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The Hybrid Approach for HLHS

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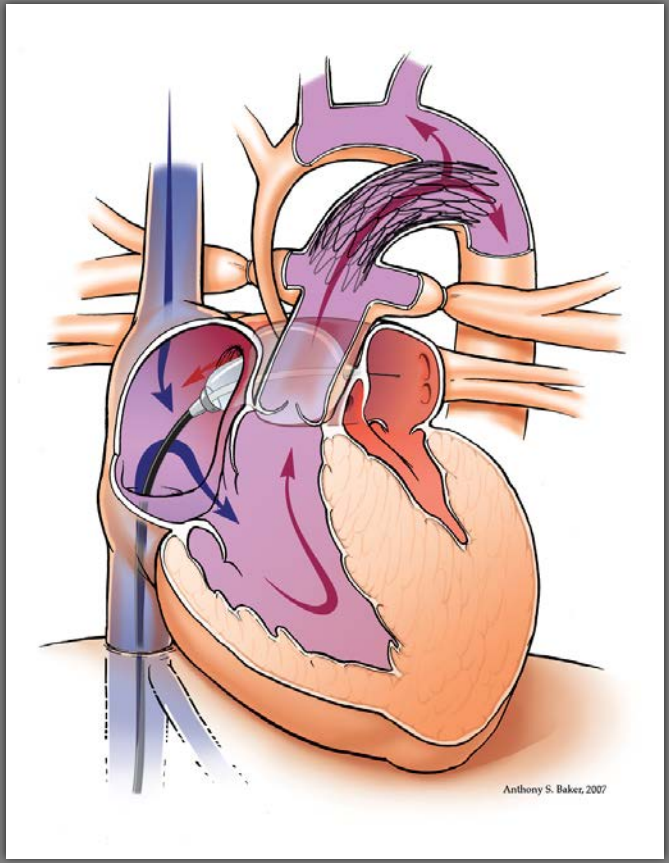
Disclosures

- None
- Off label use of FDA approved devices will be discussed

Why the Hybrid Approach

- There has been no significant improvement in over a decade, despite multiple centers, with many bright people trying. Perhaps the anatomy, physiology, and impact of the traditional procedures for HLHS have reached their limit.
- Hybrid procedure is a paradigm shift that can be a platform for learning and innovating towards improvements in managing HLHS.



CHSS Data

- Prospective, 29 institutions, 1994-2000
- 710 neonates, classic HLHS
- Survival:
  - 1 month 72%
  - 1 year 60%
  - 5 years 54%
- Fontan completion in 46%
- Mortality and morbidity concentrated around the Stage 1 procedure

Ashburn, et al, JTCVS, 5/2003

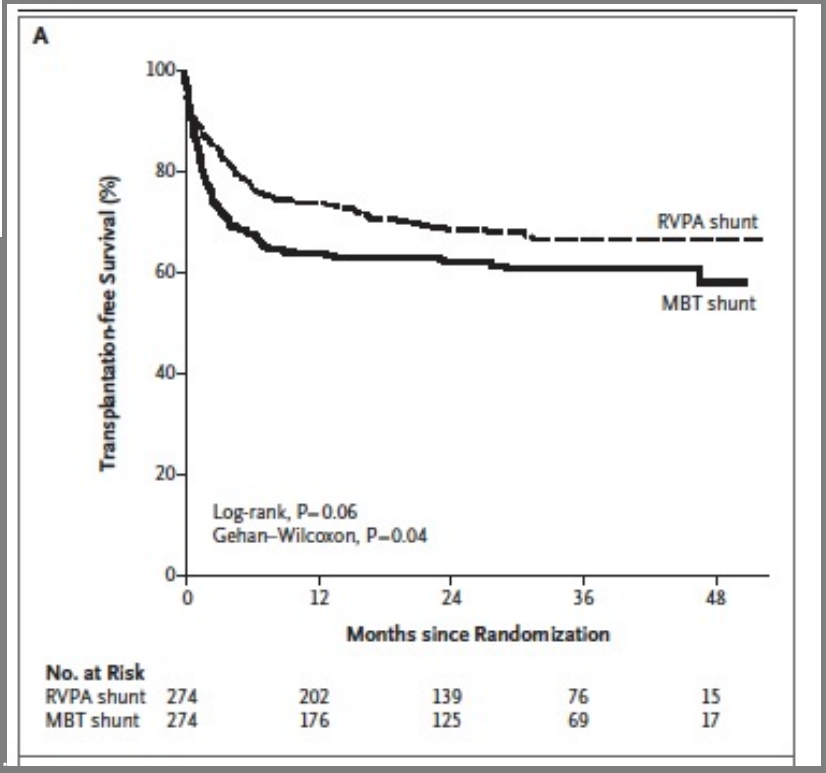
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Comparison of Shunt Types in the Norwood Procedure for Single-Ventricle Lesions

