

Transcatheter Aortic Valve Implantation (TAVI) - 5 important lessons learnt from HK experiences

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APCASH 2013



Current Status of TAVI in Asia

Feb 2010 to July 2013

	Total 672	Edwards 304	CoreValve 368
Asan Medical Center	87	36	51
Yonsei University	29		29
Seoul National University	23	3	20
Sam Sung Medical Center	10	10	
Catholic Medical Center	7	7	
Korea (23%)	156	56	100
Chiam, Tay, Singapore	130	100	30
Lee, Lan, Hong Kong	52	2	50
Paul Kao, Chang, Taiwan	52	12	40
Philippine	22		22
Thailand	36	20	16
Japan	165	100	65
China	35	10	25
Malaysia	24	4	20



CoreValve implants as of Aug 10th, 2013 (excluding ANZ)

Country	Total CoreValve Implants
Korea	100
Japan	70
Taiwan	54
Hong Kong	53
China	45
Singapore	31
Malaysia	28
Philippines	26
Thailand	16
India	16
Vietnam	1
TOTAL	440



Hong Kong Experience

Dec 2010
Queen Elizabeth
Hospital

Nov 2011
Prince of Wales
Hospital

June 2013
Union
Hospital

2010

2011

2012

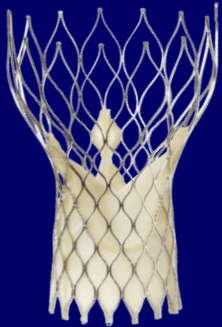
2013

May 2011
HK Adventist
Hospital

Dec 2012
Queen Mary
Hospital



Hong Kong Experience



Medtronic CoreValve - 53



Edwards Sapien - 2

27

- Queen Elizabeth Hospital

18

- Prince of Wales Hospital

7

- HK Adventist Hospital

2

- Queen Mary Hospital

1

- Union Hospital

TOTAL: 55



QEH Registry

Characteristic (N = 27)	Number (%) or Mean \pm SD
Age (yrs.)	81.6 \pm 5.2 (70 – 97 years old)
Males	18 (66.7%)
Procedural Success	96.3%
In-hospital Mortality	3.7%
30-day Mortality	3.7%

- 1 subclavian vascular complication treated with stent graft
- 1 femoral artery dissection treated with stenting
- All femoral wounds closed with Prostar/Proglide x 2
- One patient had PCI to LAD done before TAVI, returned for NSTEMI and with redo-PCI done, died 3 months after TAVI because of acute coronary stent thrombosis
- Most patients have functionally normal CoreValve with trivial to mild AR, 3 mild to mod AR



Procedure

Subclavian
4.0%

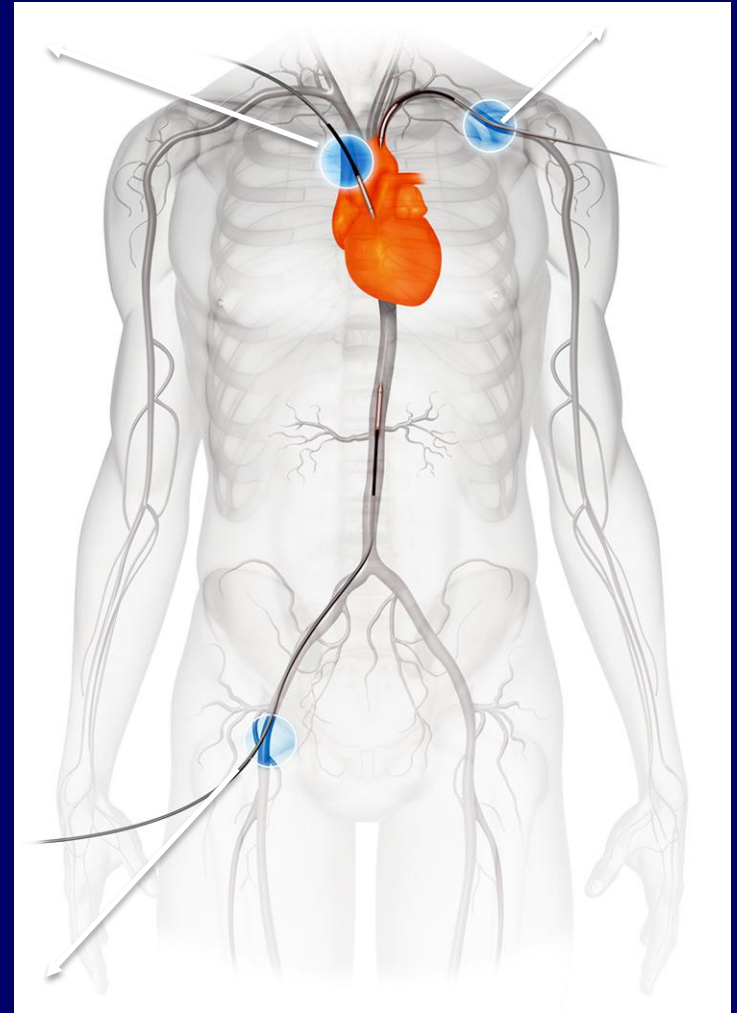
Direct Aortic
0%



26mm
55.6%

31mm
3.7%

29mm
40.7%



Transfemoral
96.0%



Clinical Outcomes after Transcatheter Aortic Valve Implantation in Asia – Results of a Multicentre Registry

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7. Seoul National University Hospital, South Korea; 8. Prince of Wales Hospital, Hong Kong
9. Ramthibodi Hospital, Thailand; 10. Sejong General Hospital, South Korea; 11. Siriraj Hospital, Thailand; 12. PLA Changhai Hospital, China; 13. St. Luke's Medical Centre, Philippines; 14. National Heart Institute, Malaysia

Characteristics

Comparison of QEH Registry – Asia Registry – ADVANCE

Characteristic	QEH Registry N = 27	Asia Registry N = 140	ADVANCE N = 996
Age (yrs.)	81.6 ± 5.2	79.1 ± 6.6	81 ± 6
Males	66.7%	51.4%	49.4%
Mean Log EuroSCORE	20.45 ± 12.1%	19.2 ± 15.9%	19.2 ± 12.4%
Weight (kg)	57.7 ± 8.7	59.1 ± 11.9	NR
Height (cm)	160.6 ± 7.3	158 ± 9	NR
Mean NYHA	2.6 ± 0.6	2.6 ± 0.7	NR
MPG (mmHg)	52.3 ± 10.6	46 ± 24	45.6
AVA (cm ²)	0.7 ± 0.2	0.7 ± 0.2	0.7
LVEF	57 ± 10.6%	57 ± 11%	NR



NR= Not Reported

Procedure & Hemodynamics

Comparison of QEH Registry – Asia Registry – ADVANCE

Variables	QEH Registry N = 27	Asia Registry N=140	ADVANCE N=996
Procedural success	96.3%	98.6%	97.8%
Serious vascular complications	7.4%	3.6%	NR
Hemodynamics			
≤ Mild PVL	88.9%	84.3%	87%
LVEF	60 ± 7.9%	61 ± 10%	NR
AVA (cm ²)	2.0 ± 0.3	1.7 ± 0.7	1.7
MPG (mmHg)	8.9 ± 2.7	9 ± 6	9.3



