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Early experience with a novel pericardial aortic prosthesis designed to provide improved durability and facilitate future valve-in-valve treatment

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Background



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

- Expansion zone facilitate future valve-in-valve (ViV) therapy
- Improved anti-calcification properties (Resilia tissue)
- Effectively eliminating free aldehydes, while protecting and preserving the tissue
- Fluoroscopically visible size markers
- Stored dry and ready to use
- Improved sustained hemodynamic performance

Methods

From October 2017 – June 2021, 81 patients (age 50±9.5 years, 62% male, logEuroSCORE II 1.6±1.5%, STS Score 0.93±0.53%) underwent elective AVR. Isolated AVR were performed via partial upper sternotomy. Indications for AVR were severe aortic regurgitation, severe aortic stenosis and mixed lesions in 48% (39/81), 27% (22/81) and 25% (20/81). 60% (49/81) of the patients had a bicuspid aortic valve.

Results

Table 1) Baseline characteristics

	N=81
Age (years)	50.3±9.5
Male	62%
EuroSCORE II	1.6±1.5%
STS Score	0.93±0.53%
Indications for AVR	
Aortic regurgitation	48%
Aortic stenosis	27%
Mixed lesions	25%
Bicuspid AV	60%

Figure 1) 30 day outcome

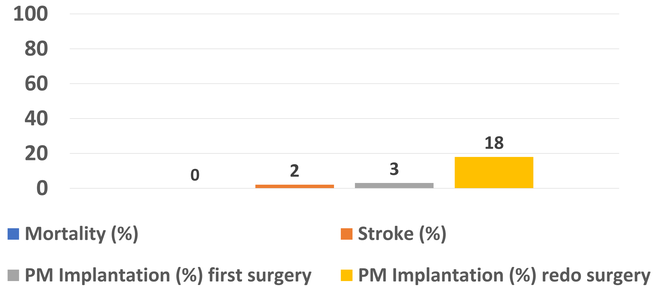


Table 2) Procedural characteristics

	N=81
Isolated AVR	56%
Combined procedures	44%
Replacement of ascending aorta	26%
CABG	16%
Mitral valve repair/replacement	9%
Bentall procedure	7%
Tricuspid valve repair	1%
Redo surgery	27%
Valve size	
21mm	2%
23mm	17%
25mm	36%
27mm	38%
29mm	7%
Duration ICU stay	2.7±3.1 days
Duration hospital stay	8.3±2.6 days
Echo mean gradient	10.3±4.8 mmHg
Echo peak gradient	18.9±6.9 mmHg
Paravalvular leakage >mild	0%

Isolated AVR was performed in 56%, combined procedures in 44%. Valve sizes used are showed in table 2. Mean procedure / cardiopulmonary bypass / aortic cross-clamp times for isolated vs. combined procedures were 214±85 / 116±46 / 80±29 and 268±103 / 159±70 / 101±45 minutes.

Echocardiography at discharge demonstrated peak/mean transvalvular gradients of 18.9±6.9/10.3±4.8 mmHg and no paravalvular leakage >mild in any patient. In-hospital and 30-day mortality were 0%. There was a significant difference in permanent pacemaker implantation rate between first and redo surgery cohorts (3% vs. 18%, p=0.04, overall: 7%). In our center, valve prosthesis selection was primarily based on patient age and surgical risk.

Conclusion:

Early experience with this novel type of pericardial valve was favourable in a mixed patient population resulting in early mortality of 0% despite a high rate of redo-surgery (27%). Durability as well as feasibility and hemodynamic advantages of ViV procedure in this new modified surgical valve must be proven in the future.