

Transcatheter Aortic Valve Implantation – Asian perspective

Paul TL Chiam
MBBS, MRCP, FACC

Consultant
National Heart Center Singapore



National Heart
Centre Singapore

SingHealth

Speakers's name: Paul Chiam

I have the following potential conflicts of interest to report:

NONE

TAVI

- 1st human TAVI – 2002 by Cribier et al

Special Report

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description

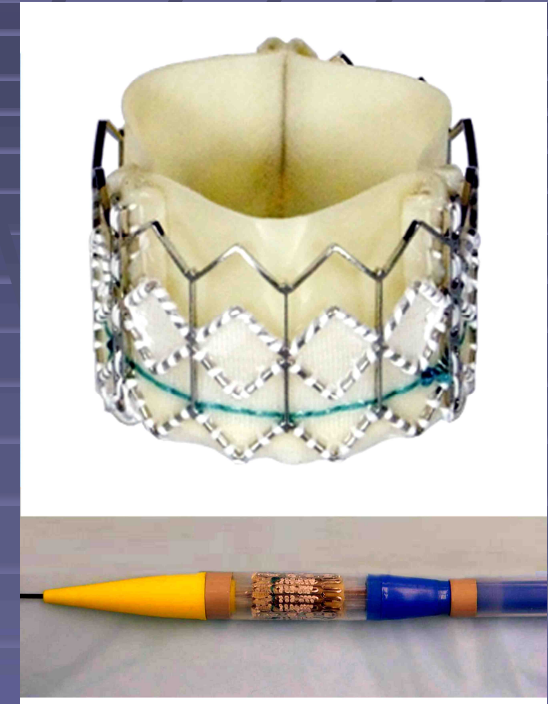
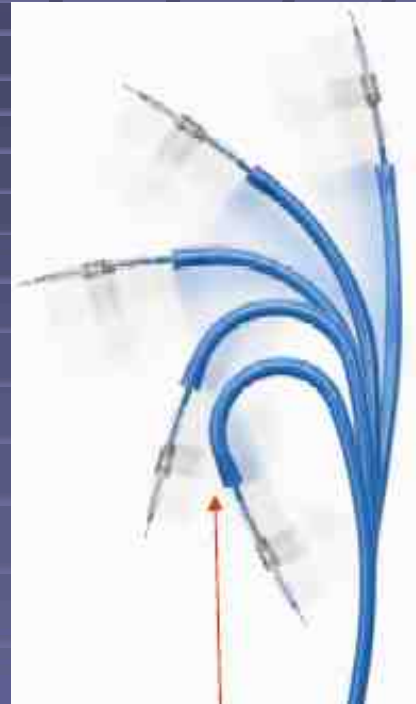
Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

Conclusions—Nonsurgical implantation of a prosthetic heart valve can be successfully achieved with immediate and midterm hemodynamic and clinical improvement. After further device modifications, additional durability tests, and confirmatory clinical implantations, PHV might become an important therapeutic alternative for the treatment of selected patients with nonsurgical aortic stenosis. (*Circulation*. 2002;106:3006-3008.)

Antegrade transvenous transseptal route

TAVI

- Edwards-Sapiens
- Balloon expandable, stainless steel frame
- Bovine (formerly equine) pericardial leaflets
- CE marked; FDA randomized trial enrolment complete
- 23mm and 26mm diameters
- Approximately 14mm and 16mm height



PARTNER TRIAL Trial



	Inclusion criteria	Primary end points	Secondary end points
Cohort A	(1) Predicted operative mortality $\geq 15\%$ or STS score ≥ 10 (2) Degenerative AS, MPG > 40 mm Hg, AVA < 0.8 cm ² , jet velocity > 4 m/s (3) \geq NYHA II	Freedom from death at 1 y	Functional improvement Freedom from MACCE Valve dysfunction Length of index hospital stay Total hospital days at 1 y QOL Improved valve function
Cohort B	(1) Risk of procedural death/serious, irreversible morbidity $> 50\%$ (2) No. 2 + 3 from above	Freedom from death during study duration	Functional improvement Freedom from MACCE Total hospital days at 1 y QOL Improved valve function

B. Exclusion criteria of the PARTNER trial

Uni-/bicuspid aortic valve
Myocardial infarction ≤ 1 m

Mixed aortic valve disease (AR $\geq 3+$)

Invasive cardiac procedure
 ≤ 30 d (≤ 6 m if DES implanted)

Preexisting prosthetic valve

Mitral regurgitation $\geq 3+$

Blood dyscrasias

Coronary artery disease requiring
revascularization

Hemodynamic instability requiring inotropics
or mechanical assistance

Need for any emergency surgery

Hypertrophic cardiomyopathy with
or without obstruction

Severe LV dysfunction ($< 20\%$)

Intracardiac mass, thrombus, or vegetation

Active peptic ulcer or GI bleeding within 3 m

Allergy to aspirin, ticlopidine, clopidogrel,
or heparin

Native aortic annulus < 16 or > 24 mm

Patient refused surgery

CVA or TIA within 6 m

Renal insufficiency or end-stage renal disease
requiring dialysis

Life expectancy < 12 m due to noncardiac
comorbidities

Significant aortic disease (aneurysm, tortuosity,
excessive atheroma, or stenosis)

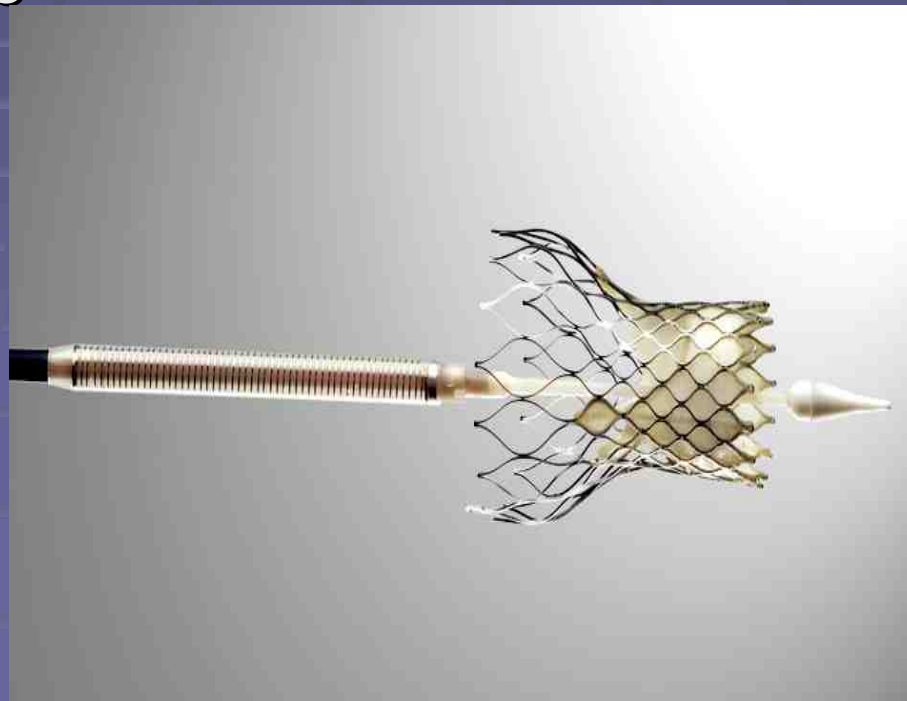
(applicable to transfemoral route only)

