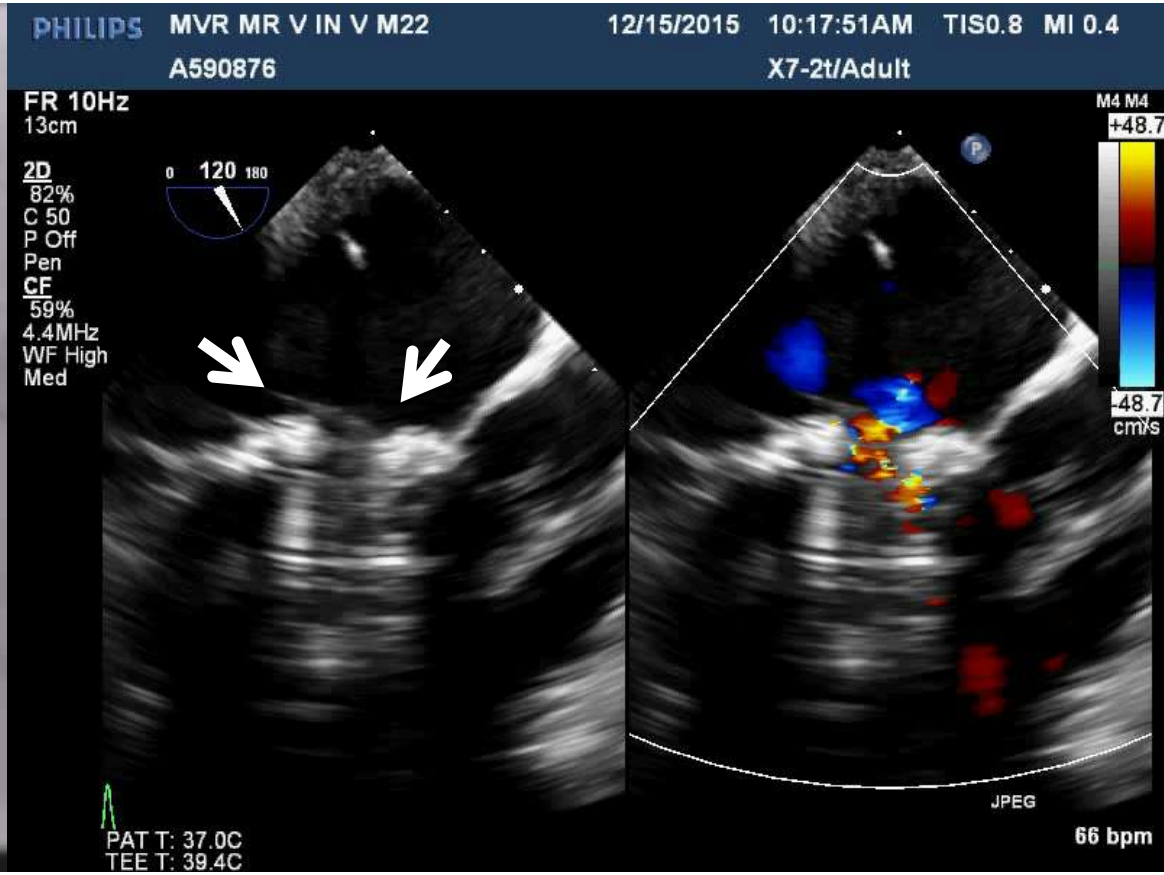


Advantage of transcatheter mitral VIV with the repositionable and retrievable Lotus valve

Re-sheathed and re-positioned

After final releasing, TEE demonstrated good positioning of the Lotus valve





Aortic and mitral VIV @ Cheng Hsin

Clinical characteristics

Parameters	Aortic VID (N=19)	Mitral VIV (N=21)	P value
Male gender, n (%)	12 (63)	9 (43)	NS
Age, yrs	75±10	65±15	0.015
Height, cm	163±8	160±10	NS
Weight, kg	68±11	57±11	0.004
BMI	25.5±3.7	22.3±3.2	0.006
Diabetes mellitus, n (%)	6 (32)	6 (29)	NS
Hypertension, n (%)	10 (53)	8 (38)	NS
Coronary A. disease, n (%)	9 (47)	11 (52)	NS
Previous PCI/CABG, n (%)	6 (32)	10 (48)	NS
PAOD, n (%)	0 (0)	4 (19)	NS
Carotid artery disease, n (%)	1 (5)	0 (0)	NS
Previous stroke, n (%)	1 (5)	7 (33)	NS
COPD, n (%)	1 (5)	2 (10)	NS

