Actualités TAVI

et indications particulières

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Conflits d'intérêt: Proctoring pour Medtronic Inc. et Edwards Lifesciences

Une seule indication reconnue

- RAC dégénératif
- Sévère, symptomatique
- A haut risque/contre-indication chirurgicale

EACTS/ESC/EAPCI Eur Heart J, 2008; 29: 1463-1470

Autres indications « off-label »

Réponse immédiate à des situations cliniques sans alternative

Evolution future des indications

Indications particulières I

- RAC dégénératif ***Dysfonction de bioprothèse chirurgicale***
- **Sévère, symptomatique**
- **A haut risque/contre-indication chirurgicale**

Transarterial Medtronic CoreValve System Implantation for Degenerated Surgically Implanted Aortic Prostheses

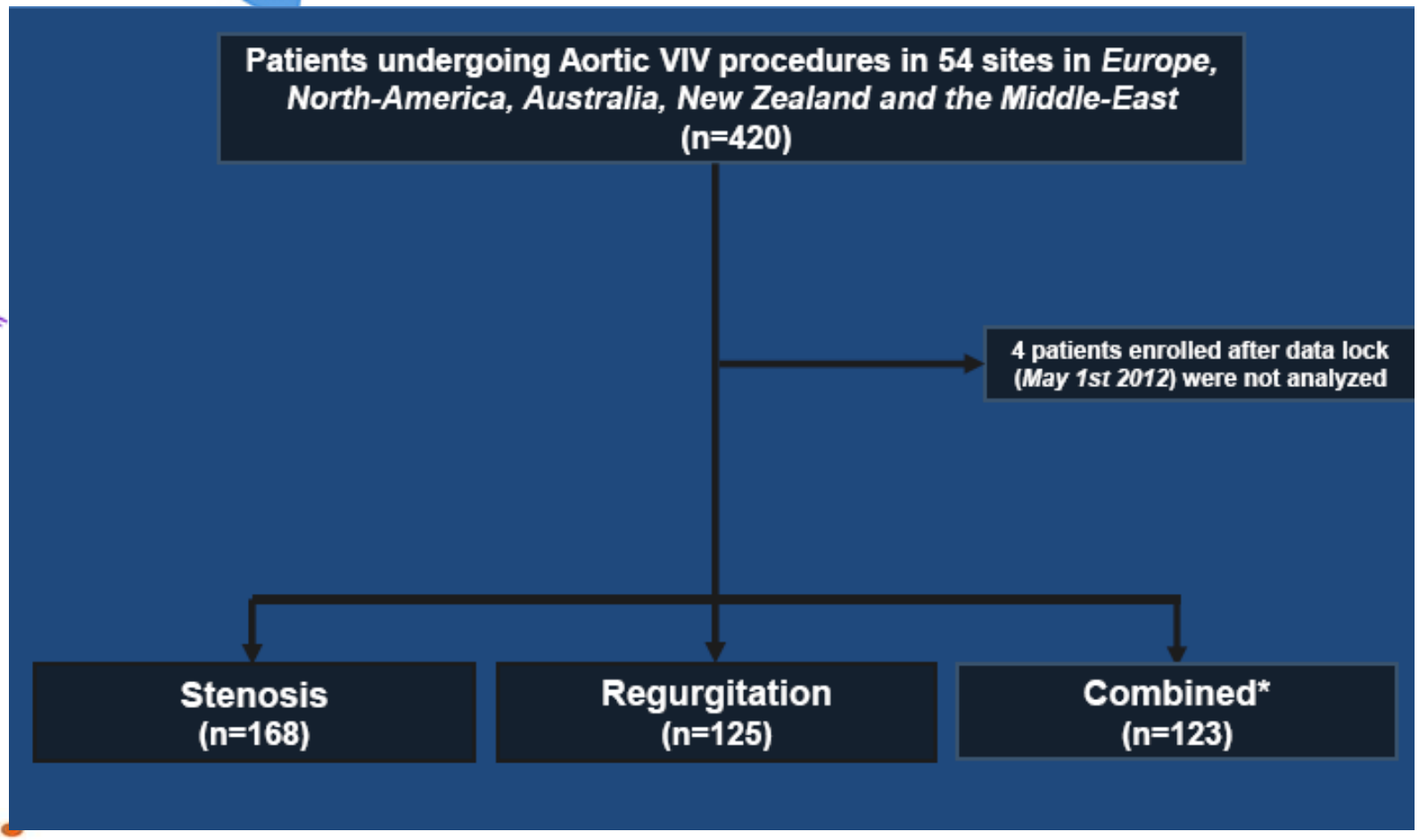
Fleur Descoutures, MD; Dominique Himbert, MD; Costin Radu, MD; Bernard Iung, MD; Caroline Cueff, MD; David Messika-Zeitoun, MD, PhD; Gregory Ducrocq, MD; Eric Brochet, MD; Patrick Nataf, MD; Alec Vahanian, MD