Iliofemoral vessels < 7 mm (transfemoral route only)

Participating in another trial

TAVI

- CoreValve
- Self-expandable THV
- Nitinol frame
- Porcine pericardial leaflets
- Longer device



Transcatheter Aortic Valve Implantation

Impact on Clinical and Valve-Related Outcomes

- 168 patients; TF 113, TA 55
- Median EuroScore 28.6%
- Median STS 9.1
- Procedural success 94.1% (1st half 89% → 2nd half 98%)
- 30-d mortality 11.3% (TF 8% vs TA 18.2%, $p=0.07$)

- 30-d mortality **1st half** 14.3% → **2nd half** 8.3%
- 30-d mortality **TF**: 12.3% → 3.6%; **TA**: 20.5% → 11.1%
- CVA 4.2% (TF 5.3% vs TA 1.8%, $p=0.43$)
- 1 yr survival 74%
- Paravalvular leak common, generally mild

Conclusions—Transcatheter aortic valve implantation can result in early and sustained functional improvement in high-risk aortic stenosis patients. Late outcome is determined primarily by comorbidities unrelated to aortic valve

Current results

- SOURCE registry
- **Transfemoral**
- N= 305
- Mean EuroScore 26.4%
- Procedural success 95%
- Procedural mortality 0.3%
- 30-d mortality **6.4%**
- CVA 3.4%
- Walther et al
- **Transapical**
- N= 168
- Mean EuroScore 27%
- Procedural success 92.8%
- 30-d mortality **15%**
- CVA 2.9%

Presented at TCT 2008

Pooled results show overall 30-d mortality ~ 10%

Procedural success 94 – 98%

TCT 2009

TAVI in Asia

- TF program –
Feb 2009
- TA program –
Mar 2009

Case Report

Singapore Med J 2009; 50(5) : 534

Percutaneous transcatheter aortic valve replacement: first transfemoral implant in Asia

Chiam P T L, Koh T H, Chao V T T, Lee C Y, See Tho V Y, Tan S Y, Lim S T, Hwang N C, Sin Y K, Chua Y L

Case Report

Singapore Med J 2010; 51(1) : 69

Percutaneous transcatheter aortic valve replacement: first transapical implant in Asia

Chao V T T, Chua Y L, Chiam P T L, Lee C Y, See Tho V Y, Tan S Y, Sin Y K, Hwang N C, Lim S T, Koh T H



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TAVI – Singapore experience

- Case selection:
- Deemed at high risk for open AVR or non-operable by 2 surgeons
- Case discussed at our combined conference

TAVI – Singapore experience

- Pre-procedure work up:
 - Echo
 - Cardiac cath/ ilio-femoral angio/ root aortogram
 - Duplex ilio-femoral arteries
 - ± CT of the distal aorta and iliofemoral vessels
 - ± CTA of the heart
- Procedure:
 - GA, TEE
 - Groin cutdown or anterolateral thoracotomy

TAVI – Singapore experience

- 17 cases to date
- 5 transfemoral, 12 transapical

- Mean age: 73 yrs (55 – 86)
- 7 males, 10 females

- Mean AVA: 0.69 cm² (0.5 – 0.8 cm²)

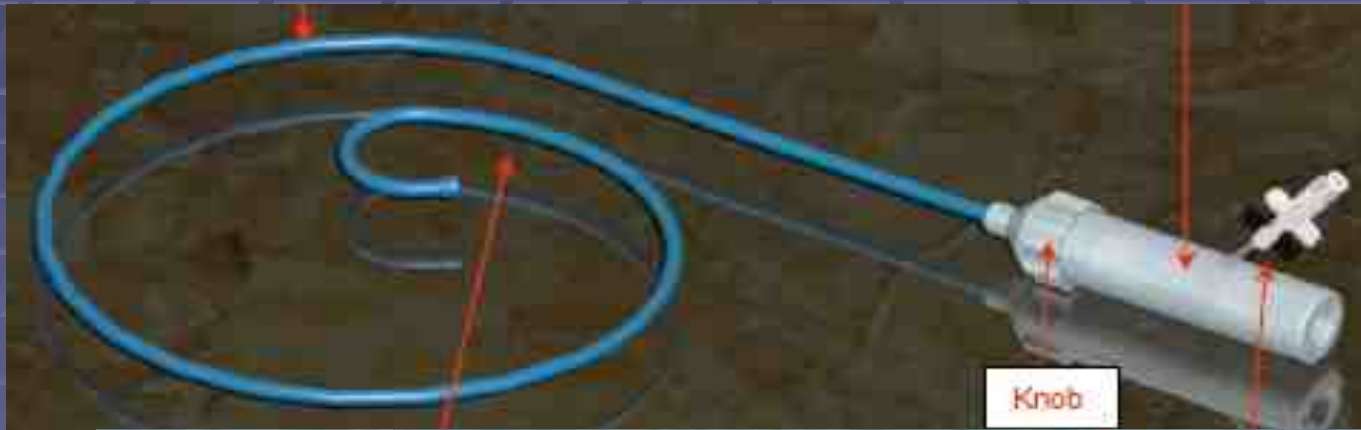
- Mean EuroScore: 15.5%

TAVI – Singapore experience

- 13 x 23mm THV, 4 x 26mm THV
- Other high risk reasons:
 - Previous mastectomy + irradiation – 2
 - Previous CABG heart with adherent cardiac structures – 1
 - Porcelain / heavily calcified aorta – 3
 - Previous MVR + elderly female + frail
 - Familial hyperlipidemia + CABG + CVAs + bilat CEA (diffuse restenosis of both CCAs/ ICAs) + occluded R vertebral + L subclavian stent + PAD
 - Severe COPD
 - Frailty – 1