Aortic and mitral VIV @ Cheng Hsin

Clinical characteristics

Parameters	Aortic VID (N=19)	Mitral VIV (N=21)	P value
Chronic kidney disease > stage 3	11 (58)	9 (43)	NS
Creatinine, mg/dL	1.3±0.5	1.5±0.4	NS
eGFR, mL/mg	59±27	68±37	NS
Uremia on chronic dialysis, n (%)	0 (0)	2 (10)	NS
Liver cirrhosis, n (%)	0 (0)	1 (5)	NS
Hemoglobin, g/dL	12.1±2.7	11.4±2.7	NS
Anemia, n (%)	12 (63)	15 (71)	NS
Albumin, mg/dL	3.5±0.3	3.4±0.4	NS
NYHA functional status, n (%)			
III	16 (84)	12 (57)	NS
IV	3 (16)	9 (43)	NS
Syncope, n (%)	0 (0)	1 (5)	NS
Logistic EuroSCORE	19.8±11.9	25.0±18.0	NS

Aortic and mitral VIV @ Cheng Hsin

Surgical valve characteristics @ VIV procedure

Parameters	Aortic VID (N=19)	Mitral VIV (N=21)	P value
Time since last SVR, yrs	10.0±4.3	8.7±3.8	NS
> 1 previous SVR, n (%)	1 (5)	4 (19)	NS
Type of bioprosthesis, n (%)			
stented, n (%)	16 (89)	20 (100)	NS
stentless, n (%)	2 (11)	0 (0)	NS
Label size, n (%)			
≦21mm	8 (45)	0 (0)	0.003
between 21mm and 25mm	4 (22)	0 (0)	NS
≧25mm	6 (33)	20 (100)	<0.0001
App true ID, n (%)			
<20mm	10 (56)	0 (0)	0.0004
between 20mm and 23mm	6 (33)	0 (0)	0.018
≧23mm	2 (11)	20 (100)	<0.0001

Aortic and mitral VIV @ Cheng Hsin

Surgical valve characteristics @ VIV procedure

Parameters	Aortic VID (N=19)	Mitral VIV (N=21)	P value
Mechanisms of failure, n (%)			
stenosis	7 (37)	4 (19)	NS
regurgitation	8 (42)	11 (52)	NS
combined	4 (21)	6 (29)	NS
stentless, n (%)	2 (11)	0 (0)	NS
Echo parameters			
Valve area, cm2	0.8±0.2	1.9±0.7	<0.0001
Valve mean gradient, mmHg	25.8±10.6	13.2±7.2	<0.0001
Left ventricular EF, %	54.5±12.7	55.1±6.9	NS
≧ moderate regurgination	12 (63)	17 (81)	NS
Right ventricular systolic pressure, mmHg	47.9±18.2	65.6±17.7	0.004
Pulmonary hypertension, n (%)	7 (37)	18 (86)	0.004

Aortic and mitral VIV @ Cheng Hsin

Procedural characteristics of aortic VIV

Parameters	CoreValve (N=12)	Sapien (N=7)	P value
Device size, n (%)			
23mm	5 (42)	5 (71)	NS
26mm	7 (58)	2 (29)	NS
Access, n (%)			
Transfemoral	11 (92)	4 (57)	NS
Transapical	0 (0)	3 (43)	NS
Trans-subclavian	1 (8)	0 (0)	NS
Implantation depth, mm	3.7±1.8	1.7±0.5	0.004
Fluoroscopic time, min	24.2±9.7	14.8±7.9	0.046
Total procedure time, min	67.3±14.6	56.1±17.4	NS
Contrast volume, mL	35.4±31.4	41.4±71.9	NS

Aortic and mitral VIV @ Cheng Hsin

Procedural and 30-day clinical outcomes of aortic VIV

Parameters	CoreValve (N=12)	Sapien (N=7)	P value
Procedural outcomes, n (%)			
Second valve needed, n (%)	2 (17)	0 (0)	NS
≧ moderate paravalvular leaks	2 (17)	1 (14)	NS
Device success, n (%)	8 (67)	6 (86)	NS
Annular rupture	0 (0)	0 (0)	NS
Coronary occlusion	0 (0)	0 (0)	NS
Surgical conversion	0 (0)	0 (0)	NS
30-day outcomes, n (%)			
Mortality	0 (0)	0 (0)	NS
Disabling stroke	0 (0)	0 (0)	NS
Non-fatal MI	0 (0)	0 (0)	NS
Major vascular access injury	0 (0)	0 (0)	NS
AKI needing dialysis	0 (0)	0 (0)	NS
Permanent pacer implantation	1 (8)	4 (57)	NS

