

FRANCE 2 :

FRench Aortic National Corevalve and Edwards Registry



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On behalf of the scientific committee and the investigators

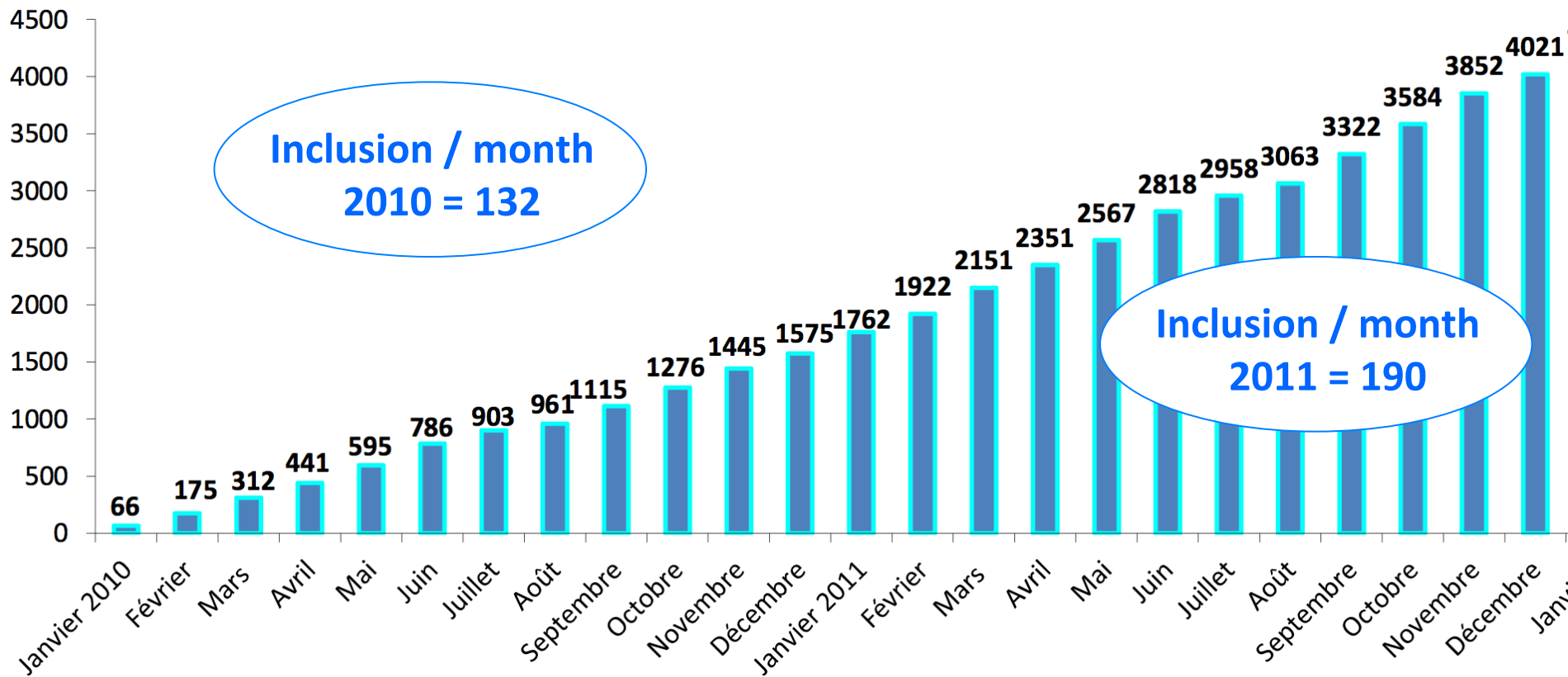
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P Leprince, A Leguerrier, M Lievre, A Prat, E Teiger**



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Current enrollment

30 June 2012: 5 587pts





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Analysis

3 933 consecutive patients- 34
centres

January 1, 2010 to December 31, 2011



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Methods

- Centers were authorized by the french Ministry of Health, on the basis of :
 - ✧ Multidisciplinary team
 - ✧ Annual volume of a least 200 surgical aortic-valve replacements
 - ✧ Previous experience of balloon aortic valvuloplasty, interventionnal cardiology