Richard G. Ohye, M.D., Lynn A. Sleeper, Sc.D., Lynn Mahony, M.D., Jane W. Newburger, M.D., M.P.H., Gail D. Pearson, M.D., Sc.D., Minmin Lu, M.S., Caren S. Goldberg, M.D., Sarah Tabbutt, M.D., Ph.D., Peter C. Frommelt, M.D., Nancy S. Ghanayem, M.D., Peter C. Laussen, M.B., B.S., John F. Rhodes, M.D., Alan B. Lewis, M.D., Seema Mital, M.D., Chitra Ravishankar, M.D., Ismee A. Williams, M.D., Carolyn Dunbar-Masterson, B.S.N., R.N., Andrew M. Atz, M.D., Steven Colan, M.D., L. LuAnn Minich, M.D., Christian Pizarro, M.D., Kirk R. Kanter, M.D., James Jaggers, M.D., Jeffrey P. Jacobs, M.D., Catherine Dent Krawczeski, M.D., Nancy Pike, R.N., Ph.D., Brian W. McCrindle, M.D., M.P.H., Lisa Virzi, R.N., M.S., M.B.A., and J. William Gaynor, M.D., for the Pediatric Heart Network Investigators

- **As reported by Dr. Ohye at the AHA 2009**
  - **~12 centers in PHN**
- **Death/txp at 1 year post-op**
  - **36% Norwood**
  - **26% Sano**
- **Serious (non-fatal) complications**
  - **~30% both groups**



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J Thorac Cardiovasc Surg. 2019 Jul;158(1):220-229. doi: 10.1016/j.jtcvs.2018.12.117. Epub 2019 Feb 28.

Thirty years and 1663 consecutive Norwood procedures: Has survival plateaued?

Mascio CE[1], Irons ML[2], Ittenbach RF[3], Gaynor JW[4], Fuller SM[4], Kaplinski M[5], Kennedy AT[6], Steven JM[7], Nicolson SC[7], Spray TL[4].

Author information

Abstract

OBJECTIVE: Hypoplastic left heart syndrome is one of the most common and challenging lesions requiring surgical intervention in the neonatal period. The Norwood procedure for hypoplastic left heart syndrome was first reported in 1983. The objective of this study was to describe early outcomes after the Norwood procedure at a single institution over 30 years.

METHODS: This retrospective cohort study included all patients with hypoplastic left heart syndrome (and variants) who underwent the Norwood procedure between January 1984 and May 2014 at a single institution. The study period was divided into 6 eras: era 1, 1984 to 1988; era 2, 1989 to 1993; era 3, 1994 to 1998; era 4, 1999 to 2003; era 5, 2004 to 2008; and era 6, 2009 to 2014. The primary outcome was in-hospital mortality after the Norwood procedure. Binomial point estimates complete with 95% confidence intervals ($CL_{0.95}$) were computed for the entire cohort and by era.

