

Procedural, 30-day, 6 month, 1 year, 2 years and 3 years outcome following CoreValve or Edwards Sapien TAVI:

results of the Belgian TAVI Registry

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On behalf of the Belgian TAVI Registry participants

Methods

- **Prospective, non-randomized multicentre registry.**
- **All consecutive patients, events and values were site recorded.**
- **No central core lab. 10% of data are controlled by audit committee of the Belgian Society of Cardiology.**
- **Patients were followed up to 3 years after implantation, by serial clinical and echocardiographic assessment.**
- **Data pooling and statistical analysis: University of Antwerp.**

Results

enrollment (till 03/2012): n=881

Medtronic CoreValve
(n=12 sites)

<i>n < 50 TAVI</i>	10
<i>n 50 - 100 TAVI</i>	1
<i>n > 100 TAVI</i>	1

Edwards Sapien
(n=12 sites)

<i>n < 50 TAVI</i>	9
<i>n 50 - 100 TAVI</i>	2
<i>n > 100 TAVI</i>	1

Total: n = 408 TAVI



Total: n = 473 TAVI



All Belgian TAVI sites are exclusive CoreValve OR Edwards Sapien sites

The Belgian TAVI Registry

baseline patient characteristics

	Edwards Sapien (n=473)	CoreValve (n=408)	Total population (n=881)	P-value
Age (yr)	83±6	82±7	83±6	0,055
Gender (♂, %)	47	47	47	<i>ns</i>
NYHA III, IV(%)	82	79	81	<i>ns</i>
AVA (cm ²)	0.61±0.15	0.64±0.15	0.63±0.15	0,001
Mean grad (mmHg)	46±15	47±16	46±16	<i>ns</i>
LVEF (%)	51±15	57±14	53±16	< 0,001
Log Euroscore (%)	29±16	24±15	27±16	< 0,001



The Belgian TAVI Registry

access and procedural outcome

%	Edwards Sapien (N=473)	CoreValve (n=408)	Total population (n=881)	P-value
access TF	61	89	74	<0.001
access TAP	36	0	19	
access SC	0	8	4	
access TAO	3	3	3	<i>ns</i>
procedural success	98	98	98	<i>ns</i>
procedural mortality	2	2	2	<i>ns</i>

TF: transfemoral
 TA: transapical
 SC: subclavian
 TAO: transaortic



The Belgian TAVI Registry 1 month MACE and survival

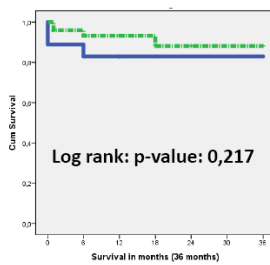
(not yet reported according to VARC)

%	Edwards Sapien (n=473)	CoreValve (n=408)	Total population (n=881)	P-value
New pacemaker	7	29	17	< 0.001
Renal failure	15	11	13	ns
Stroke - TIA	5	7	6	ns
Myocardial infarction	3	1	2	0.038
Survival	90%	91%	90%	ns

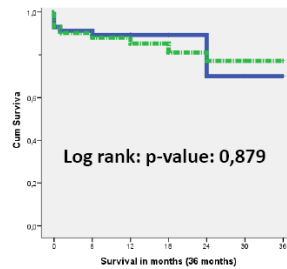


euro Medium outcome of transfemoral TAVI in relation to EuroScore
PCR Edwards Sapien vs CoreValve
2012 YEAR OF THE TEXTBOOK