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Methods

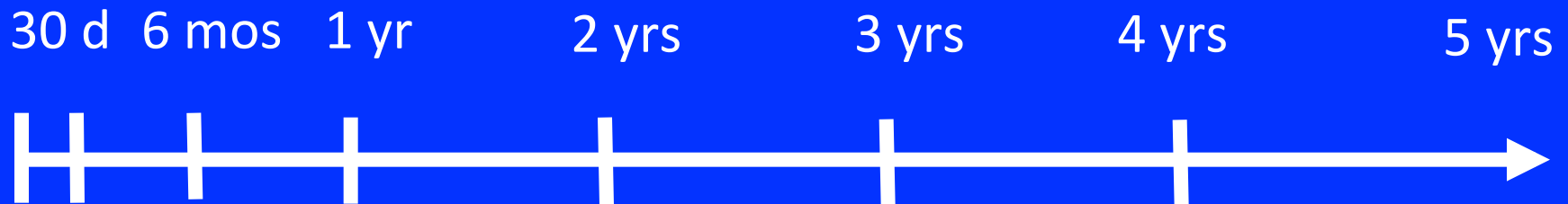
- Patients have to be symptomatic, with severe aortic stenosis, considered by the heart team to be not candidates for surgical replacement
- The registry was established under the French Societies of Cardiology and of Thoracic and Cardiovascular Surgery.



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Methods

- Clinical prospective and comprehensive registry
- All events and values site recorded
- No core lab
- Patients followed up to 3 years by serial clinical and echo assessments and 5 years by clinical status





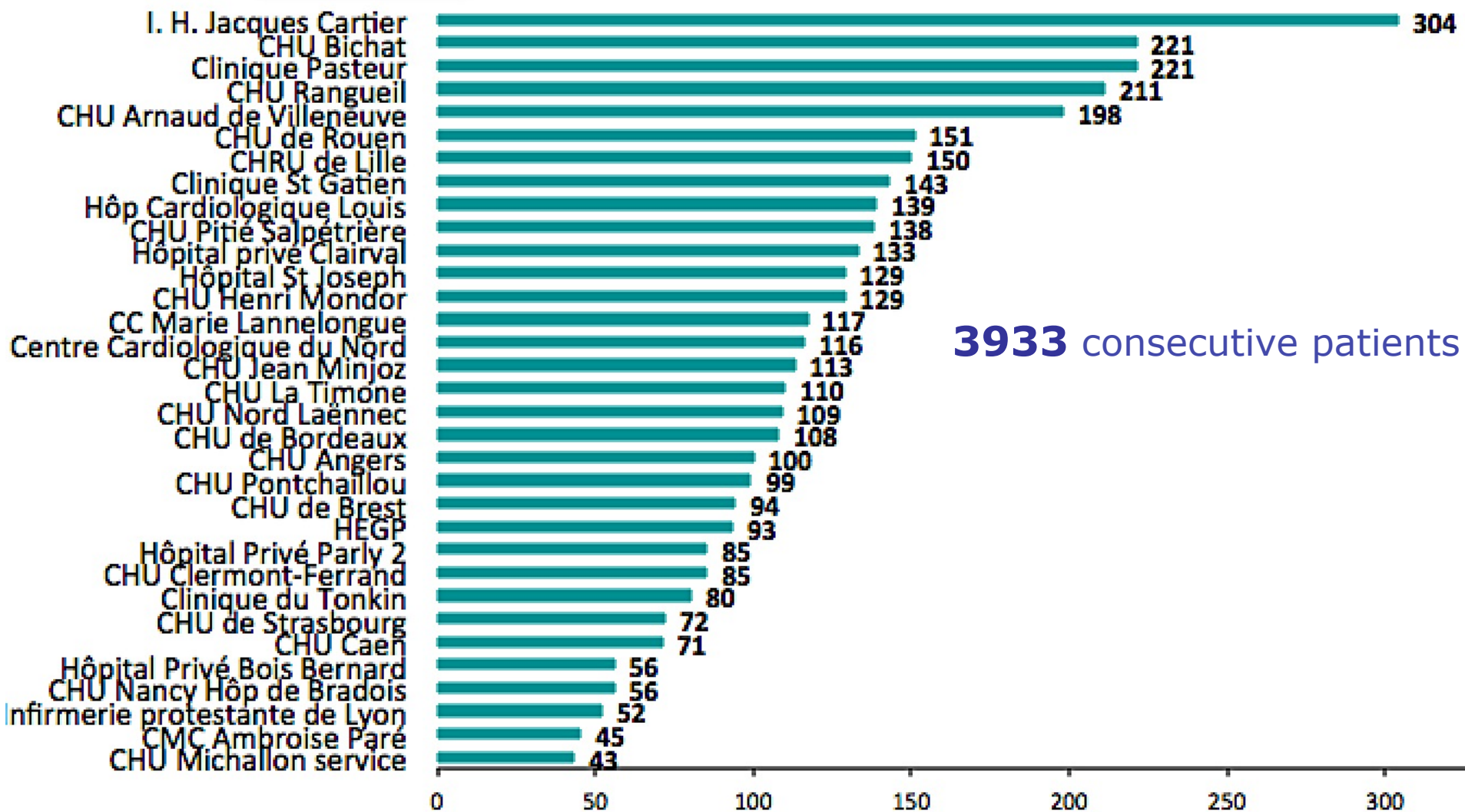
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Inclusion criteria and Endpoints