TAVI – Singapore experience

- Transfemoral procedure
- Catheter used



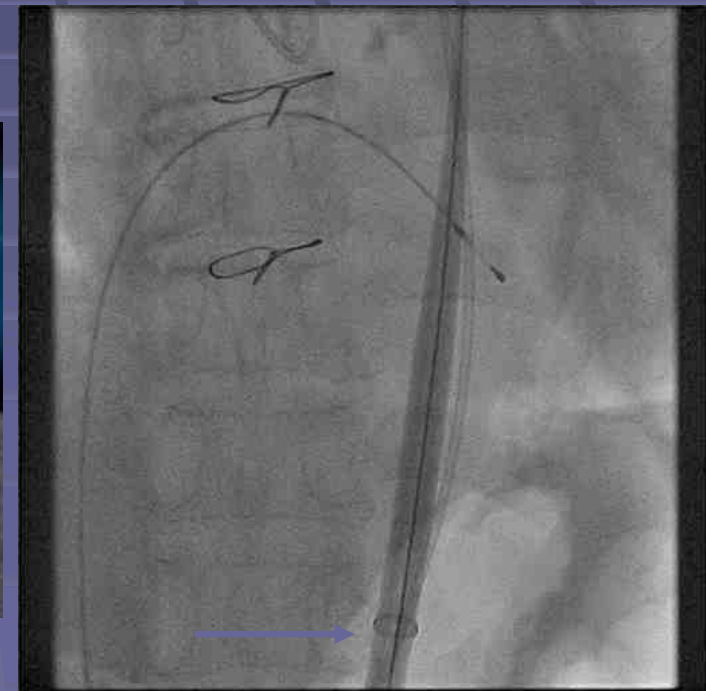
TAVI – Singapore experience

- Valve crossed and valvuloplasty performed
- Valve crimped in cath lab



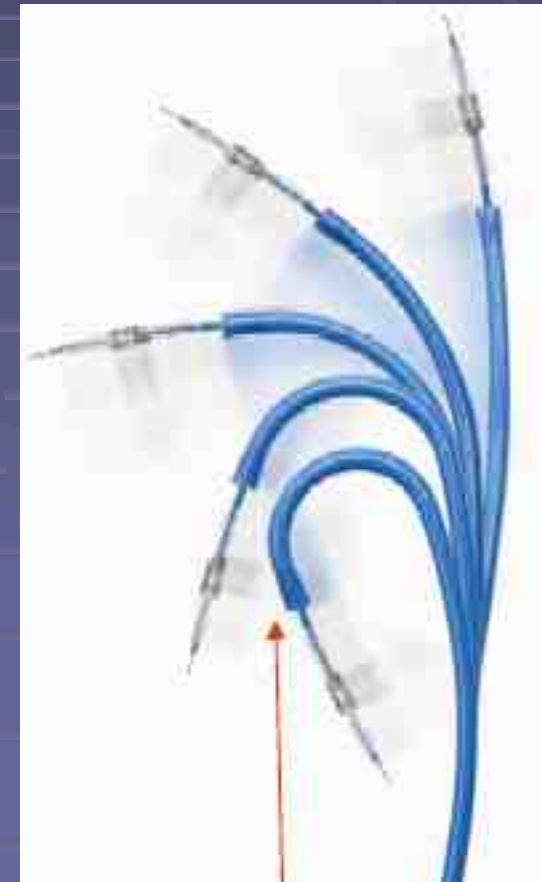
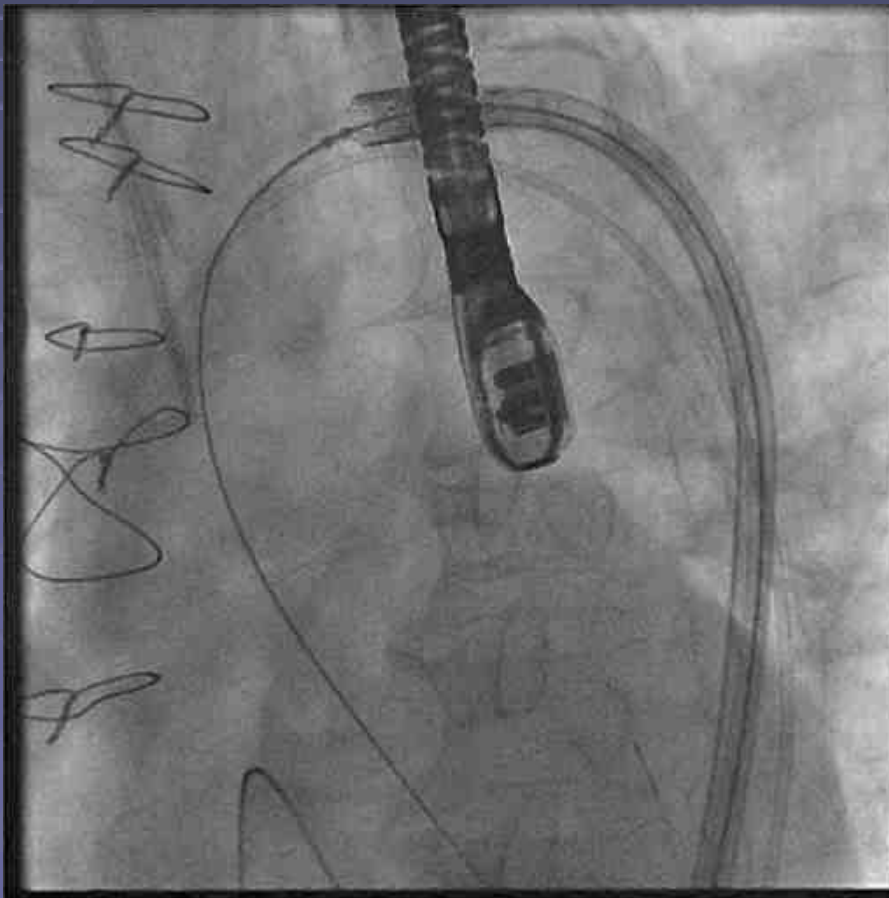
TAVI – Singapore experience

- 22F or 24F sheath placed
- Retroflex catheter placed in a loader
- Assembly advanced into sheath



