Abbott

CLINICAL INSIGHTS

TISSUE HEART VALVES

Comparison of Failure Modes of Bioprosthetic Porcine Valves versus Bovine Pericardial Valves

BACKGROUND

Porcine and bovine pericardial valves have been used for many years with good clinical outcomes for surgical mitral valve replacements (SMVR) and surgical aortic valve replacements (SAVR). There has been continued debate for many years regarding which valve type is better: porcine or bovine pericardial valves.

Previous comparisons focused on implantability, hemodynamic performance and durability. However, in the era of transcatheter valve interventions an additional consideration of suitability for future transcatheter valve-in-valve intervention has become important.

CLINICAL STUDIES

There are four recent key studies evaluating failure modes of porcine and bovine pericardial valves that provide new insights that may be of interest when deciding which valve type to choose for implant in a particular patient.

The first study by Bernard et al. was a retrospective study with 1397 Epic™ Mitral porcine valve implants performed between 2008–2021 with 10 years of follow-up. A key finding from this study was that the freedom from reoperation from structural valve deterioration (SVD) was 92.4% at 10 years.[1] The primary failure mode of SVD was valvular regurgitation due to a leaflet tear, and there were no cases of any valves requiring intervention due to leaflet calcification.[1]

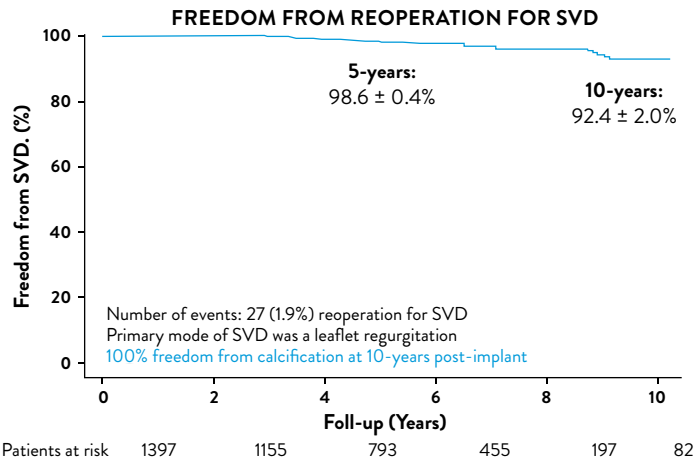

Figure 1: Bernard et al.

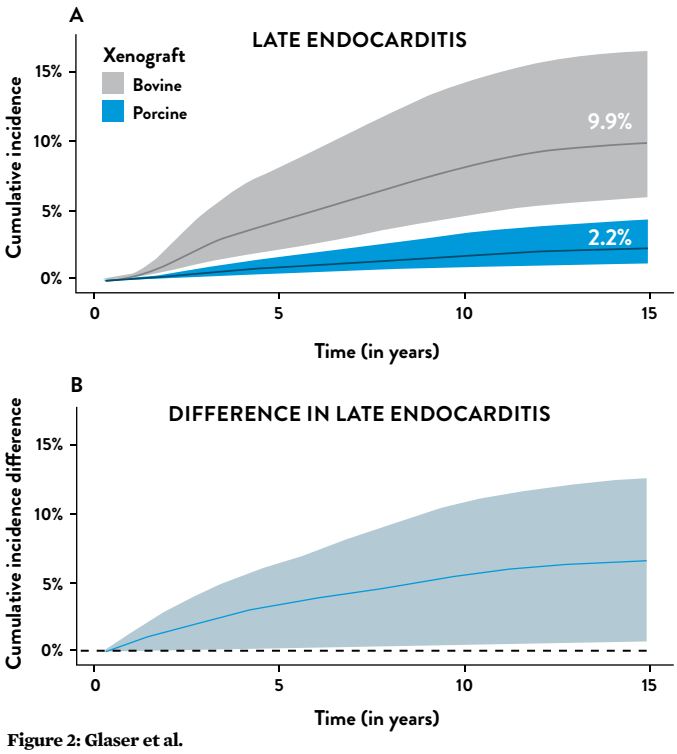

Figure 2: Glaser et al.

The second study by Glaser et al. was an observational, nationwide, population based cohort study examining 21,022 SAVR patients who received porcine and bovine pericardial valves in Sweden from 1997–2018; follow-up for endocarditis ended in 2018.