- **Inclusion criteria:**
All implanted patients
- **Primary Endpoint:**
30 day mortality, 6 month mortality, up to 5-y
- **Secondary Endpoints (up to 5-y):**
M.A.C.E., hemodynamics, Q.O.L.



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Baseline Demographics and Risk Factors

Age, y	82.8 ±7
Female, %	49.5 %
Previous MI, %	16.2 %
CAD, %	47.9 %
Previous CABG, %	17.9%
PAD, %	20.4%
Previous Stroke, %	9.9%
Dialysis, %	2.6%
Previous AVR	1.7%

Smoker, %	3.3 %
Hypertension, %	69.2 %
Diabetes, %	25.7 %
Dyslipidimia, %	47.9 %



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Baseline echocardiographic data

Ao annulus (mm)	22.1 ± 02
Gradient (mm Hg)	48.2 ± 17
AVA (cm²)	0.67 ± 0.2
SPAP (mm Hg)	45.3 ± 14
Ejection fraction (%)	53.3 ± 14



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Risk scores

L. Euroscore, %	21.8 ± 14
STS, %	14.1 ± 12

NYHA functional class

I - II	III - IV
24.6 %	75.4 %

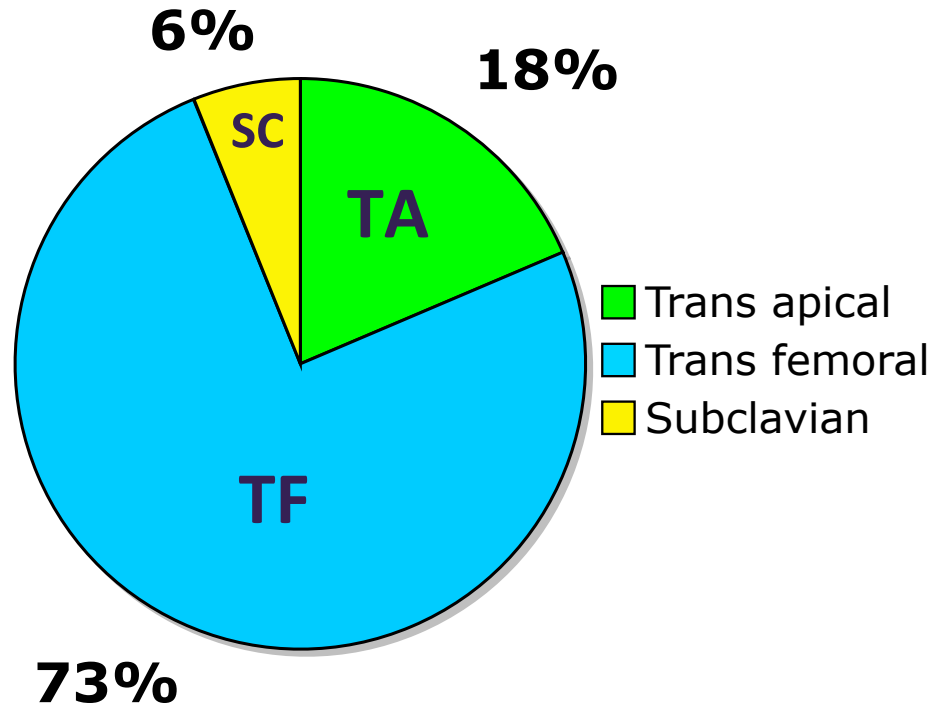
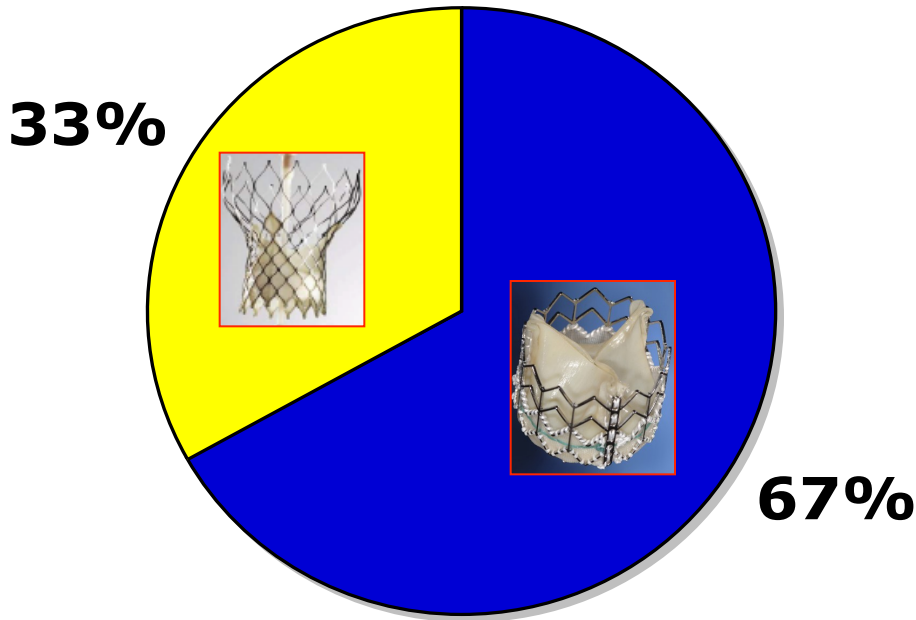


