



Balloon Valvuloplasty for Congenital Aortic Stenosis: Is it TTT of Choice ?

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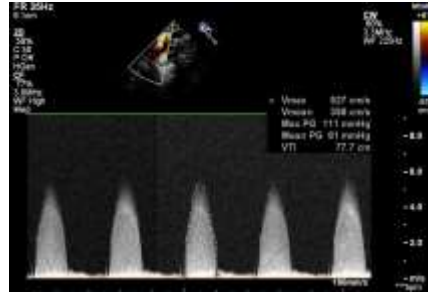
Disclosures

None related to this presentation

NB with AS - Case 1



- Newborn male
- 2.8 kg
- Severe AS
- Vmax = 5.3 m/sec;
PSG=110; M=61
- Mod. LVH with good
systolic function

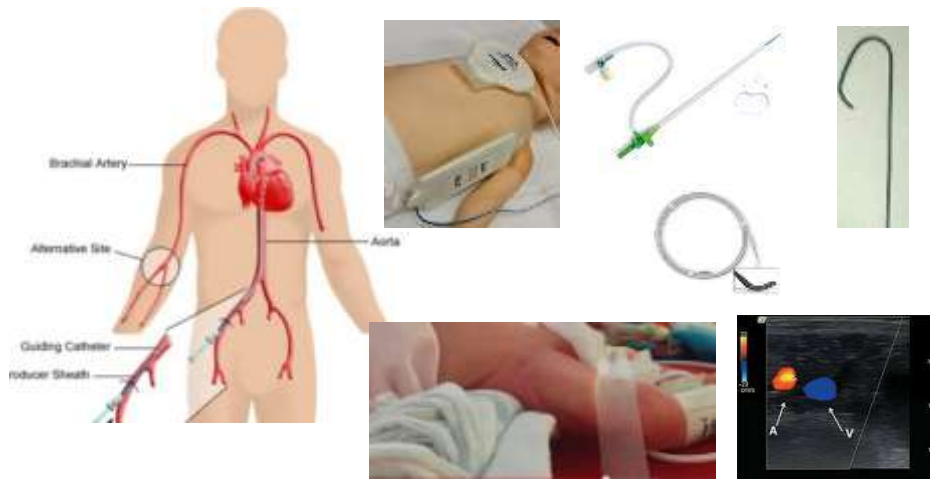


Severity of AS



	Heart catheter peak-to-peak gradient	cw Doppler Vmax <i>ACCAHA</i> <i>ESC</i>	Bernoulli peak instantaneous gradient	Bernoulli mean instantaneous gradient <i>ACCAHA</i> <i>ESC</i>	Echo aortic valve area <i>ACCAHA</i> <i>ESC</i>
Trivial					
Slight	< 30 mmHg	< 3 m/s	< 36 mmHg	< 25 mmHg	> 1.5 cm ² (> 1 cm ² /m ²)
Moderate	30-50 mmHg	3-4 m/s	36-64 mmHg	25-50 mmHg	1-1.5 cm ² (0.6-1 cm ² /m ²)
Severe	> 50 mmHg	> 4 m/s	> 64 mmHg	> 50 mmHg	< 1 cm ² (< 0.6 cm ² /m ²)

Technique of catheter intervention



What is a critical cAS ?