RESULTS: During the study period, 1663 infants underwent the Norwood procedure. Overall in-hospital mortality was 25.9% ($CL_{0.95}$, 23.8-28.0). Mortality by chronologic era was 40.4% ($CL_{0.95}$, 34.9-45.9), 33.6% ($CL_{0.95}$, 29.2-37.9), 28.7% ($CL_{0.95}$, 22.8-34.6), 14.9% ($CL_{0.95}$, 10.4-19.3), 11.2% ($CL_{0.95}$, 7.4-15.0), and 15.7% ($CL_{0.95}$, 10.3-21.1). Survival was improved in eras 4 to 6 compared with eras 1 to 3 (P all < .03). Anomalous pulmonary drainage, moderate to severe atrioventricular valve regurgitation, lower birth weight, earlier era, younger gestational age, genetic anomaly, preterm birth, race other than white or African-American, and lower weight at the Norwood procedure were associated with increased mortality. Mortality was greatest in patients with 3 or more risk factors. In the best-fitting multiple covariate model, anomalous pulmonary venous drainage, gestational age in weeks, genetic anomaly, and race other than white and African American were statistically significant contributors, after adjusting for era.

CONCLUSIONS: Survival after the Norwood procedure has plateaued despite improvements in diagnosis, perioperative care, and surgical techniques. Nonmodifiable patient characteristics are important determinants of the risk of mortality.

Morbidity

- Neurologic & Developmental Morbidity
  - After Norwood repair: Full Scale IQ
    - Kern, et al: 91
    - Mahle, et al: 86
    - Goldberg, et al: 94
  - After Cardiac Transplantation: Full Scale IQ
    - Ikle, et al: 89
  - Abnormalities of speech & language, oral aversion & poor feeding, poor adaptive behavior, & growth failure
  - Later, there is significant emotional & behavior dysfunction, low self esteem, & psychosocial and physical health issues
    - Wernovsky & Newburger, JPeds, Vol 142: Jan, 2003

Resource Utilization

MMWR Morb Mortal Wkly Rep. 2007 Jan 19;56(2):25-9. Centers for Disease Control and Prevention (CDC)

Hospital stays, hospital charges, and in-hospital deaths among infants with selected birth defects--United States, 2003.

Analysis of resource utilization for the 35 most common birth defects showed that the Norwood procedure is associated with the highest cost and the third longest length of stay.

The most expensive average neonatal hospital charges were for two congenital heart defects: hypoplastic left heart at $199,597 and common truncus arteriosus at $192,781

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Comparison of Shunt Types in the Norwood Procedure for Single-Ventricle Lesions

Richard G. Ohye, M.D., Lynn A. Sleeper, Sc.D., Lynn Mahony, M.D., Jane W. Newburger, M.D., M.P.H., Gail D. Pearson, M.D., Sc.D.,

Table 2. Outcomes and Adverse Events According to Shunt Assignment.*

Outcome	Norwood Hospitalization			Stage II Hospitalization			From Randomization to 12 Months		
	RVPA Shunt (N=274)	MBT Shunt (N=275)	P Value	RVPA Shunt (N=214)	MBT Shunt (N=184)	P Value	RVPA Shunt (N=274)	MBT Shunt (N=275)	P Value
Primary outcome									
Death or cardiac transplantation at 12 months — %							26.3	36.4	0.01
No. of outcome events							72	100	
Hospital morbidity									
Time to initial extubation — hr			0.41			0.19			
Median	126	126		22.9	16.5				
Interquartile range	85–192	91–219		7.6–40.4	5.3–33.8				
Median time on ventilator — days	7	7	0.29	2	2				
Median length of stay in intensive care unit — days	14.0	14.0	0.82	4.0	4.0				
Median length of postoperative hospital stay — days	24.0	24.0	0.80	8.0	8.0				
Open sternum — %	74	76	0.62	0	0				
Extracorporeal membrane oxygenation — %	8	12	0.26	0	0				
Cardiopulmonary resuscitation — %	13	20	0.04	3	3				