Aortic and mitral VIV @ Cheng Hsin

Echo and clinical outcomes of aortic VIV @ 30-day and later

Parameters	CoreValve (N=12)	Sapien XT (N=7)	P value
Echo parameters @ 30-day			
Valve area, cm2	1.6±0.3	1.8±0.3	NS
Valve mean gradient, mmHg	11.9±7.5	14.3±7.5	NS
Left ventricular EF, %	59.1±8.1	57.7±8.5	NS
≧ moderate regurgination	1 (8)	0 (0)	NS
Right ventricular systolic pressure, mmHg	41.3±16.9	37.0±7.3	NS
NYHA functional status, n (%)			
I/II	11 (92)	6 (86)	NS
III/IV	1 (8)	1 (14)	NS
Later outcomes, median FU of 1-yr			
Mortality	1 (8)	1 (14)	NS

Aortic and mitral VIV @ Cheng Hsin

Procedural characteristics of mitral VIV

Parameters	Lotus (N=6)	Sapien XT (N=15)	P value
Device size, n (%)			
25mm	1 (17)	0 (0)	NS
26mm	0 (0)	3 (20)	NS
27mm	5 (83)	0 (0)	<0.0001
29mm	0 (0)	12 (80)	0.009
Transapical access, n (%)	6 (100)	15 (100)	NS
Implantation depth, mm	1.7±0.5	2.7±1.3	NS
Fluoroscopic time, min	15.7±2.9	15.3±8.7	NS
Total procedure time, min	32.4±5.1	35.6±14.0	NS
Contrast volume, mL	0±0	0±0	NS

Aortic and mitral VIV @ Cheng Hsin

Procedural and 30-day clinical outcomes of mitral VIV

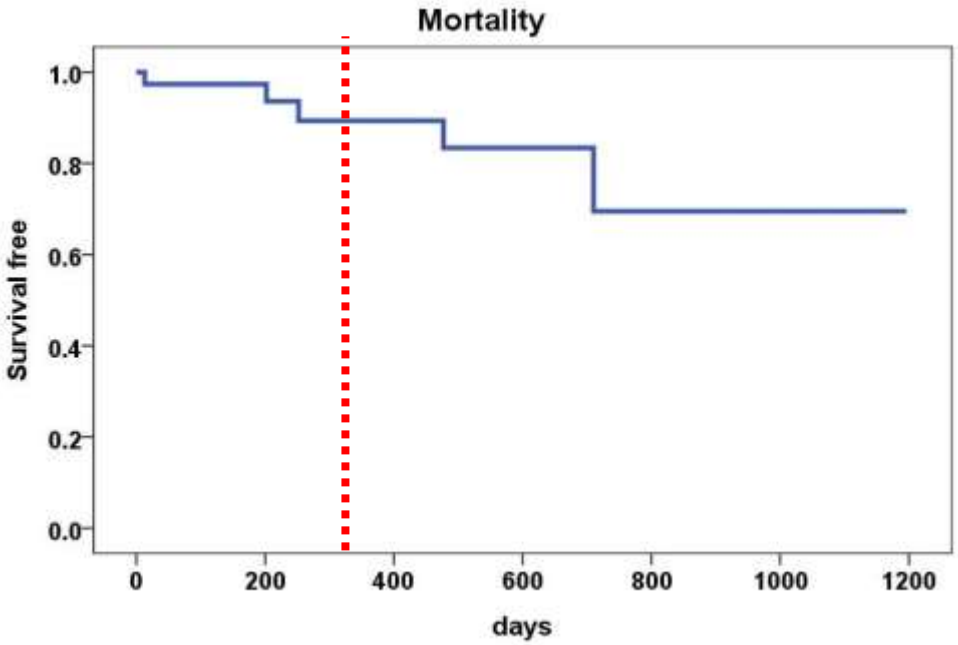
Parameters	Lotus (N=6)	Sapien XT (N=15)	P value
Procedural outcomes, n (%)			
Second valve needed, n (%)	0 (0)	0 (0)	NS
≧ moderate paravalvular leaks	0 (0)	0 (0)	NS
Device success, n (%)	6 (100)	0 (100)	NS
Annular rupture	0 (0)	0 (0)	NS
LVOT obstruction	0 (0)	0 (0)	NS
Surgical conversion	0 (0)	0 (0)	NS
30-day outcomes, n (%)			
Mortality	0 (0)	0 (0)	NS
Disabling stroke	0 (0)	0 (0)	NS
Non-fatal MI	0 (0)	0 (0)	NS
Major vascular access injury	0 (0)	1 (7)	NS
AKI needing dialysis	0 (0)	0 (0)	NS
Permanent pacer implantation	0 (0)	0 (0)	NS

