3 years after introduction of TAVI in QEH

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Introduction

- Aortic Stenosis – most common valvular heart disease in the elderly
- 4.6% in adults ≧75 years of age
- Once symptomatic, average survival 2-3 years with high risk of sudden death
- TAVI (Transcatheter Aortic Valve Implantation) or TAVR (Transcatheter AV Replacement) has emerged as a viable alternative in inoperable or high risk elderly patients with symptomatic AS
- 5-10% immediate complications
- 30-day mortality of 5.6% - 12.7%
- Reduces all-cause mortality by 27% at 3 years

CoreValve® Transcatheter Procedure

Balloon catheter threaded through sheath and into heart

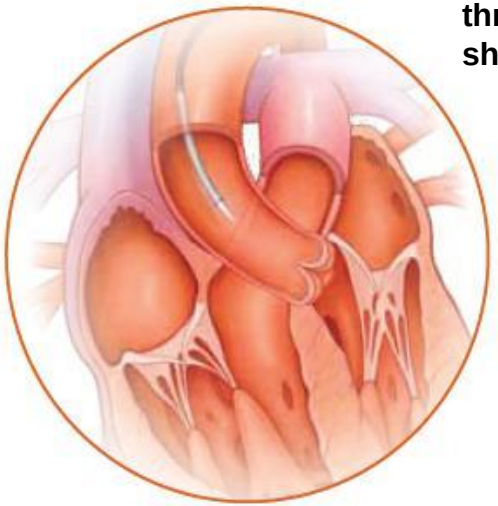


Figure 1

CoreValve placed into position over the diseased aortic valve

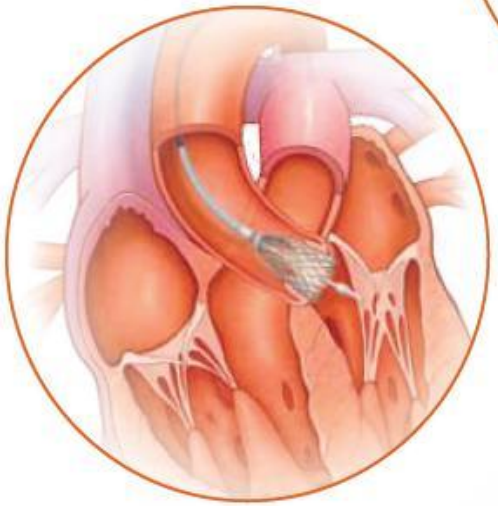


Figure 2

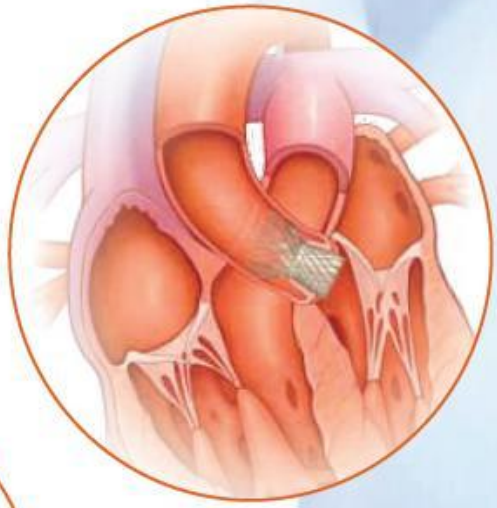
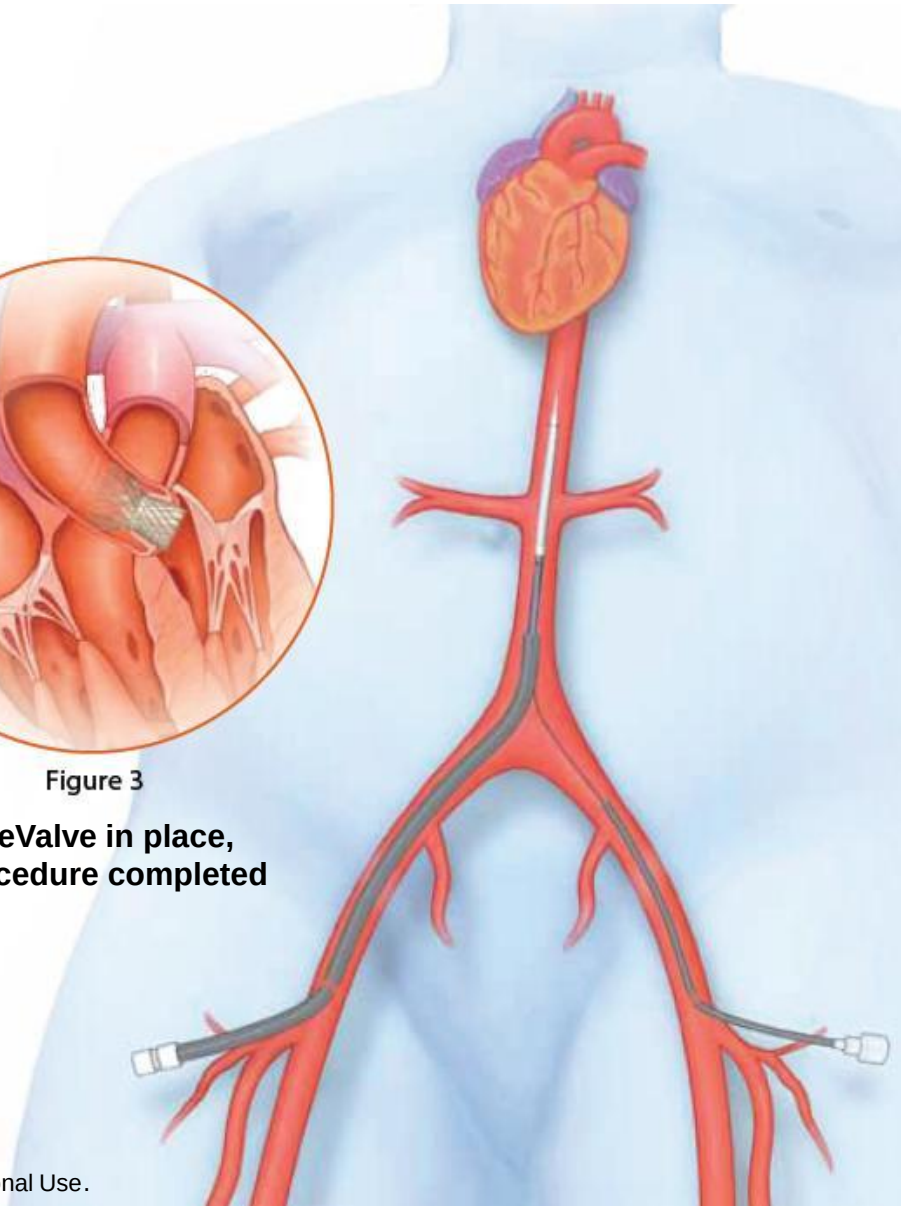


Figure 3

CoreValve in place, procedure completed



Experimental Device in the United States and Limited by Federal Law to Investigational Use.

