



醫院管理局
HOSPITAL
AUTHORITY



Masterclass III

Advances in cardiac intervention

Percutaneous valvular intervention - a novel approach

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Medical therapy

- Medical therapy provides no survival benefit for patients with severe valve disease
- Surgical intervention has to be restricted to those that are fit enough to undergo major surgery
- Leaving (in the past) about 8-10% unsuitable for any treatment

ACC/AHA Valvular Heart Disease Guidelines: Indication for AVR

- **Class 1**

- Symptomatic patients with severe AS
- Patients with severe AS undergoing CABG
- Patients with severe AS undergoing surgery on the aorta or other valves
- Patients with severe AS and LV systolic dysfunction (EF<50%)

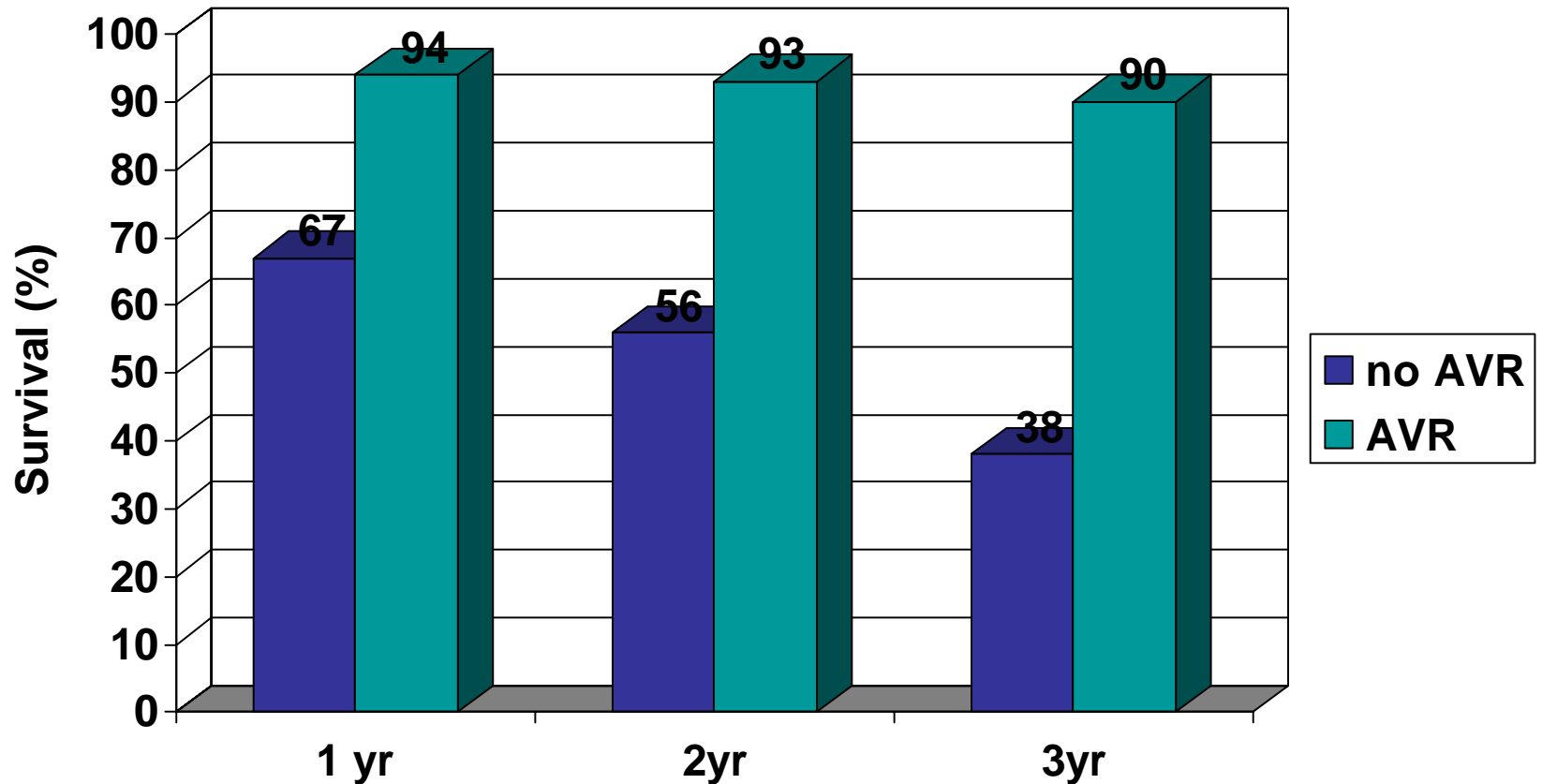
- **Class 2a**

- Patients with moderate AS undergoing CABG or other heart surgery

Definition of severe aortic stenosis

AS severity	Moderate	Severe
Jet velocity (m/s)	3.0 – 4.0	> 4.0
Mean gradient (mm Hg)	25-40	>40
Valve area (cm ²)	1.0 – 1.5	< 1.0

Survival of asymptomatic patients with severe aortic stenosis by operative status (n=338)



Professional societies

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European Heart Journal
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SPECIAL ARTICLE

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

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STS/AATS/SCAI POSITION STATEMENT

The Clinical Development of Percutaneous Heart Valve Technology

A Position Statement of the Society of Thoracic Surgeons (STS), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography and Interventions (SCAI)

Endorsed by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA)

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“The key element to establish whether patients are high risk for surgery is clinical judgment, which should be used in association with a more quantitative assessment, based on the combination of several scores”

(EACTS/ESC/EAPCI Position Statement, Eur Heart J, 2008; 29: 1463-1470)

SCTS and BCIS joint statement

- TAVI should be reserved for patients who have been considered by a multi-disciplinary team to be high risk
- Logistic Euroscore >20 or STS score >10
- For symptomatic, severe degenerative aortic stenosis (occasionally failing biological valves)
- Should be performed by a multi-disciplinary team
- There should be formal training

Infrastructure requirements

- Ability to set up an MDT
- Immediate availability of TOE, TTE
- Dedicated cath. lab or hybrid theatre
- CT scanning
- Immediate availability of perfusion service
- On-site surgical recovery and ICU
- Robust arrangements for renal support
- Access to vascular surgery and interventional radiology

Registry requirements

Case not entered into national register

No fee paid to hospital by commissioners

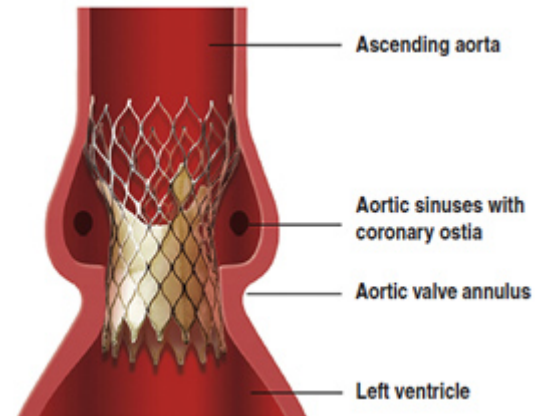
Other percutaneous valve techniques

- Valvotomy
- Mitral valve repair – Mitraclips
- Pulmonary valve interventions
- Revalving within shunts