NR= Not Reported

30-day Outcomes

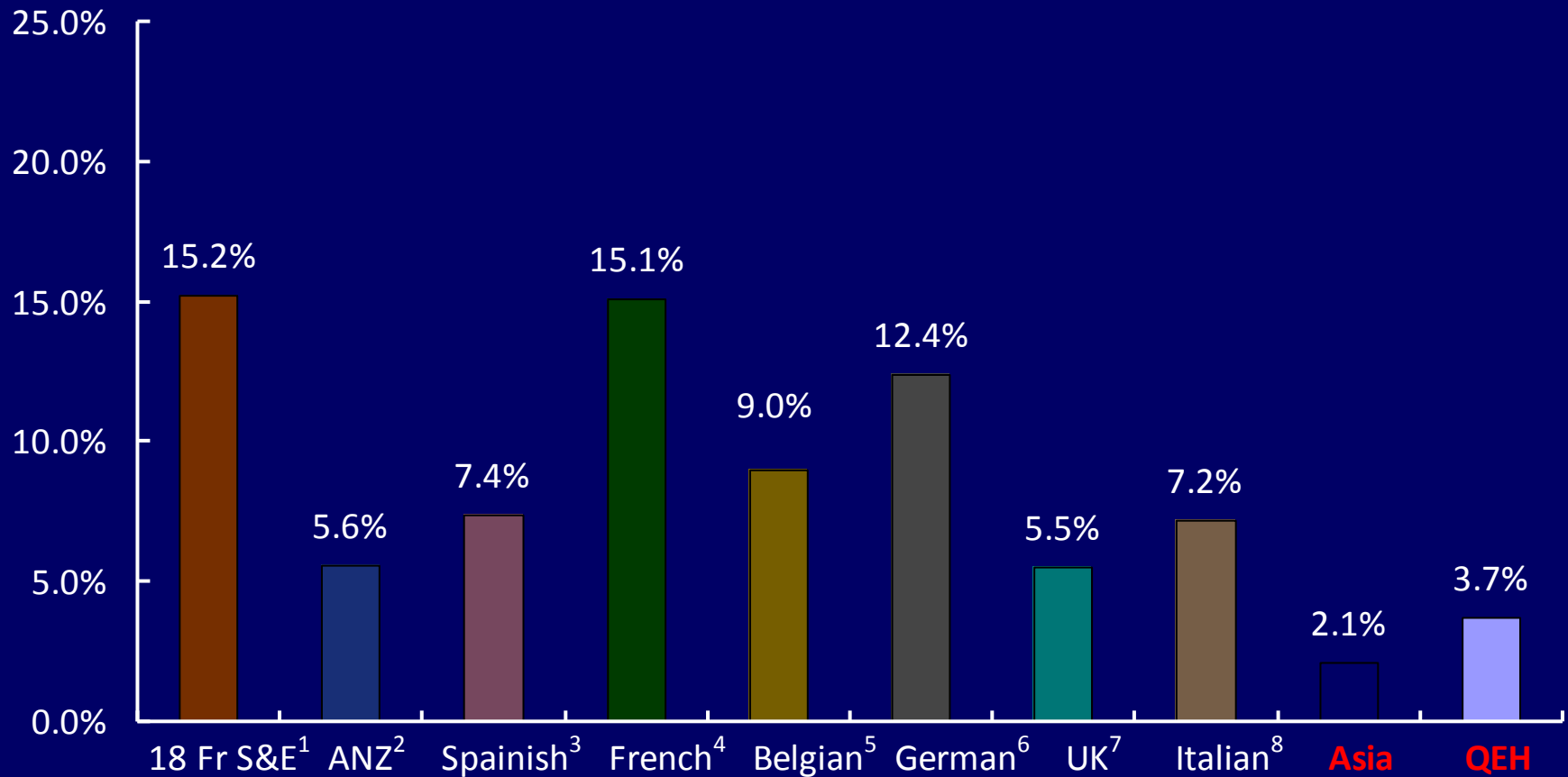
Comparison of QEH Registry – Asia Registry – ADVANCE

Variables	QEH Registry N = 27	Asia Registry N=140	ADVANCE N=996
Mortality	3.7%	2.1%	4.5%
Stroke	0%	0.7%	2.9%
NYHA	1.4	1.5	NR
Pacemaker Implantation	14.8%	15.7%	26.3%