- 10 pts, 75±10 yrs, NYHA III/IV
- 7 stented, 2 stentless bioprostheses, 1 homograft
- 7 predominant AR, 3 predominant AS
- 8 26mm, 2 29mm CoreValve
- Procedural success: 100%
- 1 hospital death, 1 minor stroke, 1 pace-maker
- Mean gradient: 13±7mmHg
- AR≤1+: 9, AR=2: 1
- No post-discharge event
- 6-month FU: NYHA I/II in 8/9 survivors

- Transcatheter aortic valve implantation might be an attractive option in this high-risk setting, but experience is still limited.
- We report a series of transarterial valve-in-valve implantation, using the Medtronic CoreValve System for degenerated aortic surgically implanted stented or stentless bioprostheses in high-risk patients.
- Our results suggest the feasibility of such an approach, with a high procedural success rate, immediate hemodynamic improvement, and acceptable clinical outcomes.
- If mid- and long-term outcomes remain favorable, this will have important clinical implications for treatment strategies of aortic stenosis in high-risk patients.

Circ Cardiovasc Intv 2011; 4: 488-94.

Global Valve in Valve Registry



V in V Immediate results

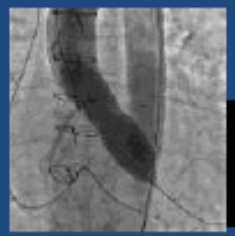
	Stenosis n=168	Regurgitation n=125	Combined n=123	P
Pre implantation valvuloplasty	35.1%	12.0%	37.4%	<0.001
Initial device malposition	7.7%	10.4%	16.2%	0.14
Attempted Valve retrieval	4.3%	5.6%	6.5%	0.70
2nd device implanted	4.8%	5.6%	8.1%	0.49
Post implantation valvuloplasty	12.9%	9.7%	7.3%	0.30
Need for an emergent surgery	4.5%	0.9%	0	0.03
Clinically-evident Coronary obstruction	4.5%	0.9%	0	0.03

V in V Coronary obstruction

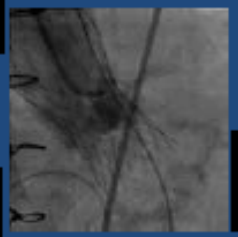
3/5 cases of VIV procedures inside stenotic Freedom valves had left-main obstruction.

Comparison with all other bioprosthesis combined (5/411): p<0.001

Center #13, case#4
Sorin Freedom Stentless 23mm (ID 21mm)
Transfemoral CoreValve 26mm

