

Minimalist TAVR: User-Friendly and with Optimal Clinical Outcomes

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Disclosure Statement of Financial Interest

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Consulting Fees/Honoraria
- Proctoring–Training activities/Honoraria

Company

- Edwards Lifesciences
- Edwards Lifesciences

What is a « Minimalist Approach » ?

- TAVR with local anesthesia and light sedation
- Pure percutaneous transfemoral approach
- Preclosing with closure devices
- TTE on demand
- ICU < 24h, Early discharge (1-3 Days)



General Anesthesia
Endotracheal Intubation

TEE

Additional vascular lines
(jugular vein / radial artery)

Advantages of sedation over GA

- 1 - Decreases the number of people in the room and is time-saving
- 2 - Avoids aortic hypotension at induction of general anesthesia
- 3 - Avoids the use of vasopressors (stability of aortic pressure)
- 4 - Allows safer TAVR in patients with severe pulmonary insufficiency with no need for tracheal intubation / ventilation
- 5 - Allows the patient to report pain, an indicator of danger
- 6 - Allows immediate detection and early treatment of neurologic events

Sedation (on demand)

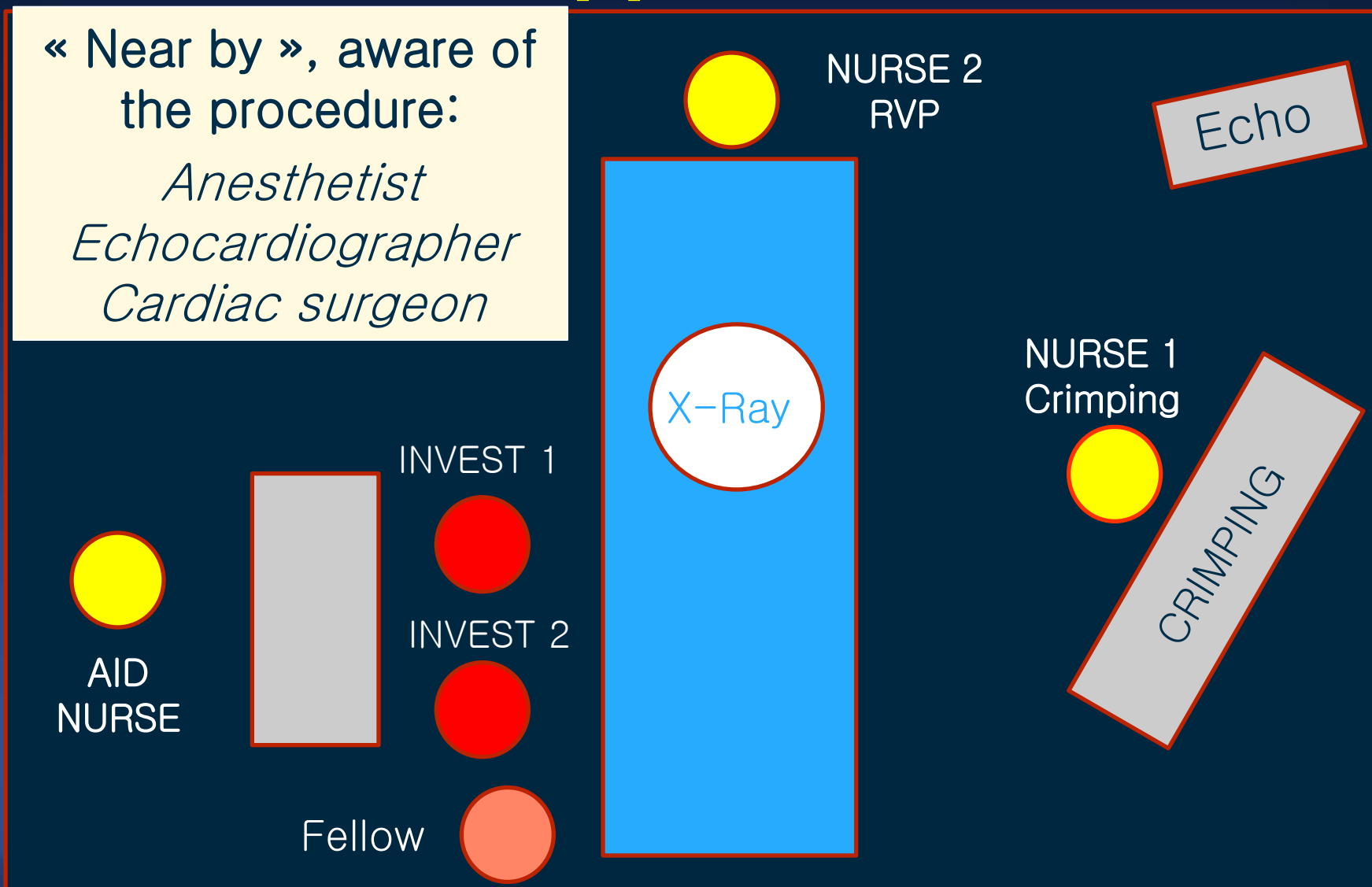
Midazolam 1 to 2 mg, Nalbuphine (morphinic) 5mg

Room set-up: Edwards Sapien XT

Minimalist approach in Rouen

« Near by », aware of the procedure:

Anesthetist
Echocardiographer
Cardiac surgeon



Minimalist Approach in Rouen



TF Sapien-XT, Sapien 3
Minimalist approach (100%)
A team of 6 in Cath-Lab



Conversion to
*G.A.,
Heart Surgery,
Vascular surgical repair*

< 1%

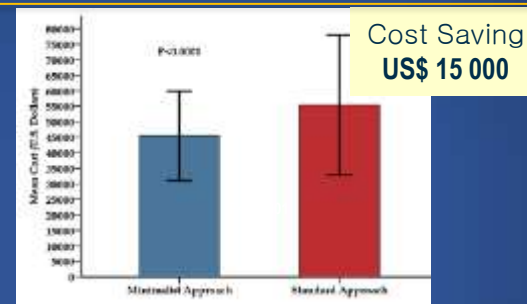
70% discharge at \leq Day-3

Minimalist Approach in USA

Emory Hospital, Atlanta, USA



- Simplifies procedure
- Results as safe as standard approach
- Maintains excellent outcomes, short and long term
- **Decreases resource utilization, hospital stay and COST**



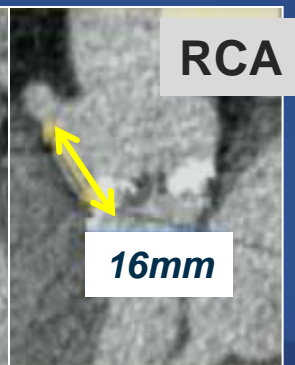
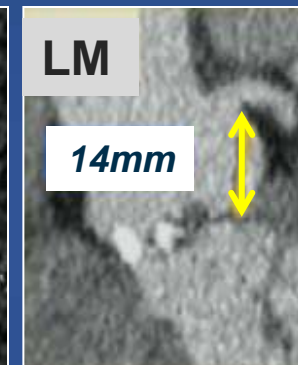
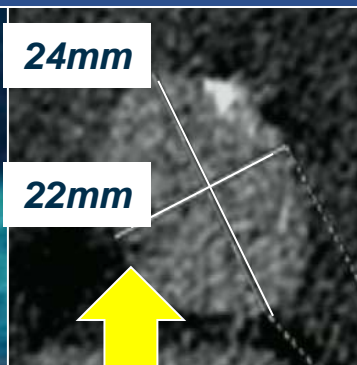
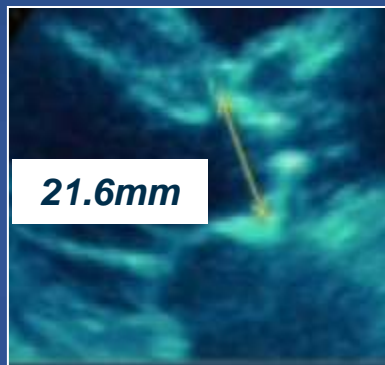
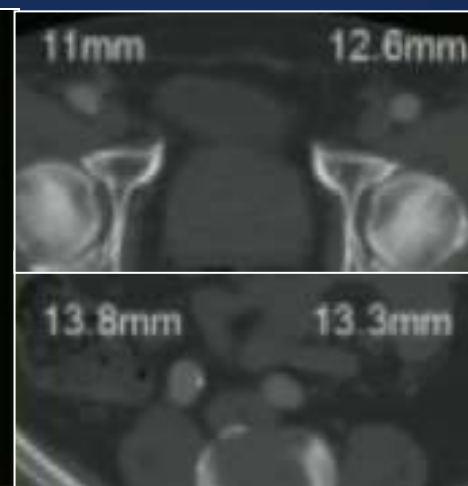
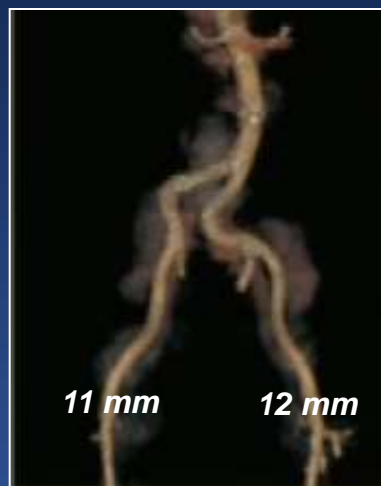
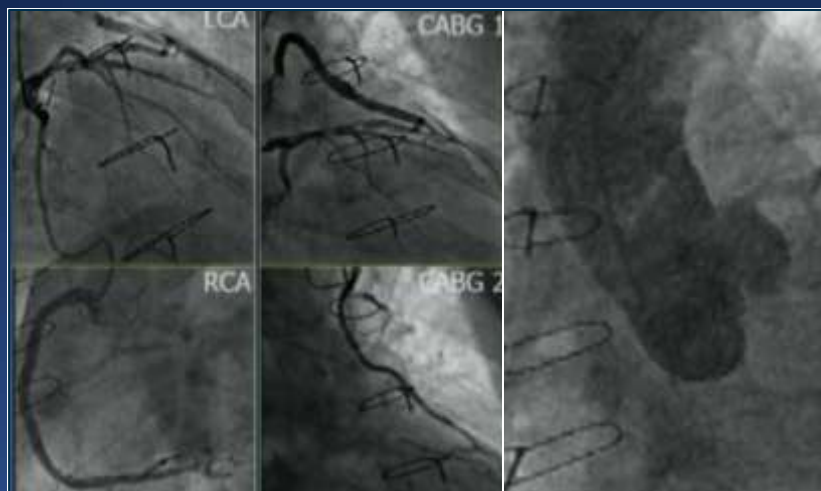
Comparative cost: minimalist vs standard