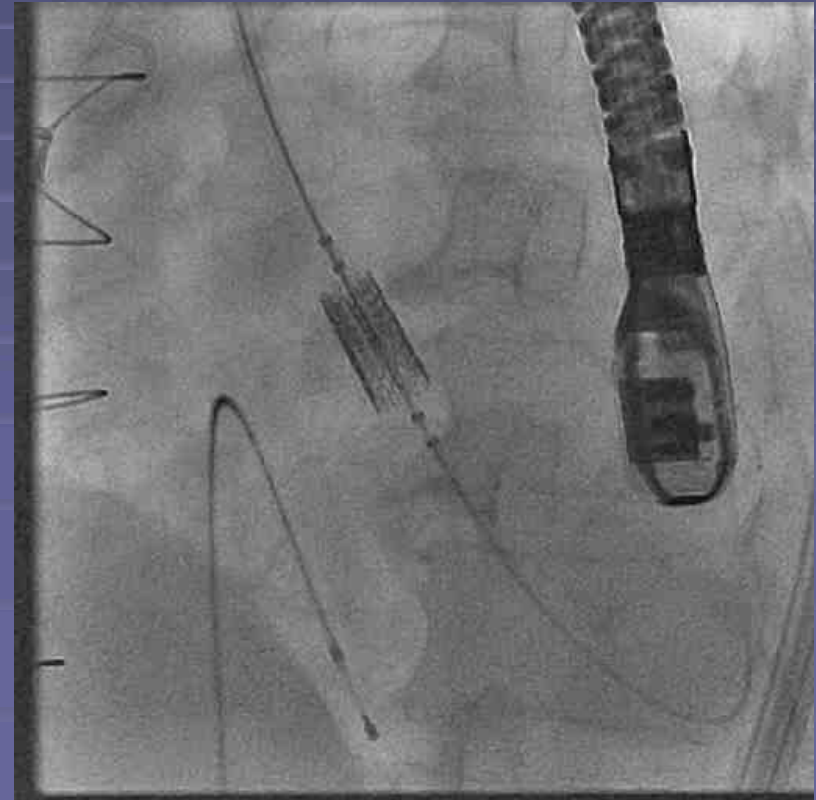
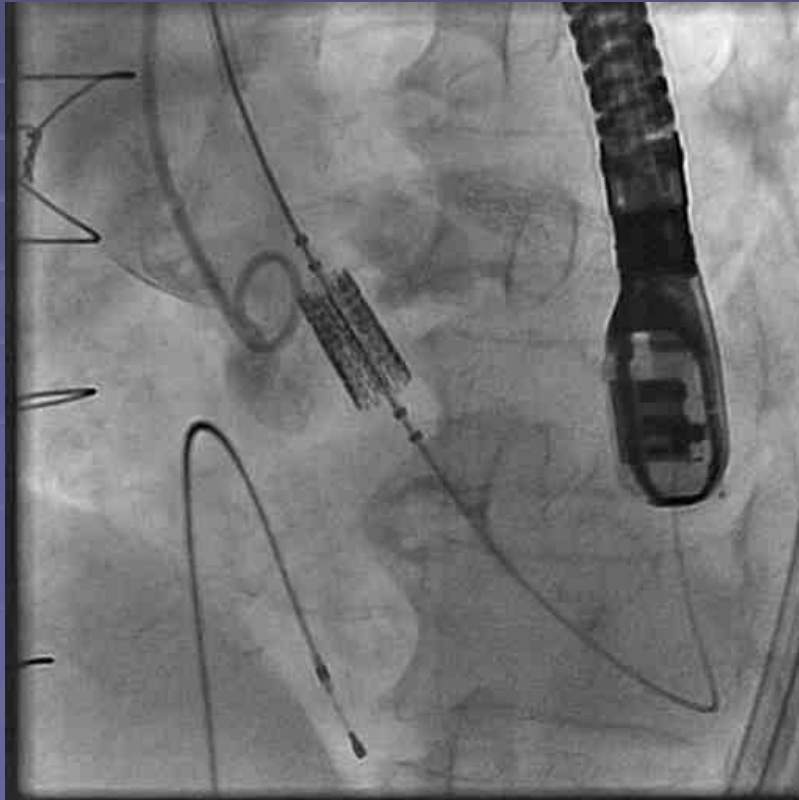
TAVI – Singapore experience

- Retroflex catheter navigated around arch



TAVI – Singapore experience

- THV placed within the native valve
- Position assessed by aortograms and TEE
- Rapid pacing initiated
- THV balloon inflated and deflated
- Pacing turned off



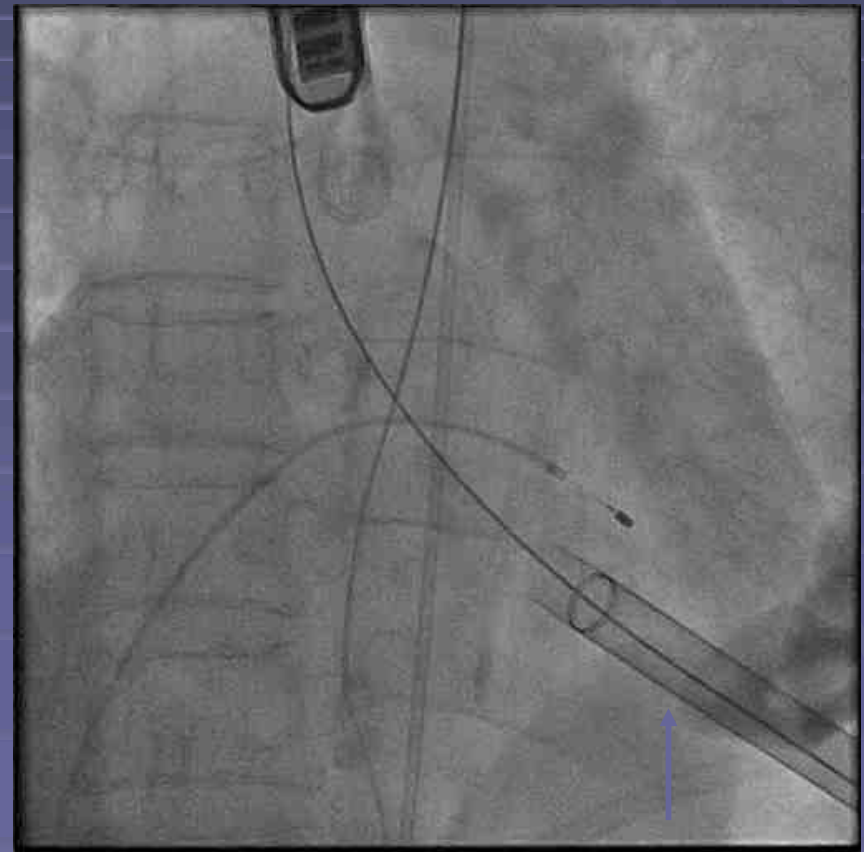
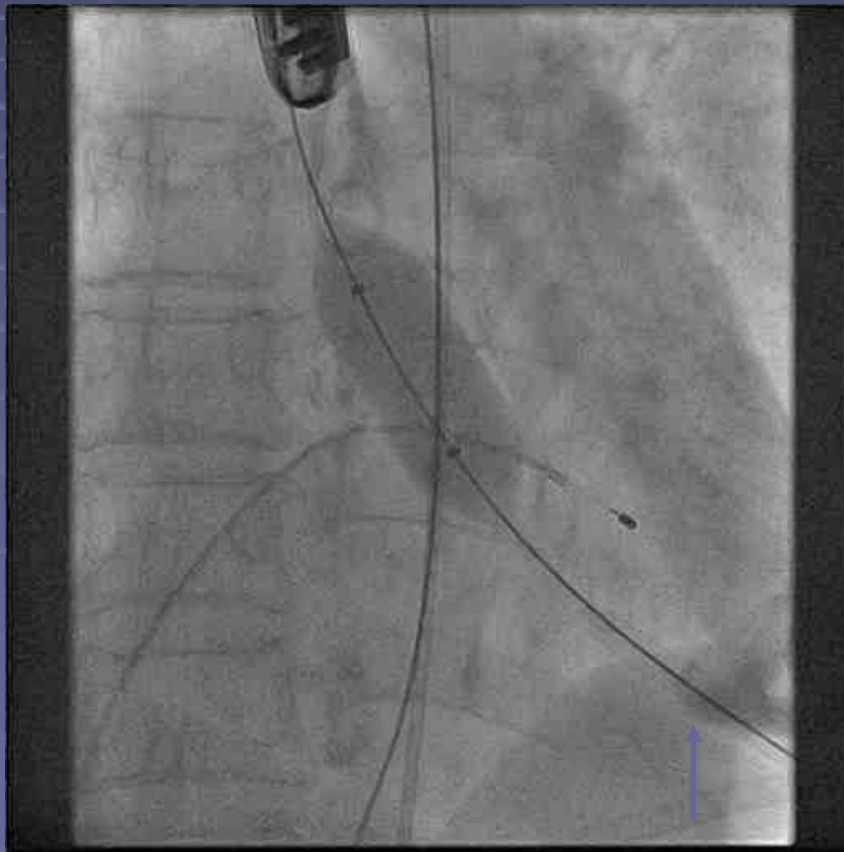
TAVI – Singapore experience