TAVI Program in QEH

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

Since 2002,
>120,000 TAVI procedures have been performed in >700 international sites

Asia:

33 TAVI centres in 11 Asian countries

Current Status of TAVI in Asia

Country	MDT CoreValve	EDW Sapien	Venus A-Valve	Symetis Acurate	Total
China	63	10	57		130
Taiwan	119	16			135
Hong Kong	62	5			67
Korea	152	100			252
Japan	81[A]	407[B]		17	505
Singapore	46	100			146
Philippines	41	0			41
Malaysia	32	10			42
Thailand	18	30			48
Vietnam	4	0	1		4
India	24	0			24
TOTAL	**642**	**678**	**58**	**17**	**1394**

Updated Apr 30th, 2014

A Include CoreValve Japan Trial and Private Import Cases
B Include Sapien AMT Trial, Sapein XT Japan Trial and commercial launch since Oct 2013

Hong Kong Experience

Dec 2010
Queen Elizabeth Hospital

Nov 2011
Prince of Wales Hospital

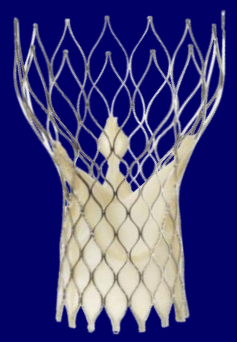
June 2013
Union Hospital

2010 2011 2012 2013

May 2011
HK Adventist Hospital

Dec 2012
Queen Mary Hospital

Hong Kong Experience



Medtronic CoreValve - 61

Edwards Sapien - 5

- 34 • Queen Elizabeth Hospital
- 7 • HK Adventist Hospital
- 19 • Prince of Wales Hospital
- 5 • Queen Mary Hospital
- 1 • Union Hospital

TOTAL: 66

QEH Registry

Characteristics (N = 34)	Number (%) or Mean ± SD
Age (yrs.)	81.2 ± 5.4 (67 – 97 years old)
Males	22 (64.7%)
Procedural Success	97.1%
In-hospital Mortality	2.9%
30-day Mortality	2.9%

- 1 subclavian vascular complication treated with stent graft
- 2 femoral artery dissection with stenting done
- All femoral wounds closed with Prostar/Proglide x 2
- One patient developed coronary artery occlusion after CoreValve implantation. Urgent surgical AVR done with ECMO support. Passed away on Day 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
- One patient died of pneumonia and end-stage COPD 1 year after TAVI
- All patients have functionally normal CoreValve with trivial to mild AR except 3 with mild to mod AR

Procedure

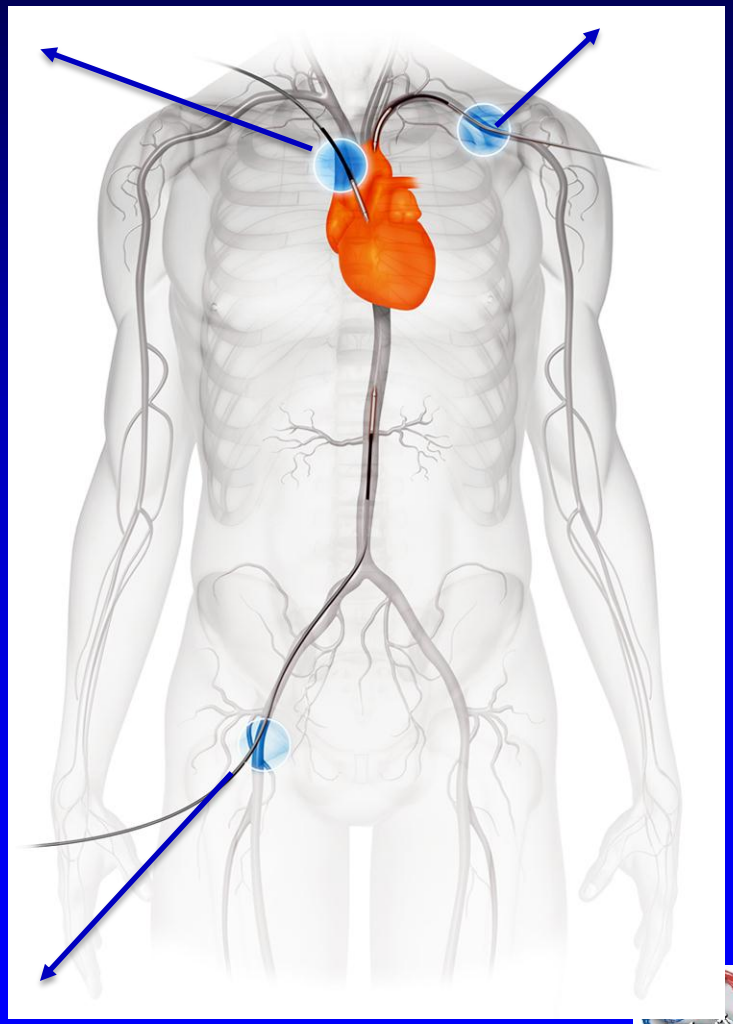
Subclavian
2.9%

Direct Aortic
0%

26mm
52.9%

31mm
5.9%

29mm
41.2%



Transfemoral
97.1%

Asia CoreValve Registry Participating Centers

Country	Center
Hong Kong	QEH
Hong Kong	PWH
South Korea	AMC
South Korea	SNUH
Singapore	NHC
Malaysia	IJN
Taiwan	NTUH
Taiwan	Cheng Hsin
Thailand	Chulalongkorn
Philippines	St Luke
China	Chengdu
China	Shanghai

