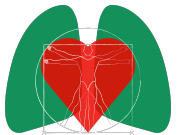


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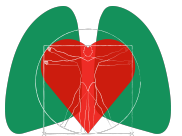
Multicenter, large scale, propensity-weighted comparison of three aortic bioprostheses: conventional stented, new-generation stented and rapid-deployment



Background / Study Objective

- The portfolio of aortic valve bioprostheses includes several different devices that have specific characteristics: design, hemodynamic properties, implantation techniques and anticalcification treatments
- An accurate knowledge of these characteristics enables surgeons to choose the most appropriate device for surgical aortic valve replacement (SAVR) in every single patient
- **Conventional stented (CS)** valves have been implanted for years and their behavior is well known
- **New-generation stented prostheses (NG)** feature new anticalcification treatment and new stent design aimed at facilitating future transcatheter valve-in-valve
- **Rapid-deployment prostheses (RD)** have been developed developed with the aim of reducing surgical times and facilitating minimally-invasive procedures

- *Aim of this retrospective, multicenter, propensity-weighted study was to evaluate early clinical and hemodynamic outcomes of CS, NG and RD aortic bioprostheses*



Methods

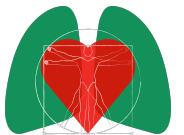
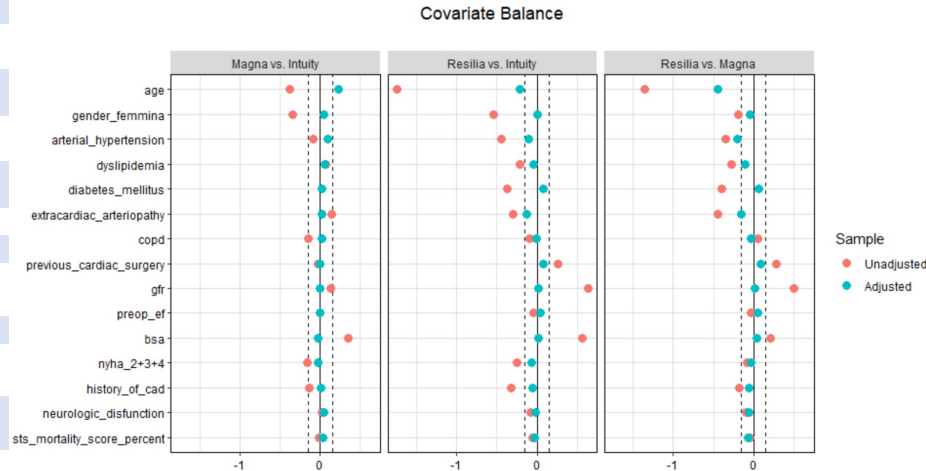
- January 2017-December 2020
- 27 cardiac surgery centers
- Multicenter, retrospective, observational study
- Propensity score weighting approach
 - For the three-arm comparison, RD has been chosen as the reference
- Inclusion criteria:
 - Isolated or combined SAVR for aortic valve stenosis
- Exclusion criteria
 - Aortic regurgitation
 - Endocarditis
 - Aortic dissection

- Study devices:
 - CS: **Magna Ease** (Edwards Lifesciences, Irvine, USA)
 - NG: **Inspiris** (Edwards Lifesciences, Irvine, USA)
 - RD: **Intuity** (Edwards Lifesciences, Irvine, USA)
- Patients: **2589**
 - Magna Ease: **296 (12%)**
 - Inspiris: **605 (23%)**
 - Intuity: **1688 (65%)**