NR= Not Reported

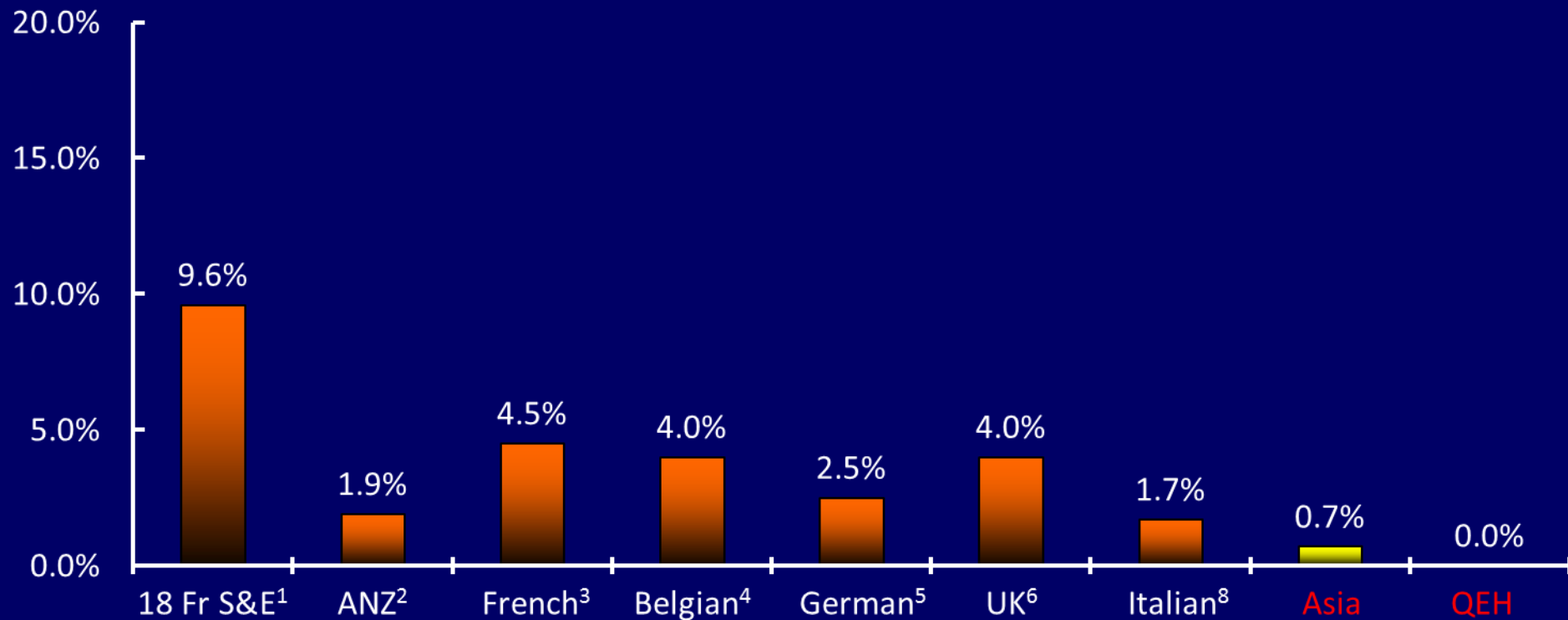
30-Day All-Cause Mortality



1. Medtronic Data on File. COR 2006-02: 18 Fr Safety & Efficacy Study Re-Analysis, August 14, 2009.
2. Meredith. VARC-adjudicated Outcomes in Inoperable and High Risk AS Patients. TCT 2010, Washington, DC.
3. Avanzas P, Munoz-Garcia AJ, Segura J, et al. Percutaneous implantation of the CoreValve® self-expanding aortic valve prosthesis in patients with severe aortic stenosis: early experience in Spain. *Rev Esp Cardiol.* 2010;63:141-148.
4. Eltchaninoff. French Registry, TAVI Facts, Figures and National Registries. EuroPCR 2010, Paris, France.
5. Bosmans. Belgian Registry, TAVI Facts, Figures and National Registries. EuroPCR 2010, Paris, France.
6. Zahn. German Registry, TAVI Facts, Figures and National Registries. EuroPCR 2010, Paris, France.
7. Ludman. UK Registry, TAVI Facts, Figures and National Registries. EuroPCR 2010, Paris, France.
8. Petronio. Italian Registry, TAVI Facts, Figures and National Registries. EuroPCR 2010, Paris, France.