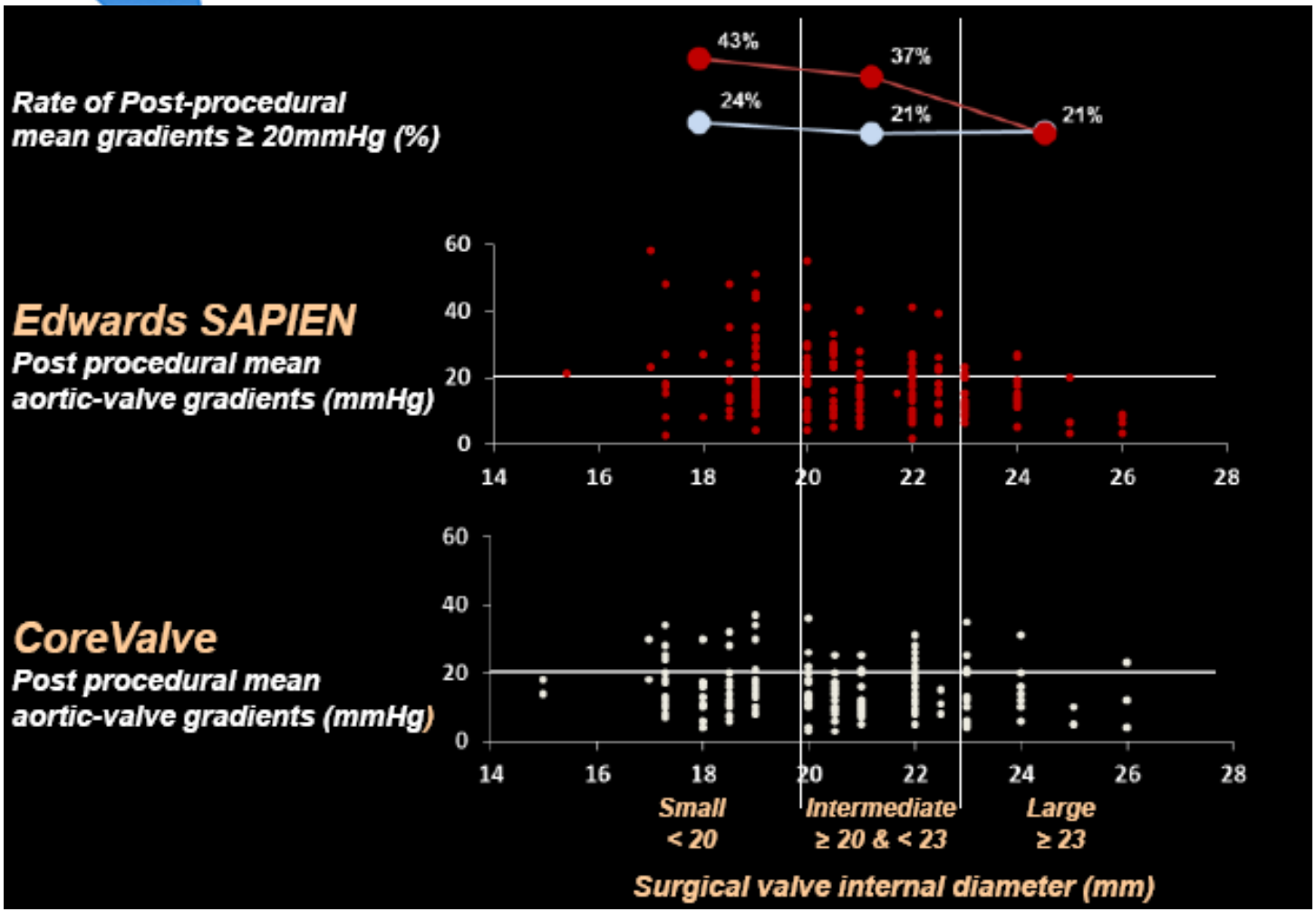


Center #29, case#7
Sorin Freedom Stentless 21mm (ID 19mm)
Balloon Valvuloplasty
before attempted CoreValve implantation