Combined LOS = 32days ECMO use = ~10%

Delayed sternal closure = ~75%

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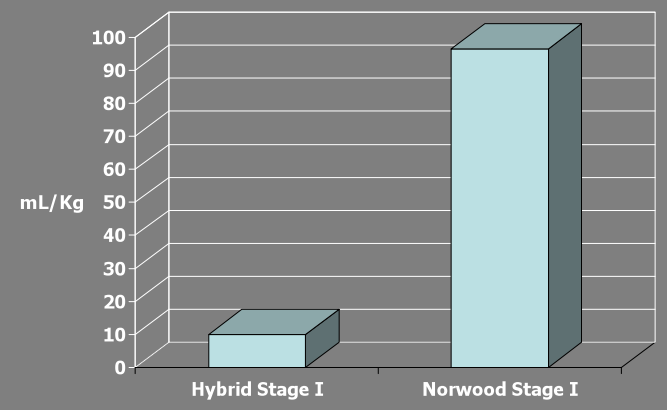
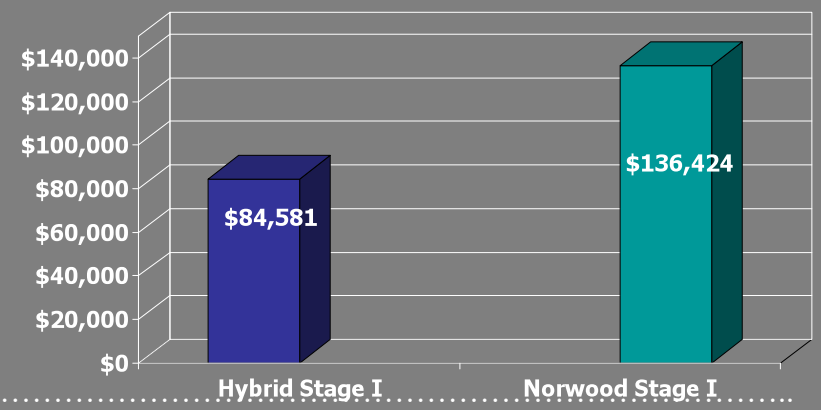
NCH Results: Combined Hybrid 1&2 (including interstage)