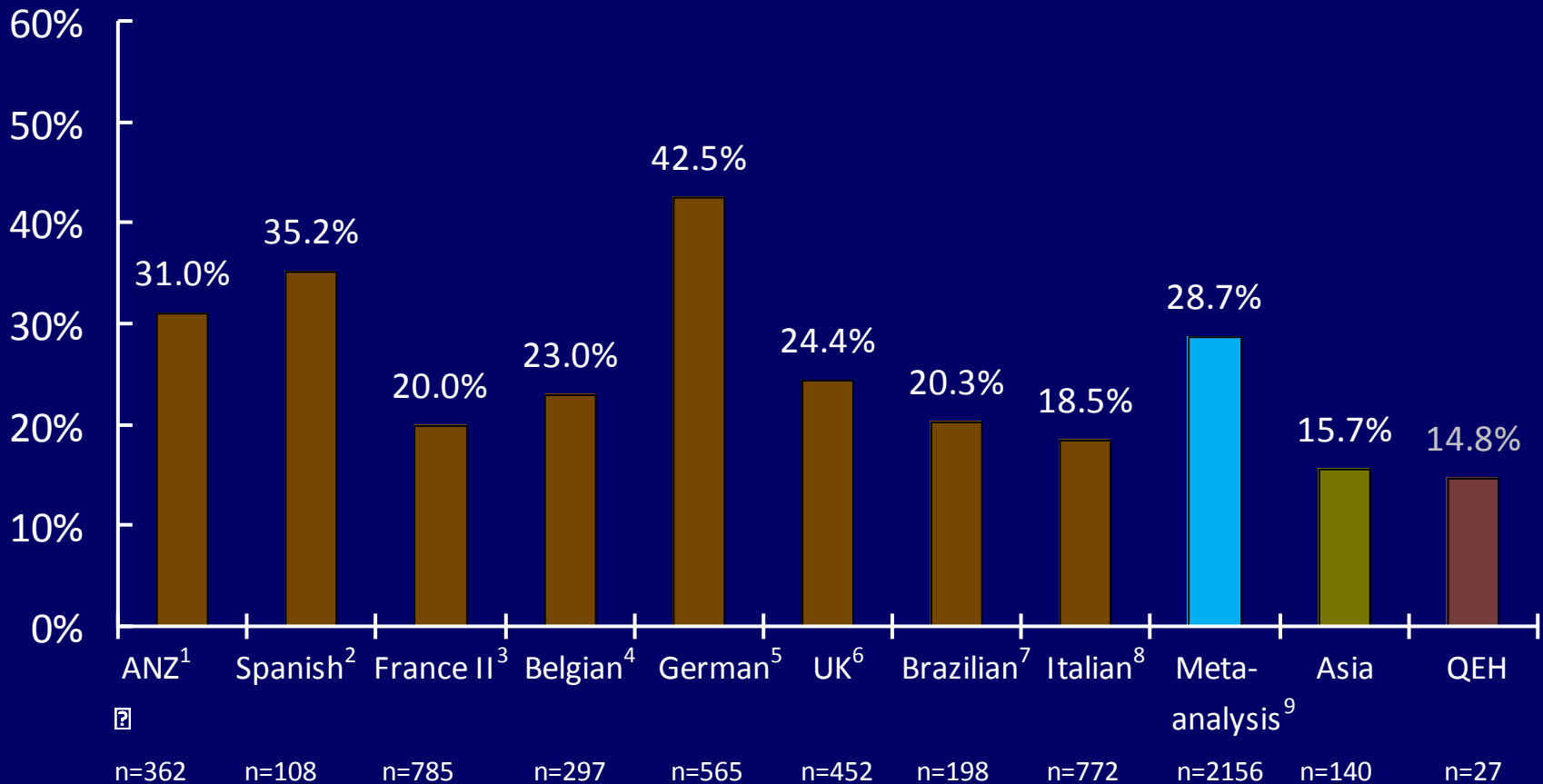
30-Day Stroke Rate



1. Medtronic. Data on file. COR 2006-02: 18 Fr Safety & Efficacy Study Re-Analysis, August 14, 2009.
2. Meredith. VARC-adjudicated Outcomes in Inoperable and High Risk AS Patients. TCT 2010, Washington, DC.
3. Eltchaninoff. French Registry, TAVI Facts, Figures and National Registries. EuroPCR 2010, Paris, France.
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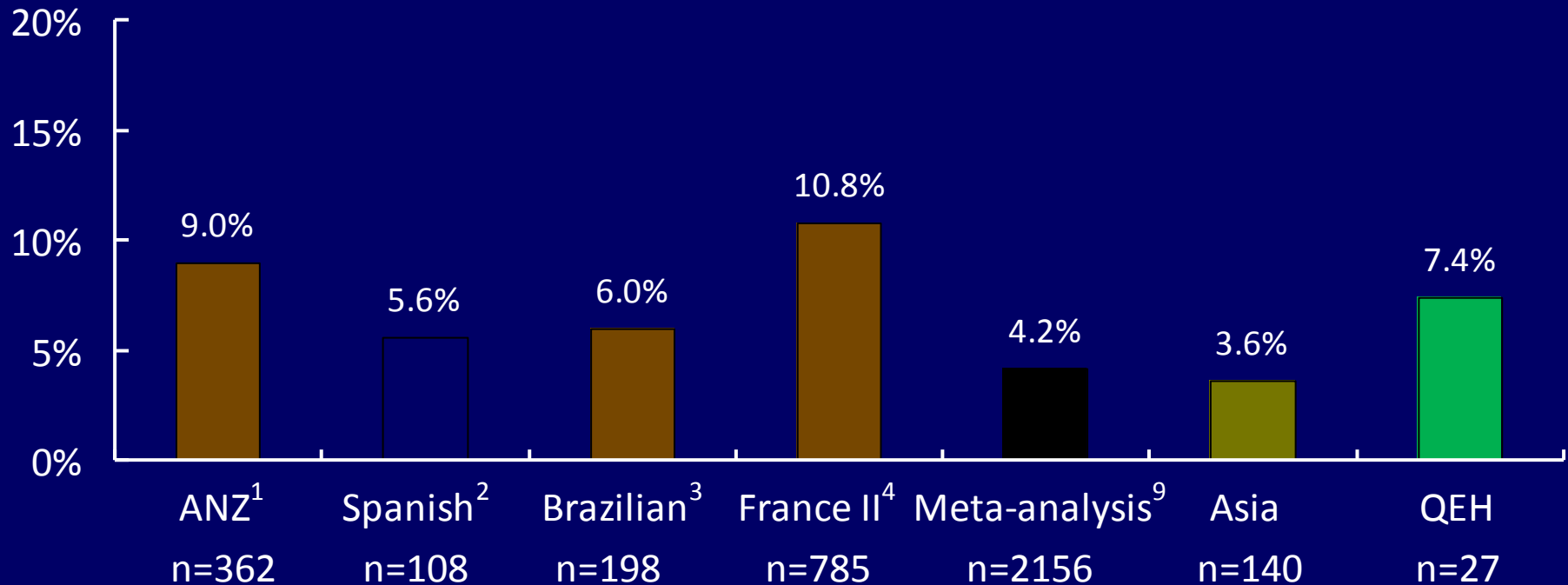
Pacemaker Implantation Rates Across Studies



1. Meredith I.T. 12 Month Results from ANZ CoreValve TAV Study. Presented at: TCT 2011. 2. Avanzas P, et al. *Rev Esp Cardiol*. 2010;63:141-148. 3. Cribier A. FRANCE II Multicenter TAVR Registry. Presented at: TCT 2011. 4. Bosmans J. Belgian TAVI Registry. Presented at: London Valves 2011. 5. Zahn R., et al. *European Heart Journal*. 2011; 32:198-204. 6. Moat N.E., et al. *JACC*. 2011; 58:158-164. 7. Brito F.S. Brazilian Registry. Presented at TCT 2011. 8. Petronio AS. Italian Registry. Presented at: EuroPCR 2010. 9. Ruiz C.E. Weighted meta-analysis of CoreValve® Outcomes. Presented at: EuroPCR 2011 (analysis sponsored by Medtronic, Inc.).



Vascular Complications

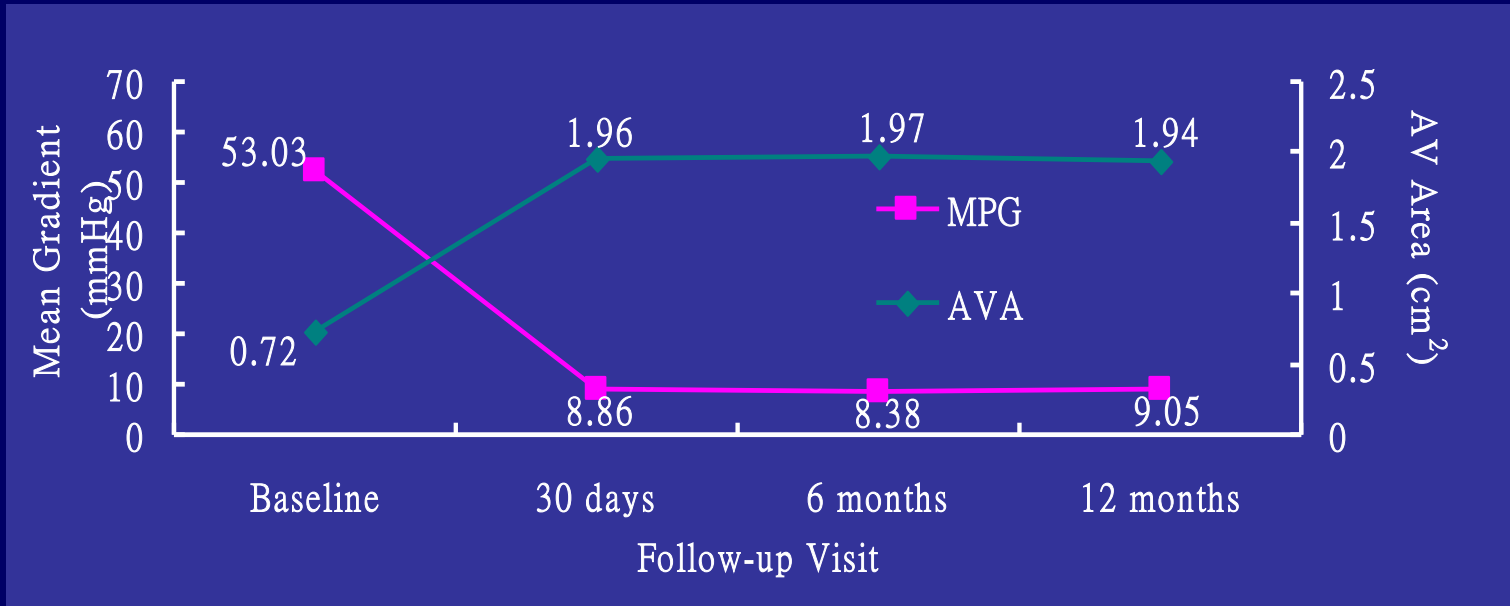


1. Meredith I.T. 12 Month Results from ANZ CoreValve TAV Study. Presented at: TCT 2011. 2. Avanzas P, et al. *Rev Esp Cardiol* 2010;63:141-148. 3. Brito F.S. Brazilian Registry. Presented at TCT 2011. 4. Cribier A. FRANCE II Multicenter TAVR Registry. Presented at: TCT 2011. 5. Ruiz C.E. Weighted meta-analysis of CoreValve® Outcomes. Presented at: EuroPCR 2011 (analysis sponsored by Medtronic, Inc.).