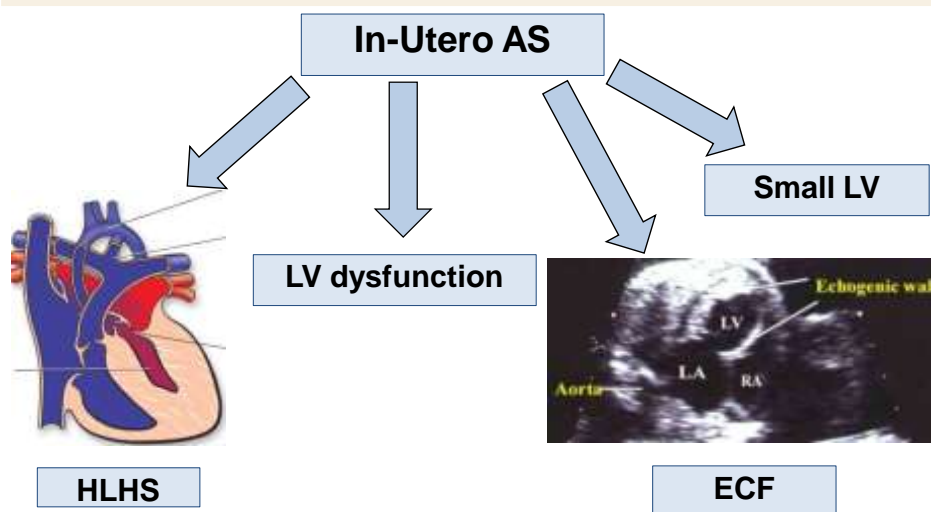
- **Reduced effective orifice area**, usually resulting from thickening and reduced motion of the valve leaflets; Incomplete opening of the semilunar valve or valve ring being small, or a combination;
- **Critical AS**-----lead to **decompensation of LV** if not treated.
- **Ductal dependent** -----the stenosis is so severe that additional perfusion of the circulation through an open ductus is necessary to sustain life.

Therapy for cAS- Pre-balloon



- If **HF** is present it is advisable to treat it before the valve procedure
- With **prostaglandin** the systemic perfusion may be supported.
- If there is isolated impairment of LV pumping function with dilated ventricle and decrease CO, **inotropic support** and **loop diuretics** are indicated.

In-Utero AS



Predictors of Failure of Bi Ventricular Repair by Multivariate Analysis



Risk Factor	P	OR	95% CI
All patients (n=72)			
Moderate/large VSD	0.001	22	(3.6, 136)
Unicommission AoV	0.006	16	(2.2, 112)
Smaller MV annulus	0.02	2.2*	(1.1, 4.5)
Smaller LVEDVM	0.03	1.9*	(1.1, 3.3)

Marcy et al. Predictors of Outcome of biventricular repair in infants with multiple obstructive lesions. Circulation 2001; 104:682-87

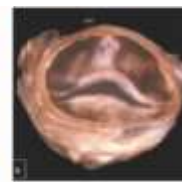
Valve Morphology ?



Bicuspid



Bicuspid with raphe



Bicuspid with raphe + calcification, retraction



TRICUSPID
25%



BICUSPID
60%



MONOCUSPID
15%

Valve Morphology



Excellent Surgical results and Tricuspid valve

	<u>Bicuspid</u>	<u>Tricuspid</u>
<u>Absence of reintervention in 10 years</u>		
Bhabra M. Ann Thorac Surg 2003 (Birmingham)	33%	92% (p < 0.01)
Hraska V. Ann Thorac Surg 2012 (St Augustin)	50%	90% (p = 0.03)
<u>Absence of Replacement in 10 years</u>		
Bhabra M. Ann Thorac Surg 2003 (Birmingham)	57%	100% (p < 0.01)
Hraska V. Ann Thorac Surg 2012 (St Augustin)	60%	100% (p < 0.01)

And Bicuspid better than Monocuspid

Aortic Insufficiency



- Increased risk with larger balloon: annulus ratio (but Hamidi Manesh et al reports differently#)
- Increased risk with young age *
- Increased risk with bicuspid, asymmetrically thick valves
- Increased risk with time

*Fratz S, Gildein HP, Balling G, Sebening W, Genz T, Eicken A, Hess J. Aortic valvuloplasty in pediatric patients substantially postpones the need for aortic valve surgery. A single center experience of 188 patients after up to 17.5 years of follow-up. *Circulation* 2007;117:1201-1206

Conclusion: This study did not show any significant relationship between the balloon to annulus ratio during interventional dilatation and the degree of aortic regurgitation following the procedure. (J Interven Cardiol 2013;26:200-207)

BAV in neonates and young infants- AUBMC Experience



BAV in neonates and young infants- AUBMC Experience



- Retrospective review of medical records, cath lab & surgical data base and echocardiograms
- All patients treated by BAV are included
- 2005-2016
- Excluded : Sub or supra AS, ECMO, prenatal aortic valve modification, and patients intended for SV palliation at the time of the BAVP.