Babaliaros et al, JACC Interv 2014

Optimal Screening for procedural success

Clinical case SAPIEN XT

- Age: 84 y-old male , NYHA Class 3
- CABG 1996 (LIMA-LAD, Saphenous 1st diagonal branch)
- Past medical history: Diabetes, CAD, Severe COPD
- Gradient: 38mmHg, AVA: 0.70cm² PAP: 48mmHg LVEF: 56%



CT Area 495 cm² : 26mm THV <10% oversizing

Minimalist Strategy:

Optimal Vascular Approach is Crucial

Contra-lateral catheterization



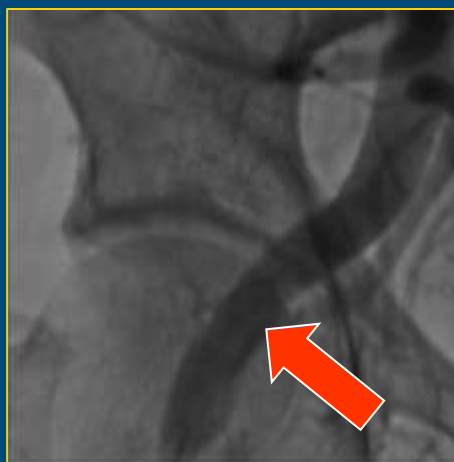
8F Sheath in FV

- Pacing lead (6F)
- Drug / Fluid administration

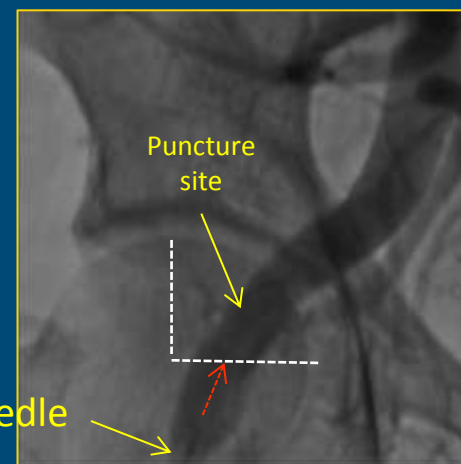
6F Sheath in FA

- Pigtail
- Cross over catheters

Target FA catheterization