Trans-catheter aortic valve implantation (TAVI)



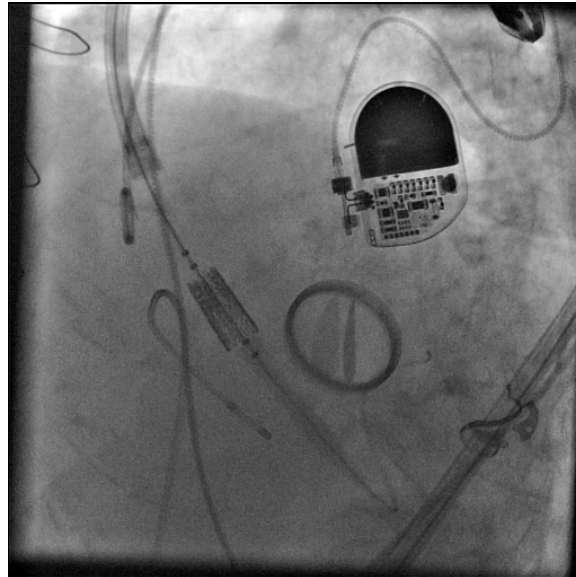
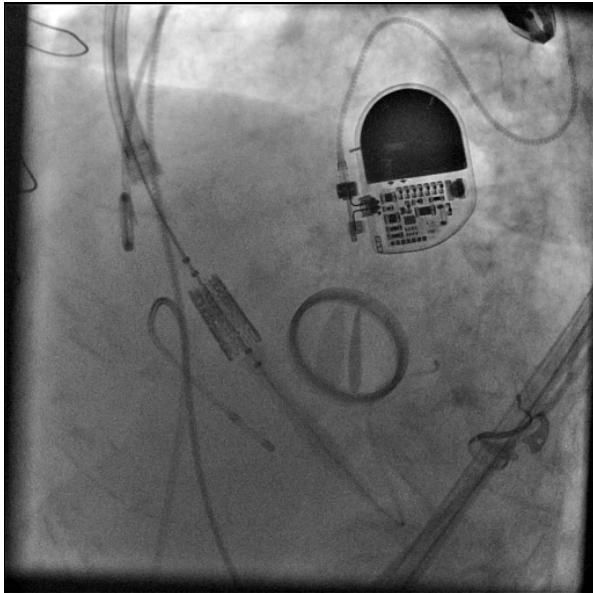
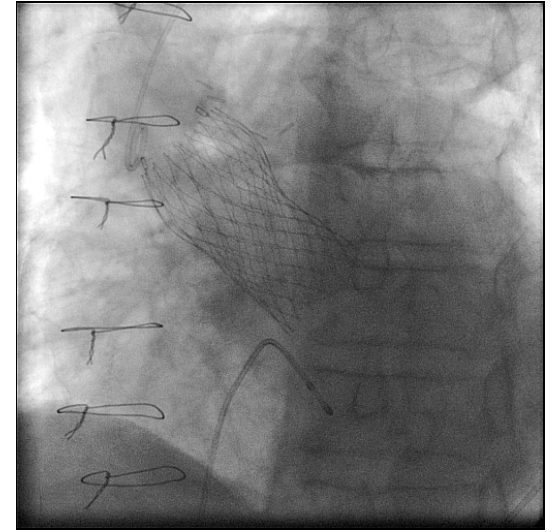
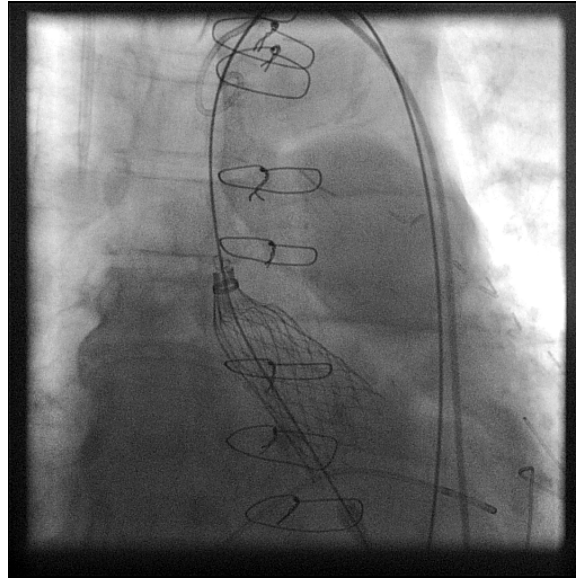
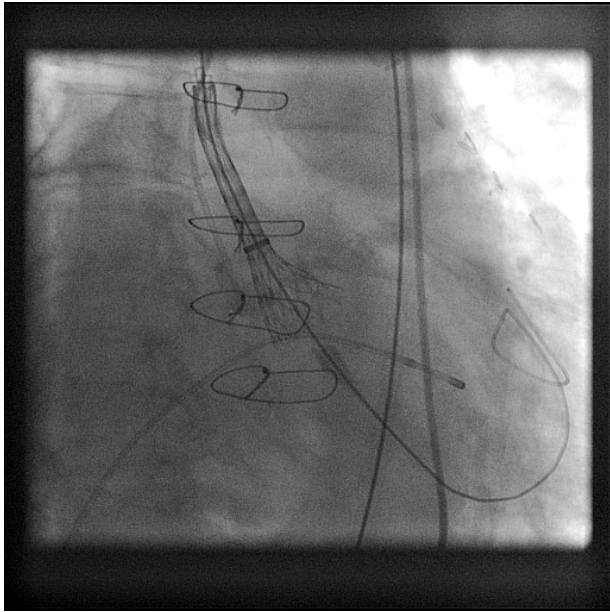
Medtronic Corevalve



Edwards Sapien Valve



All operators have a role in obtaining a precise implant



New Skills

- Detailed pre-procedural peripheral aortic and valvular anatomy
- Large bore closure devices/ Bail out closure of large vessels
- Peripheral vascular interventional skills
- Less usual access routes (Transapical, Axillary, Transaortic)
- Observing multiple imaging implant modalities (procedural TEE)
- Team synchrony vital
- Specifics of acute post-procedural geriatric care

Access Site



Steps in TAVI Team Training

- Established site team visit to observe case
- Simulator training (whole Team)
- Proctored cases (about 4 to 10)
- Proctor 1st operator
- Proctor assistant operator
- Proctor observed case(s)
- Proctor/Company certification
- Centre going solo
- Outcome-revalidation continuum

Why is this important?