Characteristics



30 patients

- Mean Age: **74 days** (1 – 300 days);
- Isolated 63% (19 patients)
- M: F ratio is 4:1
- **LV dysfunction** was a common finding in (56%).
- **Prostaglandin** was used in 20% of patients prior to the procedure

Baseline Characteristics



	Newborns (n=15)	Infants (n=15)
Mean Body Weight	3.6 kg (1.9-7)	5.3 kg (2.9-9.6)
Mean Aortic Annulus Diameter	6.4 mm (4.7-8)	8.2 mm (6-11)
Aortic Valve Anatomy		
Unicuspid	0 (0%)	0 (0%)
Bicuspid	6 (40%)	6 (40%)
Tricuspid	9 (60%)	9 (60%)

Associated Anomalies (11/30; 37%)



Coarctation of COA	7 (21%) (3 Surgery and 3 Balloon); 1 trivial COA
VSD	2 (6%); muscular small; no intervention
MV regurgitation	1 (3%); surgery at 4 years repair of cleft
Ebstein	1 (3%); mild ; also COA
Shone; MS, AS and CoA	1 (3%); also COA ;

Outcomes

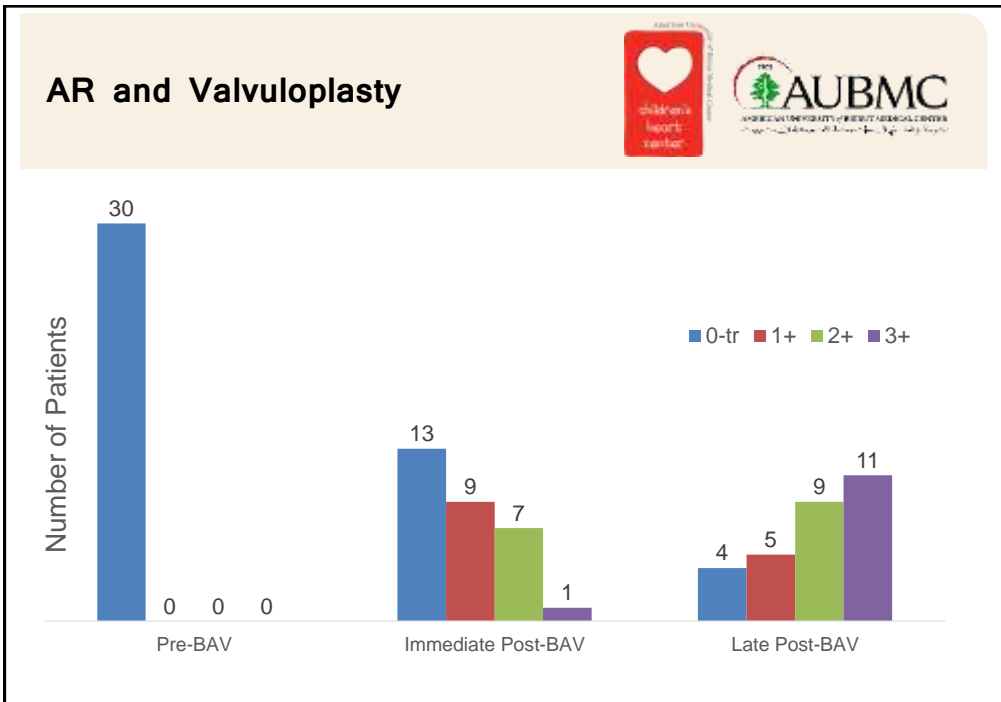
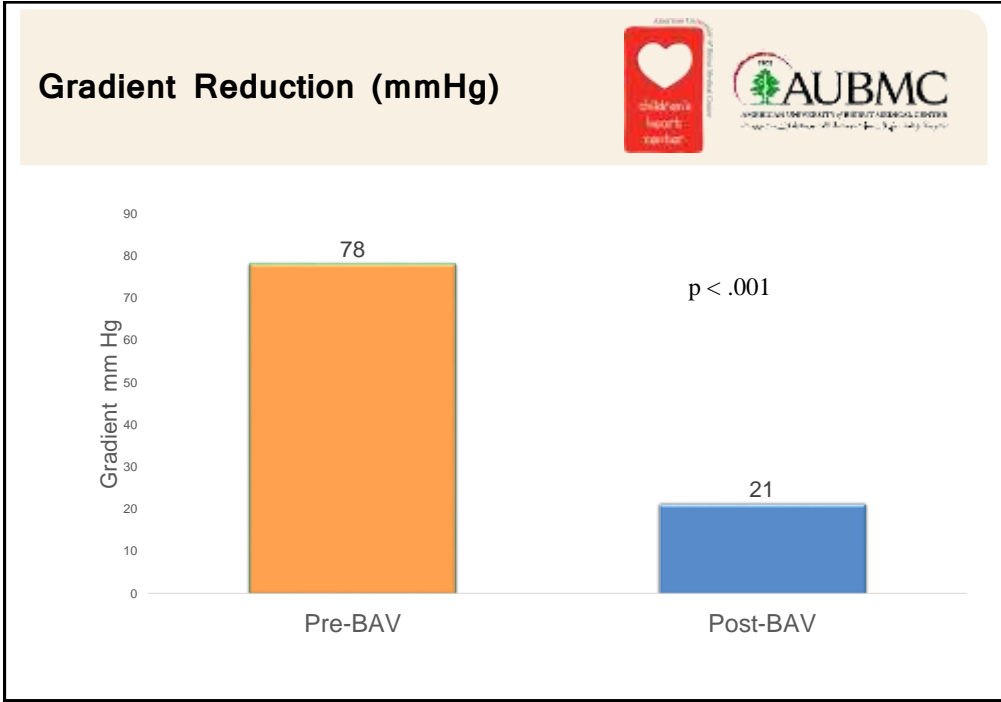