Selection of puncture site



Needle

FA puncture with angio

Prostar 10F



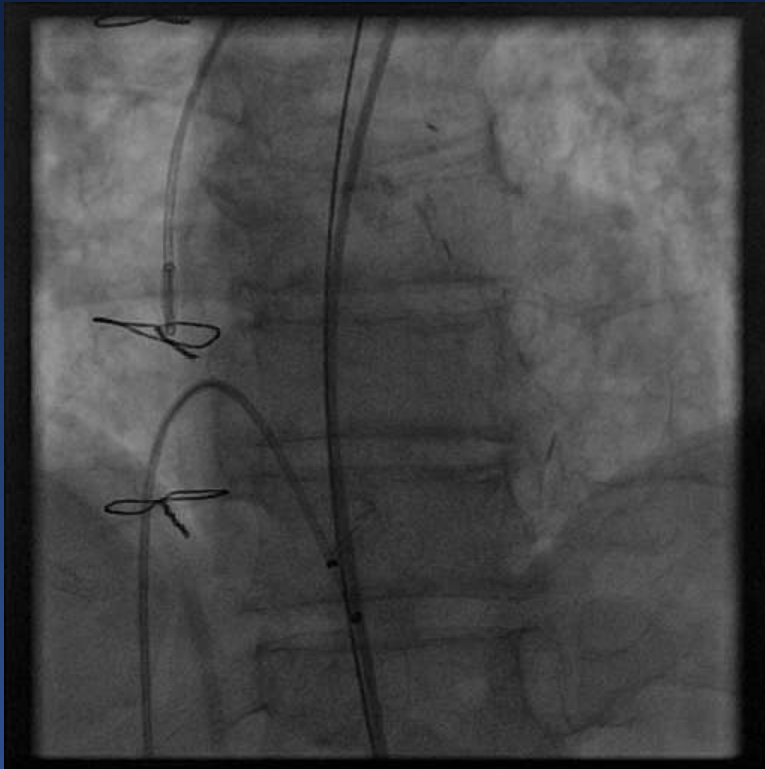
Preclosing technique

Selection of C-arm angulation

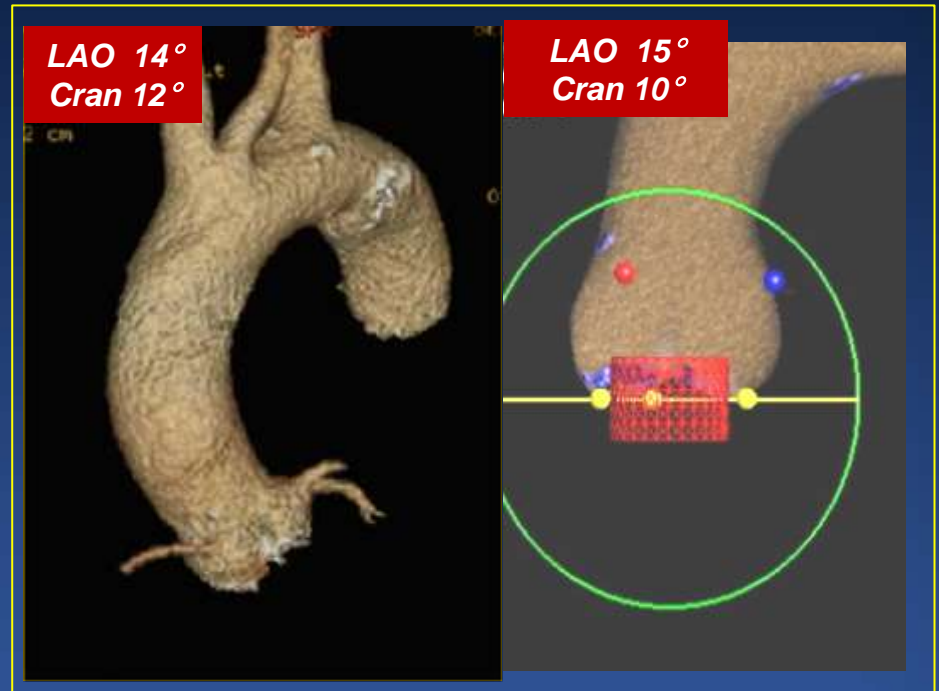
Clinical case



First angulation selected from CT Scan indications



LAO 15° / Cranial 12°



MSCT

Heart Navigator

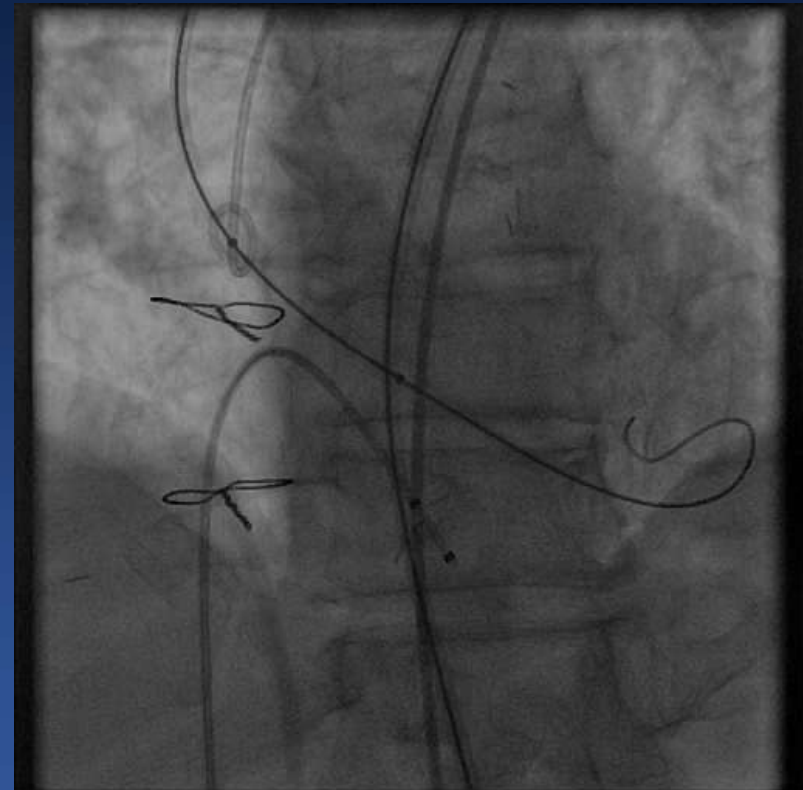
Three cusps aligned

Balloon sizing (23mm balloon)

The ultimate peri-procedural way of valve sizing

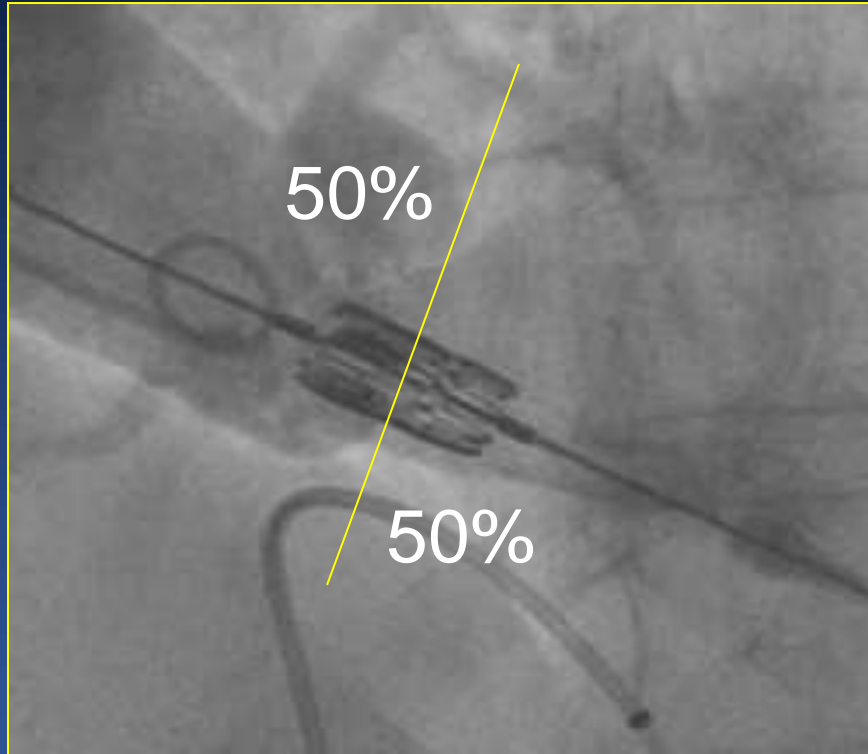
- 1- Visual comparison
balloon size / annulus size
- 2- Assessment of AR at full
balloon inflation
- 3- Assessment of risk of
LM occlusion with native
valve