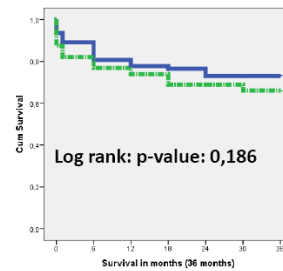
EuroScore 0-10



EuroScore 10-20



EuroScore > 20

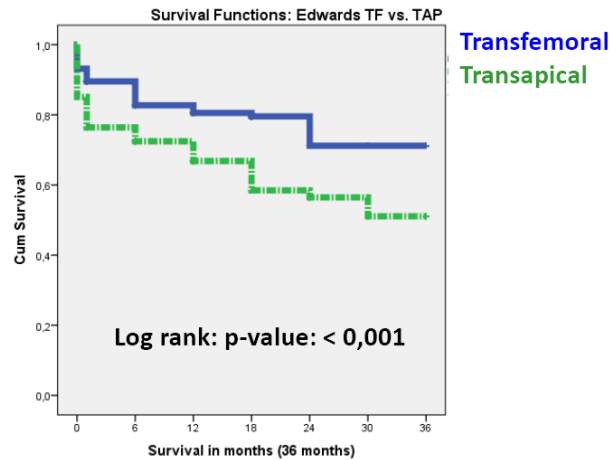


The Belgian TAVI Registry *Edwards transfemoral vs transapical (1 month)*

Patient Characteristics	Edwards TF n = 259	Edwards TAP + TAO n=137	P-value
Age (yr)	83±6	82±6	0,011
LVEF (%)	50±15	52±14	ns
Log Euroscore (%)	28±15	31±17	ns
Carotid dis (%)	18	34	< 0.001
Diabetes (%)	29	24	ns
PVD (%)	23	56	< 0.001
Porcelain ao (%)	5	14	0.001
Prev CABG (%)	22	35	0.004
1 month MACE			
Pacemaker (%)	6	9	ns
Renal failure (%)	12	20	0.024
Stroke-TIA (%)	3	8	0.020



Outcome of Edwards Sapien transfemoral compared to transapical access

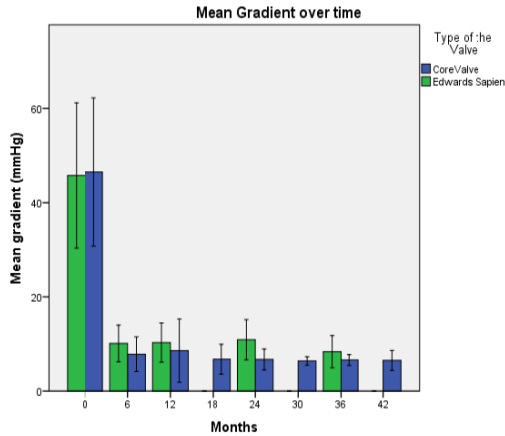


	Survival	1	6	12	18	24	30	36
Edwards TF	no	19	30	46	50	51	55	55
	yes	259	210	153	90	38	28	23
Edwards TAP	no	24	38	43	51	58	59	61
	yes	137	116	92	59	29	21	13

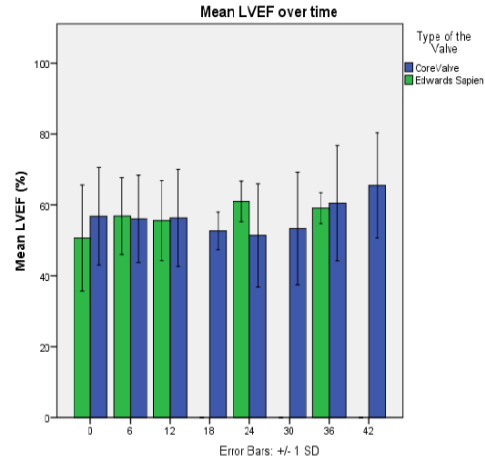


Evolution of mean gradient and LVEF over time Edwards Sapien vs CoreValve

Mean gradient



LVEF



Error Bars: +/- 1 SD

n	1	6	12	18	24	30	36	42
MG	796	304	94	13	26	5	16	2
LVEF	822	300	90	9	25	3	13	2



Conclusions

- The Belgian TAVI Registry confirms the high rate of procedural success of TAVI (both Edwards and CoreValve) in a high-risk elderly symptomatic population, refused for surgical AVR.
- Although not randomized, no major short-term and mid-term outcome differences between the CoreValve TF and Edwards Sapien TF groups could be demonstrated except increased need of definitive pacemaker in the CoreValve group.
- The consistently higher short-term and mid-term mortality after Edwards Sapien transapical implantation remains unexplained and needs further study but might be partially related to the higher risk profile of this patientgroup.
- CoreValve direct aortic and subclavian access is a promising alternative for patients without femoral access
- Mid-term echographic valve function remains excellent, both for the Medtronic CoreValve and the Edwards Sapien valve.