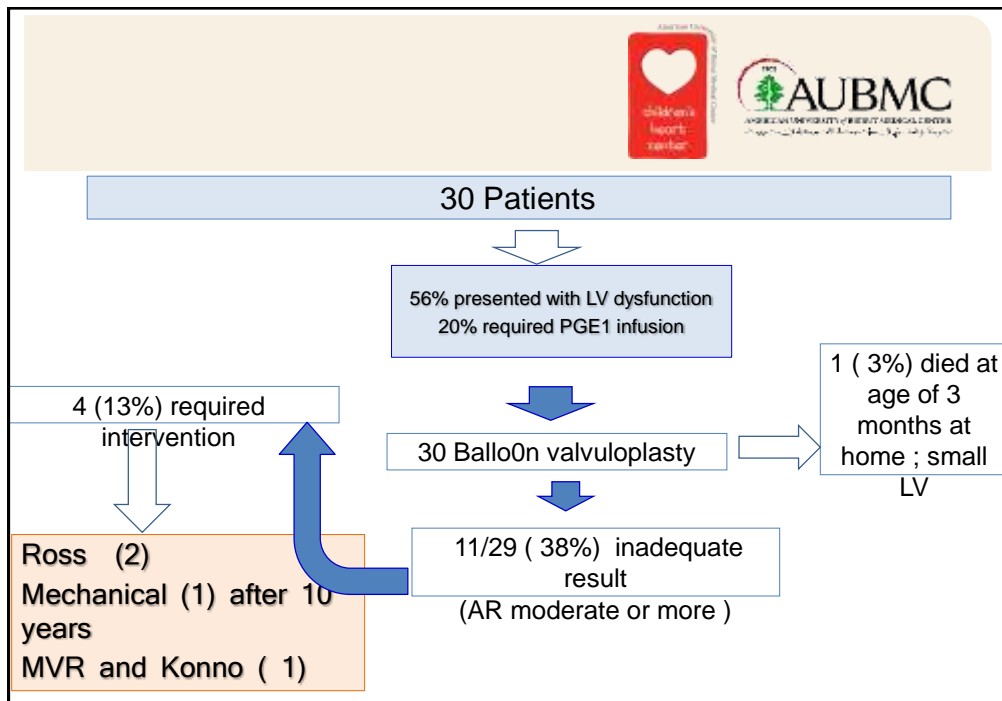
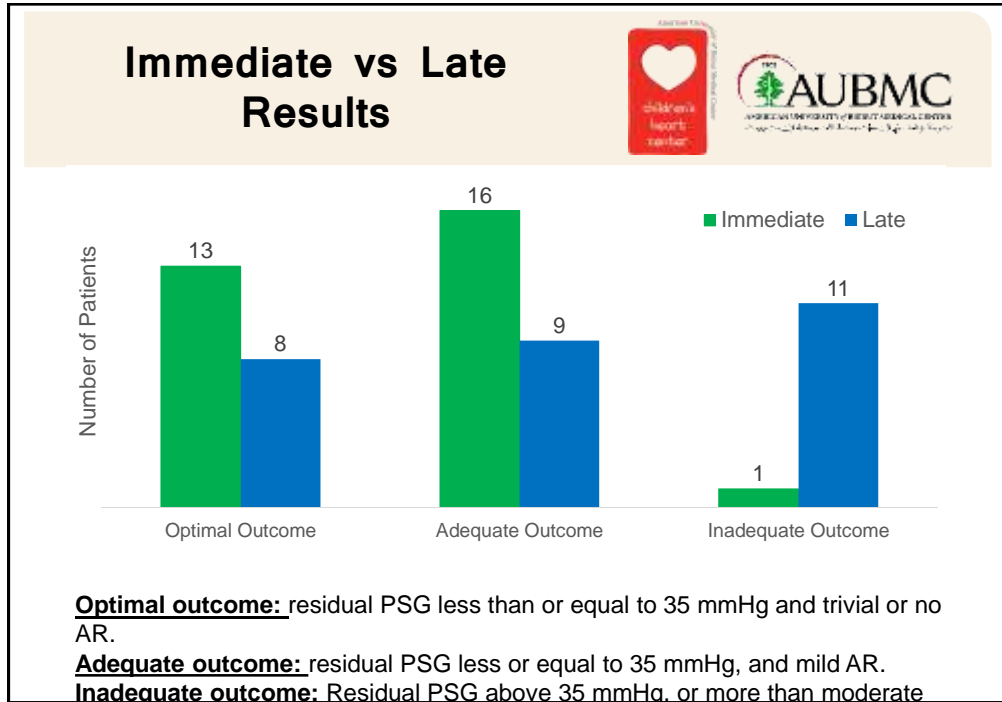
IMMEDIATE RESULTS:

- Mortality **0% in Hospital**
- Residual gradient > 35mmHg: **3.3 %** (1 pt.; 40 mmHg)

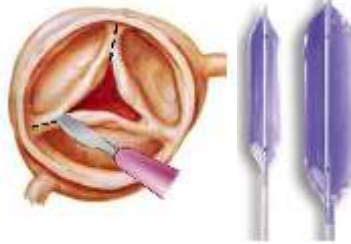
LATE RESULTS (Mean follow-up 7 yrs; Range: 0.5 – 11 yrs)

- Mortality 1 late death (at home age of 3 months)
- Aortic stenosis: Trace to mild (70%); Mild to Moderate (27%); At least Moderate (3%)
- Re-intervention: **13 %**





Balloon vs. Surgery Pendulum Swings ?



- ❑ (AS) accounts for 2/3 of the LVOTO lesions.. (SAV) was the standard therapeutic intervention,
- ❑ In 1984 Lababidi et al described (BAV),
- ❑ 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 when asked how infants would be typically managed, 77% reported almost always a BAV; and 23% a variable approach with the type of intervention decided upon on a case-by-case basis.

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Aortic Valve and Surgery



Resection of nodular dysplasia



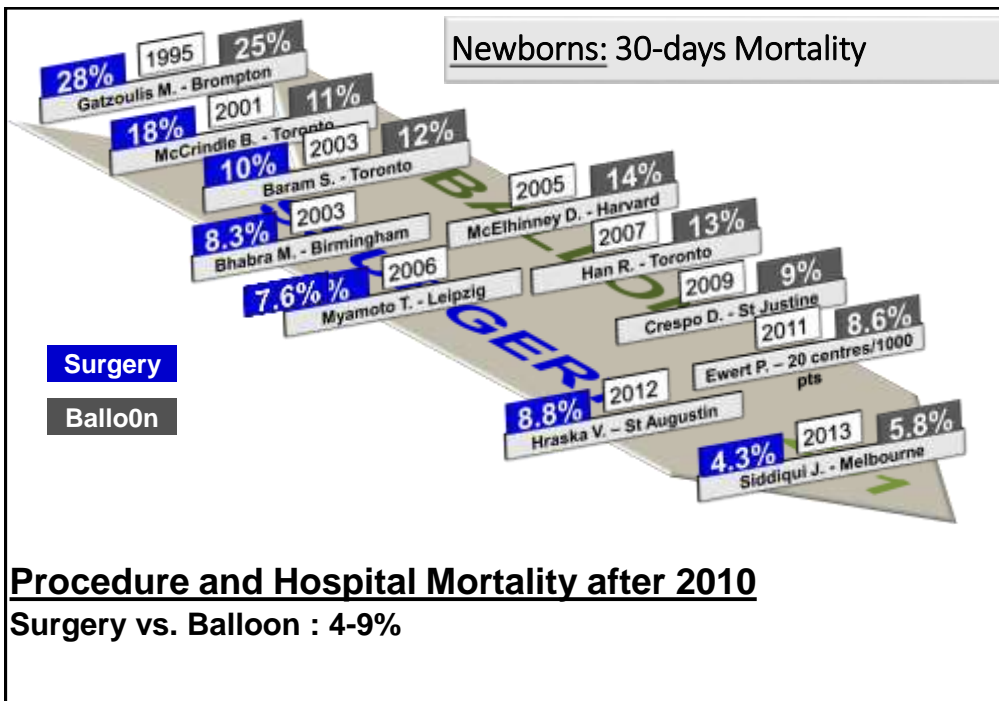
Thinning of leaflets

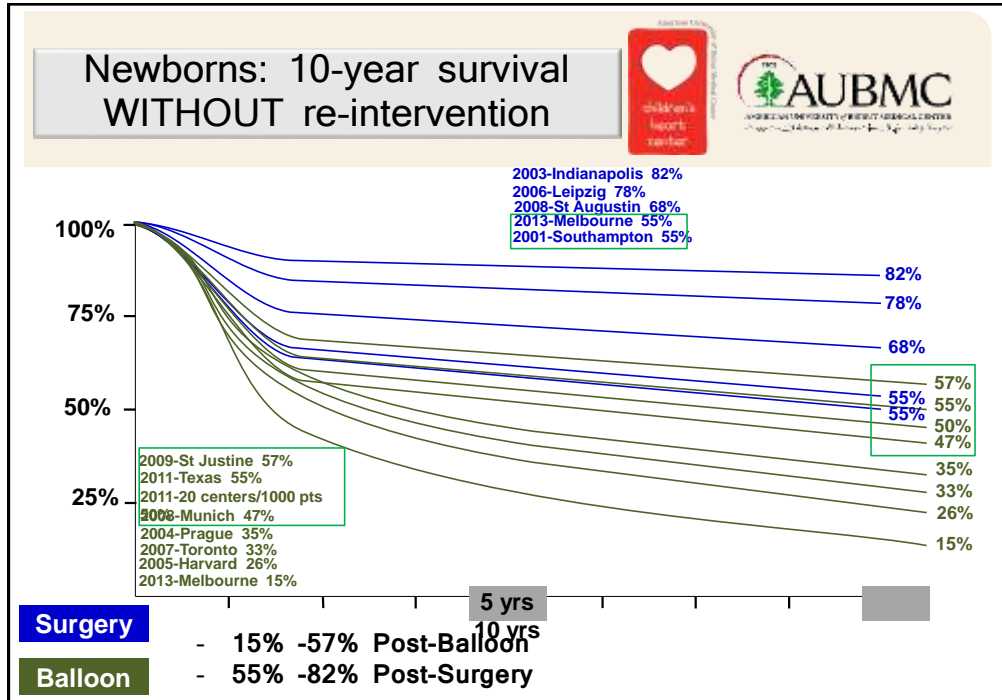


Recreation of interleaflet triangles



Creation of neo commissures





Surgical Valvotomy Versus Balloon Valvuloplasty for Congenital Aortic Valve Stenosis: A Systematic Review and Meta-Analysis

Overall 2368 patients from 20 studies were included in the analysis, including 1835 (77%) in the BAV group and 533 (23%) in the SAV group.

[95% CI 68–77] for SAV, $P=0.001$). Results were unchanged in a sensitivity analysis restricted to infants (<1 year of age).