Contrast:
15ml at 10ml/sec

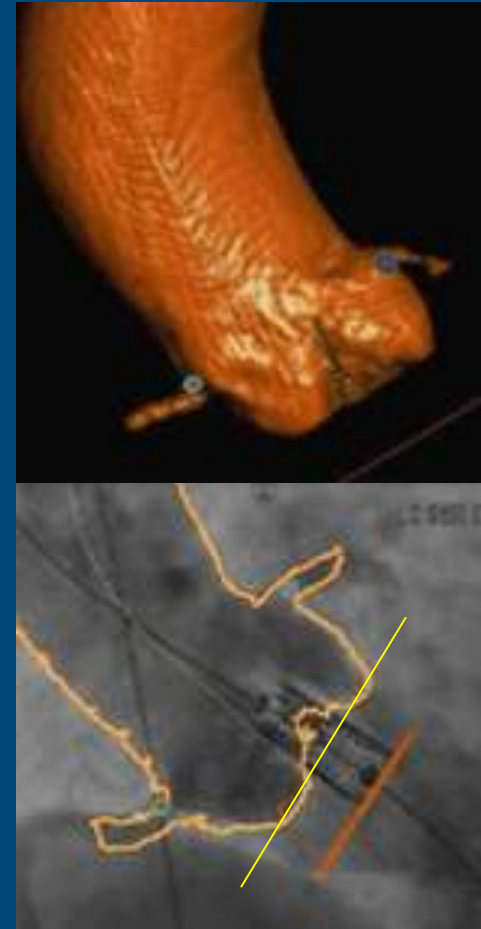


Mild AR with 23mm balloon:
26mm valve size confirmed
No LM occlusion

Meticulous valve positioning based on fluoroscopy / angio guidance (No TEE)



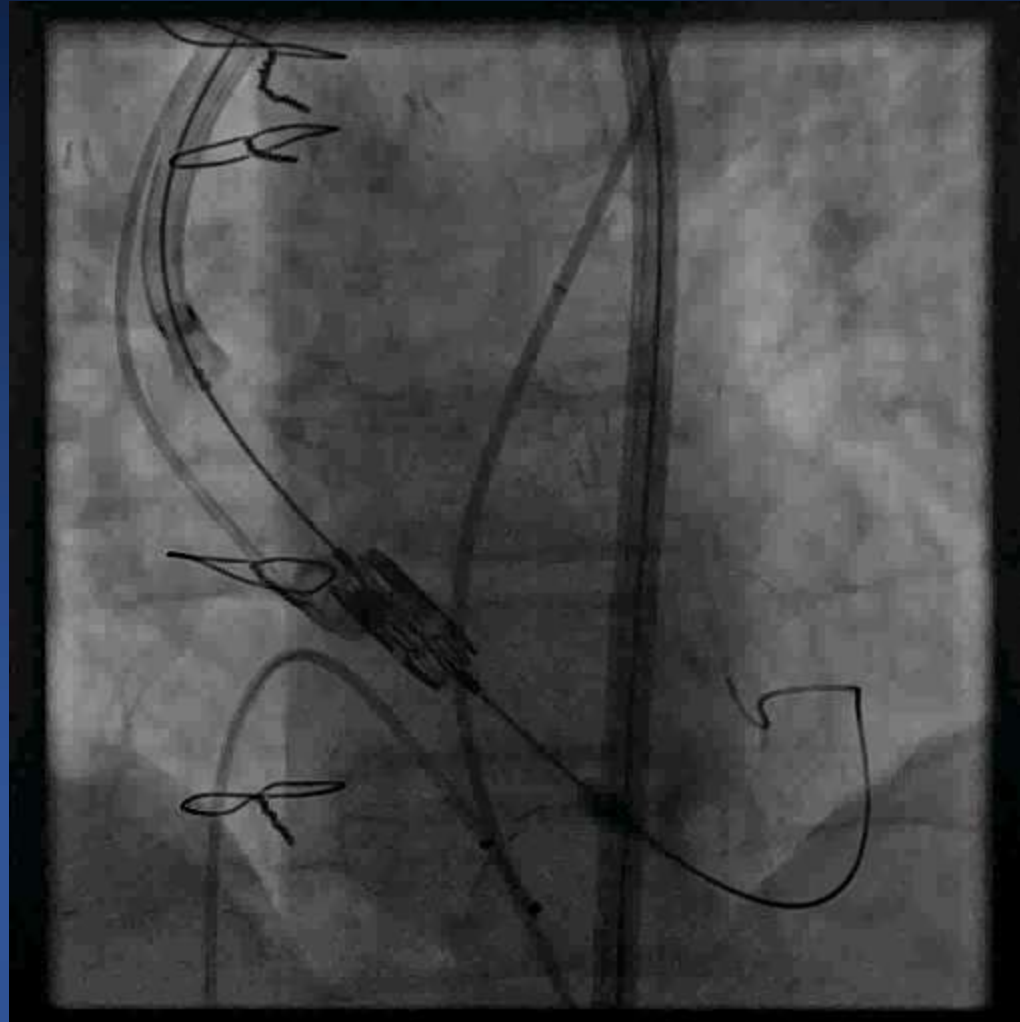
Angiography guided positioning with Rapid Ventricular Pacing