Characteristics

Comparison of QEH Registry – Asia Registry – ADVANCE

Characteristic	QEH Registry N = 34	Asia Registry N = 285	ADVANCE N = 996
Age (yrs.)	81.2 ± 5.4	79.3 ± 7.3	81 ± 6
Males	64.7%	54%	49.4%
Mean Log EuroSCORE	19.4 ± 12.0%	22 ± 19%	19.2 ± 12.4%
Weight (kg)	57.2 ± 9.4	59.8 ± 12.2	NR
Height (cm)	159.3 ± 7.9	158 ± 9	NR
Mean NYHA	2.7 ± 0.6	2.6 ± 0.7	NR
MPG (mmHg)	51.6 ± 10.7	54 ± 20	45.6
AVA (cm^2)	0.7 ± 0.2	0.6 ± 0.2	0.7
LVEF	55.5 ± 11.5%	51 ± 22%	NR

NR= Not Reported

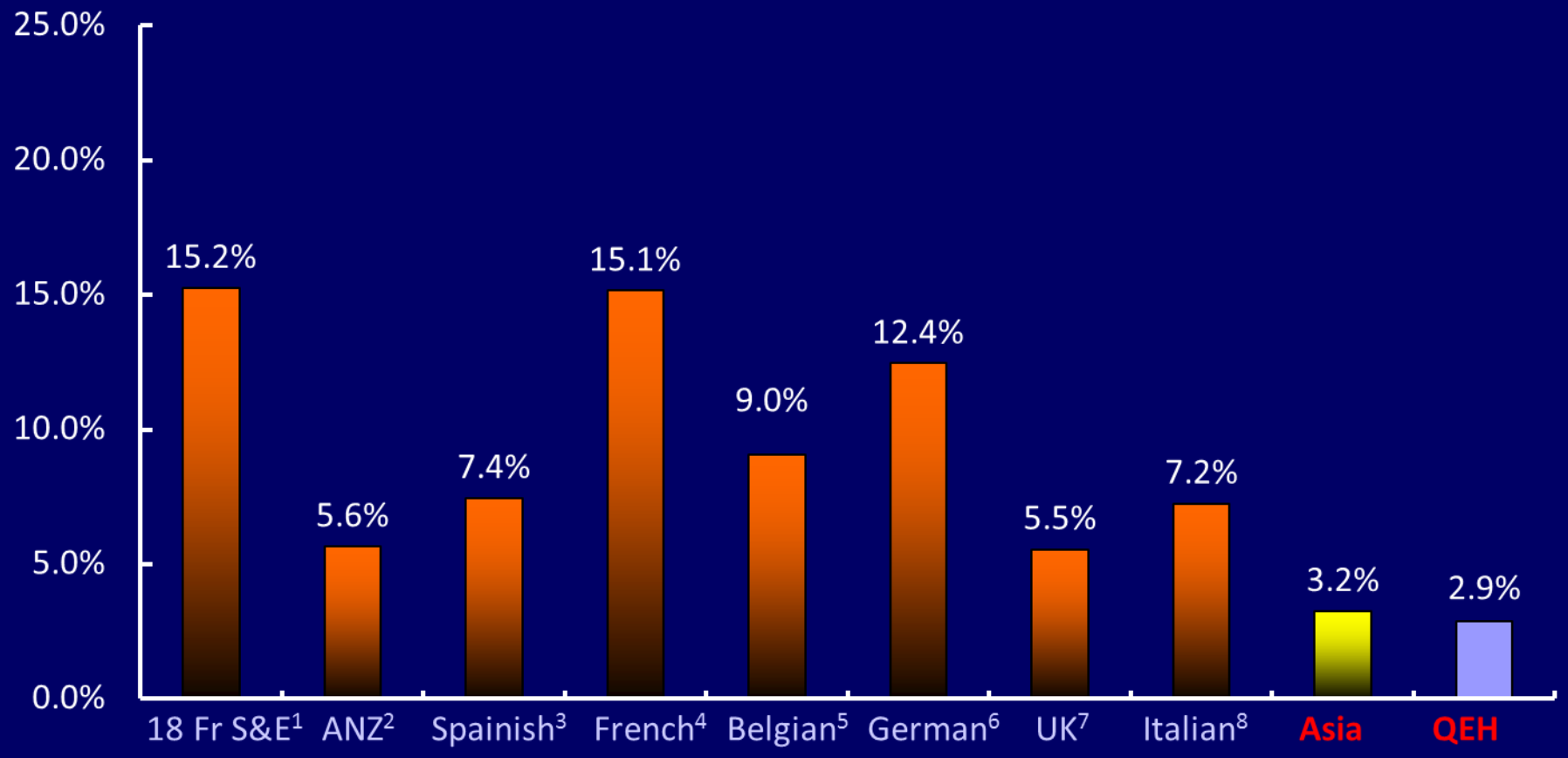
30-day Outcomes

Comparison of QEH Registry – Asia Registry – ADVANCE

Variables	QEH Registry N = 34	Asia Registry N=285	ADVANCE N=996
Mortality	2.9%	3.2%	4.5%
Stroke	0%	1.8%	2.9%
NYHA	1.5	1.5	NR
Pacemaker Implantation	14.7%	15.4%	26.3%