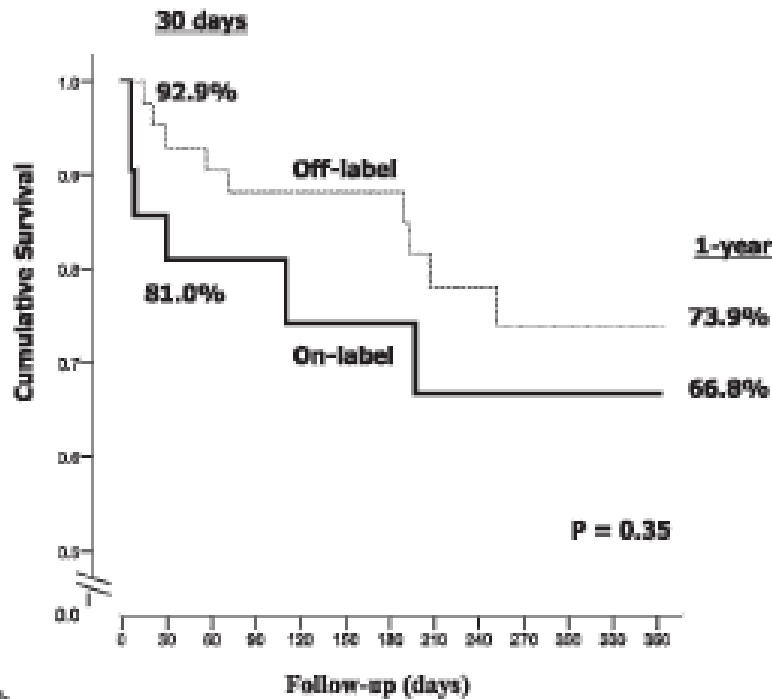
- Gurvitch et al (Vancouver) – abstract ACC.10

	First half	Second half
STS score	9.8	9.1
Procedural success	92.8%	96.8%
Mortality (30 days)	13.6%	6.4%
Need for pacemaker	7.2%	4.8%

Causes of death

- Causes of death (day)

- Tamponade (6)
- Sepsis (29)
- Induction (0)
- Stroke (24)
- Sepsis (15)
- Heart block (8)
- Stroke (10)



Partner EU registry

(Schachinger et al, Euro PCR 2009)

	Trans-femoral (%)	Trans-apical(%)
Death	8.1	18.8
Stroke	3.2	2.9
MI	1.6	4.3
Cor. Obstruction requiring stent	0	2.9
Emergent surgery	1.6	2.9
Valve embolisation	3.2	1.4
Pacemaker	1.6	4.4
Vascular complic'ns	26	2.9
Bleeding	Incl. above	8.5

THE PARTNER TRIAL: Placement of AoRTic TraNscathetER Valve Trial

- End points
 - Freedom from death
 - Cohort A: Edwards Sapien Valve{Transfemoral or Transapical} vs. other surgical valve
 - Cohort B: Edwards Sapien Valve{transfemoral} vs. medical therapy

English experience

- 1,019 records (about 10% of the world experience)
 - **26** centres
 - 5-129 per centre
 - **994** TAVI
 - 7 AVR
 - 18 Medical Rx

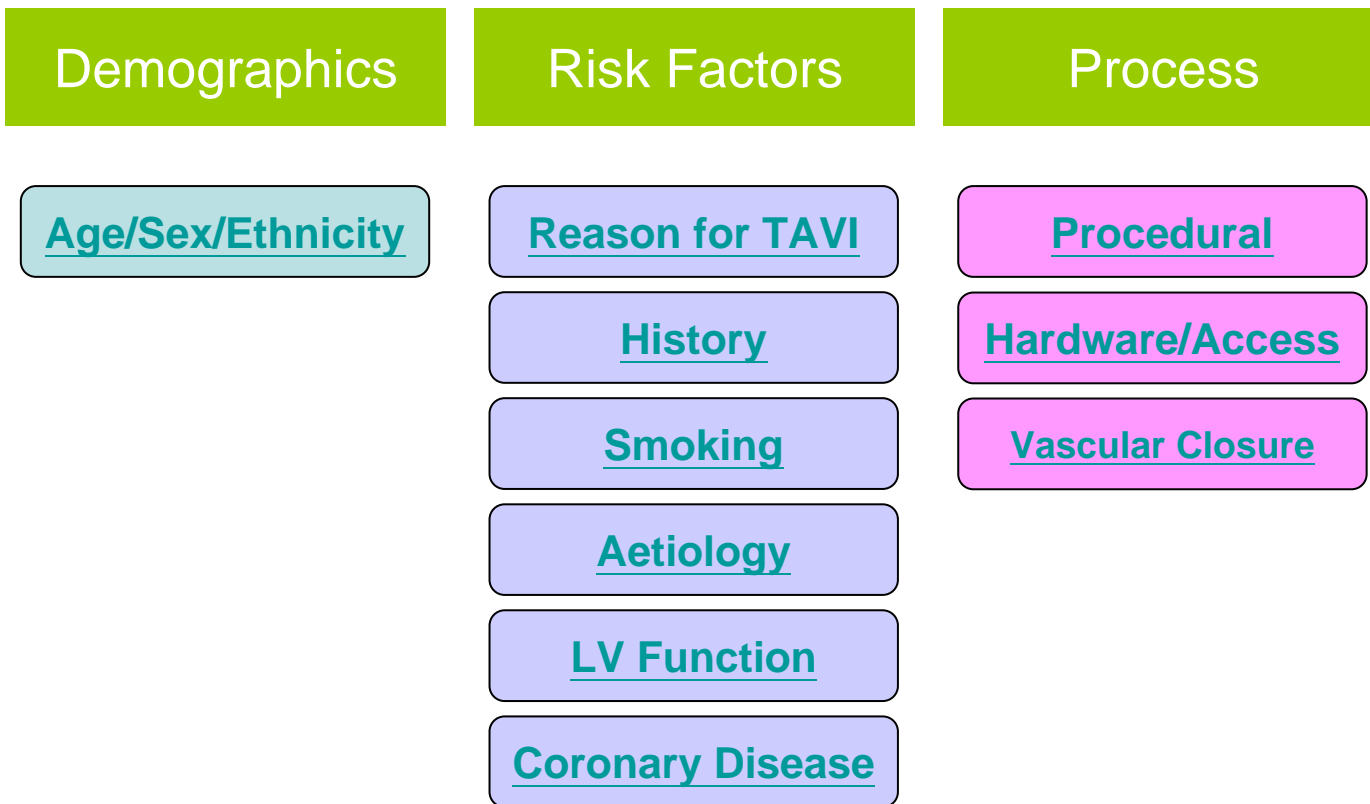
Participation (TAVI cases)