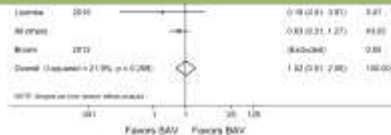
Conclusions—Although higher rates of reintervention suggest improved outcomes with SAV, indications for reintervention may vary depending on initial intervention. When considering the benefits of a less-invasive approach, and clinical equipoise with respect to more clinically relevant outcomes, these findings support the need for a randomized controlled trial. (*J Am Heart Assoc.* 2016;5:e003931 doi: 10.1161/JAHA.116.003931)

Key Words: aortic surgery • aortic valve stenosis • balloon aortic valvuloplasty • congenital heart defects • meta-analysis

Forest plot comparing incidence of moderate or greater aortic valve regurgitation prior to discharge or at early postoperative follow - up (A) and hospital or 30 - day mortality (B) by intervention.



no difference in long-term survival or freedom from aortic valve replacement but significantly more re-intervention in the BAV group



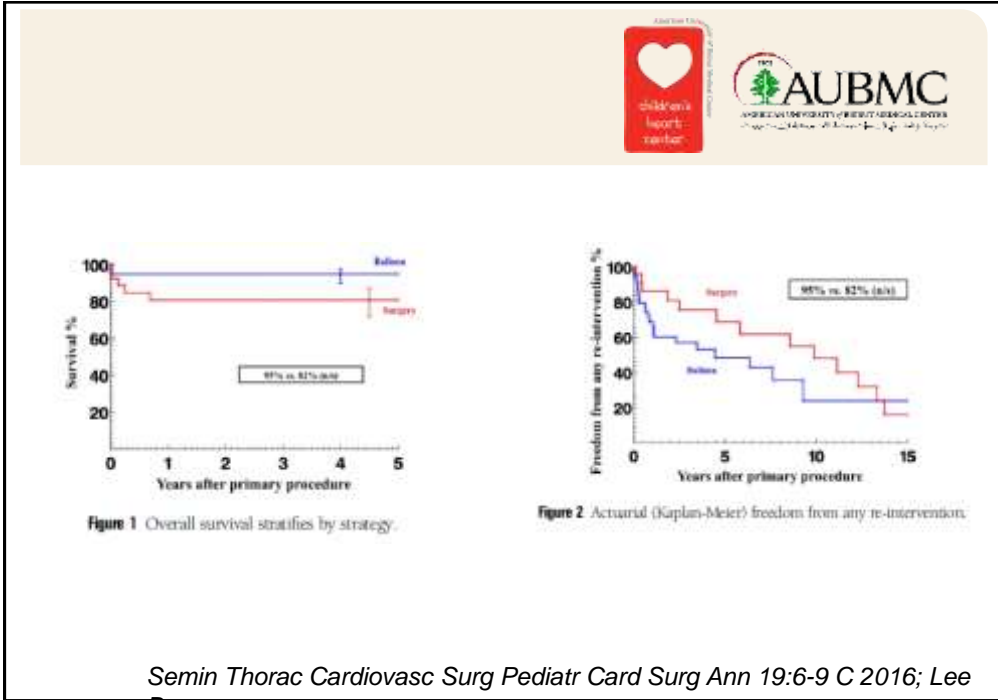
Garick D. Hill et al. J Am Heart Assoc 2016;5:e003931

© 2016 Garick D. Hill et al.