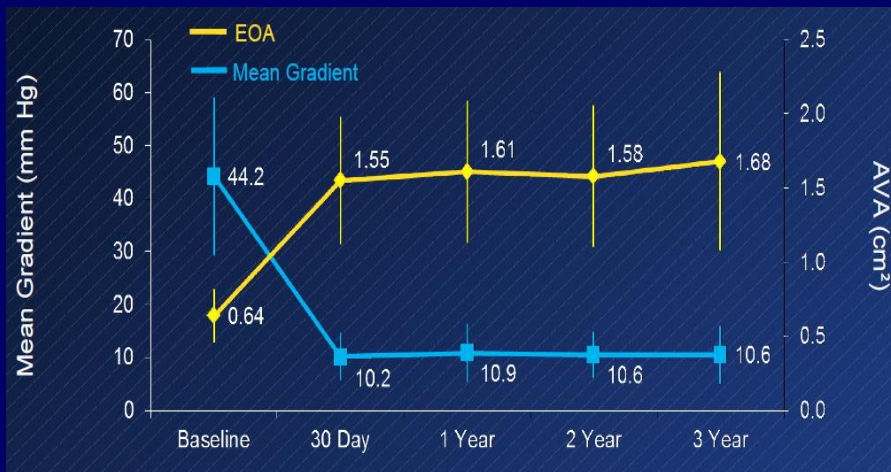


Mean Gradient & Valve Area

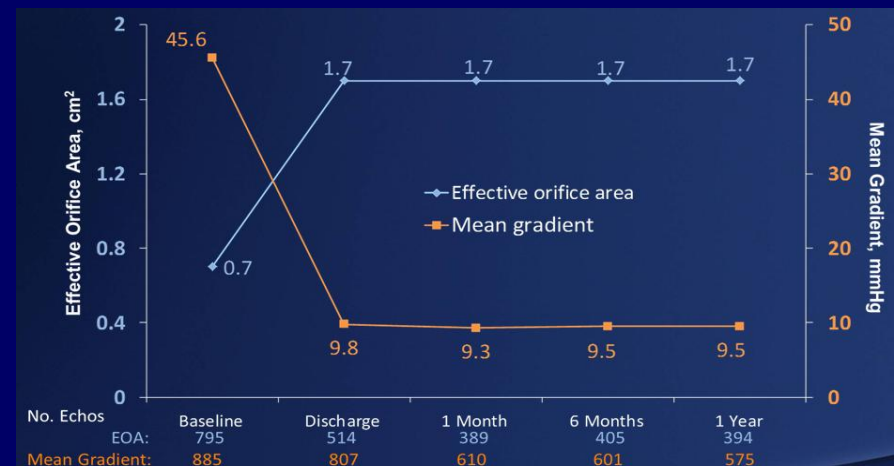
QEH
Registry



The PARTNER Trial

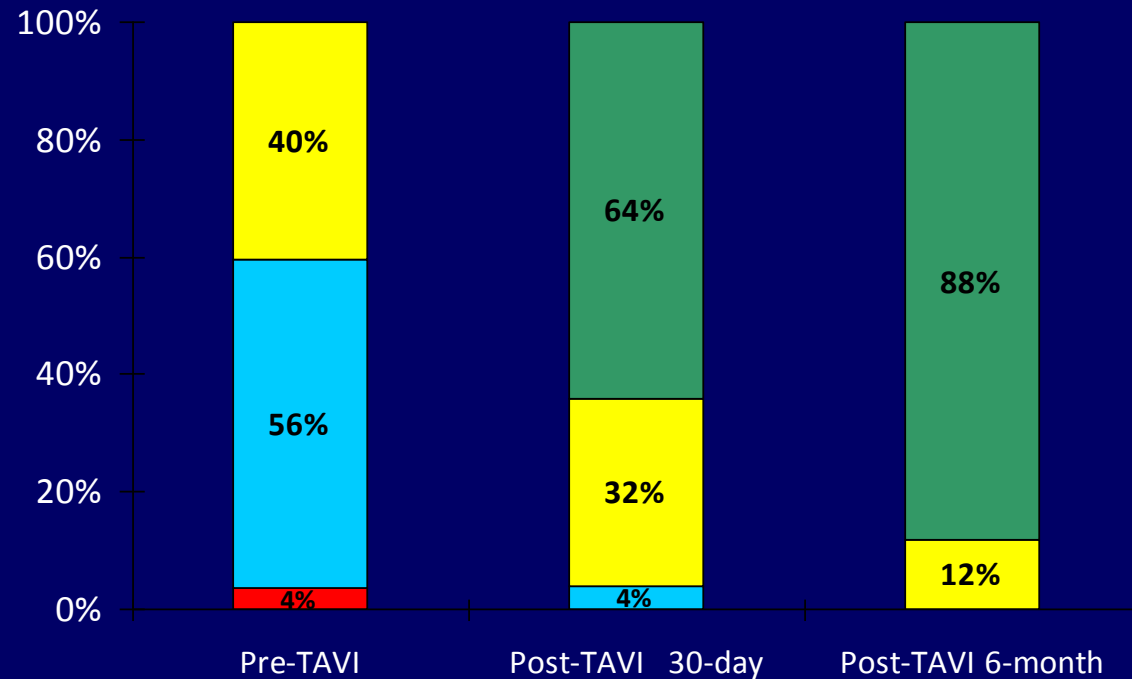


CoreValve ADVANCE Study

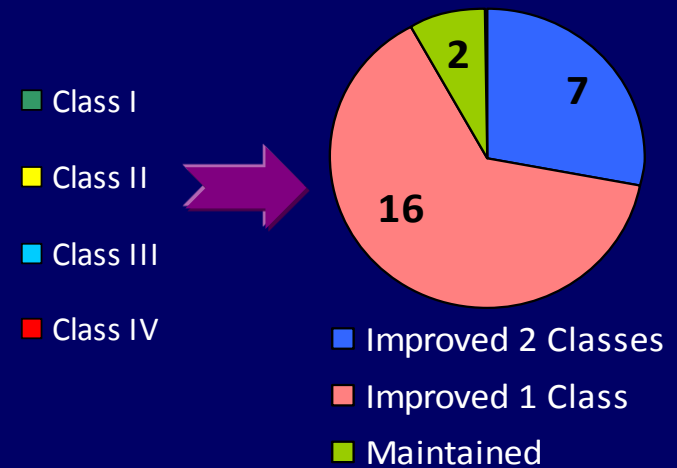


QEH | Symptom Status (NYHA Class)