Intra-operative Blood Utilization



Patient Charges



- Combined LOS = 21days
- ECMO = 0
- Delayed sternal closure = 0

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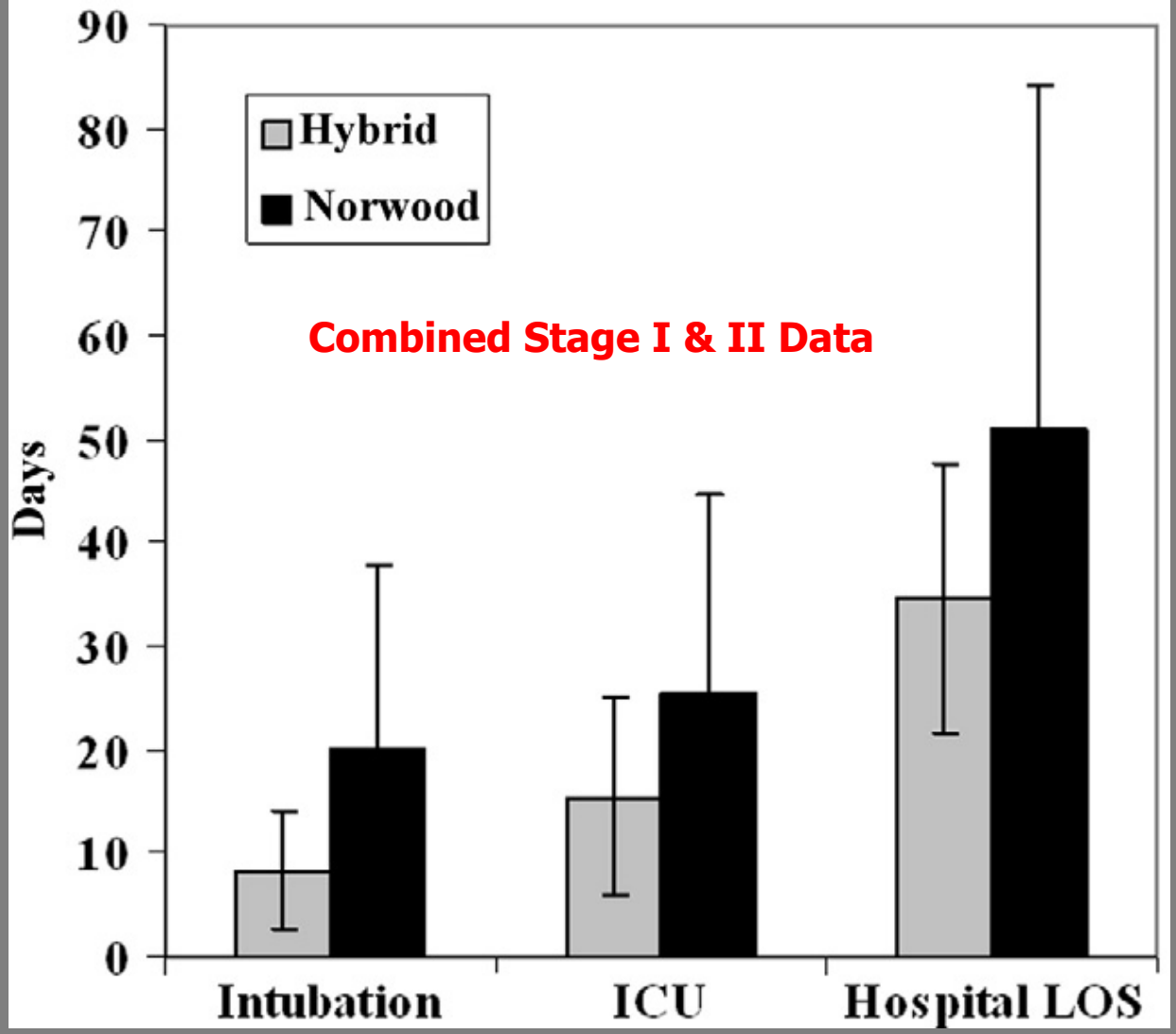

Clinical Outcomes, Program Evolution, and Pulmonary Artery Growth in Single Ventricle Palliation Using Hybrid and Norwood Palliative Strategies

Osami Honjo, MD, et al. Ann Thorac Surg 2009;87:1885–93

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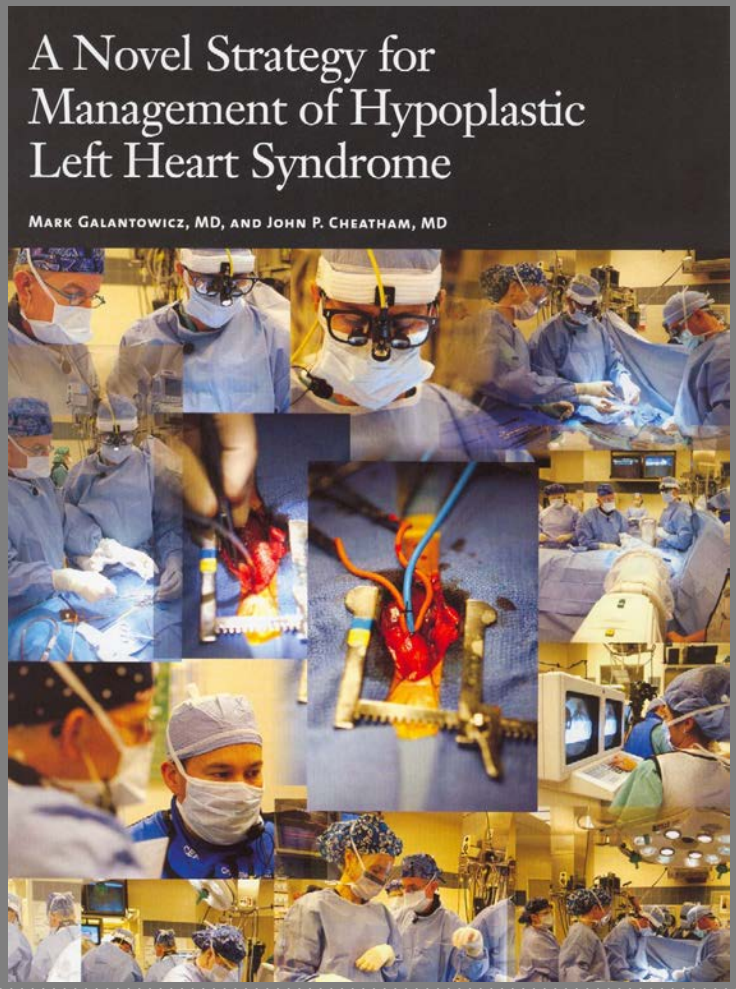
Current Indications



