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Clinical And Hemodynamic Results Of Two Novel Pericardial Xenografts For Biologic Aortic Valve Replacement.

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Background



Insprirs Resilia (Edwards Lifesciences, Irvine, CA,USA)



Avalus (Medtronic, Dublin, Ireland)

The use of bioprosthetic aortic valve replacement is also increasing in younger patients, and indications are increasingly influenced by patient preference and HeartTeam approval according to current guidelines.

The Edwards Inspiris (Edwards Lifesciences, Irvine, CA, USA) and the Avalus (Medtronic, Dublin, Ireland) are two novel bovine pericardial prostheses with limited clinical data. We herein report on our indicational concept and early results with these valves.

Methods

From October 2017 – August 2021, 100 patients underwent elective AVR or combined procedures. 81 patients received a SAVR using the INSPIRIS (group 1) and 19 patients the AVALUS (group 2) prosthesis (age 50±9.5 vs. 75±4.9 years, p=0.001; 62% vs. 73% male, p=0.13; EuroSCORE II 1.6±1.5% vs. 1.9±0.8%, p=0.01; STS Score 0.9±0.53% vs. 1.9±0.8%, p=0.001). Acute clinical and hemodynamic results are presented according to VARC-2 definitions.

Results

Table 1) Baseline characteristics	Group 1 N=81	Group 2 N=19	p value
Age (years)	50.3±9.5	75±4.9	0.001**
Male	62%	73%	0.13
EuroSCORE II	1.6±1.5%	1.9±0.8%	0.01*
STS Score	0.93±0.53%	1.9±0.8%	0.001**

Figure 1) 30 day outcome

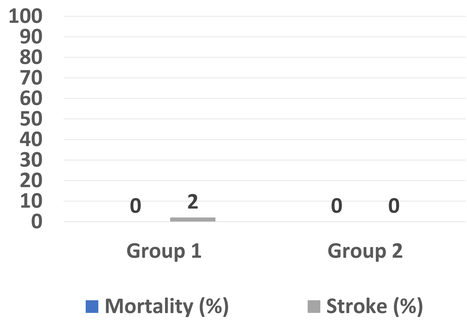


Table 2) Procedural characteristics	Group 1 N=81	Group 2 N=19	p value
Combined procedures	44%	73%	0.04
Replacement of ascending aorta	26%	21%	0.78
CABG	16%	16%	1.0
Mitral valve repair/replacement	9%	37%	0.005**
Bentall procedure	7%	5%	1.0
Tricuspid valve replcaement	1%	16%	0.02*
Redo surgery	27%	5%	0.06
Echo mean gradient	10.3±4.8 mmHg	10.1±3.3 mmHg	0.2
Echo peak gradient	18.9±6.9 mmHg	18.2±4.7 mmHg	0.7
paravalvular leakage >mild	0%	0%	1.0

Indications for AVR were severe aortic regurgitation, severe aortic stenosis and mixed lesions in 41% (41/100), 37% (37/100) and 22% (22/100) in the overall cohort. 50% (50/100) of the patients had a bicuspid aortic valve and isolated AVR was performed in 50% (50/100). Group 1 had a significantly lower rate of combined procedures 44% vs. 73% (p=0.04) compared to group 2.

Combined procedures showed significant differences between both groups for mitral valve repair/replacement 9% vs. 37% (p=0.005) and tricuspid valve replacement 1% vs. 16% (p=0.02). Rates of replacement of the ascending aorta 26% vs. 21% (p=0.78), CABG 16% vs. 16% (p=1.0), Bentall procedure 7% vs. 5% (p=1.0) and redo surgery 27% vs 5% (p=0.06) presented no significant difference.

Echocardiography at discharge demonstrated peak/mean transvalvular gradients of 18.9±6.9/10.3±4.8 vs. 18.2±4.7/10.1±3.3 (p=0.7/p=0.2) and no paravalvular leakage >mild in any patient. In-hospital and 30-day mortality were 0% in both groups including redo and combined procedures.

Conclusion:

Combined procedures were performed significantly more frequently in group 2, most likely due to the significantly higher patient age. The overall cohort demonstrated excellent acute hemodynamic outcomes and mortality of 0%. These two valves have complementary indications in our experience. Further studies and follow-up are necessary to evaluate durability and hemodynamic data.