St Thomas Hospital	129	Hammersmith Hospital	27
Royal Brompton Hospital	118	Papworth Hospital	27
Glenfield Hospital	96	New Cross Hospital	23
King's College Hospital	79	Queen Elizabeth Hospital, Edgbaston	17
Royal Sussex County Hospital	63	Southampton General Hospital	15
Leeds General Infirmary	62	Freeman Hospital	13
Bristol Royal Infirmary	48	James Cook University Hospital	13
St George's Hospital	48	University Hospital of North Staffs	12
Wythenshawe Hospital	48	Derriford Hospital	9
Barts and the London	33	Manchester Royal Infirmary	7
John Radcliffe Hospital	32	Nottingham City Hospital	6
Victoria Hospital	30	London Bridge Hospital	6
Liverpool Heart and Chest Hospital	27	Morrison Hospital	5

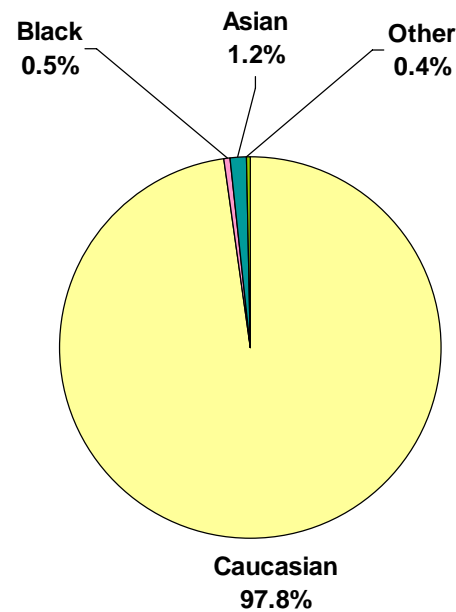
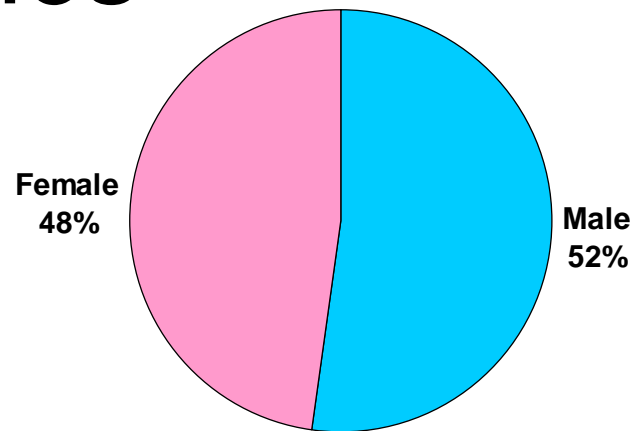
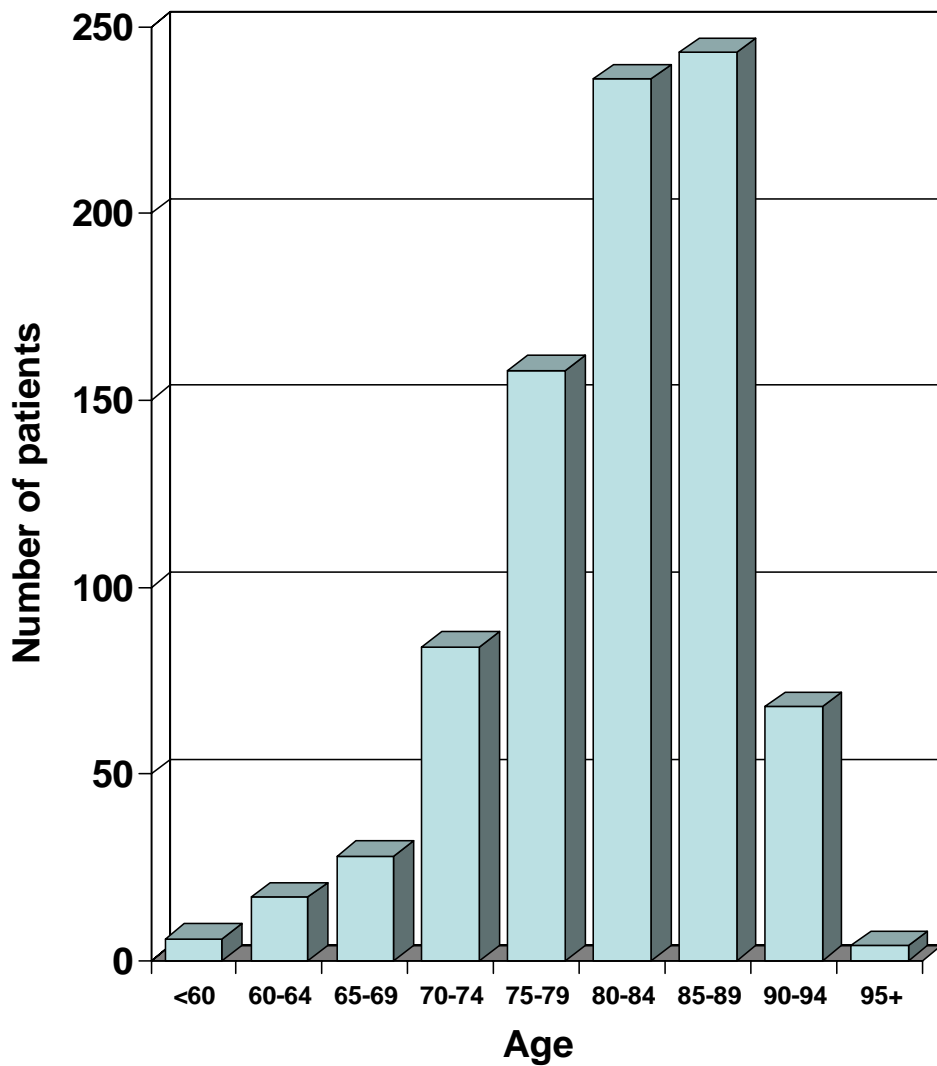
961 England
11 Scotland
15 Wales
7 Overseas