Patients-baseline

Variables	Intuity (N=1688)	Magna (N=296)	Inspiris (N=605)	Combined (N=2589)	P- value
Age (y)	75 [70-79]	71.5 [66-76]	60 [53-65]	72 [64-78]	<0.001
Female gender	807 (48%)	94 (32%)	139 (23%)	1040 (40%)	<0.001
Body surface area (m ²)	1.8 [1.67-1.93]	1.88 [1.75-2.01]	1.9 [1.77-2.03]	1.83 [1.69-1.96]	<0.001
Dyslipidemia	935 (56%)	176 (59%)	275 (46%)	1386 (54%)	<0.001
Arterial hypertension	1350 (81%)	228 (77%)	373 (62%)	1951 (76%)	<0.001
Diabetes mellitus	406 (24%)	74 (25%)	59 (10%)	539 (21%)	<0.001
NYHA functional class					<0.001
I	134 (8%)	40 (14%)	98 (16%)	272 (11%)	
>II	1535 (92%)	256 (86%)	506 (84%)	2297 (89%)	
Peripheral arterial disease	269 (16%)	62 (21%)	35 (6%)	366 (14%)	<0.001
COPD	232 (14%)	27 (9%)	64 (11%)	323 (13%)	0.018
Neurological dysfunction	57 (3%)	11 (4%)	13 (2%)	81 (3%)	0.265
GFR (mL/min/1.73 m ²)	70 [53.65-85.95]	80 [63.25-90.53]	87.78 [71.29-97.94]	75.02 [58.76-91]	<0.001
Coronary artery disease	532 (32%)	77 (26%)	110 (18%)	719 (28%)	<0.001
Previous cardiac surgery	73 (4%)	11 (4%)	62 (10%)	146 (6%)	<0.001
STS Score (%)	1.9 [1.32-2.82]	1.3 [0.95-2.08]	0.95 [0.65-1.52]	1.66 [1.08-2.58]	<0.001
LVEF (%)	60 [55-65]	60 [55-65]	60 [55-65]	60 [55-65]	0.359



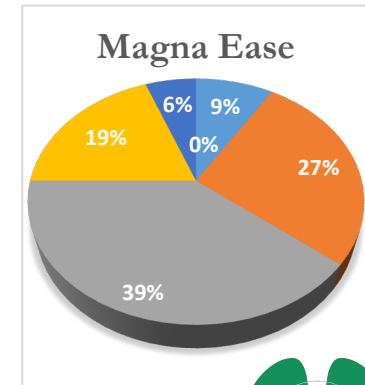
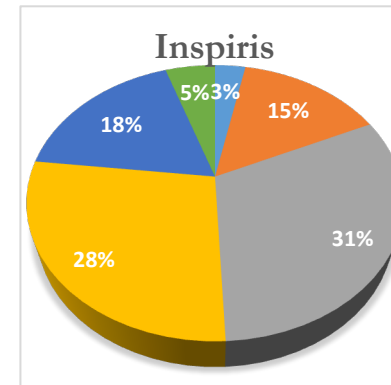
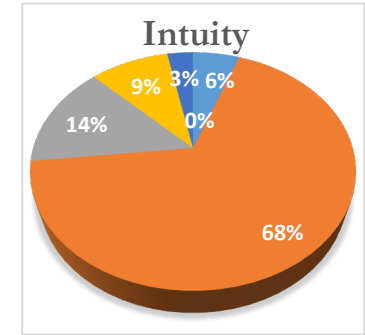
Results 1

Intra-operative variables

Variables	Intuity (N=1688)	Magna (N=296)	Inspiris (N=605)	Combined (N=2589)
Cardiopulmonary bypass time (CPB) (min)				
<u>Isolated SAVR</u>	82.5 [65-101]	110 [95-123]	90 [77.5-111]	87 [68.25-107]
<u>Combined procedure</u>	120 [95-147.5]	168.5 [145-194.25]	130 [104-150]	130 [102-162]
<u>Overall</u>	91 [71-118]	135 [109-175]	107 [86-134]	99.5 [77-130]
Aortic Cross Clamp time (ACC) (min)				
<u>Isolated SAVR</u>	55 [45-70]	87 [75-98]	70 [60-85]	60.5 [48-77]
<u>Combined procedure</u>	83 [67-106]	131 [110-149]	101.5 [80-118]	96 [73-122]
<u>Overall</u>	62 [48-81]	105 [85-134]	82 [66-107]	71 [53-95]