- Catheter and wire removed
- Position, gradient and AR assessed by TEE
- Aortogram

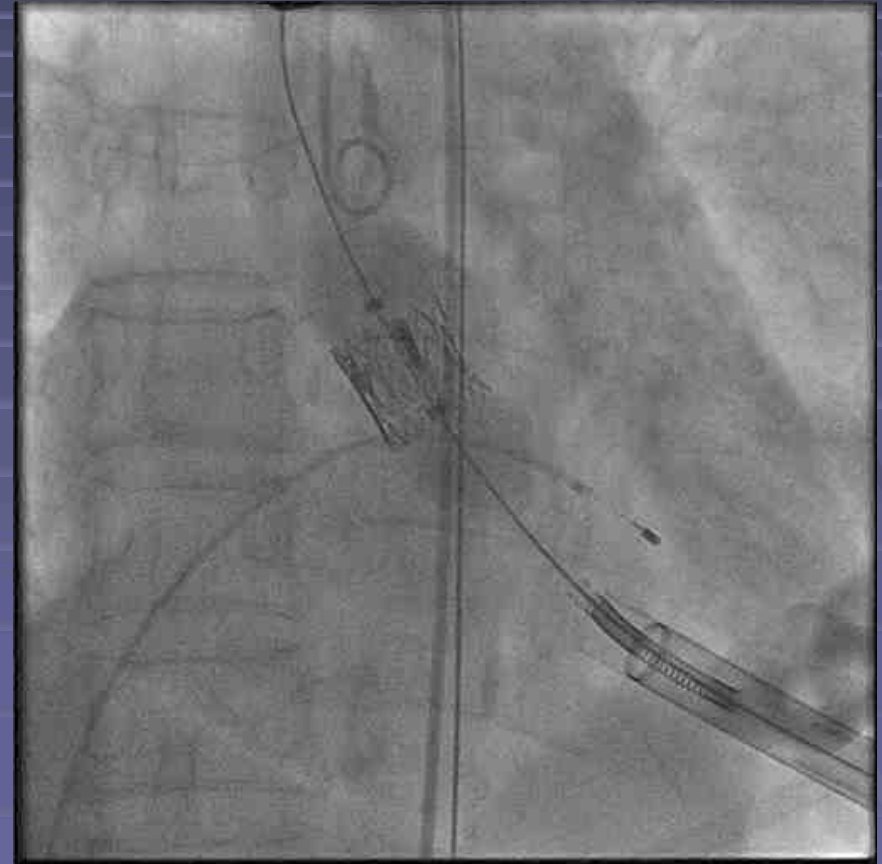
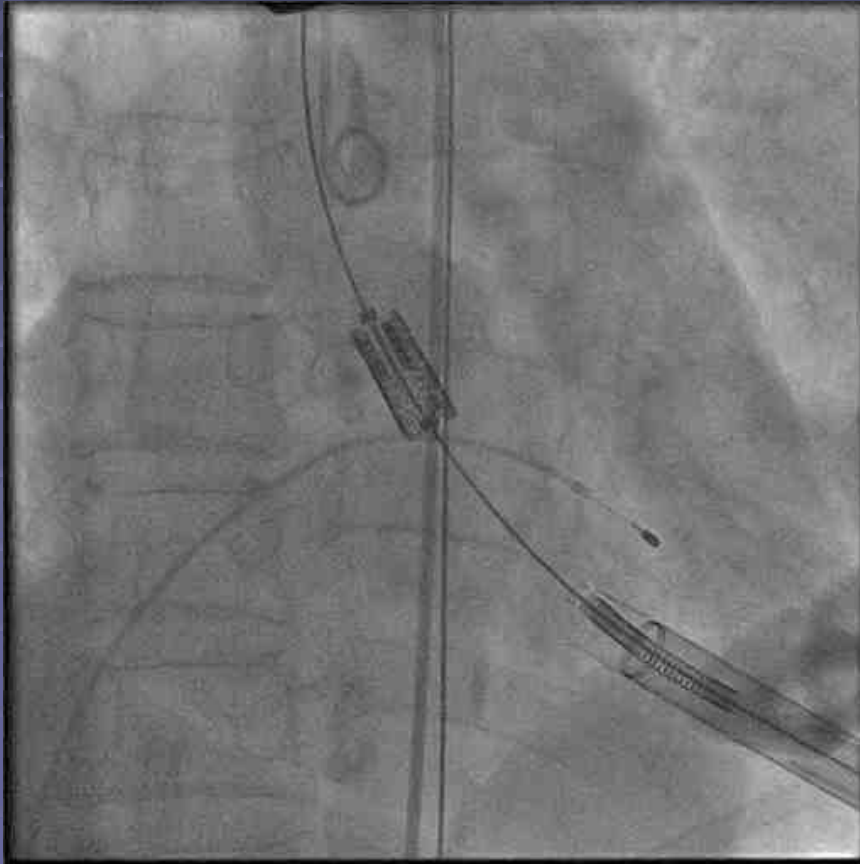