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Valves and approaches used

Valves

Approach



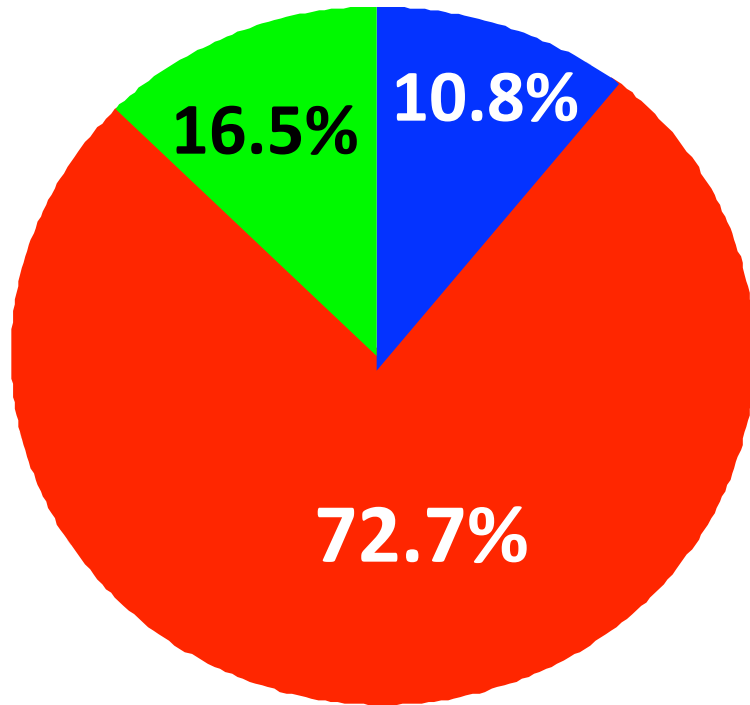
- Edwards
- CoreValve

- Trans apical
- Trans femoral
- Subclavian



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Procedural characteristics



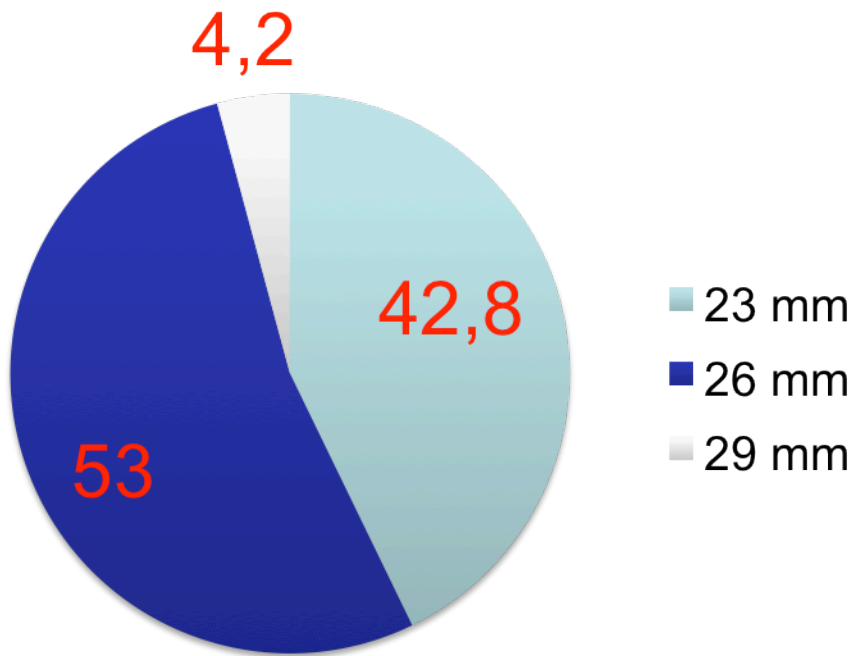
- Operative room