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CLINICAL STUDIES
(continued)

A key finding from this study was that SAVR patients who received bovine pericardial valves had a higher risk of developing late endocarditis compared to those that received porcine valves.[2]

The third study by Keshishi et al. was a retrospective study examining 278 patients from 2007–2019 who had their porcine or bovine pericardial valve explanted. One key finding of this study was the failure modes of the different bioprosthetic valves: bovine pericardial valves primary failure mode was stenosis from calcification, porcine valves primary failure mode was regurgitation from cusp tears. Importantly, the failure mode for porcine valves does not translate to more emergency procedures.[3] The failure modes echoed the findings from the fourth study, Uchino et al. a single center retrospective study with the additional finding that the time to detection of SVD was shorter for porcine valves compared to bovine pericardial valves.[4] The second key finding was that the incidence of stroke was ten times greater in bovine pericardial valves than in porcine valves.[3]

BIOPROSTHETIC VALVE EXPLANTS	PORCINE (N = 183)	BOVINE PERICARDIAL (N = 95)
Mean Age (years)	64 (54–72)	66 (52–73)
Years to Failure	11.4 (7.4–14.9)	9.8 (4.2–12.9)
Primary Failure Mode	Regurgitation	Stenosis
Mean Gradient (mm hg)	18.0 (11.0–31.0)	25.5 (16.8–43.7)*
Severe Regurgitation	45.3%	19.8%
Emergency Procedures	10.9%	11.6%
Interoperative Stroke	0.5%	5.3%**
30-day Freedom From Stroke	97.3%	92.6%**

Figure 3: Keshishi et al.

*P-value < 0.001; **P-value = 0.04.

DISCUSSION

Reintervention on failed porcine and bovine pericardial bioprosthetic valves may be performed with either a repeat surgical valve replacement or a transcatheter valve-in-valve intervention. The Keshishi et al. study demonstrated that reoperation on failed bovine pericardial bioprosthetic valves has a higher risk for a peri-procedural stroke relative to a reoperation on a failed porcine bioprosthetic valves.[3] The higher risk for stroke with reoperation on a failed bovine pericardial bioprosthetic valve may relate to having more leaflet calcification with a higher risk for the calcium to embolize during reoperation and cause a stroke.

Meanwhile, the Glaser et al. demonstrated that bovine pericardial bioprosthetic heart valves have a higher risk for late endocarditis relative to porcine bioprosthetic valves.[2] The higher risk for late endocarditis may relate to having more time for bacterial overgrowth in the presence of leaflet calcification as a result of the gradual onset of symptoms and delayed detection. Bioprosthetic endocarditis classically requires a surgical valve replacement since all infected tissues and the bioprosthesis must be removed to fully eradicate the infection, such that the option for a transcatheter valve-in-valve intervention may no longer be possible in this setting.[2]

CONCLUSION

Both porcine and bovine bioprosthetic valves, if implanted long enough, will ultimately fail and require a reintervention. Based on these four recent studies, the failure mode of valvular regurgitation due to a leaflet tear seen with porcine bioprosthetic heart valves may be advantageous.

A leaflet tear on a porcine bioprosthetic heart valve may be detected earlier and have less risk for causing a peri-procedural stroke at the time of reintervention and less risk for resulting in late endocarditis. Also, a porcine valve leaflet tear does not appear to require more emergency surgery relative to the failure mode of valvular stenosis seen with bovine pericardial valves.

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Important Safety Information

EPIC™ PLUS/EPIC™ PLUS SUPRA PORCINE TISSUE VALVES

INDICATIONS FOR USE

The Epic™ Plus valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve.

The Epic™ Plus Supra valve is indicated for patients requiring replacement of a diseased, damaged, or malfunctioning native aortic heart valve. It may also be used as a replacement for a previously implanted aortic prosthetic heart valve.

CONTRAINDICATIONS

None known.

POTENTIAL ADVERSE EVENTS

Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include: angina; cardiac arrhythmias; endocarditis; heart failure; hemolysis; hemolytic anemia; hemorrhage, anticoagulant/antiplatelet-related; leak, transvalvular or paravalvular; myocardial infarction; nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other); prosthesis regurgitation; stroke; structural deterioration (calcification, leaflet tear, or other); thromboembolism; valve thrombosis. It is possible that these complications could lead to: reoperation; explantation; permanent disability; death.

REFERENCES

1. Bernard, Jérémy, et al. "Long-term echocardiographic data, mechanisms of failure, and reintervention outcomes of the Epic valve in mitral position—a large observational cohort." The Journal of Thoracic and Cardiovascular Surgery (2023).
2. Glaser, Natalie, et al. "Prosthetic Valve Endocarditis After Aortic Valve Replacement With Bovine Versus Porcine Bioprostheses." Journal of the American Heart Association (2023): e031387.
3. Keshishi, Melanie, et al. "Comparison of Modes of Failure and Clinical Outcomes Between Explanted Porcine and Bovine Pericardial Bioprosthetic Valves." Cardiovascular Pathology (2023): 107516
4. Uchino, Gaku et al. "Modes of the bioprosthetic valve failure of the porcine and pericardial valves in the mitral position." European journal of cardio-thoracic surgery : official journal of the European Association for Cardiothoracic Surgery vol. 62,1 (2022): ezab506. doi:10.1093/ejcts/ezab506

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