TAVI – Singapore experience

- Transapical procedure

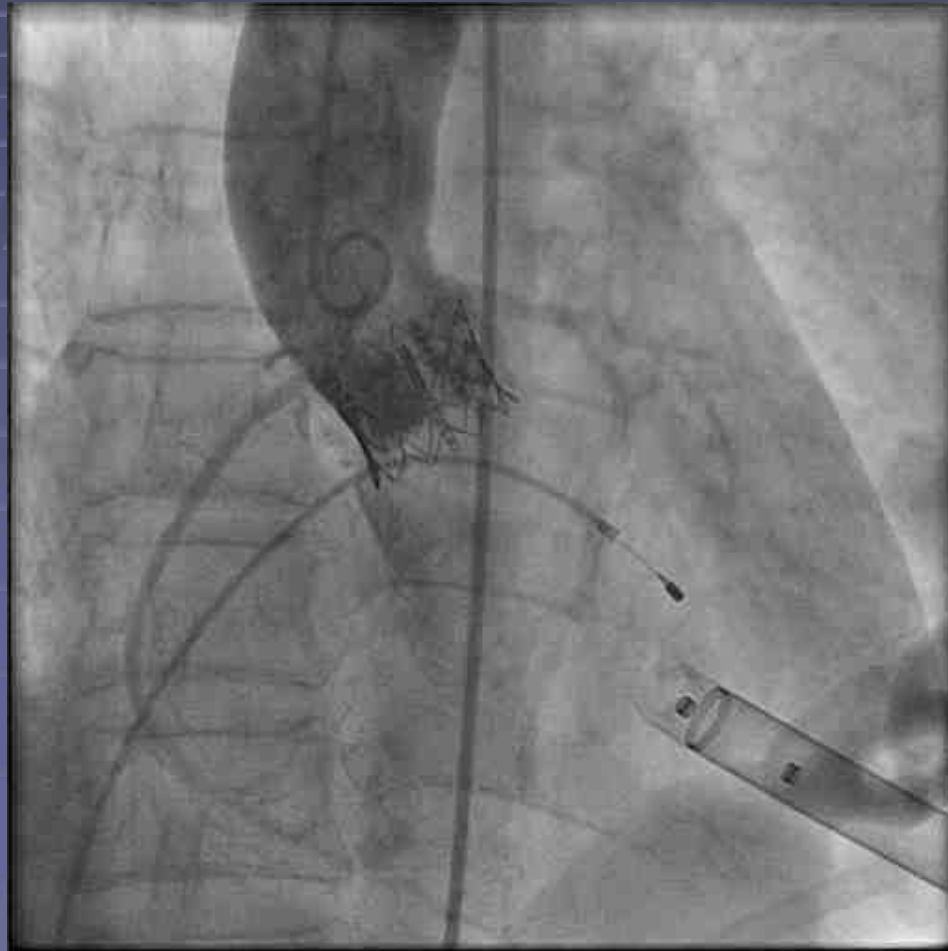


TAVI – Singapore experience



TAVI – Singapore experience

Final result



TAVI – Singapore experience

- Results:
 - 15 successful cases
 - 2 deaths
 - 1 TF approach due to iliac artery rupture (despite suitable anatomy) – due to aortic dissection
 - 1 TA approach due to migration of THV and subsequent hemodynamic compromise
- Other complications:
 - 1 limited iliac artery dissection (TF)
 - 4 pleural effusions (TA) – 1 resolved, 3 required pleurocentesis

TAVI – Singapore experience

- Remaining 13 were well at 1 month, 2 well at discharge
- 1-2 NYHA class improvement
- Average MPG: 12 mmHg (9 – 20)
- Paravalvular leak – trivial (7), mild (4), none (4)

- Conclusions:
- TAVI feasible in Asian patients although not without complications
- ?? Due to smaller build, ??? Increased frailty (esp elderly females)

TAVI – Singapore experience

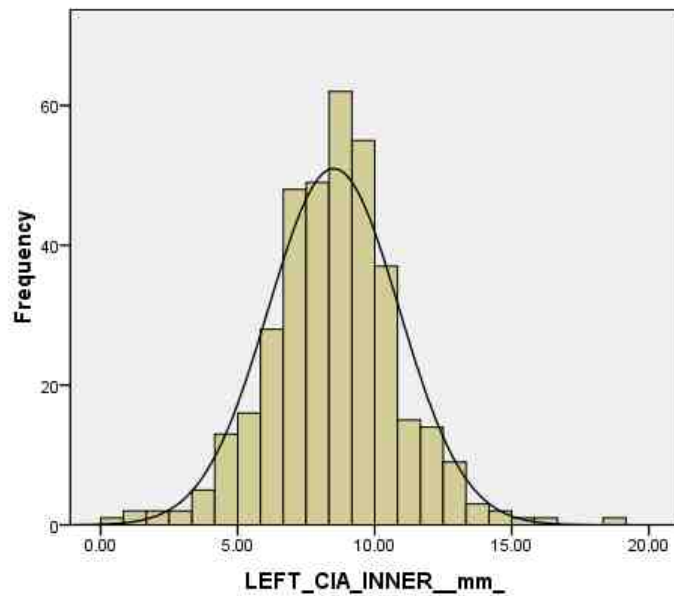
- Further data required to refine selection criteria and validate role of TAVI in Asian patients
- Awaiting device improvements:
 - Sapien XT THV – cobalt chromium stent (compared to current stainless steel) → lower profile THV
 - Retroflex 3 delivery catheter → facilitate crossing of aortic valve
 - 18F delivery sheath → reduced vessel size required and reduced vessel injury

Need for TA

- Current Edwards sheath size is 22F (~ 8.3mm)
- 18F sheath by 4th quarter 2010 (hopefully) !!!
- Current CoreValve sheath size 18F (~6.7mm)
- However, significant minority of Asians may have ilio-femoral < 6mm
- Particularly if also concomitant PAD

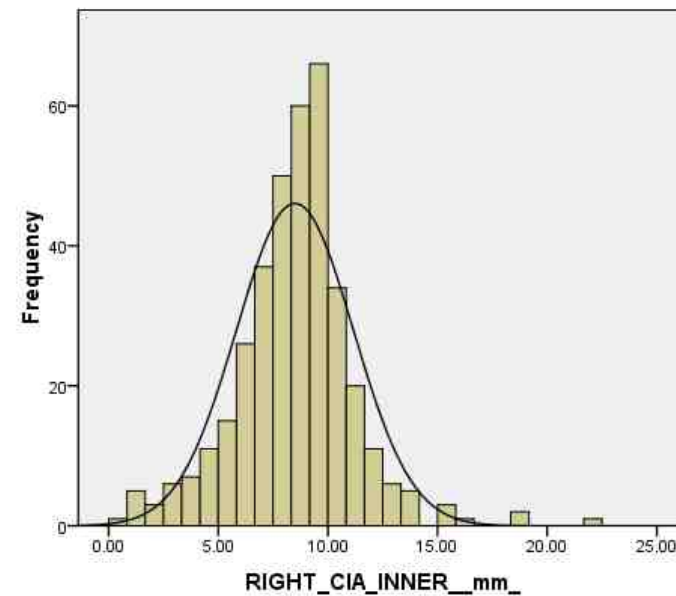
Iliac dimensions in Asian patients referred for U/S of aorto-iliacs