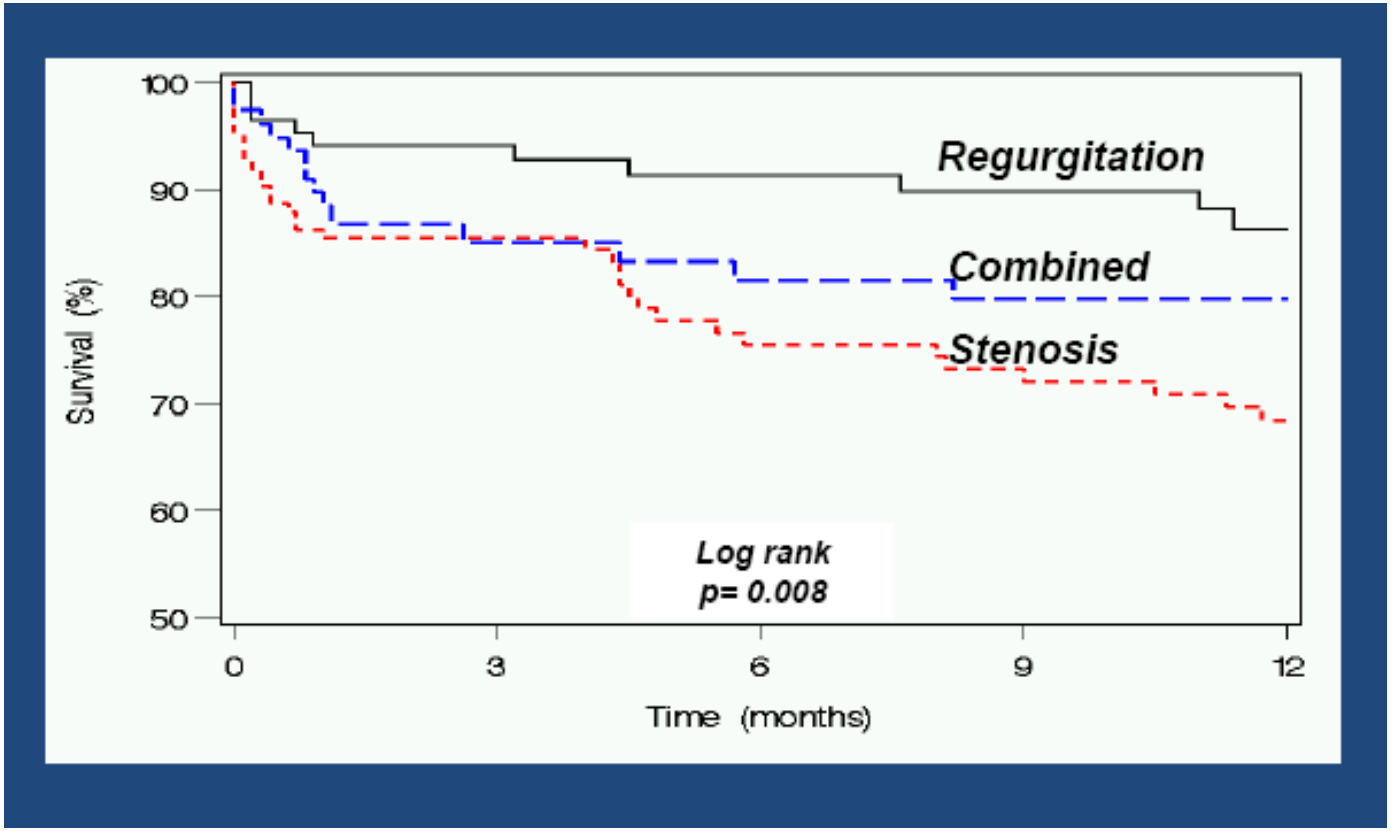


Center #53, case#7
Sorin Freedom Stentless 25mm (ID 23mm)
Transfemoral CoreValve 26mm

V in V Post implantation gradients



V in V 1-year survival



V in V Predictors of mortality

The strongest independent predictor for 1-year mortality post VIV was baseline bioprosthesis stenosis

	HR	95% Confidence Interval	p
Baseline stenosis vs. combined	7.1	2.27 – 20.0	0.001
Baseline stenosis vs. regurgitation	3.7	1.54 – 8.33	0.003
STS score (%)	1.03	1.01 – 1.05	0.01
Baseline left-ventricular ejection-fraction (%)	0.97	0.95 – 1.0	0.045

Included in the analysis and found non- significant:
Patient age during VIV procedure, gender, diabetes mellitus, baseline renal failure and the device used during VIV procedure (Edwards SAPIEN vs. CoreValve).