- Cath-lab
- Hybrid room

General anesthesia, %	69.0 %
Per-procedure TEE, %	61.3 %

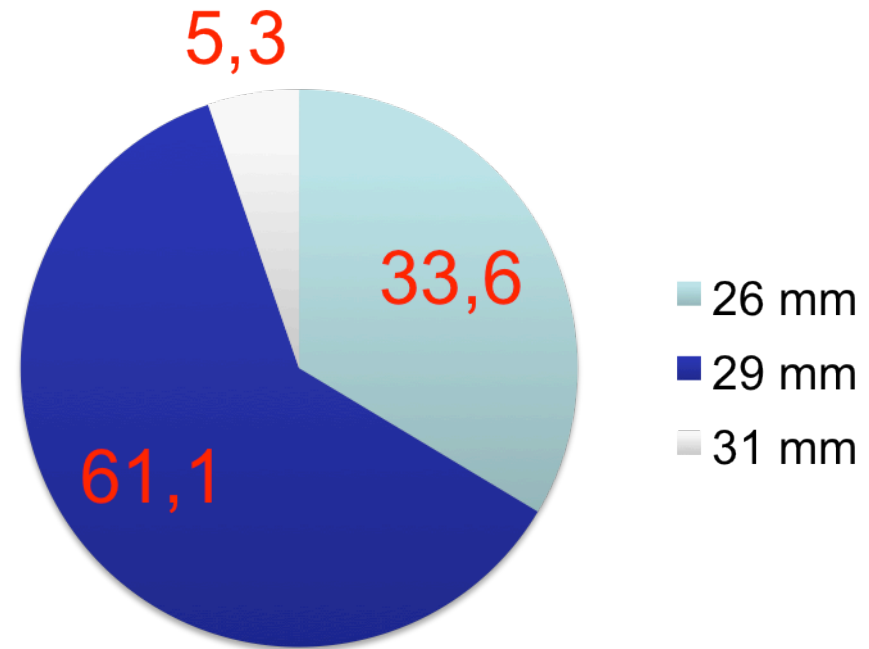


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Procedural characteristics



Edwards



CoreValve



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Implantation Success

Device success rate: 97.0% (3929/3933)