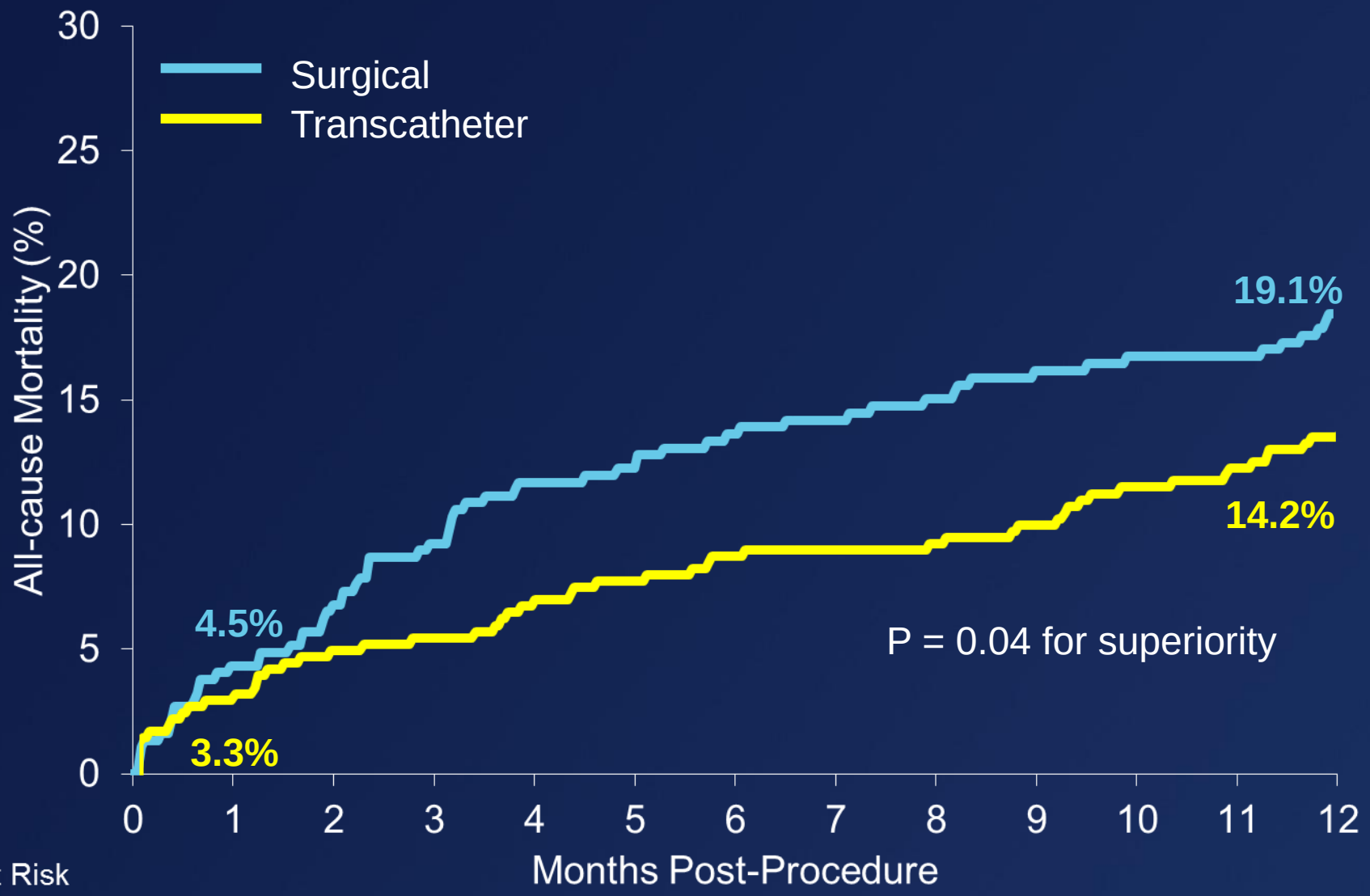
NR= Not Reported

30-Day All-Cause Mortality



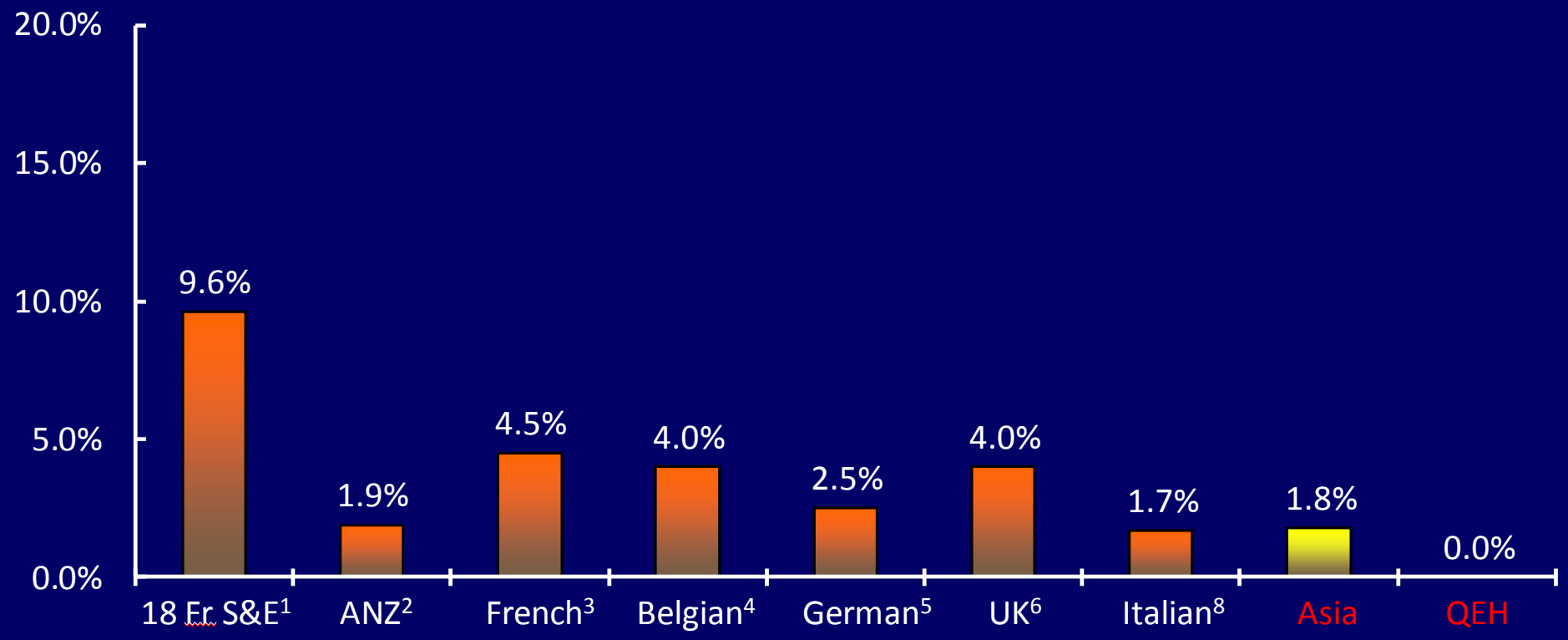
1. Medtronic Data on File. COR 2006-02: 18 Fr Safety & Efficacy Study Re-Analysis, August 14, 2009.
2. Meredith. VARC-adjudicated Outcomes in Inoperable and High Risk AS Patients. TCT 2010, Washington, DC.
3. Avanzas P, Munoz-Garcia AJ, Segura J, et al. Percutaneous implantation of the CoreValve® self-expanding 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.