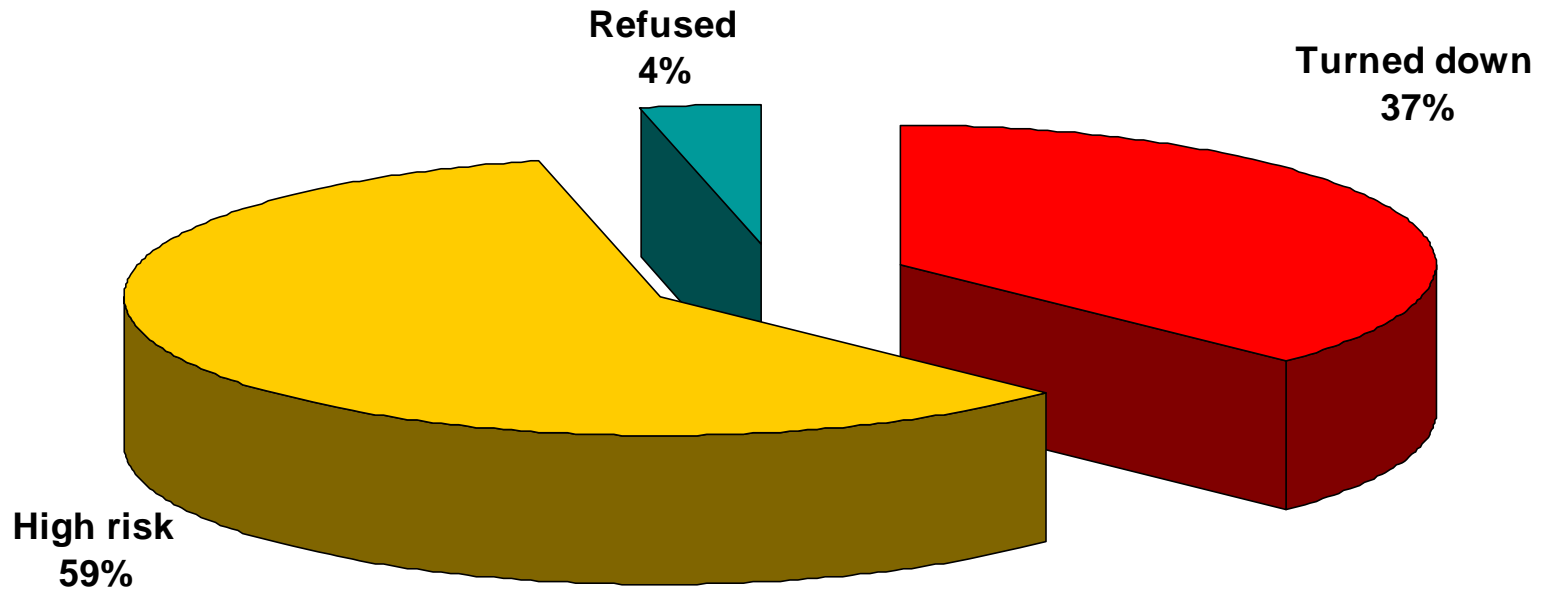
Analysis of all TAVI cases to 31/12/2009 (n=872)