Indications particulières II

- RAC dégénératif ***sur bicuspidie***
- **Sévère, symptomatique**
- **A haut risque/contre-indication chirurgicale**

Bicuspid aortic valve and TAVI

- **Excluded from major registries and trials**
- **Still considered contraindication for TAVI**
  - ***EACTS/ESC/EAPCI Eur Heart J, 2008; 29: 1463-1470***
  - ***2012 ACCF/AATS/SCAI/STS Expert Consensus Document on TAVR, J Am Coll Cardiol.* 2012 Jan 30.**
- **Potential risks:**
  - **prosthesis misdeployment**
  - **leaflets distorsion**
  - **intra / periprosthetic regurgitation**
  - **limited durability**

TAVI experience in BAV

Methods Eleven patients (age 52 to 90 years) with symptomatic severe BAV stenosis underwent TAVI at 3 Canadian tertiary hospitals between May 2006 and April 2010. All patients were considered high risk for surgical aortic valve replacement. Edwards-SAPIEN transcatheter heart valves (Edwards Lifesciences, Inc., Irvine, California) were used. Transfemoral or transapical access was selected, depending on the adequacy of femoral access.

Results Access was transfemoral in 7 patients and transapical in 4 patients. There were no intraprocedural complications. Significant symptomatic and hemodynamic improvement was observed in 10 of 11 patients. Baseline aortic valve area of 0.65 ± 0.17 cm^2 and mean transaortic pressure gradient of 41 ± 22.4 mm Hg were improved to 1.45 ± 0.3 cm^2 and 13.4 ± 5.7 mm Hg, respectively. Two patients had moderate perivalvular leaks. At the 30-day follow-up there were 2 deaths due to multisystem failure in 2 transapical patients. In 1 patient an undersized, suboptimally positioned, unstable valve required late conversion to open surgery.

Conclusions TAVI in selected high-risk patients with severe BAV stenosis can be successfully performed with acceptable clinical outcomes but will require further evaluation. (J Am Coll Cardiol Intv 2010;3:1122–5)

Rationale for CoreValve implantation in BAV

- Supra annular position / function of the leaflets
- Safe anchorage of the prosthesis
- Large aortic annulus
- Minimal traumatism of the annulus

TAVI in BAV, Bichat Experience

- 338 consecutive TAVI from Jan. 2009 to Mar. 2012
- 17 documented BAV (5%)
- 13 males, 80±10 ans
- EuroSCORE: 17±11%; STS: 8±5%
- Mean gradient 60±19mmHg; AVA: 0.8±0.3cm²
- Calcium score: 4553±1872 AU (CT)
- Annulus diameter: 25±2mm (Echo); 26±2mm (CT)

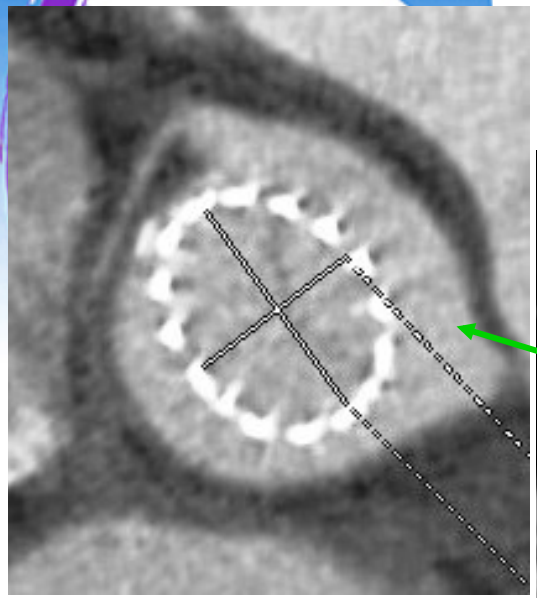
TAVI in BAV, Bichat Experience

- Transfemoral n=16; subclavian: n=1
- 29mm: n=14; 26mm: n=2; 31mm: n=1
- Success: n=16
  - 1 peri AR 3+, surgery, in-hospital death
- Mean gradient 11±4mmHg
- Peri AR ≤1+ (n=15), 2+ (n=1)
- Implantation depth: 7±5mm (CT)
- Median hospital stay: 9 days (interquartile, 2 days)