NYHA Classification



Changes in NYHA Classification

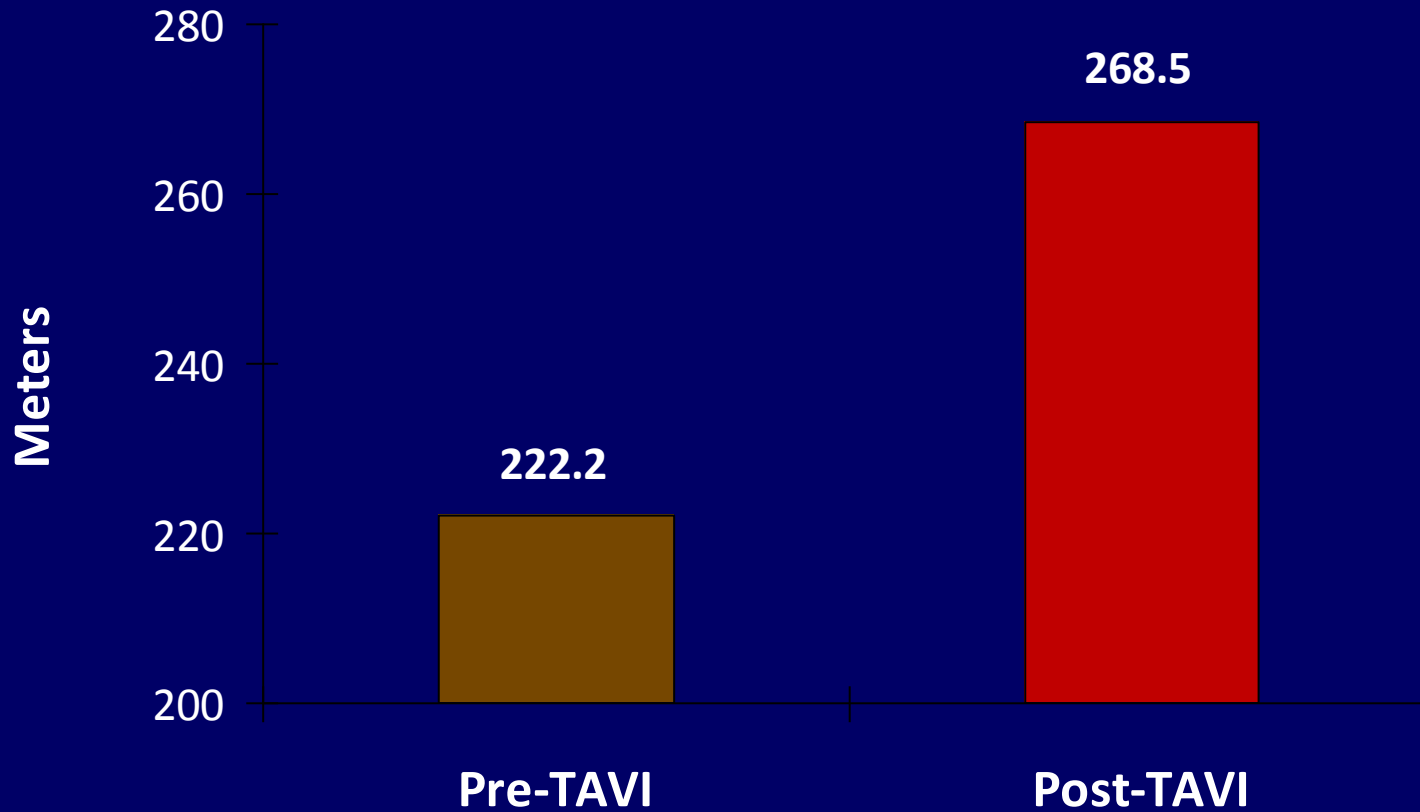


* NYHA: New York Heart Association Functional Classification for Heart Failure Stages

(Class I = Best, Class IV = Worst)



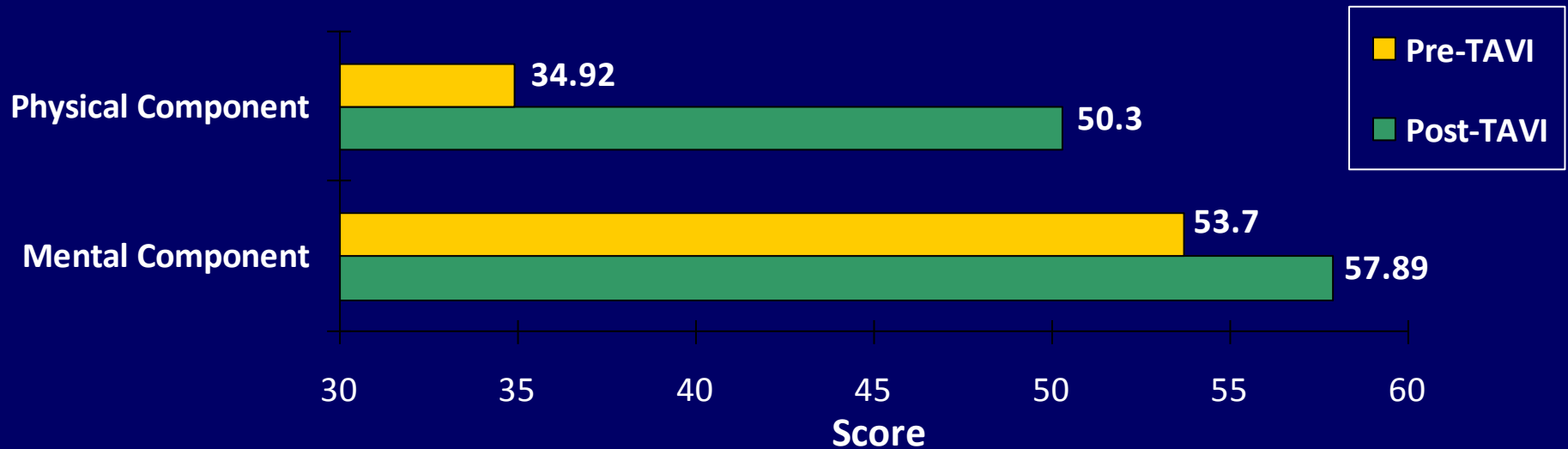
6-Minute Walk Test



Paired-sample t-test: $p < 0.05$



Measurement for Quality of Life (SF-12)