LEFT_CIA_INNER_mm_



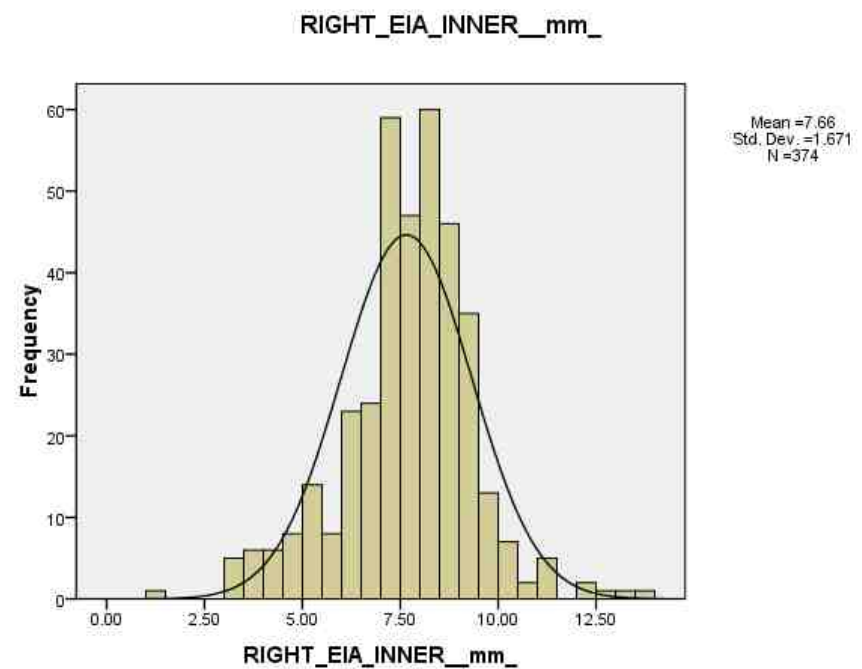
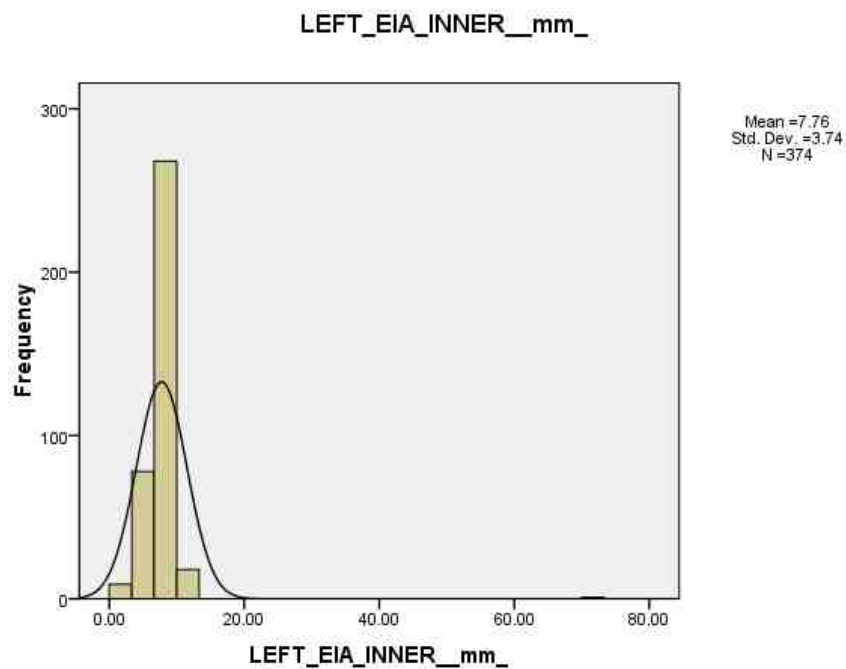
Mean =8.51
Std. Dev. =2.387
N =366

RIGHT_CIA_INNER_mm_



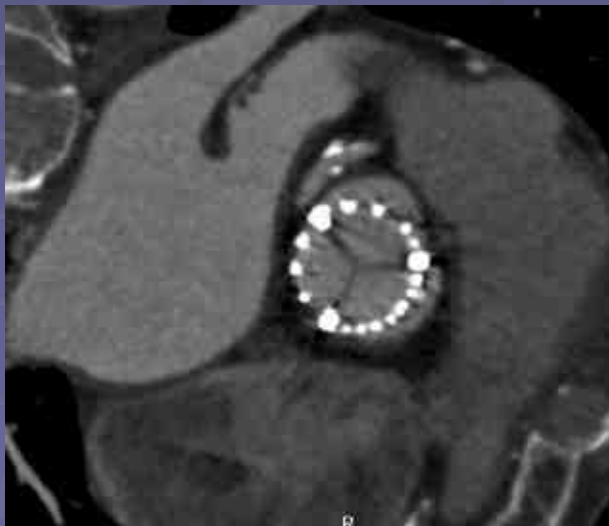
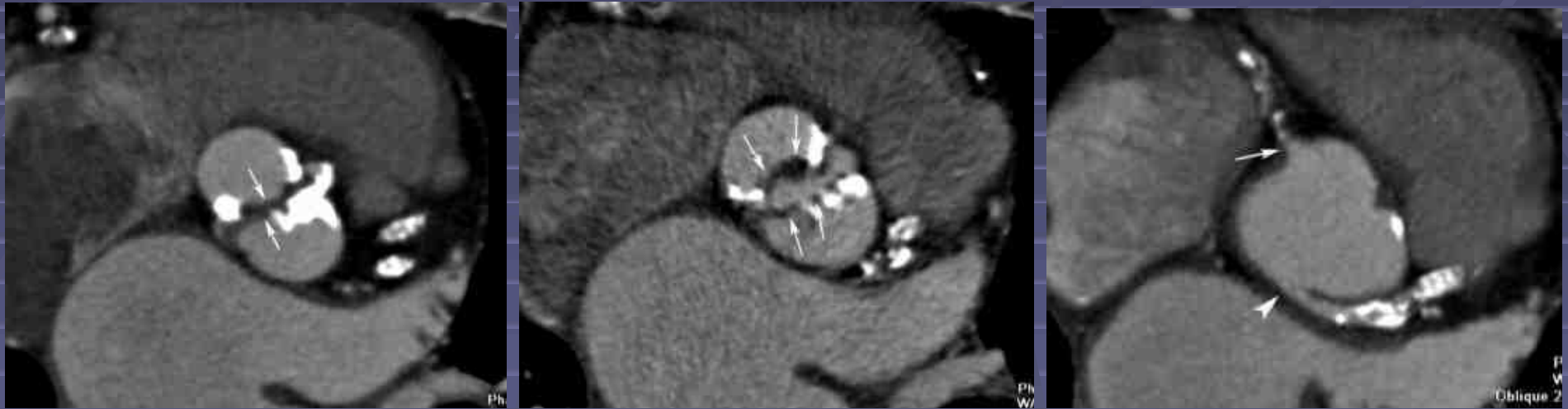
Mean =8.49
Std. Dev. =2.67
N =370

412 patients, mean age 66 ± 12 yrs



- Stenosis > 50% present in 12%
- Iliac tortuosity mod-severe in 10%
- Age \geq 80 years significant predictor of vessels < 6mm

TAVI in selected bicuspid AS ??