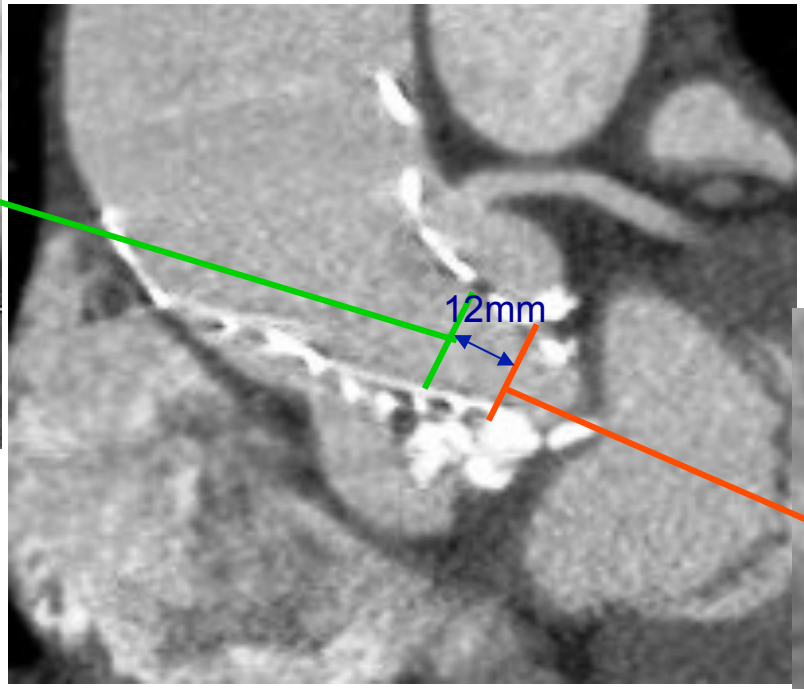
TAVI in BAV, Bichat Experience

- FU: 15/16 pts
- Mean duration: 8±7 months
- 1 death / aortic dissection at M8
- No other clinical event
- NYHA class ≤ II (n=12), III (n=2, comorbidities)
- No prosthetic structural deterioration / dysfonction

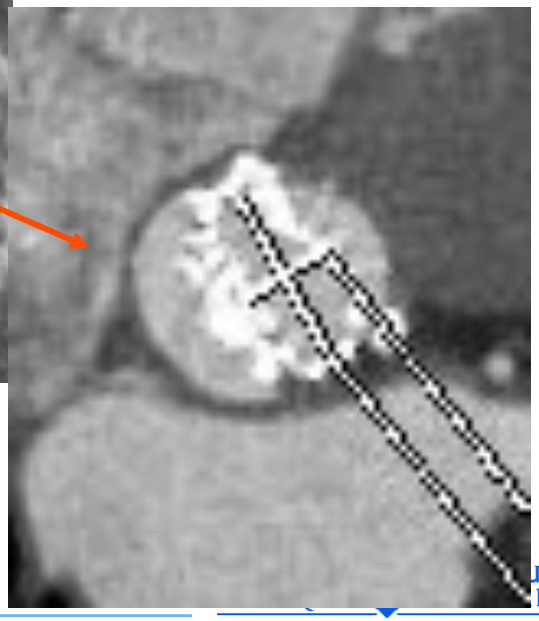
CT Scan, post implantation



Supra annular level



Annular level



Himbert et al Am J Cardiol 2012 (in press)