Bridge to Recovery

- Hybrid Stage 1 procedure can effectively be used as a bridge to recovery and/or decision.
  - can salvage a late diagnosis patient
  - allow co-morbid states to improve; intra-cranial bleed, renal insufficiency
  - stabilize for other non-cardiac procedures; CDH
  - allow cardiac recovery; RV fxn, TR
  - allow education and time for family to decide what they want

Pediatr Cardiol. 2009 Jan;30(1):77-9. Epub 2008 Jul 15.

"Rapid two-stage" Norwood operation in a child with multiorgan failure.

Schmitz C, Schirrmeister J, Herberg U, Kozlik-Feldmann R, Stüber F, Welz

Department of Cardiac Surgery, University of Munich, Marchioninistr. 15, 81377 Munich, Germany.
christoph.schmitz@med.uni-muenchen.de

Ann Thorac Surg. 2003 Jan;75(1):277-9.

Bilateral pulmonary artery banding for resuscitation in hypoplastic left heart syndrome.

Ishizaka T, Ohye RG, Suzuki T, Devaney EJ, Bove EL.

Abstract

We report a case of a hypoplastic left heart syndrome with a nearly intact atrial septum and an obstructed anomalous pulmonary to systemic venous connection. Surgical atrial septectomy followed by bilateral pulmonary artery banding provided an optimal condition for the Norwood operation.

Delayed traditional approach

- Can even use the Hybrid Stage 1 procedure to delay an eventual Norwood or Sano palliation.
  - Theoretically, bridging a baby out of a neurologically vulnerable period to a potentially safer age to undergo open heart surgery.

Eur J Cardiothorac Surg. 2009 Dec;36(6):973-9. Epub 2009 Jul 8.

Early results of bilateral pulmonary artery banding for hypoplastic left heart syndrome.

Sakurai T Kado H, Nakano T, Hinokiyama K, Shiose A, Kajimoto M, Joo K, Ueda Y.

Department of Cardiovascular Surgery, Fukuoka Children's Hospital, 2-5-1 Toujinmachi, Chuuo-ku, Fukuoka, 810-0063, Japan.

"In conclusion, our study supports the use of PAB with PGE1 for the management of HLHS. Bilateral PAB with continuous PGE1 administration may improve early and intermediate mortality..."