Dyna CT Guidance

Valve Positioning

Aortography with rapid pacing



Valve Delivery

RVP



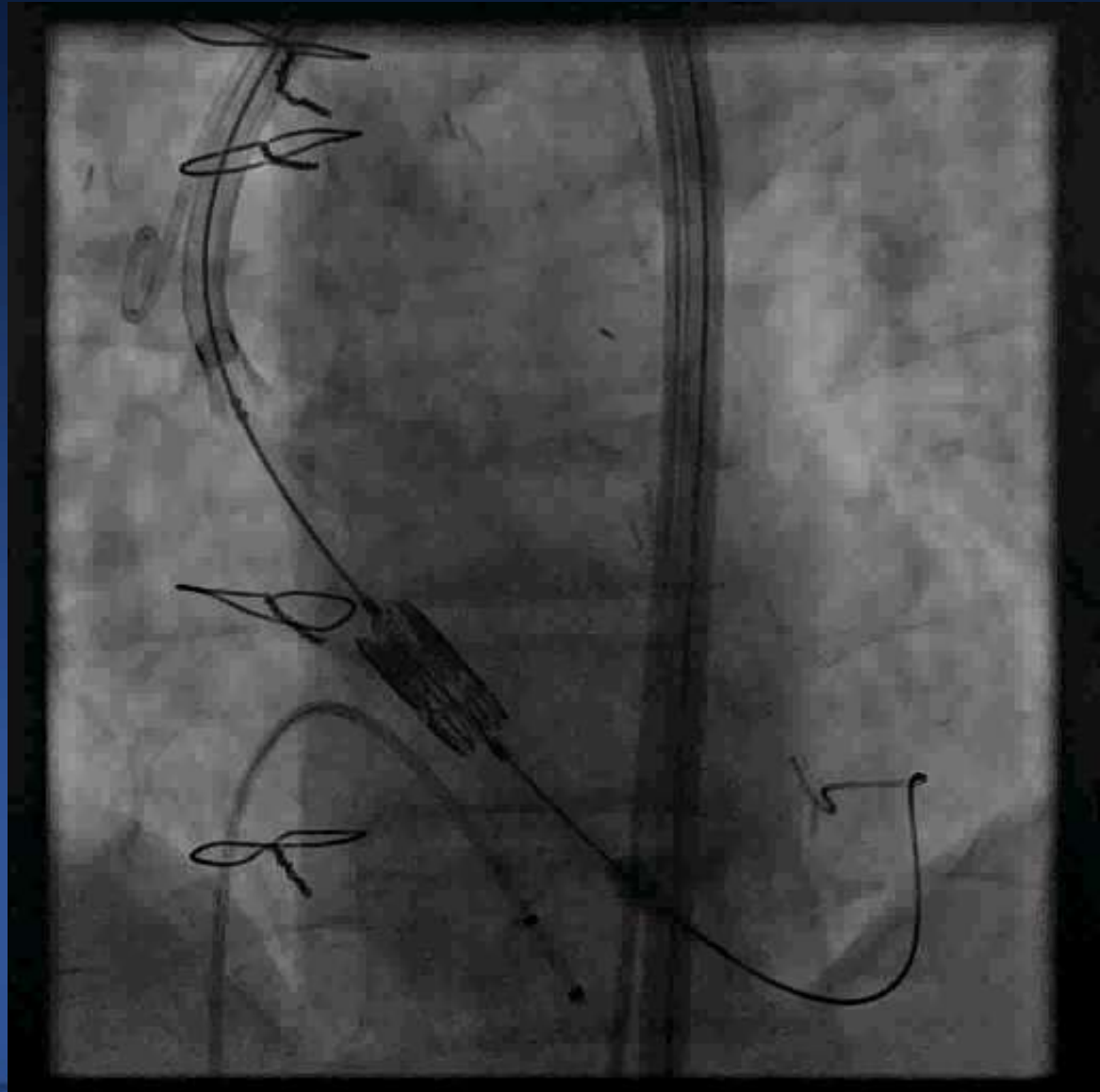
Balloon
inflation
(5 sec)