Primary Endpoint: 1 Year All-cause Mortality



No. at Risk				
Surgical	357	341	297	274
Transcatheter	390	377	353	329

30-Day Stroke Rate



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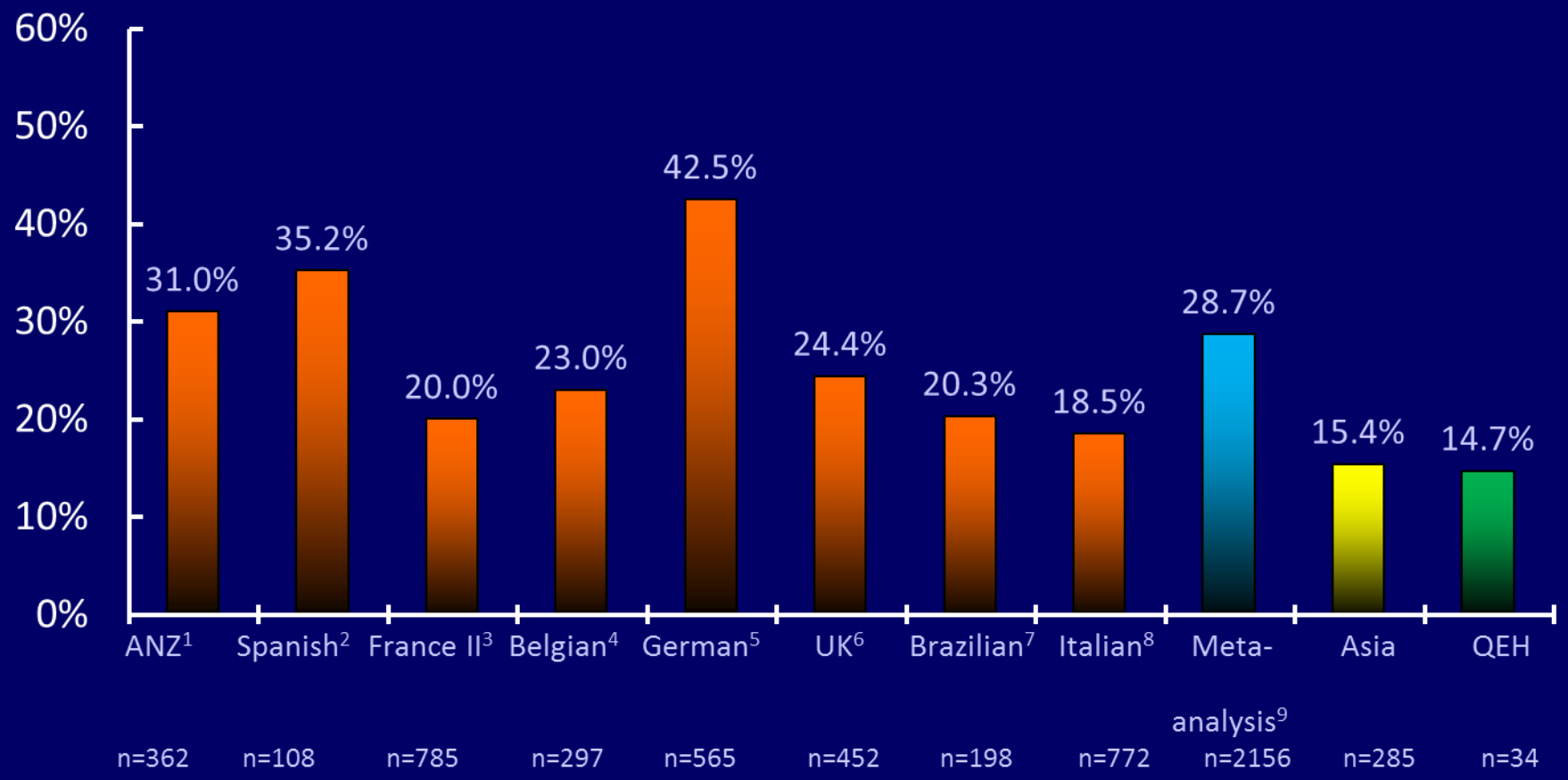
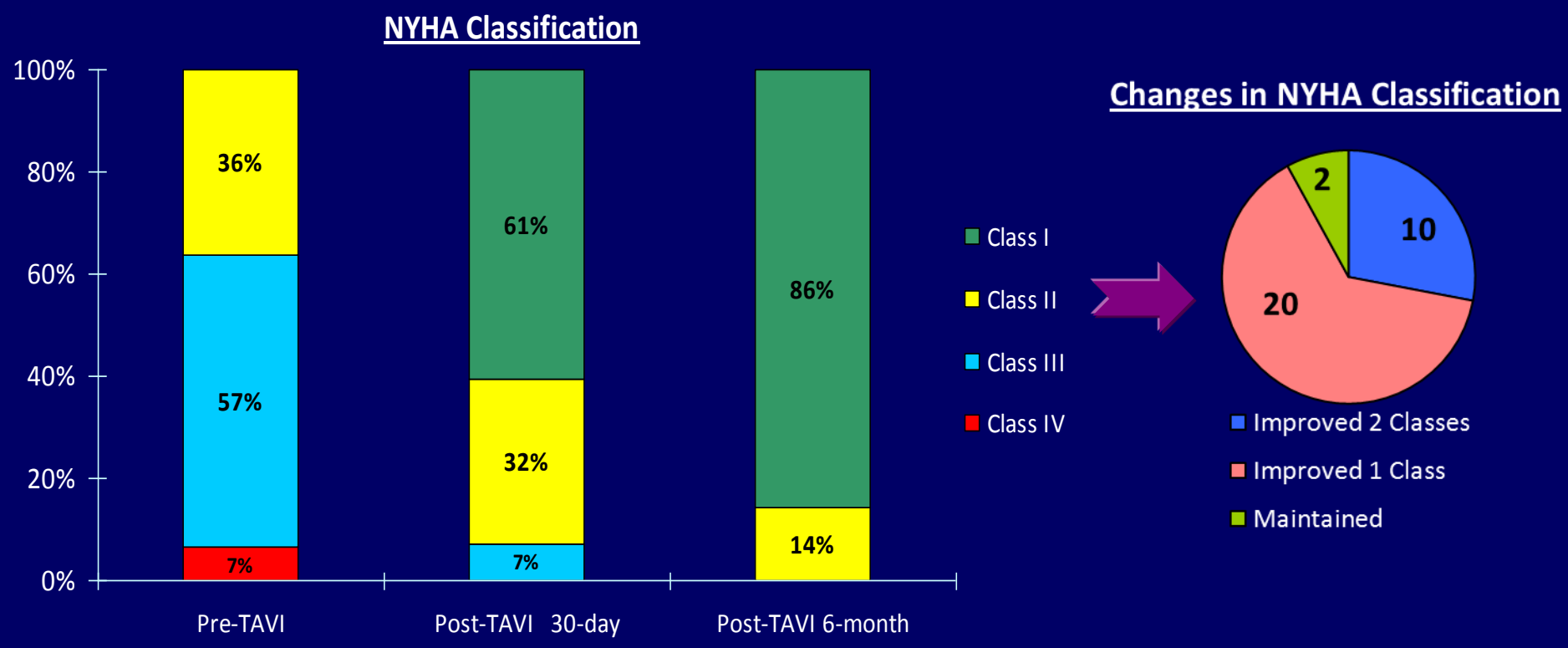
Pacemaker Implantation Rates Across Studies



