

Neonatal Aortic Stenosis is a Surgical Disease: An Interventional Cardiologist View

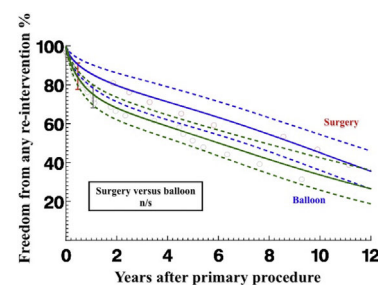
Lee Benson

The application of balloon valvotomy as primary treatment for neonatal congenital aortic stenosis is contentious. In this debate, we discuss data comparing outcomes of a percutaneous and surgical strategy between two tertiary centers that have adopted opposite therapeutic strategies. The outcomes with surgical and balloon therapies appear comparable. These contemporaneous data validate the empiric switch to primary balloon valvotomy in the modern era.

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The following is the con view, from a debate with Dr. Viktor Hraska, which took place at the AATS meeting in Seattle, April 2015.

Congenital aortic valve stenosis (AS) accounts for two thirds of the obstructive lesions affecting the left ventricular outflow tract. While surgical aortic valvotomy (SAV) was the standard therapeutic intervention, in 1984 Lababidi and colleagues described percutaneous catheter-based balloon aortic valvuloplasty (BAV), reporting immediate obstruction relief in infants and children.¹ Despite an initial high rate of procedural complications, techniques improved over time and refinements in the procedure established the short-term safety and efficacy of BAV in neonates, infants, and children.²⁻⁴ At most centers, BAV has become the standard of care for infants and children with AS requiring intervention. Indeed, a recent survey of 13 unselected North American pediatric cardiology interventional units (Dr. D.W. Benson, personal communication) when asked how infants would be typically managed, reported that no unit responded with almost always a SAV; 77% reported almost always a BAV; and 23% a variable approach with the type of intervention decided upon on a case-by-case basis. Then, when asked if there existed equipoise between strategies, and the unit participated in a clinical trial where interventions were randomized to SAV or BAV, would there be willingness to randomize, none agreed to



Freedom from any re-intervention. All 95 procedures (whether primary or secondary).

Central Message

The outcomes of surgical and balloon therapies for neonatal AS are comparable. Data validate the empiric switch to primary balloon valvotomy.

randomize infants. As such, in many units BAV has superseded surgical intervention. Nevertheless, application in the neonate remains contentious and debate continues as to which procedure is most appropriate in this age group, as reflected by Dr. Hraska's position. To address this question, comparative contemporary data is lacking, particularly in regard to longer-term follow-up, where such data could support or refute which treatment strategy is preferable. For this debate, we summarize data comparing the outcomes of SV versus BAV between two tertiary centers that adopted opposing strategies spanning the same era (Dr. Gruschen Veldtman, personnel communication).

Between 1986 and 2005, SAV was the strategy for infants with critical AS at Southampton General Hospital, UK, and all cases included undergoing a biventricular repair strategy (group

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The data set presented herein is part of a larger study under analysis (Forsey et al. Abstract J AM Coll Cardiol 2012;59(13s1):E817-817. [http://dx.doi.org/10.1016/S0735-1097\(12\)60818-3](http://dx.doi.org/10.1016/S0735-1097(12)60818-3)).

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A; $n = 27$). Between 1986 and 2004, BAV was the strategy used for infants with critical AS undergoing a biventricular repair at The Hospital for Sick Children, Toronto, and all such cases from this center (group B; $n = 52$) were included. Statistical analysis was robust, using parametric time-related techniques using multiple hazard phases with transitions from index intervention to mutually exclusive competing end-states (re-intervention or death without re-intervention)^{5–8} and a modulated renewal methodology to examine relative durability of successive interventions.⁷ All interventions – regardless of when and in whom they occurred – were analyzed in aggregate. The model was stratified to whether the intervention was the index, or a first or second re-intervention, and so forth. For risk-hazard analyses, variables were tested in a univariate and multivariate (risk-adjusted) fashion using parametric automated forward stepwise regression. Incorporation of baseline demographic and morphologic variables allowed risk-adjustment for patient-specific factors. The relative strategy (group A or B) was then inserted into risk-adjusted models to assess the impact of the opposing strategies. Reliability of variables reaching statistical significance ($P < .05$) was tested using bootstrap resampling in which automated random training datasets are generated ($n = 1000$) against which the variables are tested. Reintervention risk was evaluated and characterized as early (< 5 years) or late (> 5 years).

Study Population

Data was reviewed on 79 consecutive neonates. SAV was performed on 27 and BAV in 52 newborns. Follow-up for SAV was 12.9 ± 6.17 years and for the BAV group was 11.2 ± 4.05 years. There was no significant difference in demographic, echocardiographic, or morphological data with Table 1 showing comparisons between the two groups. While baseline echocardiographic data was generally well matched, peak gradient was higher in the BAV group.

Mortality

Survival pattern is summarized in Figure 1. Late survival appeared to be established by 1 year following the procedure

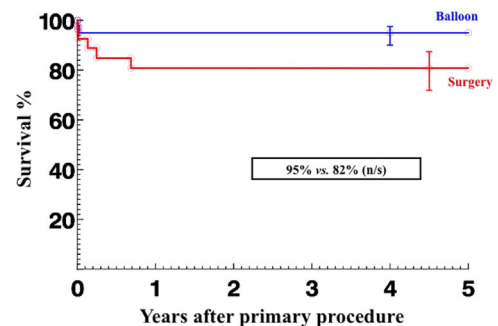


Figure 1 Overall survival stratified by strategy.

(82%; SAV vs 91%; BAV, $P = .15$). The apparently greater early mortality observed in the SAV group was not statistically significant. There were no significant independent predictors of early or late mortality when adjusting for age, weight, sex, presence of duct dependent circulation, or echocardiographic findings.

Re-Intervention After Initial Procedure

Time-related freedom from re-intervention is shown in Figure 2. At 5 years, freedom from re-intervention between the BAV group was 52% versus 78% for SAV, but this trend did not reach significance ($P = .09$). Similarly, at 10-year follow-up, freedom from re-intervention was 30% and 16% for the BAV and SAV groups, respectively ($P = .60$). The overall risk for re-intervention was highest in the first few months after either intervention and declined to its lowest point in the first 4 years (hazard ratio of 5), at which point the risk steadily increased over the course of follow-up (Fig. 3).

Need for Ross or Aortic Valve Replacement During Follow-Up

Freedom from a Ross procedure for either group is depicted in Figure 4, showing no important differences between groups

Table 1 Patient Demographics

	SAV (n = 27)	BAV (n = 52)	P Value
Age at intervention (days)	7.9	7.3	0.79
Weight (kg)	3.3	3.45	0.29
Male (%)	92	75	0.11
Duct open (%)	48	62	0.42
Annulus size (mm)	6.5	6.42	0.81
Annulus Z-score	-2.55	-2.93	0.59
Peak gradient (mmHg)	61	90	0.003
LV function	1.52	1.02	0.16
Number of cusps	2.5	2.4	0.36
LVEDD (mm)	20.1	18.9	0.45
Balloon ratio	–	0.96 ± 0.12	–
Clamp time (mins)	14.3 ± 5.07	–	–
Follow-up (yrs)	12.9 ± 6.17	11.2 ± 4.05	0.17

Abbreviations: LV, left ventricular; LVEDD, left ventricular end-diastolic dimension.

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