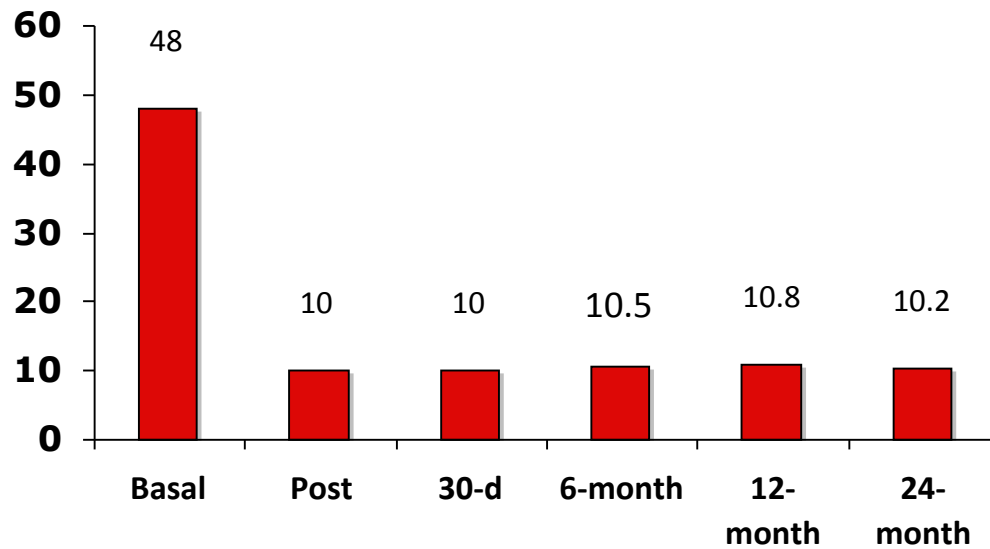
Definition: successful delivery and deployment of the valve



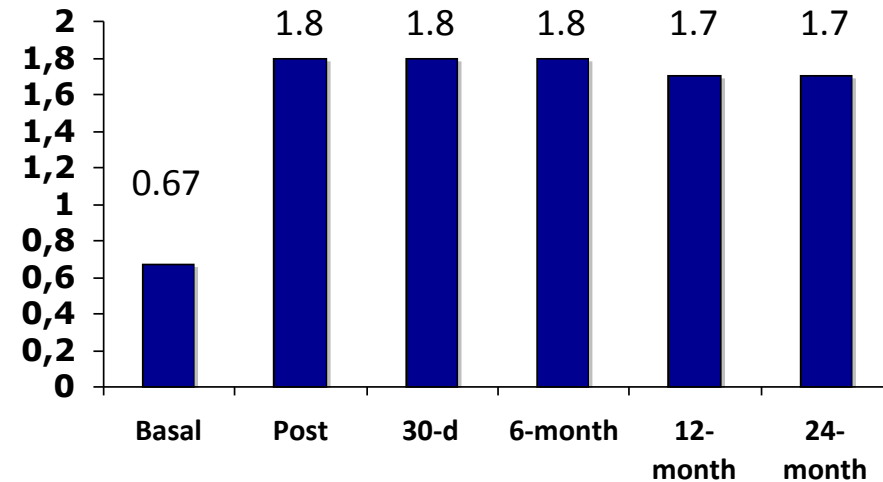
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Hemodynamics after implantation



Mean gradient (mmHg)



