REPLY: INSPIRIS DURABILITY IN THE PULMONIC POSITION: AGE MAY MATTER, BUT MORE THAN FOR OTHER VALVES?

Reply to the Editor:

We appreciate the comments by Shikata and Miyaji regarding our retrospective, single-center experience with the Inspiris Resilia valve (Edwards Lifesciences) in the pulmonic position in pediatric and adult cohorts with congenital heart disease. In our propensity score-matched cohort, we demonstrated significantly lower 2-year freedom from valve failure—driven mostly by pulmonary regurgitation—among patients who received an Inspiris valve compared with other prostheses. Additionally, implantation of the Inspiris valve in the native right ventricular outflow tract was associated with earlier development of at least moderate pulmonary regurgitation than use within a conduit.

Shikata and Miyaji similarly evaluated the performance of the Inspiris valve in a cohort of 13 adults with previously repaired tetralogy of Fallot. At 5.2-year follow-up, they saw no structural valve degeneration. The authors hypothesized that age at pulmonary valve replacement (PVR) may account for the difference in Inspiris durability between the 2 studies. A multicenter study by Baird and colleagues demonstrated a 5-fold greater risk of reintervention in patients who underwent PVR at age younger than 18 years, although there was no association between age and reintervention among those older than age 18 years. As Shikata and Miyaji point out, in our series, valve failure occurred predominantly during the early teenagers or young adulthood, which prompted us to perform additional exploratory analyses to assess the influence of age at PVR on Inspiris failure.

Among all Inspiris patients in our propensity-score matched cohort (N = 70; median age, 19.5 years [IQR, 12.9-31.6 years]), those in the first age quartile (younger than age 12.9 years) had the lowest freedom from valve failure, although this did not reach statistical significance (Q1: 30.6% ± 16.0% vs Q2: 60.3% ± 4.8% vs Q3: 80.0% ± 17.9% vs Q4: 47.6% ± 21.9%; log-rank \(P = .39\)) (Figure 1). Similarly, the cumulative incidence of valve failure was significantly higher among recipients of the Inspiris valve than among recipients of other valves in the subgroup of patients in the first age quartile (hazard ratio, 5.27; 95% CI, 1.43-19.49; Gray’s test \(P = .01\)) (Figure E1), although when we plotted the age-dependent hazard of valve failure with an Inspiris valve compared with all other prostheses, we did not see a significantly greater hazard of failure with Inspiris for any given age (Figure E2). Finally, we conducted a subanalysis of adult (ie, older than age 18 years) PVR patients only. In a matched cohort of 32 adult patient pairs, we saw no difference in valve failure between valve types (2-year freedom: Inspiris, 61.6% ± 16.2% vs non-Inspiris, 78.6% ± 8.9%; log-rank \(P = .37\)) (Figure E3).

Overall, these exploratory analyses suggest that age may influence Inspiris durability, although maybe not more or less so than its influence on other valves. Consistent with Baird and colleagues, durability of the Inspiris valve was comparable to other valve types in adult patients older than age 18 years. This raises the question of technical differences between pediatric and adult PVR procedures. With respect to implantation technique, we orient the prosthesis in the native right ventricular outflow tract with a posterior angulation to align with the course of the main pulmonary artery. Because this does not vary between valve type or surgeon, Inspiris failure compared with other valves is likely unrelated to implantation technique. We did notice that all prostheses—regardless of type—were significantly oversized in younger children compared with older children and adults (Figure E4). Because the implantation technique and sizing strategy were the same for all prosthesis types, this suggests another mechanism for early failure of the Inspiris valve.

We continue to caution against the use of the Inspiris bioprosthesis in the native right ventricular outflow tract until hemodynamic analyses and larger multicenter studies are able to shed light on its true durability, particularly in pediatric populations.

![Figure 1](image-url)
Letter to the Editor

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Conflict of Interest Statement
The authors reported no conflicts of interest.

The Journal policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

References

https://doi.org/10.1016/j.jtcvs.2024.03.004
FIGURE E1. Probability of valve failure in Inspiris versus non-Inspiris patients plotted against time since pulmonary valve replacement (PVR) in patients in the first through fourth age quartile (A-D). Numbers of patients at risk are included in the lower panel. Shaded area is 95% CI.
FIGURE E2. Age-dependent hazard of valve failure with an Inspiris valve (Edwards Lifesciences), compared with a non-Inspiris prosthesis. Shaded area is 95% CI. Dashed lines represent a hazard ratio of 1. PVR, Pulmonary valve replacement.

FIGURE E3. Kaplan-Meier plot of freedom from valve failure stratified by valve type in a matched cohort of adult patients only. Numbers of patients at risk are included in the lower panel. Shaded area is 95% CI. PVR, Pulmonary valve replacement.

FIGURE E4. Indexed valve size plotted against age at pulmonary valve replacement (PVR). Dots represent individual patients. Solid line represents the smoothed trend in the data, with 95% CI shaded. Inspiris valve is manufactured by Edwards Lifesciences.