Physical Component

Paired-sample t-test: $p < 0.05$

Mental Component

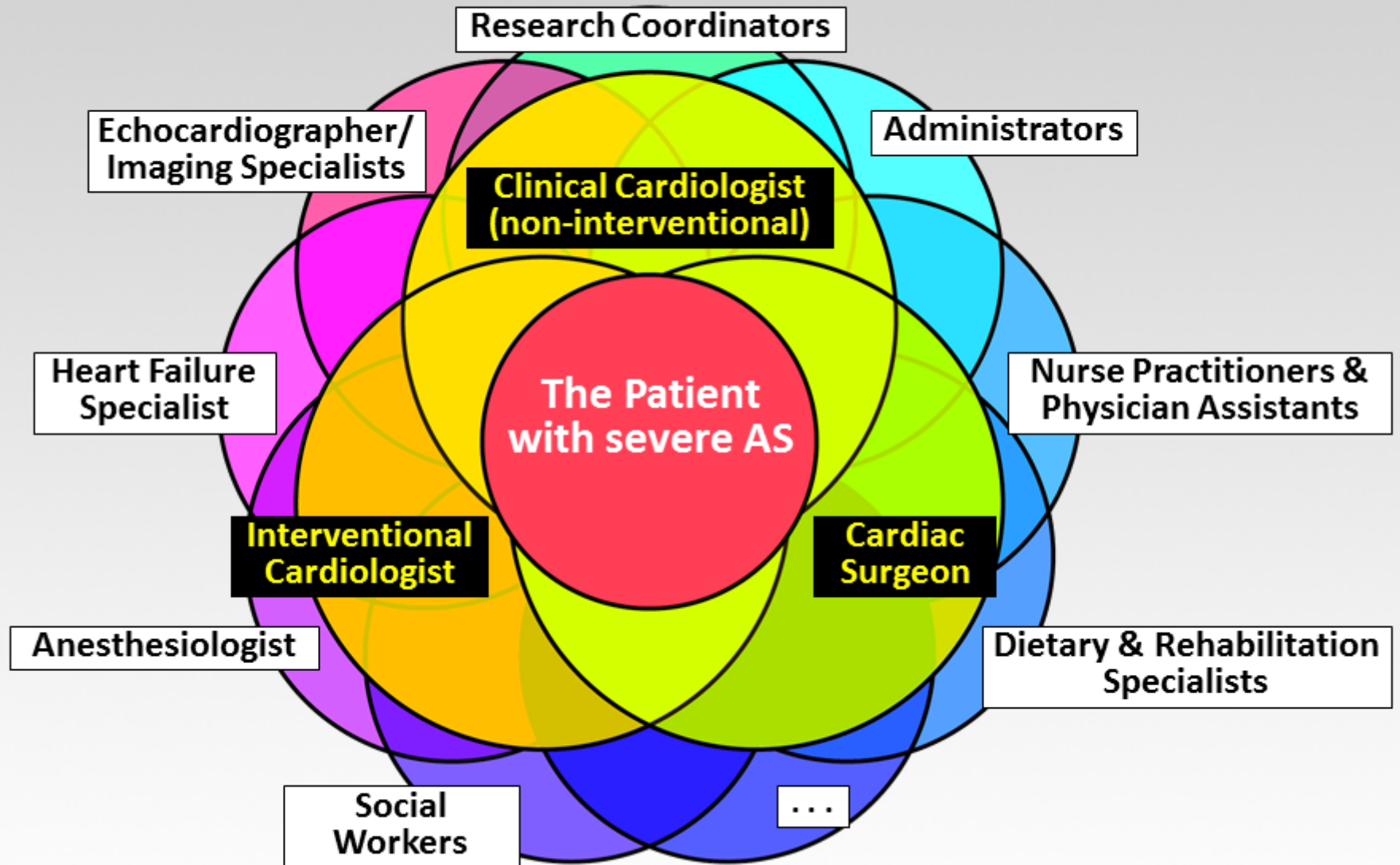
Paired-sample t-test: $p < 0.05$



5 important lessons learnt...



The Multidisciplinary Heart Team

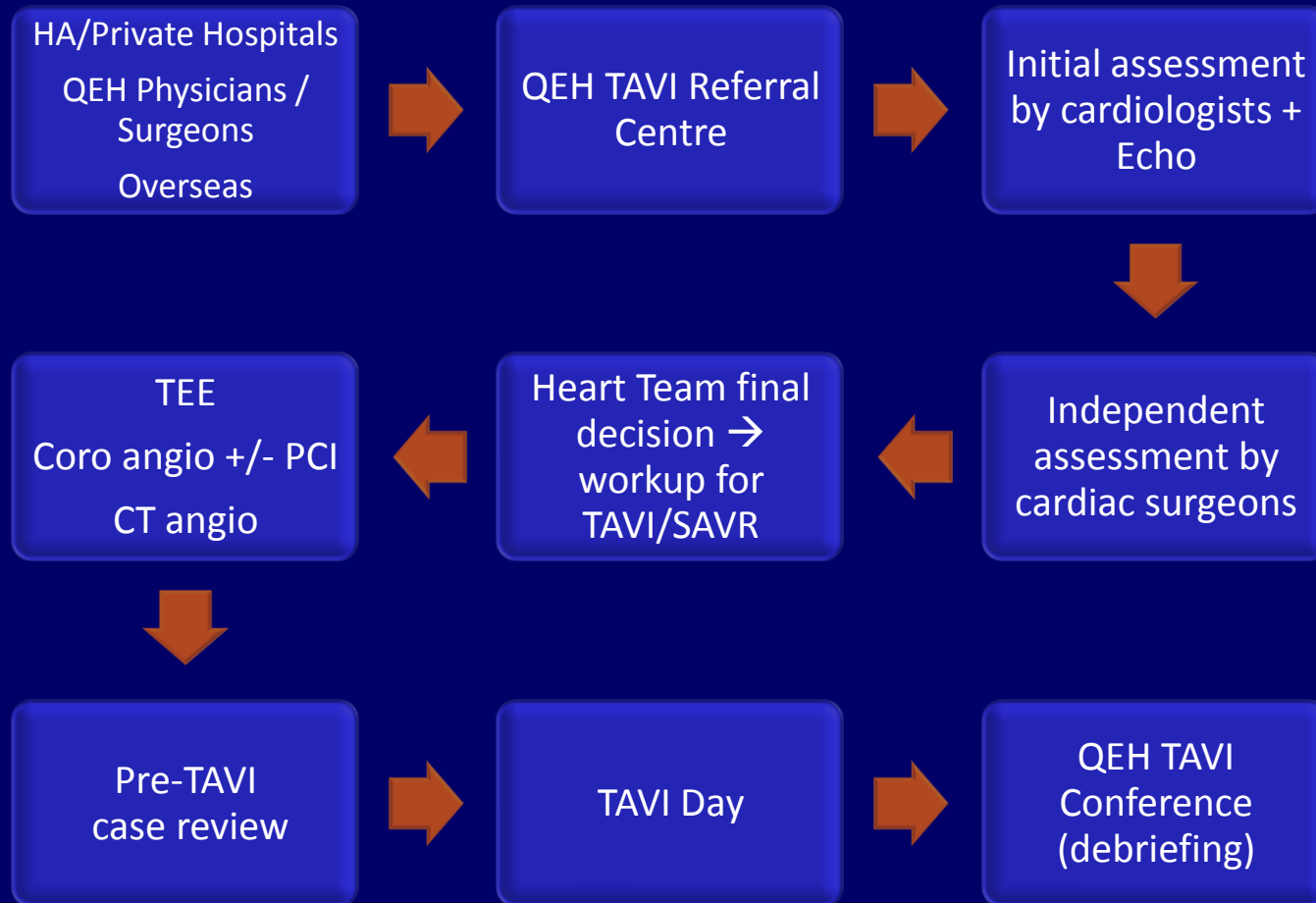


TAVI Program in QEH

- Extremely high-risk procedure
- Multi-disciplinary Heart Team formed in 2009:
 - Interventional Cardiologists
 - Echo Cardiologists
 - Cardiac Surgeons
 - Cardiac Anaesthesiologists
 - Radiologists
 - Cardiac Nurses



Queen Elizabeth Hospital Patient Flow



...Patient selection is a critical success factor for transcatheter aortic valve implantation...

ESC Congress 2010

Thomas, J Am Coll Cardiol Intv 2010;3:1103–9



Potential TAVI Patients

Patients to Consider for TAVI Referral

- **Patient has severe, symptomatic aortic stenosis**
- **Patient is high risk for surgical aortic valve replacement or is inoperable**
- **Patient was previously rejected for surgical aortic valve replacement**

Patients NOT Recommended for TAVI Referral

- Severe ventricular dysfunction (LVEF < 20%)
- End-stage renal disease requiring chronic dialysis
- **Life expectancy less than 12 months**
- Mitral regurgitation greater than grade 2



Who Is Too Sick for TAVR?

Patients in whom the presence of multiple comorbidities, especially frailty, overwhelm the likelihood of functional recovery despite successful TAVR

TAVR

**Medical
therapy**



Porcelain aorta
Hostile chest
RIMA/LIMA anatomy

Severe COPD
Liver cirrhosis

Dementia

Severe frailty

Proposed Indication for TAVI

- Inoperable severe symptomatic native aortic stenosis with NYHA functional class II or greater and reasonable life expectancy
 - Severe symptomatic native aortic stenosis defined as echo derived valve area of $\leq 0.8 \text{ cm}^2$ (EOA index $\leq 0.5 \text{ cm}^2$), and mean gradient $> 40 \text{ mmHg}$ or jet velocity $> 4.0 \text{ m/s}$.
 - *Inoperable:*
 - Risk of death or serious irreversible morbidity of SAVR as assessed by cardiologist and cardiac surgeon is $\geq 50\%$ at 30 days.