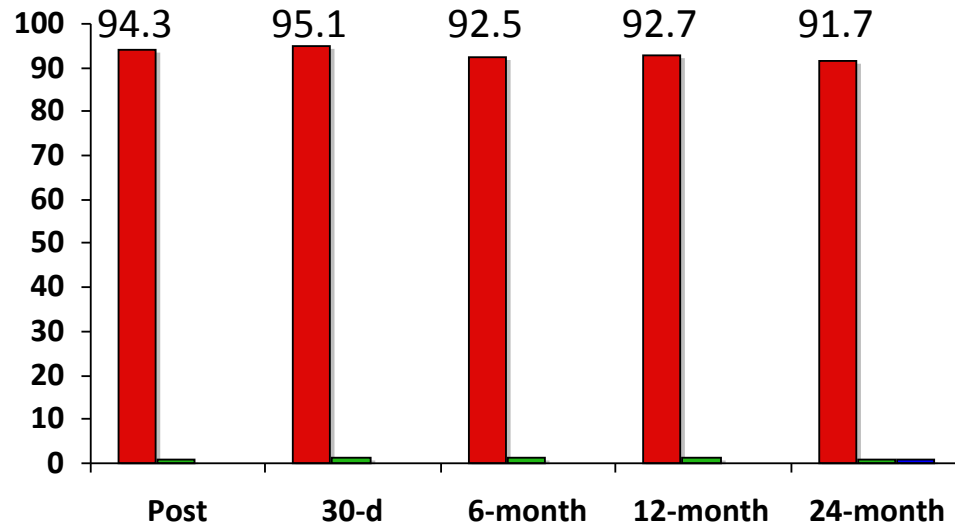
Effective Valve Area (cm²)



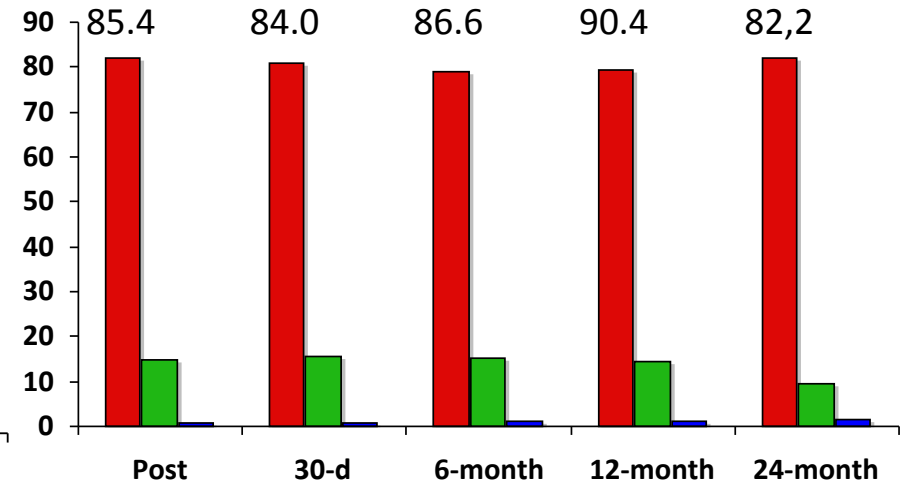
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Aortic regurgitation (grade)