Indications particulières III

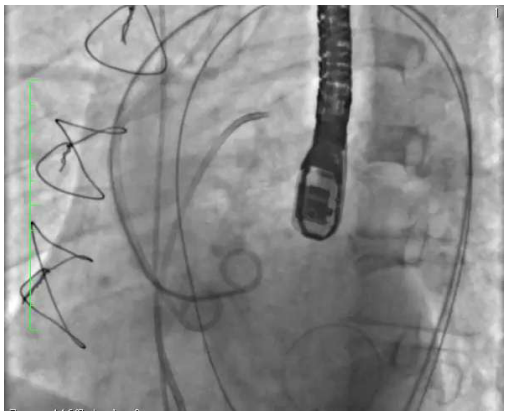
- RAC dégénératif ***IA pure***
- **Sévère, symptomatique**
- **A haut risque/contre-indication chirurgicale**

TAVI for pure AR General considerations

- Younger / lower risk profile than AS
- Aortic root disease (not only valve disease)
- Heterogeneity of causes / mechanisms

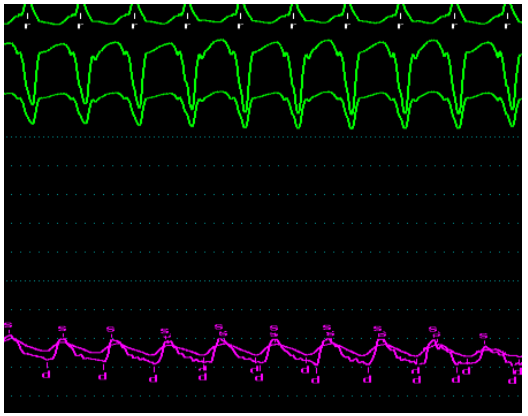
TAVI for pure AR Technical issues

- **Aortic annulus visualization?**
  - **Double pigtail technique**



- **Valve positioning?**
  - **Rapid / ’slow/rapid’ pacing**

    180/200 120/140 bpm



- **Valve fixation?**

AR multicentre registry (n=31)

Age, yrs	**75±10**
Logistic EuroSCORE	**28±19%**
Degenerative cause*	**64%**
Procedural success	**97%**
2 valves required	**19%**
Paravalvular AR	
2+	**16%**
>2+	**6.5%**
30-day mortality	**6.5%**
30-day stroke	**6.5%**
1-year mortality	**12.5%**

***Others**
Endocarditis
Ao aneurysm
Radiation
Ao dissection
Inflam. diseases

Roy, Euro PCR 2012

Indications particulières IV

- **RAC dégénératif**
- **Sévère, symptomatique**
- **A** haut risque/contre-indication chirurgicale
  risque intermédiaire

FRANCE 2

Multidisciplinary consensus 98%

FRANCE 2

L. Euroscore, %	21.9 ± 14
STS, %	14.4 ± 12

FRANCE – FRANCE 2

Multidisciplinary consensus 98%

FRANCE

L. Euroscore, %	25.6 ± 11.4
STS, %	18.9 ± 12.8

FRANCE 2

L. Euroscore, %	21.9 ± 14
STS, %	14.4 ± 12

Towards lower risk

Reasons for extending TAVI to lower risk

1) Results of TAVI are better in moderate that in high-risk patients
2) TAVI is not inferior to SAVR in moderate risk patients
3) Haemodynamic performances of transcatheter heart valves are better than those of surgical valves
4) LV recovery is better after TAVI than SAVR
5) TAVI is less expensive than SAVR

Reasons for not extending TAVI to lower risk

1) **Procedural complications:**
   1) **vascular,**
   2) **strokes,**
   3) **pace-maker**