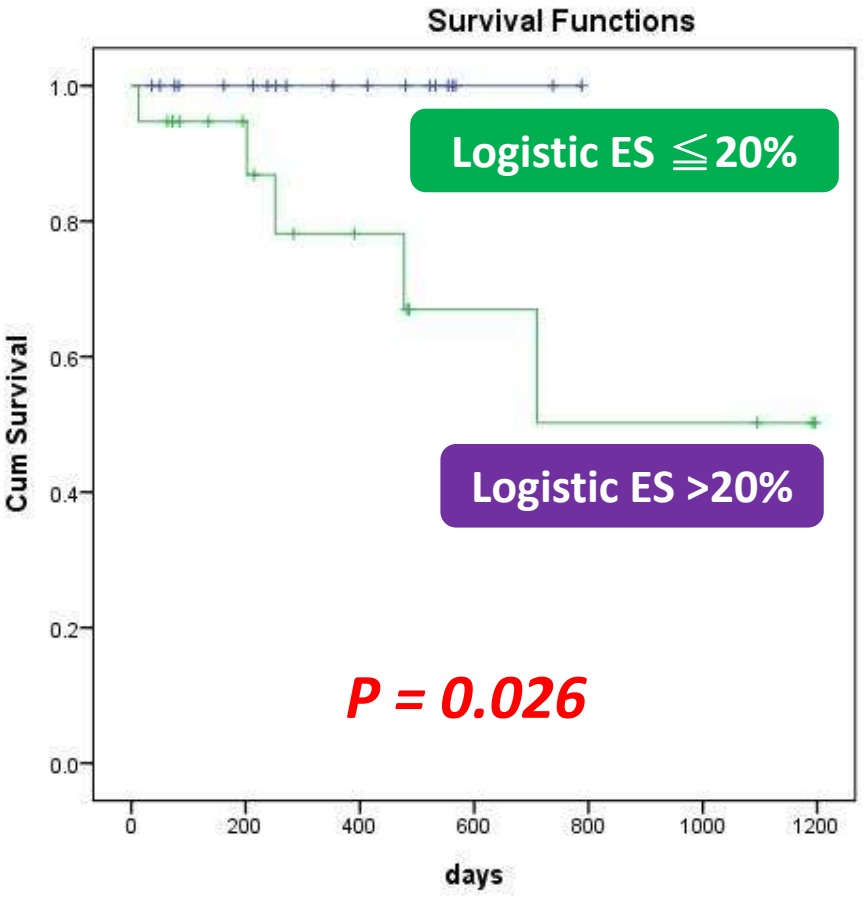
Aortic and mitral VIV @ Cheng Hsin

Echo and clinical outcomes of mitral VIV @ 30-day and later

Parameters	Lotus (N=6)	Sapien XT (N=15)	P value
Echo parameters @ 30-day			
Valve area, cm2	2.1±0.8	1.8±0.3	NS
Valve mean gradient, mmHg	7.8±3.6	6.3±1.5	NS
Left ventricular EF, %	53.0±16.6	59.3±4.1	NS
≧ moderate regurgination	0 (0)	0 (0)	NS
Right ventricular systolic pressure, mmHg	37.0±13.2	46.8±12.7	NS
NYHA functional status, n (%)			
I/II	4 (67)	8 (53)	NS
III/IV	2 (33)	7 (47)	NS
Later outcomes, median FU of 1-yr			
Mortality	1 (17)	3 (20)	NS

Aortic and mitral VIV @ Cheng Hsin





Logistic EuroSCORE > 20% is a strong determinant of long-term mortality.

Conclusions

- Aortic and mitral VIV implantation can be considered as **an acceptable alternative** to re-do open heart surgery for elderly high-risk surgical patients with bioprosthetic degeneration.

- **Proper sizing**, **selection of appropriate devices**, and **precise implantation depth** are the keys to success in transcatheter VIV procedures.

- The mid-term clinical and hemodynamic outcomes of transcatheter VIV implantation **are encouraging.**

- In patients undergoing conventional surgery with a bioprosthesis, **efforts should be made to implant a larger bioprostheses**, allowing for a future VIV implant with optimal hemodynamics and clinical outcomes.

Transcatheter Heart Valve Team at Cheng Hsin

>290 THV interventions in 4.5 years

Team leader

Prof. Jeng Wei

曹殿萍 主任

殷偉賢 主任

Cardiologists

Surgeons

尤和平 醫師

陳怡誠 醫師

李國楨 醫師

李永在 醫師

熊名琛

曾芸軒

蔡勝國

周毅鵬

Imaging specialists

Anesthesiologists

邱俊雄 體循師

Radiographers, perfusionist, nursing staffs……..

Thank You and Have a Nice Day!