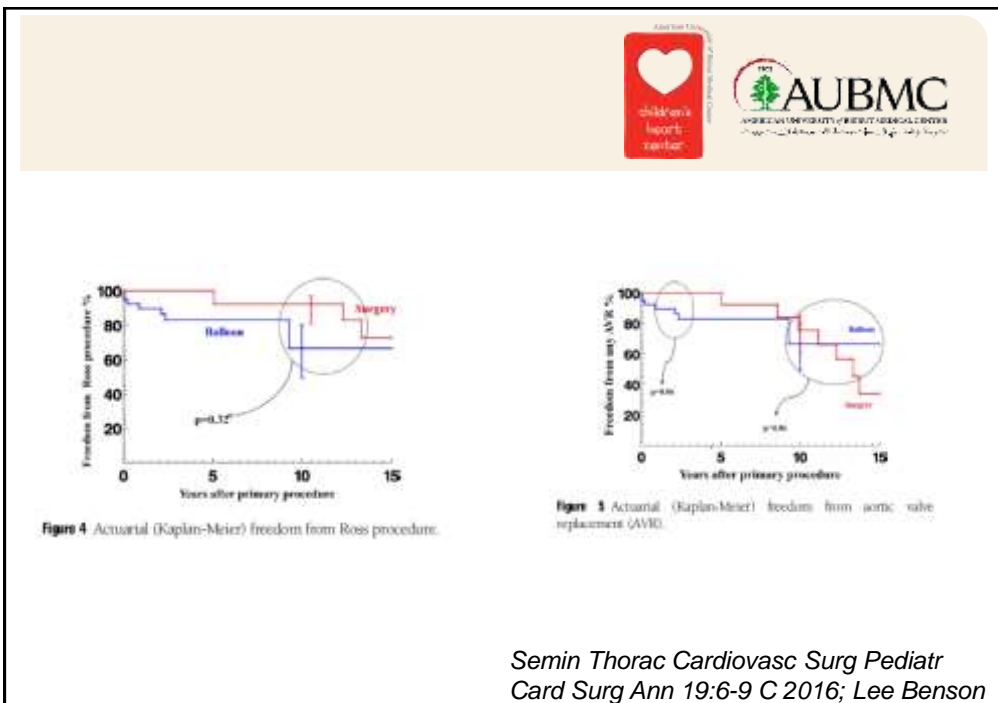
Neonatal Aortic Stenosis is a Surgical Disease: An Interventional Cardiologist View

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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Acute Success of Balloon Aortic Valvuloplasty in the Current Era

A National Cardiovascular Data Registry Study



Etien A. Sou, MD,¹ Jeffrey D. Zampieri, MD,² Kevin F. Kennedy, MS,¹ Natalie Iqbal, MD, MSc,¹ Diego Portas, MD,¹

Of the 1,026 isolated BAV procedures captured in IMPACT, 2.4% of patients did not survive to hospital discharge.

patient cohorts.

RESULTS Of the 1,026 isolated BAV procedures captured in IMPACT, 718 (70%) were “successful.” Success rates were 70.8% for noncritical AS (n = 893) and 62.7% for critical AS (n = 133). Multivariate analysis revealed that prior cardiac catheterization, mixed valve disease, baseline aortic valve gradient >80 mm Hg, baseline aortic insufficiency greater than mild, presence of a bicuspid, and multiple leaflet perforations were associated with unsuccessful BAV in the noncritical AS cohort. There were no factors associated with unsuccessful procedures in the critical AS group. No procedural deaths occurred, but 2.4% of patients did not survive to hospital discharge. Adverse events occurred in 15.8% of all cases and were more frequent in procedures performed for critical AS (30.0% vs. 14.7%, p < 0.001).

CONCLUSIONS BAV is an effective treatment for congenital AS with low rates of mortality and adverse events. Patients with critical AS have a higher risk for procedure-related adverse events. (J Am Coll Cardiol Intv 2013;5:170-181) © 2013 by the American College of Cardiology Foundation.

Balloon Aortic Valvuloplasty Procedures (N=1126)

Excluded (N=100)
1. Single Ventricle (N=20)

Of the 1,026 isolated BAV procedures captured in IMPACT, 718 (70%) were “successful.”

BAV is an effective treatment for congenital AS with low rates of mortality and adverse events

Success (N=69)

- Optimal Outcome (N=40)
- Adequate Outcome (N=29)
- Inadequate Outcome (N=41)

Success (N=649)

- Optimal Outcome (N=314)
- Adequate Outcome (N=335)
- Inadequate Outcome (N=267)

Conclusions



- BAV is a safe and effective modality to treat cAS in newborns and young infants, even in the presence of additional anomalies (i,e, CoA)
- Early and late mortality rates are low
- AR remains a major concern and may increase with time and may require surgical intervention.
- Repeat BAV successful for recurrent AS

Conclusions



- If the structures of the left side of the heart are severely hypoplastic/valve ring is too small or in cases of ECF, IV repair may be necessary.
- Balloon versus surgery is center specific and randomized data are needed to assess the superiority of a procedure over another.
- No clear data documenting the superiority of BAV vs. SAV; at our Center BAV is TTT of Choice.