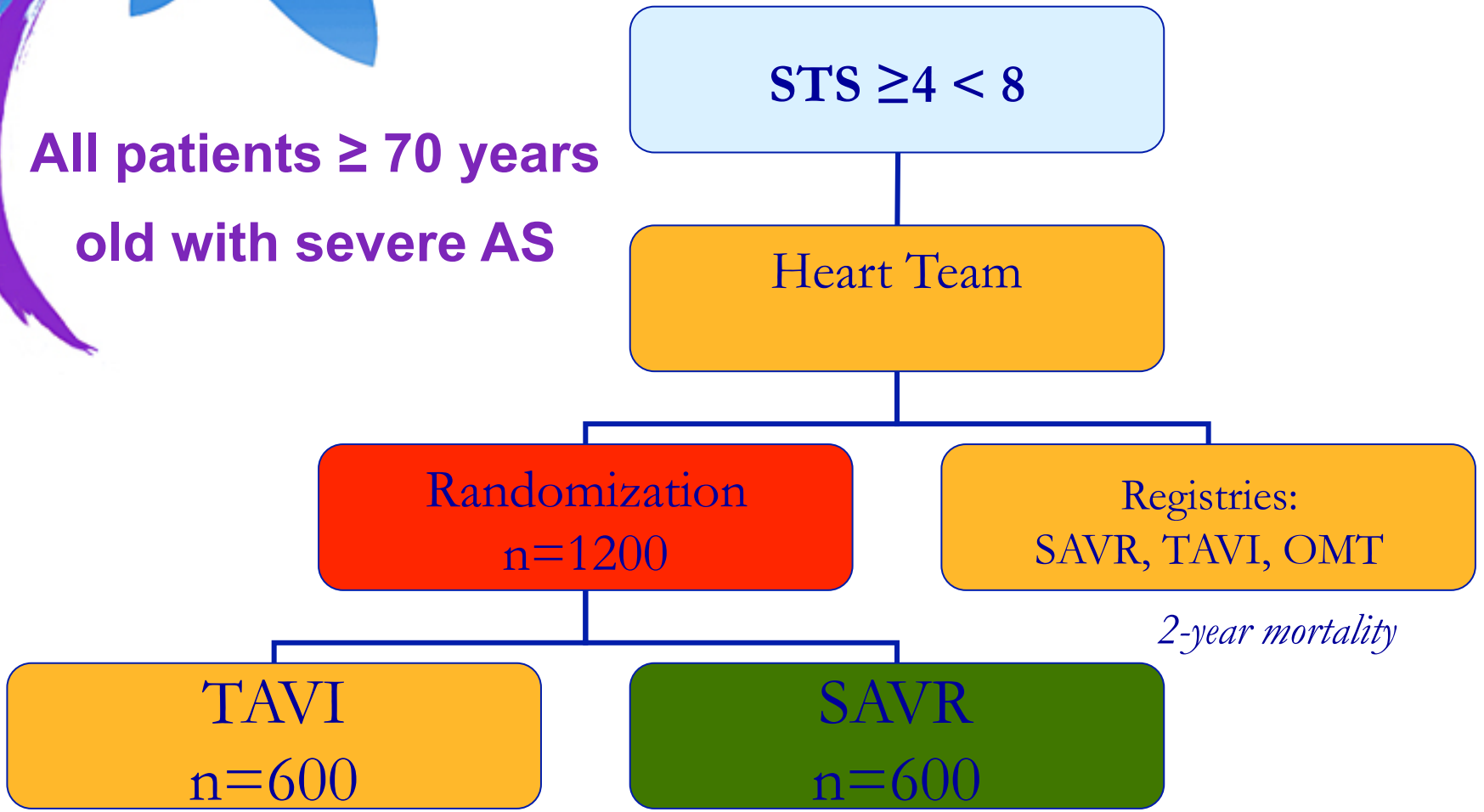
2) **Mid/long-term impact of mild/moderate paravalvular aortic regurgitation**

3) **Durability?**

Need for controlled trials!

SURTAVI Trial

All patients ≥ 70 years old with severe AS



Mortality all causes + major strokes at 2 years, non inferiority

5 years FU

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Conclusion

- TAVi is feasible with a high success rate and good clinical outcomes in various specific, off-label indications
- To be proposed on a case by case basis, by a dedicated Heart Team, if no alternative available (compassionate indication)
- The choice of the valve may be oriented by the indication itself
    - CoreValve may offer theoretical advantages for valve-in-valve and bicuspid cases,
    - and the only current solution for pure native AR
- Careful prospective evaluation of compassionate indications is mandatory (local and multicentre registries)
- Other indications should not be accepted out of prospective controlled multicentre trials