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;58:1. 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.).

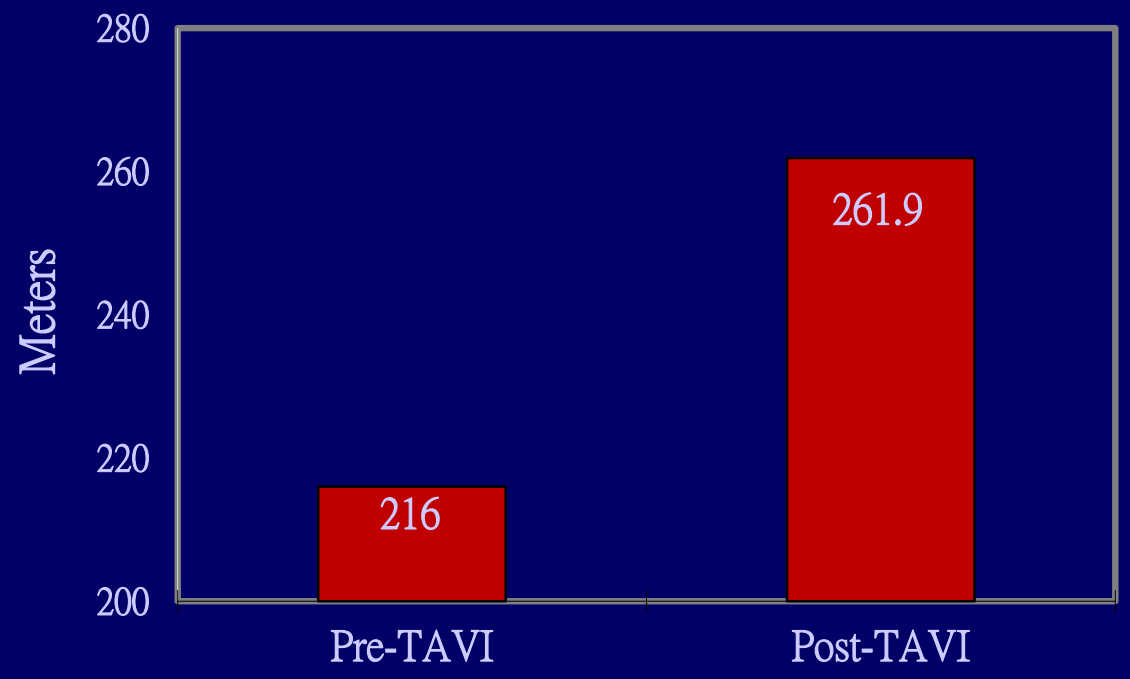
QEH | Symptom Status (NYHA Class)



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

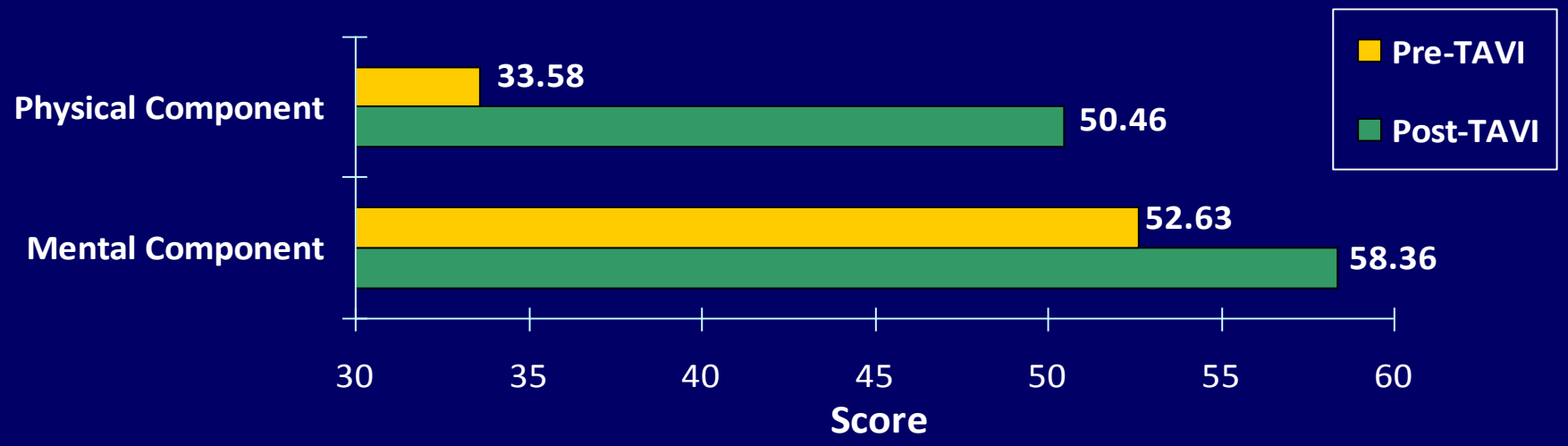
(Class I = Best, Class IV = Worst)