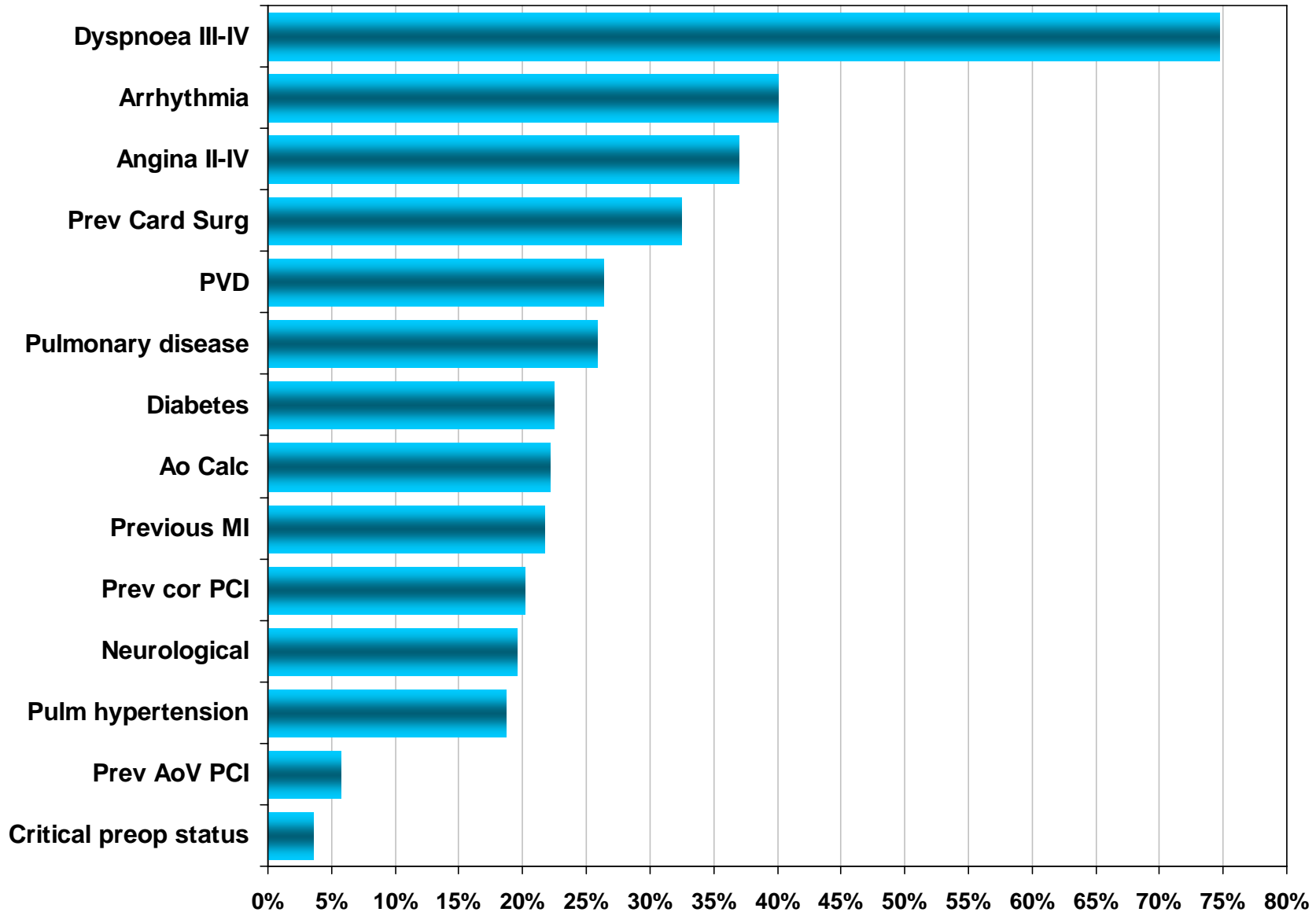
Demographics



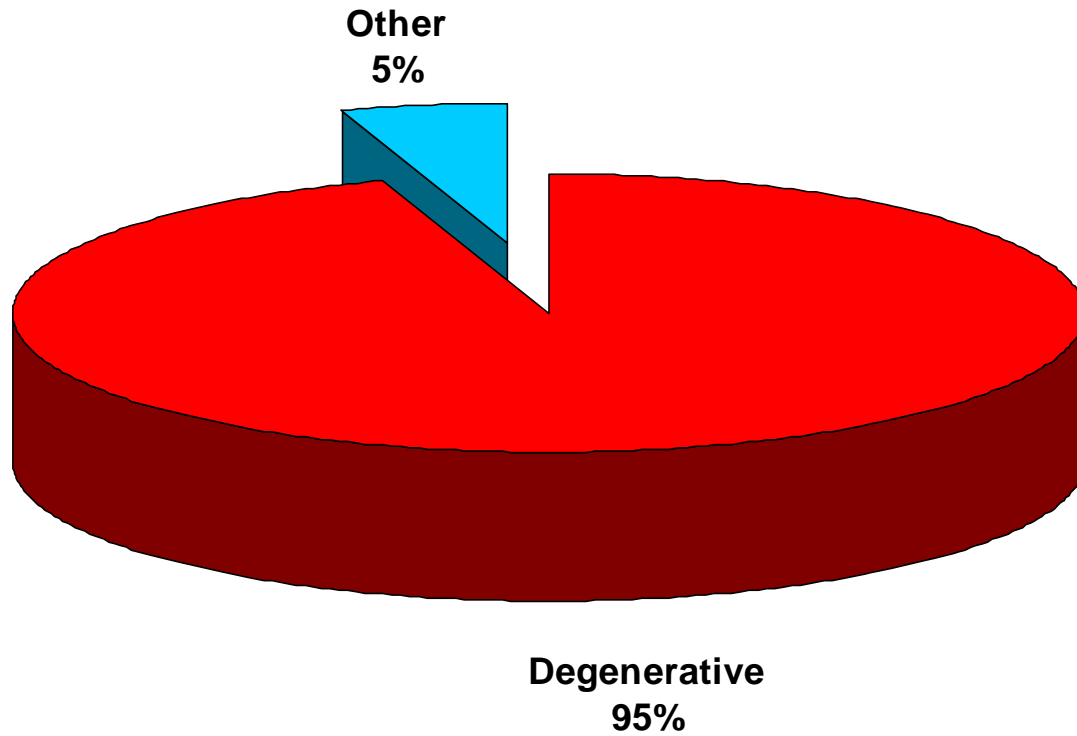
Indication



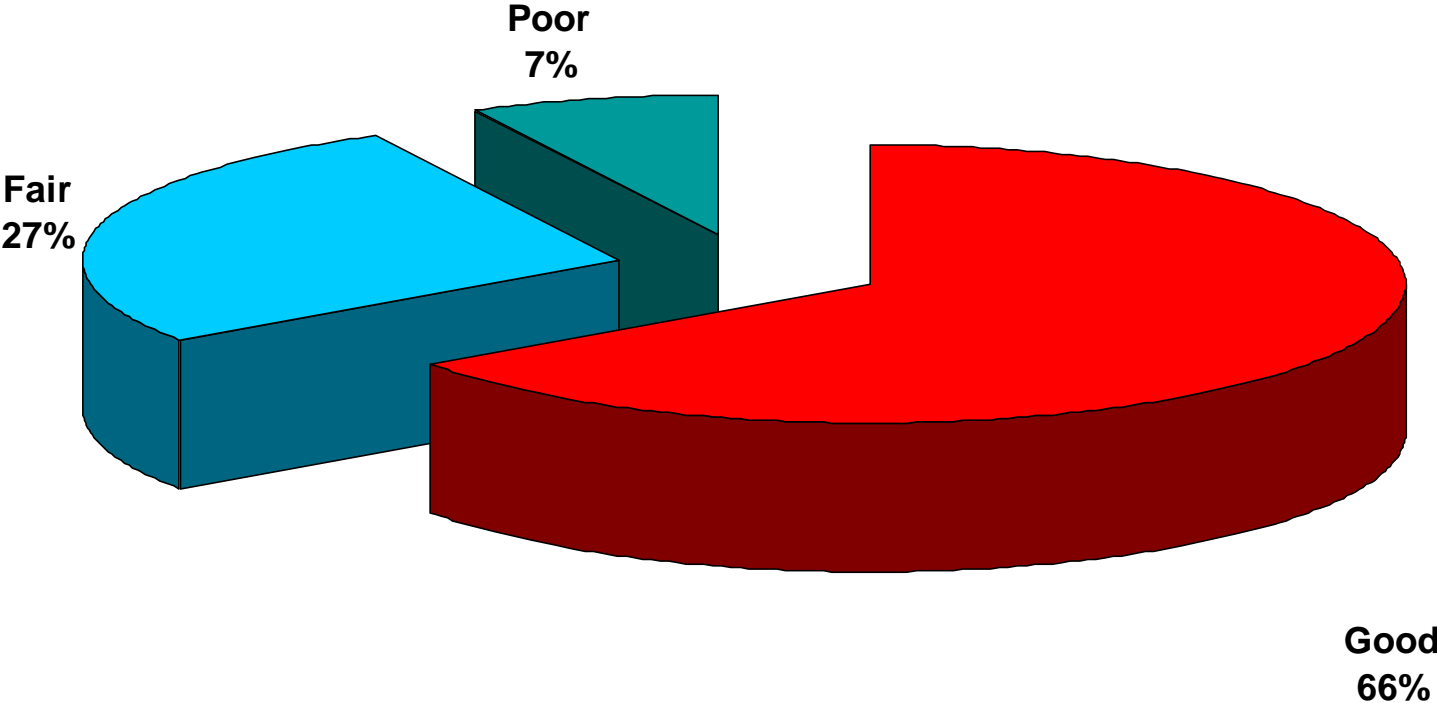
Symptoms and other descriptors



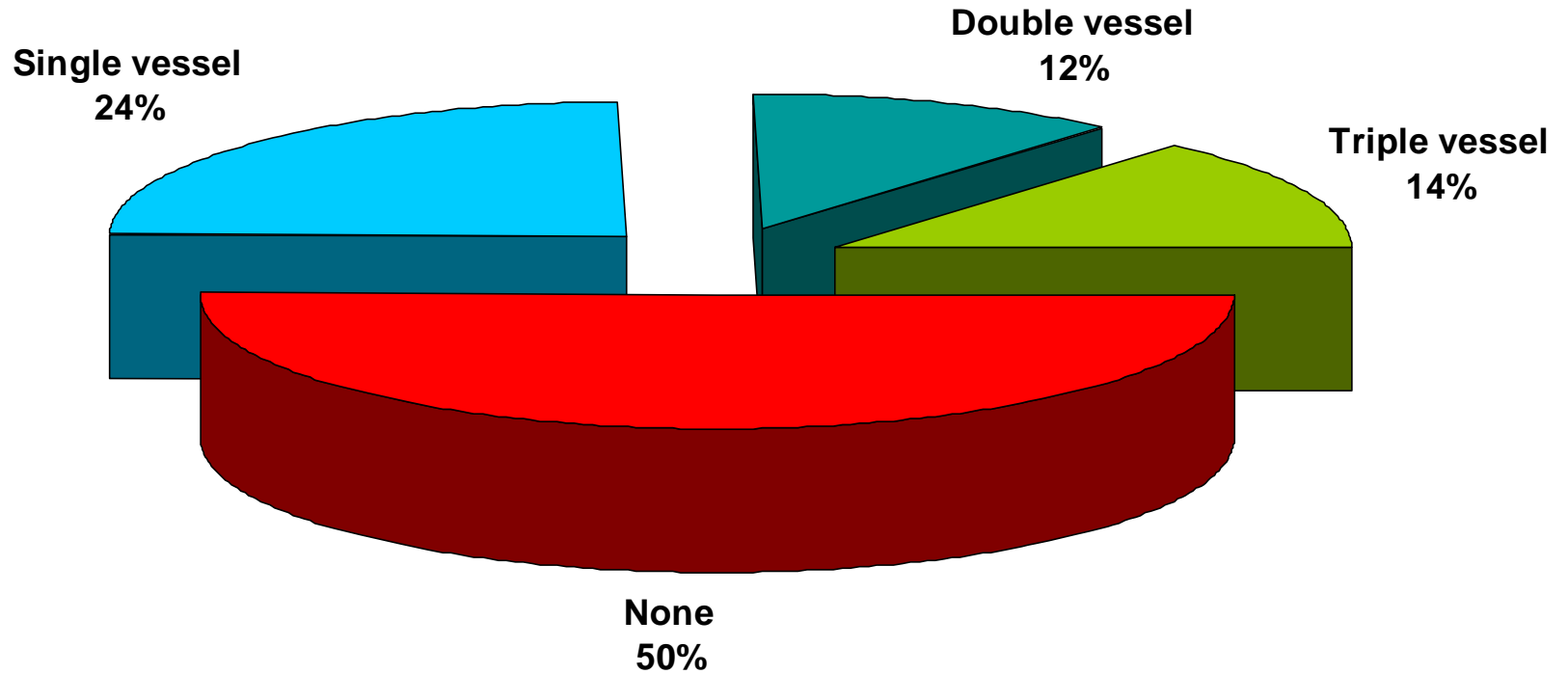
Aortic Valve Disease Aetiology



Left Ventricular Function



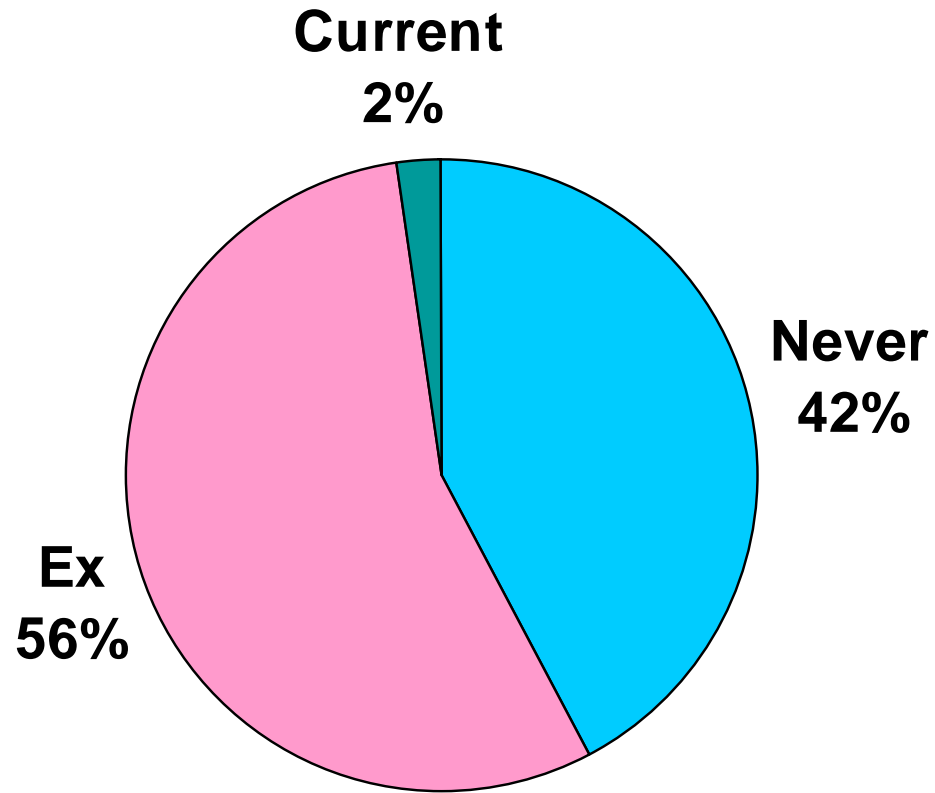
Coronary Disease



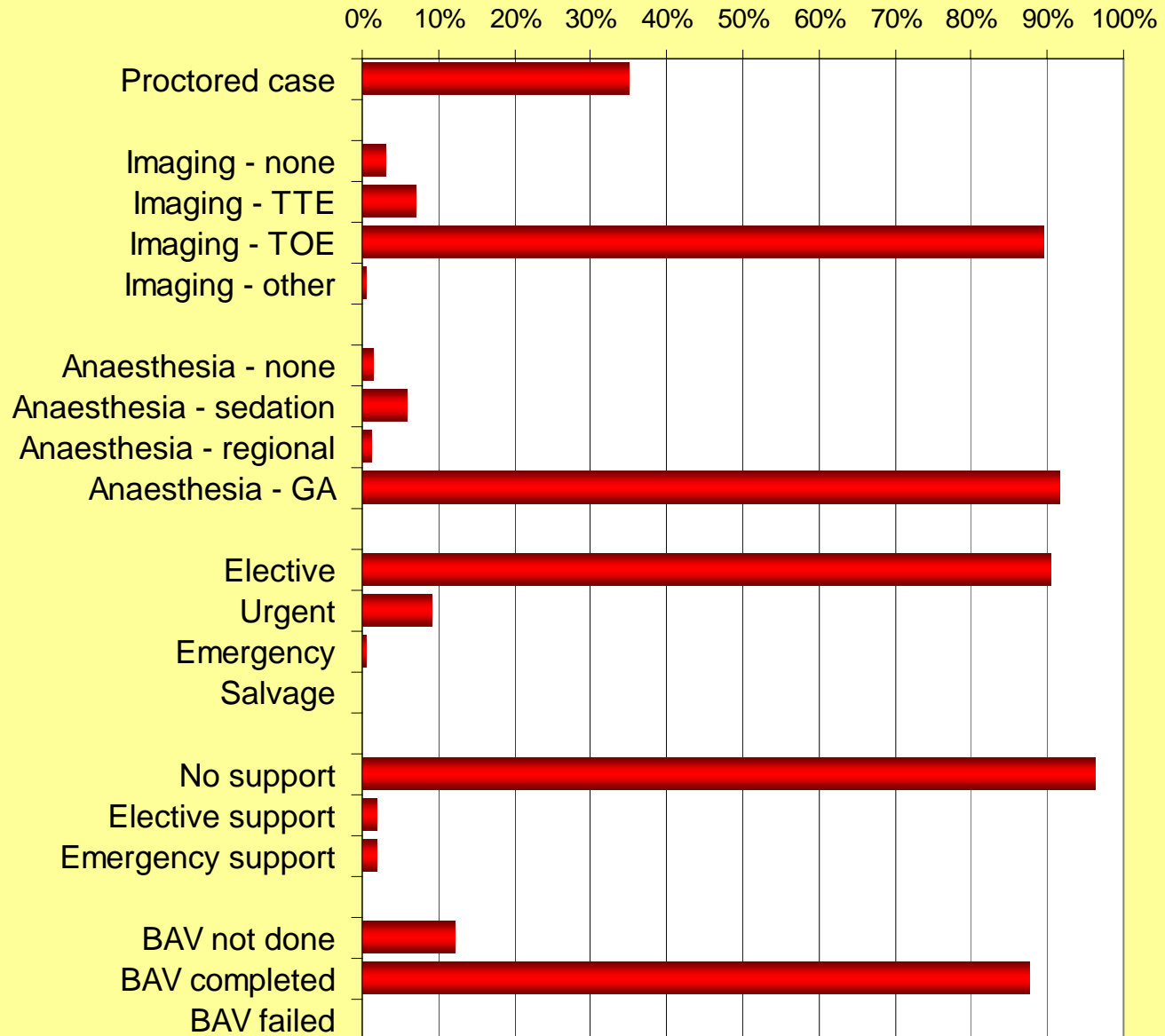