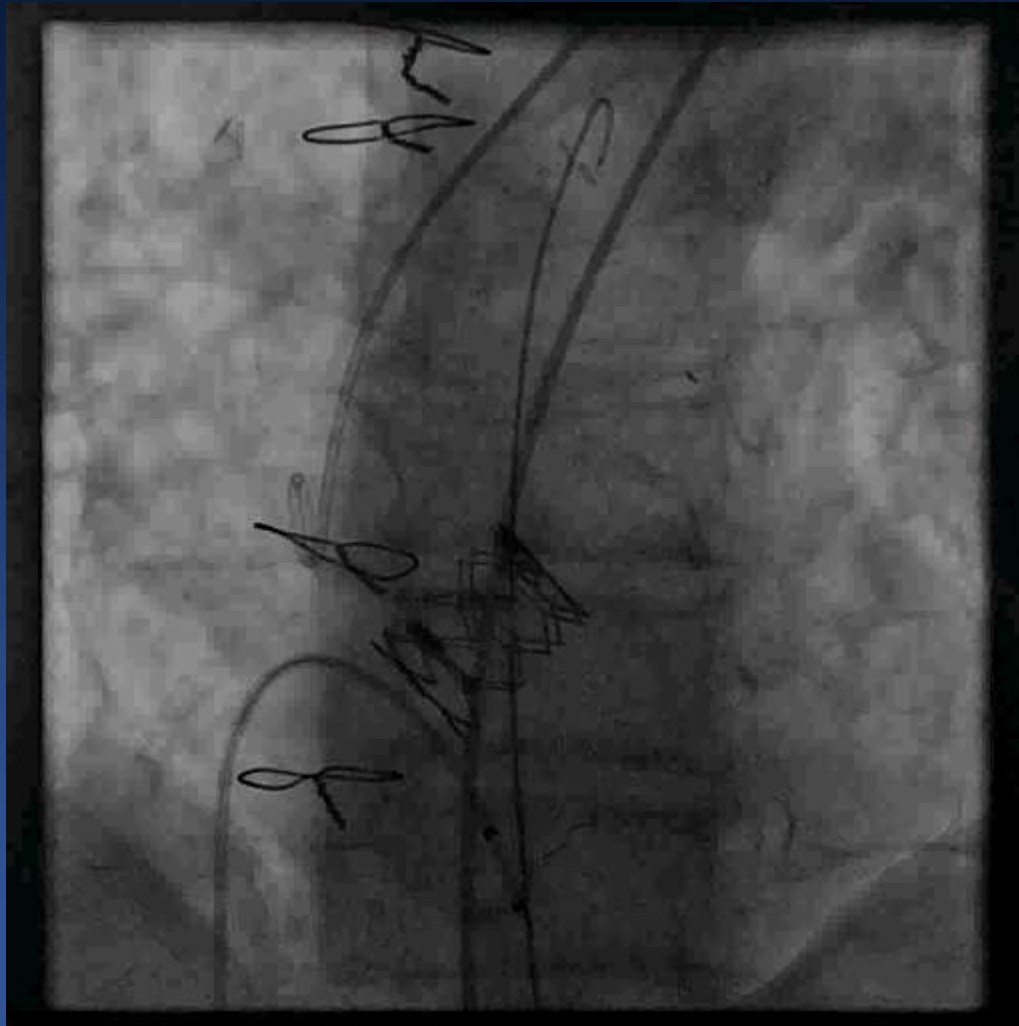
Balloon
Deflation



Stop pacing



Assessment of results without TEE

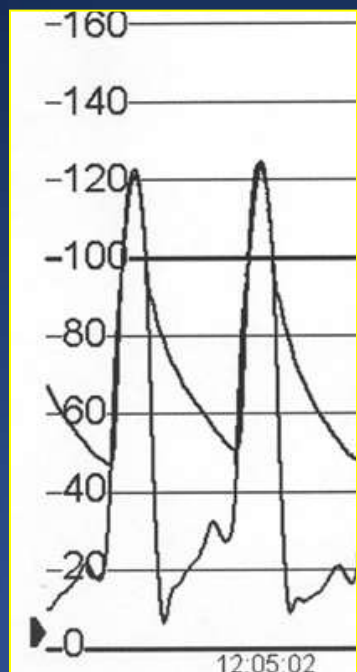


Aortography

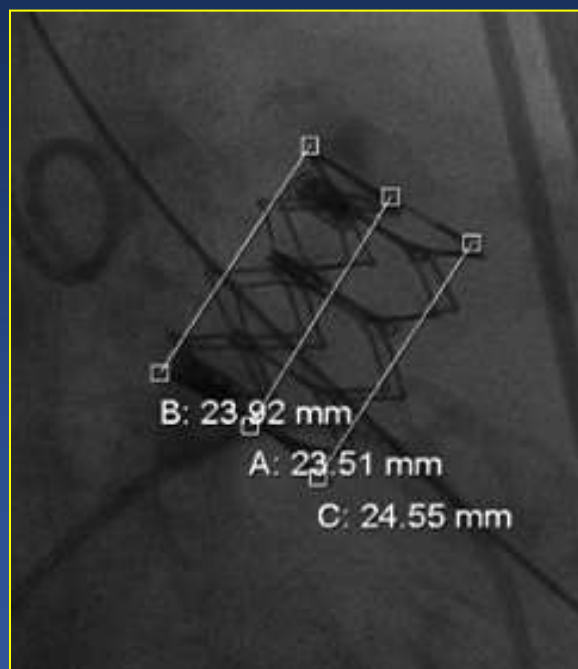
AR= Sellers classification

Assessment of results without TEE

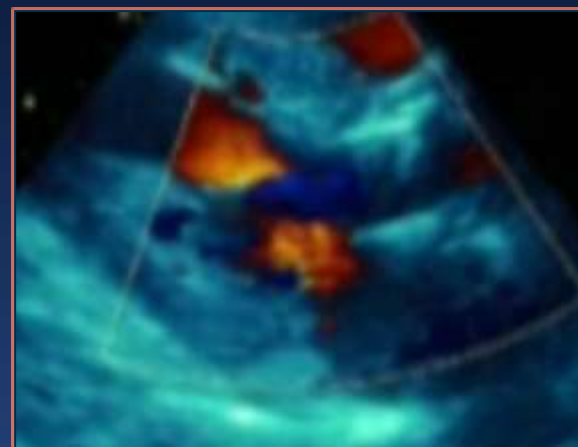
Pressures, Fluoro and TEE



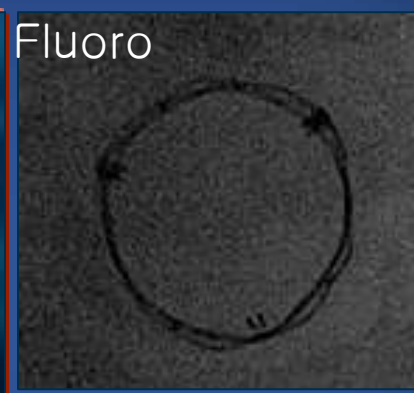
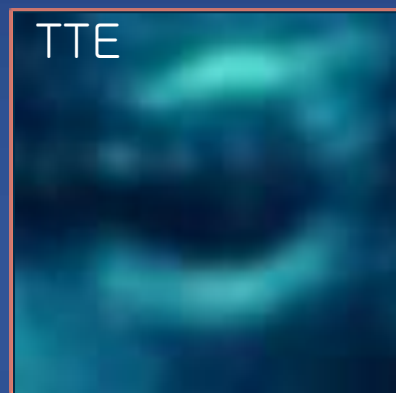
Pressures
(AR index)



Valve
diameters

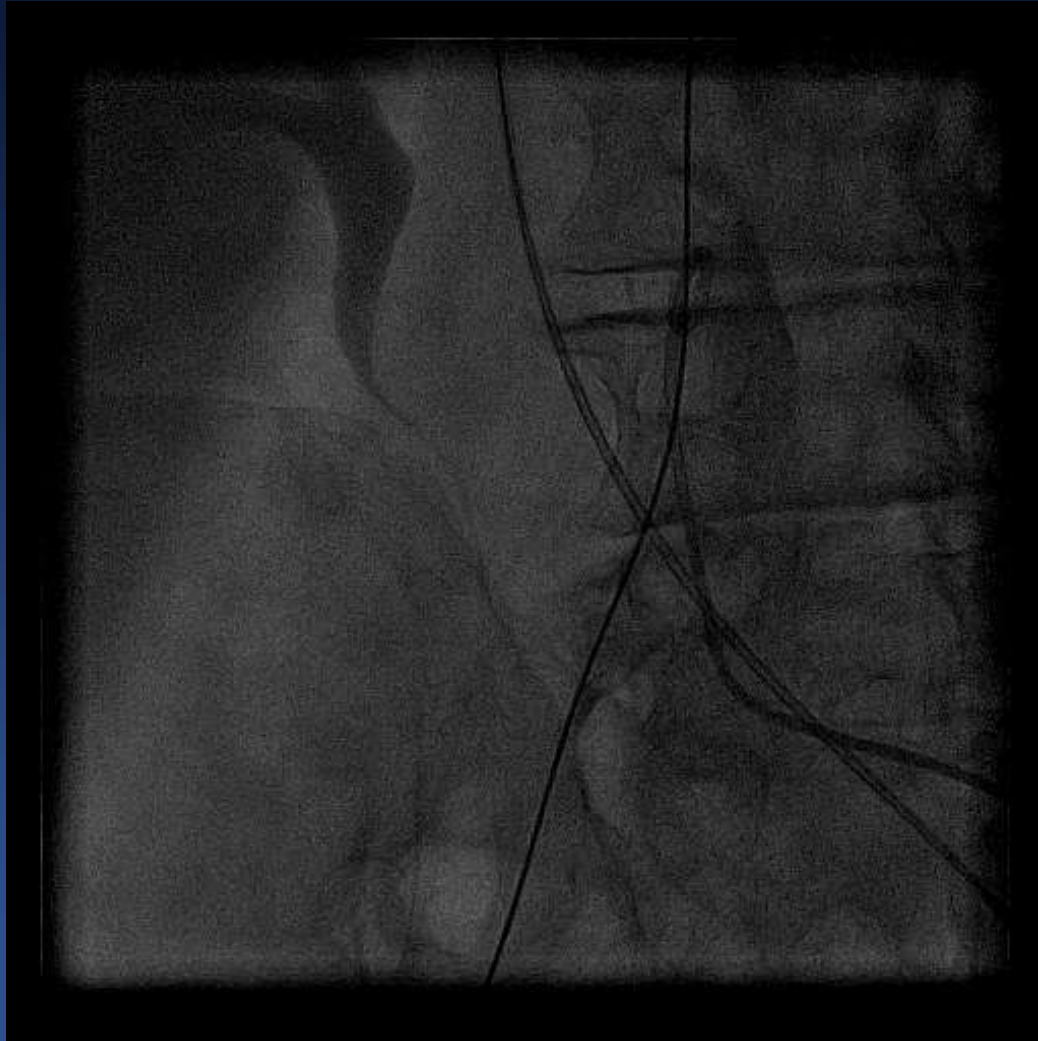


TTE: degree and
location of AR



Circular valve expansion

Sheath removal



Angiography peri-and post-sheath removal



Prostar closure

Rouen - Clinical Case, Minimalist TF - SAPIEN XT

Duration of the procedure: 45 min

Volume of contrast administered: 80ml

24h in ICU

No complication

Discharge at Day-2, back home

Conclusions

The minimalist approach (No GA, no online TEE) for TF-TAVR is safe, efficient and cost effective

- 1 - Complete information on valve anatomy, calcification, aorta, and LV function must be obtained during the screening phase
- 2 - Each procedural steps *including femoral puncture and closing* matters for an optimal outcome
- 3 - Rapid expansion of this minimalist strategy can be observed with the launch of ultra-low profile delivery systems
- 4 - This strategy can already be applied in > 80% of patients with decreased resource utilization, hospital stay and cost