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: $p<0.05$


2ND ASIA PACI
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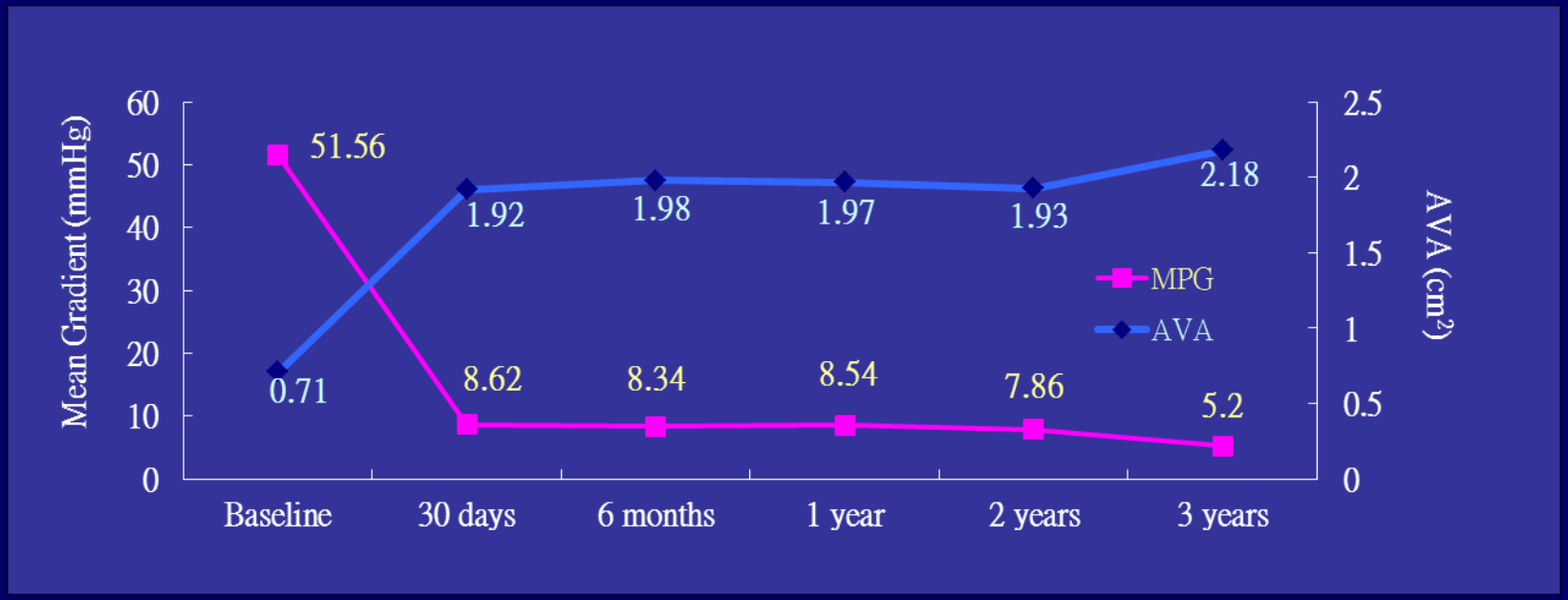
T SYMPOSI
-9 JANUA
011, HONG
AUDIO VISUAL
TECHNICIAN

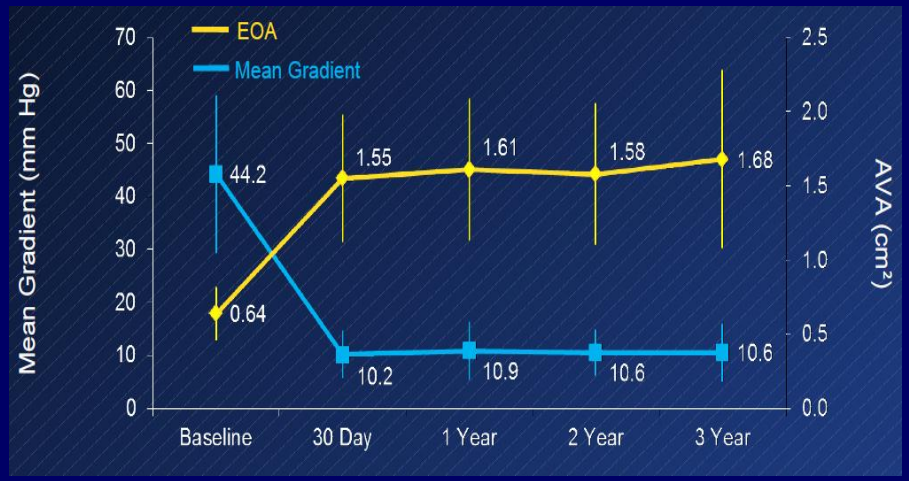
	Pre TAVI (n = 34)	1 month Post TAVI (n = 32)	1 year Post TAVI (n = 23)	2 years Post TAVI (n = 13)	3 years Post TAVI (n = 5)
AVA	0.71 +/- 0.17	1.92 +/- 0.31	1.97+/- 0.34	1.93 +/- 0.39	2.18 +/- 0.27
MPG	51.56 +/- 10.74	8.62 +/- 2.61	8.54 +/- 2.78	7.86 +/- 2.34	5.2 +/- 2.08
Cumulative Mortality	--	2.9%	8.8%	8.8%	8.8%