Prosthesis size

■ 19 ■ 21 ■ 23 ■ 25 ■ 27 ■ 29



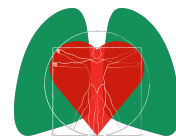
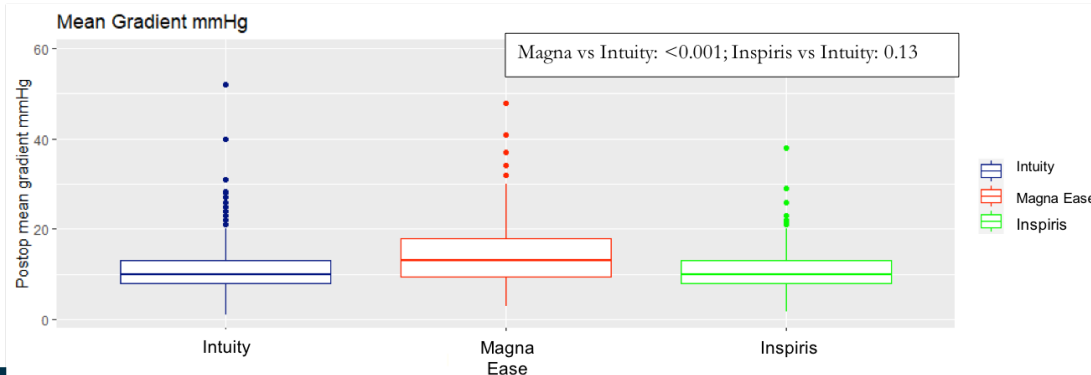
Device comparison	Average Marginal Effect	Lower	Upper	P-value
ME vs Intuity				
<u>CPB Isolated</u>	23.37	19.13	27.61	<0.001
<u>CPB Combined</u>	46.38	38.56	54.19	<0.001
<u>ACC Isolated</u>	27.44	24.3	30.58	<0.001
<u>ACC combined</u>	42.85	37.38	48.31	<0.001
Inspiris vs Intuity				
<u>CPB Isolated</u>	3.33	-1.003	7.67	0.132
<u>CPB Combined</u>	7.68	-0.55	15.91	0.067
<u>ACC Isolated</u>	10.56	7.34	13.78	<0.001
<u>ACC combined</u>	11.18	5.51	16.84	<0.001



Results 2

Variables	Intuity (N=1688)	Magna (N=296)	Inspiris (N=605)	Combined (N=2589)
VARC device success	1610 (96%)	283 (96%)	581 (96%)	2475 (6%)
New PM implantation	104 (6%)	17 (6%)	9 (2%)	130 (5%)
VARC all-cause mortality	30 (1.7%)	7 (2%)	3 (1%)	42 (2%)
- Isolated SAVR	11 (1%)	0 (0%)	0 (0%)	
VARC CV mortality	23 (1%)	5 (1.7%)	3 (1%)	33 (1%)
VARC AMI	11 (1%)	3 (1%)	2 (0%)	16 (1%)
VARC stroke	40 (2%)	9 (3%)	7 (1%)	56 (2%)

Device comparison	Odds Ratio	Lower-Upper	P-value
ME vs Intuity			
VARC device success	0.98	0.69-1.36	0.89
New PM implantation	1.06	0.81-1.38	0.68
VARC all-cause mortality	2.61	1.70-3.99	0.48
VARC CV mortality	2.78	1.71-4.49	0.48
VARC AMI	1.15	0.57-2.32	0.69
VARC Stroke	1.31	0.91-1.89	0.15
Inspiris vs Intuity			
VARC device success	0.92	0.64-1.33	0.66
New PM implantation	0.41	0.28-0.61	<0.001
VARC all-cause mortality	1.32	0.69-2.51	0.39
VARC CV mortality	1.93	0.98-3.79	0.06
VARC AMI	0.19	0.05-0.69	0.01
VARC Stroke	0.54	0.33-0.91	0.02



Conclusion

- CS, NG and RD aortic bioprostheses provide all excellent early clinical and hemodynamic outcomes
- There were no differences in terms of major postoperative complications. The incidence of new pacemaker implantation was similar between RD and CS but it was significantly lower in NG
- RD can be implanted with shorter surgical times than CS and NG
- RD and NG showed similar significantly lower peak and mean gradients overall and by size (not shown) compared to CS

