How to build a TAVI Team

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Disclosure

Consultant and involved in the Training / Proctoring program for Edwards Lifesciences
Growing interest in the medical community

- > 40,000 treated Pts worldwide
- Improved and satisfactory immediate and mid-term results in high risk patients

Edwards Sapien balloon expandable
CoreValve self expandable

CE mark 2007
Near all operators are willing to learn and apply this technique

This raises several questions:

- Who should do these procedures?
- Which centers should be open?
- How to get prepared and organized?
- How to get trained?
Multiple new issues for the physicians

• Caring with unusually sick patients and choosing the best therapeutic option
• Creating a cohesive multi-disciplinary team
• Returning to basics (crossing aortic valve)
• Learning new interventional and surgical procedures (new devices, larges introducers, new technical modalities)
• Facing new specific complications
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)

Alec Vahanian, Ottavio Alfieri, Nawwar Al-Attar, Manuel Antunes, Jeroen Bax, Bertrand Cormier, Alain Cribier, Peter De Jaegere, Gerard Fournia, Arie Pieter Kappetein, Jan Kovac, Susanne Ludgate, Francesco Maisano, Neil Moat, Friedrich Mohr, Patrick Nataf, Luc Pierard, José Luis Pomar, Joachim Schofer, Pilar Tornos, Murat Tuzcu, Ben van Hout, Ludwig K. Von Segesser, and Thomas Walther

European Heart Journal (2008) 29, 1463-1470
Should be concerned high volume and experienced centers for both AVR and interventional cardiology

With expertise in structural heart disease intervention and high-risk valvular surgery

• AVR > 200 per year
• PCI > 600 per year
Each step is crucial to achieve a safe procedure

Staff and Team preparation

Equipment, imaging modalities

Patient Screening

Pre-implantation valvotomy

Large sheath insertion

Valve positioning and delivery

Devices retrieval
High quality imaging matters

• Ideally: Hybrid room for all procedures

• If hybrid room not available:
  - *Cath-Lab adapted to meet surgical sterility*
  - *Operating room with validated mobile C-arm for the transapical approach*

GENERAL ELECTRIC: OEC 9800 & 9900
ZIEHM: Vision R & FD
PHILIPS: BV Pulsera
SIEMENS: Artis U
Key factors for a successful procedure:

Patient selection

Aortic valve assessment: anatomy, calcium distribution, valve sizing

Selection of access: Vascular imaging

Multiple Disciplinary Approach

Technique of BAV and RVP

THV positioning and delivery

Prevention and treatment of complications
Close cooperation of team specialists in valve disease
Each procedural step matters

Arterial access

Percutaneous? Arterial cut-down? Lateral sternotomy

General or local Anesthesia?

FEMORAL

APICAL

SUB-CLAVIAN

FEMORAL
Each procedural step matters

**Ballon pre-dilatation**

- Crossing the valve; wire selection and preshaping
- Balloon selection, preparation and positioning
- Rapid ventricular pacing
- Simultaneous aortogram (validation of THV size)
Each procedural step matters

Preparation and use of introducers and delivery systems

EDWARDS

NovaFlex (TF)

COREVALVE

Ascendra (TA)

CoreValve delivery system
Each procedural step matters

**THV positioning and delivery**

**EACH DETAIL MATTERS !**

**EDWARDS**

**COREVALVE**

**Transfemoral**  **Transapical**  **Transfemoral**
## Prevention and treatment of complications

Be prepared to manage the complications

### VASCULAR complications:
- Aorta balloon occlusion
- Covered /non covered stents
- Surgical repair

### TAMPONADE:
- Pericardial drainage

### CORO. Occlusion:
- Stenting
- Cardiac assistance

### OTHER SEVERE COMPLICATIONS

POSSIBILITY OF CONVERSION TO SURGERY
Organize POST-implantation phase

- In-hospital management
- Compliance to Registries
  *(ideally with a research nurse)*
- Organize the follow-up
Training is the KEY!

- Acquiring basic, then advanced device specific skills
- Acquiring knowledge of valve disease (clinical, catheterization techniques, imaging)
- Working in a sterile environment
- Understanding the equipment
- Anticipating and treating complications
Training sessions organized by both companies

**EDWARDS**
- Rouen- *France*  
  (1 or 2 per month)
- Leipzig- *Germany*  
  (1 or 2 per month)
- Nyon- *Switzerland*
- Vancouver- *Canada*
- New-York- *USA*

**COREVALVE**
- Switzerland  
  (2 per month)
- On-site
• Simulators
• Didactic
• Cases review
• Hands on
• Live cases
The learning curve is permanent from one case to the other.
It has to re-start after each technological advancement.

The impact of the learning curve on the safety of TAVI has been fully demonstrated.
On site-proctoring

- Organized by both companies
- Clinical assistance for the first cases
- After re-assessment of each patient’s screening
- Ideally $\geq 2$ cases/day (pre-selected cases)
- Same 2 operators (main + assistant)
- Proctored cases:
  - 4 to 6 for Edwards
  - 15 for Corevalve
- Certification
Optimal training of the team

Valve crimping

Specific training of nurses by the company’s clinical specialists

Assistance for the first 10 cases
Start of certified centers

- Start with optimal cases (*ex: good femoral access, no EF depression*)
- Short delay after on site proctoring
- Same two trained operator
The TAVI Team
Summary

- Importance of physician and staff training validating training and proctoring programs
- Dedicated cath-labs and / or hybrid OR with optimal imaging capabilities
- Interventional vs surgical operators no competition, no fight, optimal partnership
- Team work for screening and procedures
Conclusions

- Even though results are good in experienced teams, there is a learning curve and training/proctoring is crucial.

- TAVI should be used in selected centers with experience of valvular disease.

- Training and personal preparation of the operators and their team, patient’s selection and cooperative work are crucial for the success and the future of the procedure.