Left main stem disease: 51/774 (6.6%)



Smoking



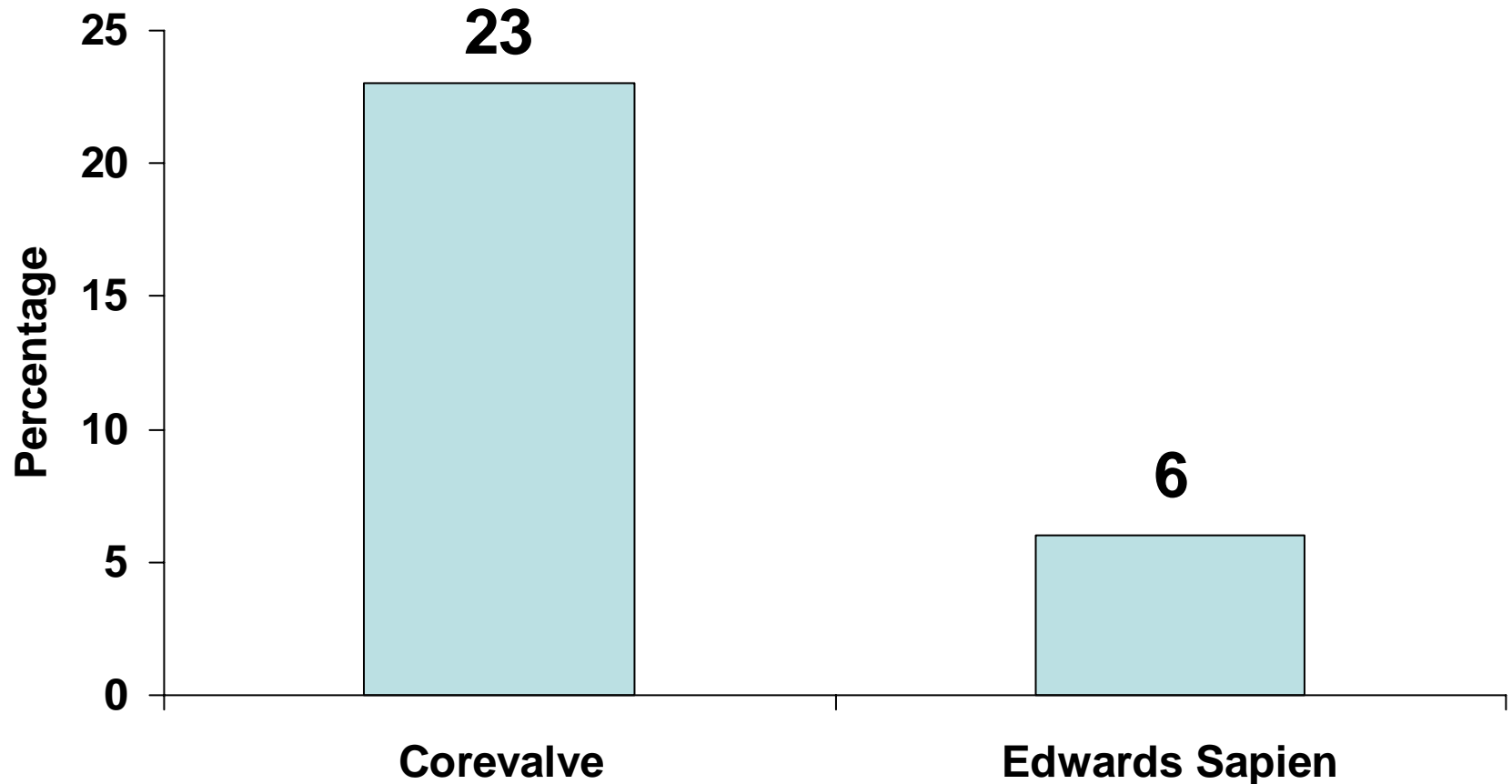
Procedural



	Corevalve	Edwards	?	Total	Deployed
Transfemoral	387	170	7	564	98.0%
Transapical	0	208	3	211	98.1%
Other	37	1	3	41	92.5%
Unknown	22	2	5	29	85.0%



Permanent pacemaker requirement by valve type



Conclusions

- TAVI is an exciting new technology
- Special attention must be paid to planning when developing such a service
- Particular training is necessary if the treatment is to be offered with maximum safety
- Minimise the 'learning curve'

Caveats

- Not enough data on longevity yet
- Not enough data to advise a switch from conventional surgery for all patients
- Insufficient data to be certain whether this intervention is cost-effective