- Grade 0-1
- Grade 2
- Grade 3



Central

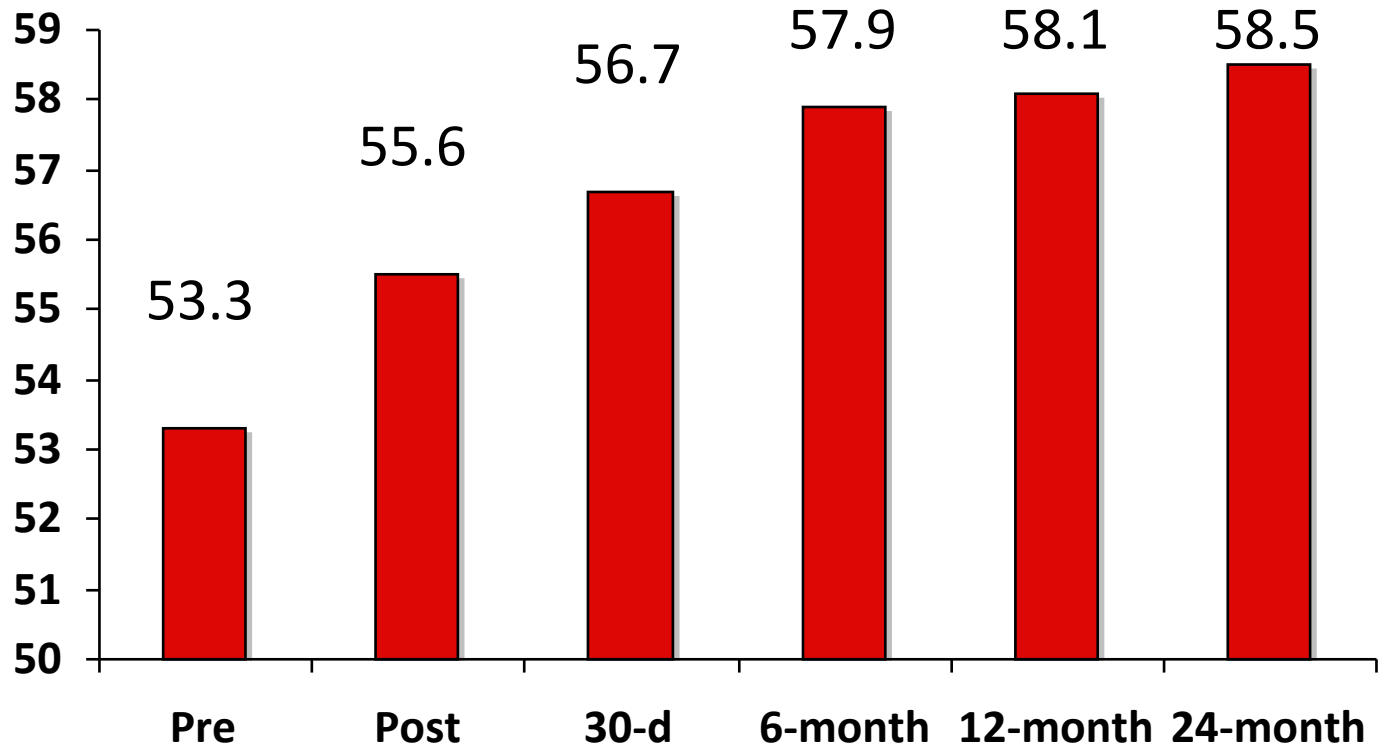


Peri-prothhetic



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LV Ejection fraction (%)



$P < 0.001$



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KM Mortality rate

	FU
30-day	99%
6-month	99%
12-month	98%

	30-day		6-month		12-month	
Global	367	9.5 %	640	18 %	762	24.1 %
CV	269	7.0 %	389	11 %	430	13.6 %



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KM Mortality rate Type of Valve



	30-day		6-month		12-month	
Edwards	246	9.6%	422	17.6%	501	23.3%
CoreValve	115	9.0%	212	18.5%	254	25.5%

	Edwards	CoreValve
L. Euroscore	21.9 ± 14.0	21.4 ± 14,3



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KM Mortality rate Access

	Mortality			
	TF Edwards n=1049	TF CoreValve n=1812	TA Edwards n=700	SC CoreValve n=225
30-day			14.7%	10%
24-month			31.4%	31.1%



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Major complications

	Global N = 3933	Edwards N= 1634	CoreValve N=785
Vascular complications	11.8%	11.6%	12.2%
New Pacemaker	15.8	11.8%	24.0%
Bleeding(+tamponade)	17.7%	17.8%	17.5%
Stroke	4.6%	4.6%	4.7%



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Predictive factors of 24-month mortality

Over 20 risk factors were analyzed:

- **Logistic Euroscore,**
- **Periprosthetic regurgitation grade 2 or higher,**
- **trans apical approach**
- **NYHA functional class**
- **Creatinemia > 200 $\mu\text{mol/L}$**
- **Dyslipidimia**
- **Previous Aortic surgery**

Were predictors of 1 year mortality by multivariate analysis



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Economic evaluation

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Meryl Darlington, Isabelle Durand-Zaleski

Unité de recherche clinique en économie de la santé d'Ile-de-France



Mean cost of hospital stay € 31 973

Varies with:

Implantation sites: Cath lab <
hybrid room < operative room

Approach: Arterial approach
cheaper (no difference anymore
by type of valve)

Mean tariff reimbursed to hospital for TAVI : € 32 320

Mean hospital cost* for HR surgery AVR : € 40 417

*National cost data base



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Conclusions

- The FRANCE 2 registry is **the largest prospective and exhaustive registry** evaluating both Edwards and CoreValve bioprosthesis
- This registry demonstrates a high success rate with excellent and sustained hemodynamic and clinical improvement
- Total hospital cost is covered by tariff in France
- Results are comparable between the 2 valves, except for higher rate of new pacemaker with the Corevalve