Pre-TAVI imaging assessment

- TTE +/- TEE
- Coronary angiogram +/- Aortogram & Peripheral angiogram
- MSCT



Major roles of CT in TAVI

- Iliofemoral Arterial System
 - Size, Calcification, Tortuosity, Plaques
- Annulus size measurement
- 3D annular & root morphology & dimensions
- Amounts of calcium in valve
- Relationship of annulus to both coronary ostia
- Valve positioning during implantation
- Post TAVI assessment



Known Predictors for PPM in CoreValve

81/270 pts (33%) permanent PM within 30 days; Median time = 4 days
Baseline ECG: RBBB 65.2%, LBBB 43.8%, and normal QRS 27.6%

1. Peri-AVB (OR 6.29, $P < 0.001$),
2. Balloon pre-dilatation (OR 2.68, $P < 0.001$),
3. Prolonged QRS duration (baseline) (OR 3.45, $P = 0.02$)
4. Large CV prosthesis (29mm) (OR 2.50, $P = 0.019$)
5. IV septum diameter (OR 1.18, $P = 0.025$),
6. Depth of implantation (too low & deep),
7. Calcification several small sized of articles



J Cardiovasc Electoro 2011 (32 articles, 5258 pts analysis)
Khawaja et al. Circulation 2011;123:951-60 (270 pts analysis)



Permanent Pacemaker Predictor

Analysis from Multicenter Registry for CoreValve in Asia

- 117 patients (81.2 ± 5.1 years) from 6 centers
- 23 patients (19.7%) required PPM, within a median time-to-insertion of 7 days (interquartile range, 5–13 days)
- QCA analysis, CT diameter, CT perimeter analysis in all Patients



Stretching Index

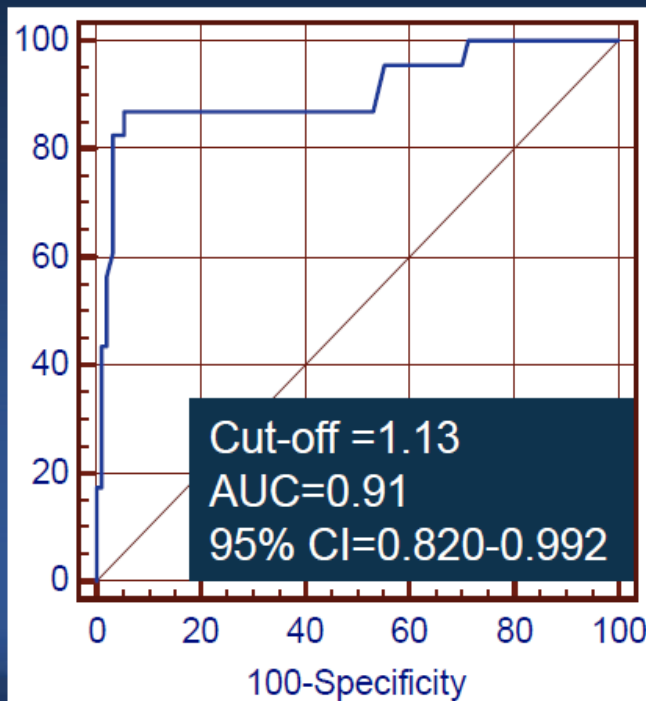
Device Perimeter (Calculated)

Annulus Perimeter



Stretching Index **Cut-Off** for Permanent Pacemaker

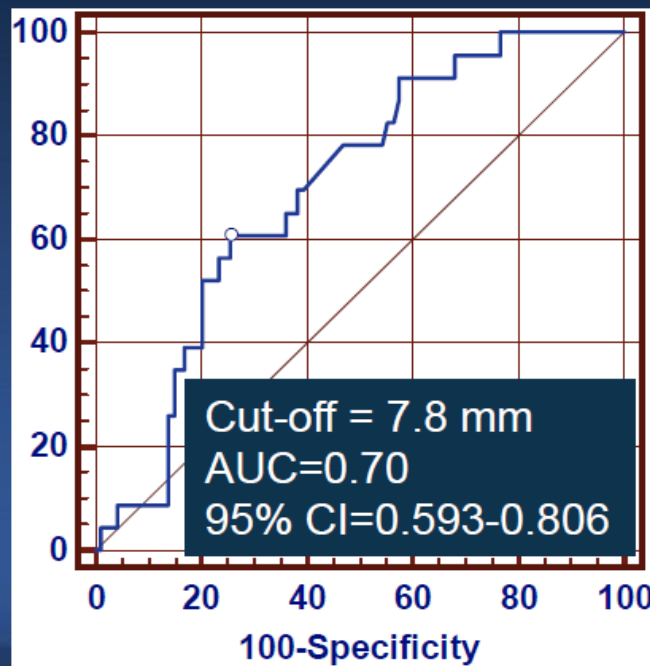
Device Perimeter
Annulus Perimeter **> 1.13**



Sensitivity 86.96%
Specificity 94.68%
PPV 80%
NPV 96.74%
Accuracy 93.2%

Implanted Depth **Cut-Off** for Permanent Pacemaker

Implanted Depth > 7.8 mm



Sensitivity 60.87%
Specificity 74.47%
PPV 35.14%
NPV 87.5%
Accuracy 70.94%

Combined Criteria Of Depth and Stretching Index

**Implanted
Depth
7.8 mm**

<i>PPM :</i> 11%	<i>PPM :</i> 100%
<i>PPM :</i> 0%	<i>PPM :</i> 67%

**1.13
Stretching Index**

Not too big and not too deep

Appropriate Size of Device Selection

(CT perimeter Stretching Index < 1.13)

And Shallow Implantation (Depth < 7.8 mm) -

Can Avoid Permanent Pacemaker Insertion
after Core Valve.



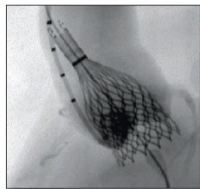
Complication management & Simulator training

- CoreValve Simulator training (Symbionix)
- Scenario simulation for TAVI Heart Team on complication management
- Debriefing sessions post-TAVI



Flexible Solutions

The ANGIO Mentor™ family of products exemplifies Sionix's commitment to provide educators and clinicians with flexible, cost-effective solutions suitable for a wide range of settings.



Aortic Valve Replacement

Provides practice on endovascular implantation of an aortic valve bioprosthesis. The practiced steps include navigating through the aortic arch and crossing the LV using fluoroscopy and cineangiography to find the best angulation for visualizing the aortic valve annulus, pressure gradient measurements, aortic balloon valvuloplasty including rapid pacing and accurately positioning and deploying an aortic valve bioprosthesis. Complications include LV perforation. Virtual patients vary in heart orientations, annulus sizes, degrees of valve calcification and LV hypertrophy.



5 important lessons learnt

- Multi-disciplinary Heart Team
- Patient Selection
- Pre-TAVI imaging assessment
- Size of CoreValve and depth of implantation
- Complication management & Simulator training





Surgical AVR
The "Past"

TAVI
The "Future"



TAVI 2-YEARS CELEBRATION



Thank you!