Percutaneous Transcatheter Heart Valve
Implantation in a Bicuspid Aortic Valve

Chiam et al.
JACC Cardiovascular Interventions (In
press)

TAVI

- How to assess these technologies and approaches?

STATE-OF-THE-ART PAPER

Percutaneous Transcatheter Aortic Valve Implantation: Assessing Results, Judging Outcomes, and Planning Trials

The Interventionalist Perspective

Paul T. L. Chiam, MBBS, MRCP, Carlos E. Ruiz, MD, PhD, FACC

TAVI

- Implantation: ease and accuracy
- Immediate: dislodgement / embolization, valve hemodynamics
- Peri-procedural (up to 30-days)
 - MACCE
- Short term (up to 1 yr)
 - Valve function, symptom improvement, LV indices
- Long term (> 1 yr)
 - Valve durability, QOL

TAVI

- Complications common to both:
 - Vascular injury (femoral route)
 - Valve embolization
 - Misplacement
 - Coronary obstruction
 - Inducing MR
 - Paravalvular leak
 - ?? Stent fracture
- Solution:
 - Smaller profile device
 - Retrievable and repositionable

TAVI

Percutaneous transcatheter aortic valve implantation: Evolution of the technology

Paul T.L. Chiam, MBBS, MRCP,^{a,b} and Carlos E. Ruiz, MD, PhD, FACC, FESC^{a,c}

New York, NY; and Singapore, Singapore

Treatment of severe AS will greatly evolve as these new and emerging technologies improve. Enhancement in device designs and increasing operator experience will make this technology safer and allow its application to a wider patient population. (Am Heart J 2009;157:229-42.)

What is the future

- Improved devices
 - Profile
 - Deliverability
 - Retrievability
 - Repositionability
 - Durability
- Demonstration of non-inferiority to surgical AVR in high risk groups
- Extending indications to lower risk populations

TAVI

- Impact of TAVI on treatment of AS
 - More patients can now be offered treatment
 - Choice of surgical valves
 - ? More bioprosthesis at younger age
 - ?? Treatment of severe asymptomatic disease
- Longer term durability data will determine these issues

Case Report

Percutaneous Aortic Valve Replacement for Severe Aortic Regurgitation in Degenerated Bioprosthesis: The First Valve in Valve Procedure Using the Corevalve Revalving System

Peter Wenaweser, MD, Lutz Buellesfeld, MD, Ulrich Gerckens, MD, and Eberhard Grube* MD, FACC

Catheterization and Cardiovascular Interventions 72:143–148 (2008)

VALVULAR HEART DISEASE

Original Studies

First Percutaneous Transcatheter Aortic Valve-in-Valve Implant With Three Year Follow-Up

Carlos E. Ruiz,^{1*} MD, PhD, FACC, FSCAI, Jean C. Laborde,² MD, Jose F. Condado,³ MD, Paul T.L. Chiam,¹ MBBS, MRCP, and Jose A. Condado,³ MD

Transcatheter Valve-in-Valve Implantation for Failed Bioprosthetic Heart Valves

John G. Webb, MD; David A. Wood, MD; Jian Ye, MD; Ronen Gurvitch, MD; Jean-Bernard Masson, MD; Josep Rodés-Cabau, MD; Mark Osten, MD; Eric Horlick, MD; O. Wendler, MD; Eric Dumont, MD; Ronald G. Carere, MD; Namal Wijesinghe, MD; Fabian Nietlispach, MD; Mark Johnson, MD; Christopher R. Thompson, MD; Robert Moss, MD; Jonathon Leipsic, MD; Brad Munt, MD; Samuel V. Lichtenstein, MD, PhD; Anson Cheung, MD

Background—The majority of prosthetic heart valves currently implanted are tissue valves that can be expected to degenerate with time and eventually fail. Repeat cardiac surgery to replace these valves is associated with significant morbidity and mortality. Transcatheter heart valve implantation within a failed bioprosthesis, a “valve-in-valve” procedure, may offer a less invasive alternative.

Methods and Results—Valve-in-valve implantations were performed in 24 high-risk patients. Failed valves were aortic (n=10), mitral (n=7), pulmonary (n=6), or tricuspid (n=1) bioprostheses. Implantation was successful with immediate restoration of satisfactory valve function in all but 1 patient. No patient had more than mild regurgitation after implantation. No patients died during the procedure. Thirty-day mortality was 4.2%. Mortality was related primarily to learning-curve issues early in this high-risk experience. At baseline, 88% of patients were in New York Heart Association functional class III or IV; at the last follow-up, 88% of patients were in class I or II. At a median follow-up of 135 days (interquartile range, 46 to 254 days) and a maximum follow-up of 1045 days, 91.7% of patients remained alive with satisfactory valve function.

Conclusions—Transcatheter valve-in-valve implantation is a reproducible option for the management of bioprosthetic valve failure. Aortic, pulmonary, mitral, and tricuspid tissue valves were amenable to this approach. This finding may have important implications with regard to valve replacement in high-risk patients. (*Circulation*. 2010;121:1848-1857.)

FIM devices



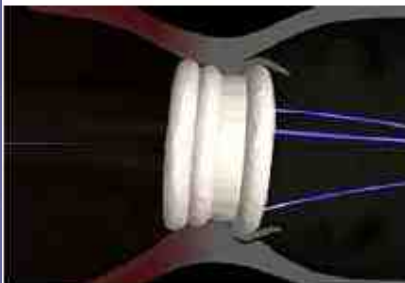
Pariagua



Enable



AorTx



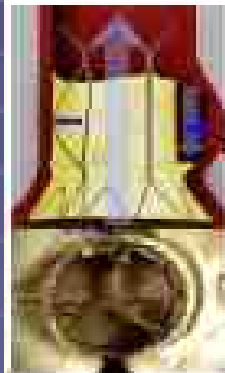
Direct Flow



Lotus



Perceval



Jenval/alive



Pre-clinical devices



Zogdi



Valve change



Lutter



PercValve



Heart Leaflet