Mean Gradient & Valve Area

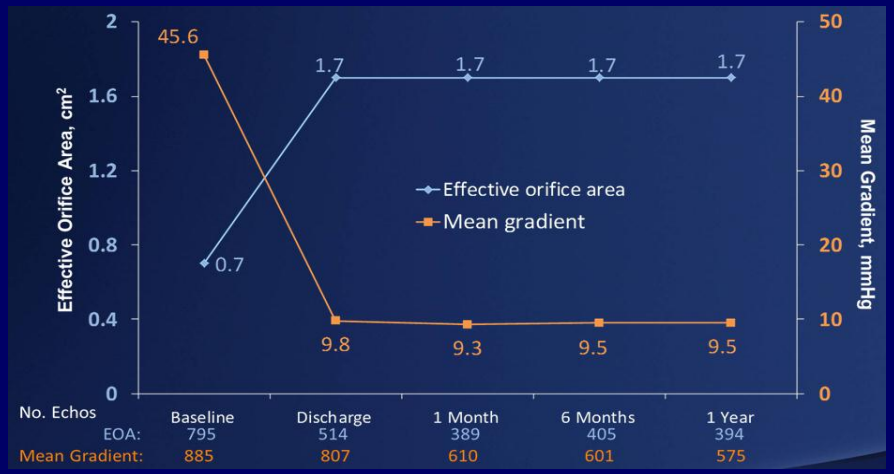
QEH Registry



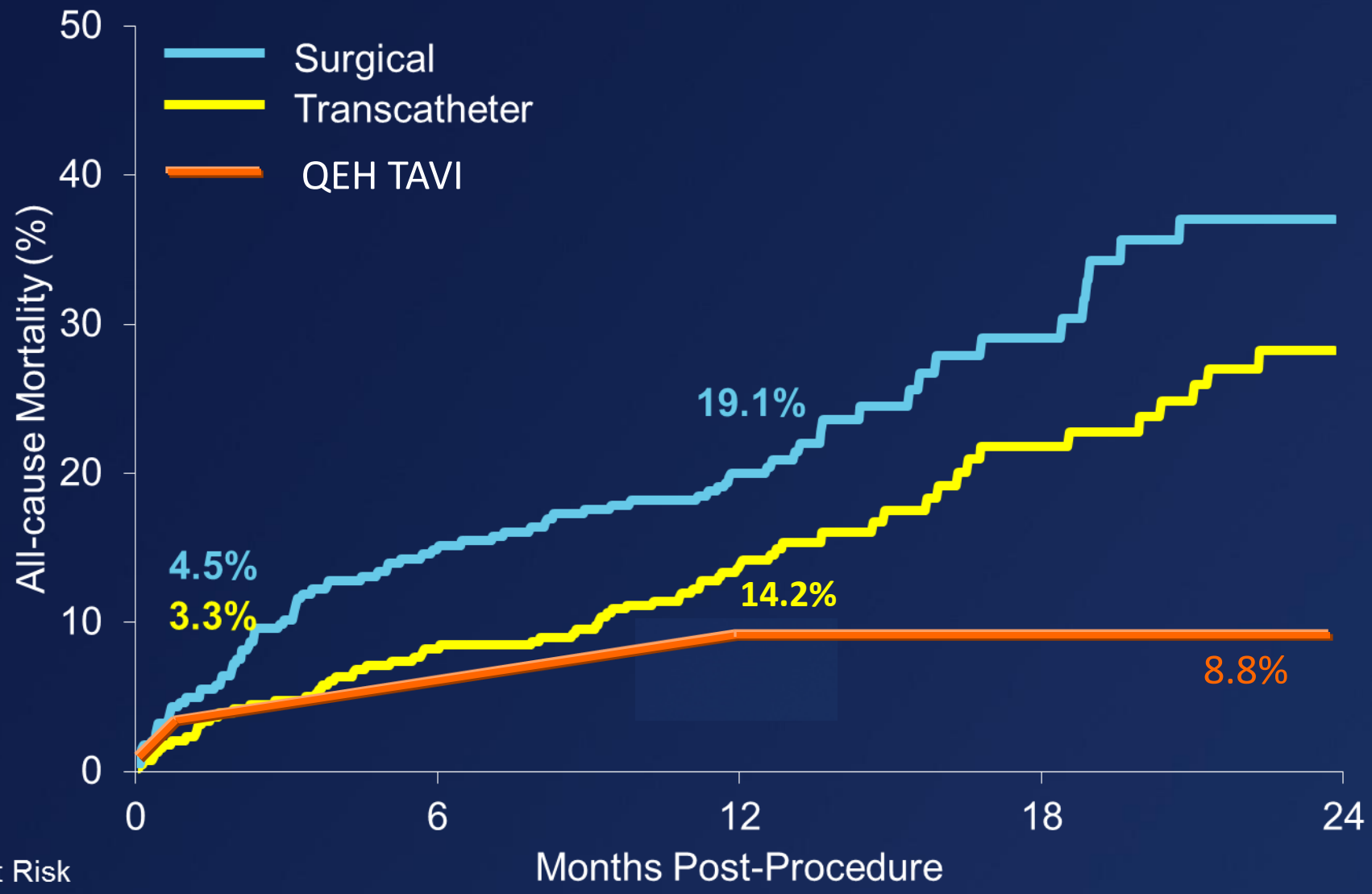
The PARTNER Trial



CoreValve ADVANCE Study



2-Year All-cause Mortality



No. at Risk				
Surgical	357	341	274	28
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TAVI 3-YEARS CELEBRATION

Surgical AVR

The "Past"

TAVI

The "Future"

Conclusions

- TAVI – rapid adoption worldwide as a viable treatment option for inoperable or high-risk symptomatic severe AS patients
- Improve survival with better quality of life (QoL) and functional capacity
- Multi-disciplinary Heart Team approach
- Promising short- and intermediate-term outcome results in Hong Kong
- Benefits maintained at 3 years after TAVI


Thank you!
Queen Elizabeth Hospital