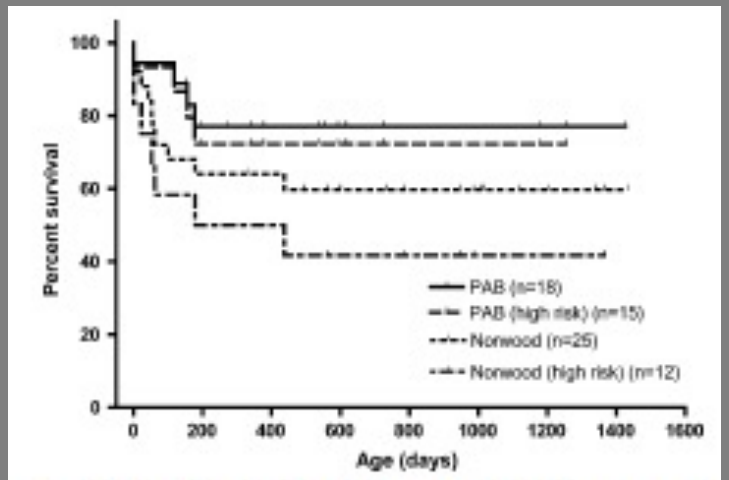


Fig. 1. Kaplan–Meier actuarial survival curves according to the management of strategy and for the high-risk patients in each group.

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4 Stage Hybrid Approach

- Modified Hybrid Stage 1
  - Branch PA bands + PGE1 for 6 weeks
  - Optimizing the time for brain maturation and pulmonary vasculature maturation/stabilization while balancing the ease of PA band removal and preserved PA size/compliance
- Stage 2 = Norwood or Sano + PA band removal
- Stage 3 = Glenn or hemi-Fontan
- Stage 4 = Fontan

Bridge to Heart Transplant

- Hybrid Stage 1 can be an effective bridge to heart transplantation.

REVIEW

A Review of Ductal Stenting in Hypoplastic Left Heart Syndrome: Bridge to Transplantation and Hybrid Stage I Palliation

D. J. DiBardino, D. B. McElhinney, A. C. Marshall and E. A. Bacha

"Off-pump palliation followed by heart transplant or further staged palliation should be considered for these hypoplastic left heart syndrome patients."

Artrip, et al; Ann Thorac Surg 2006;82:1259-9

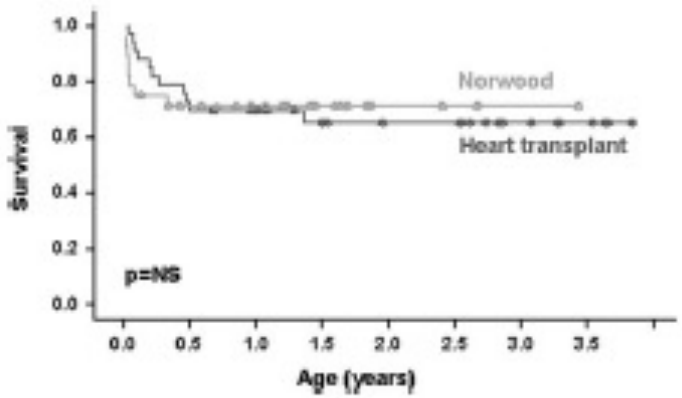

Fig 1. Kaplan–Meier survival curves. There was no statistical difference between midterm survival for patients referred for a Norwood procedure or heart transplantation.

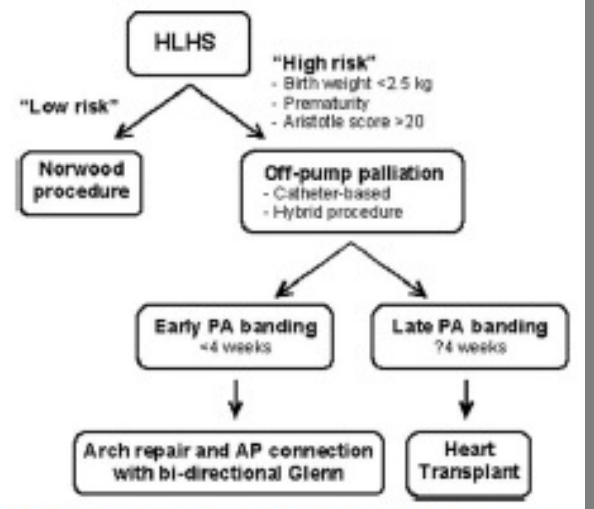

Fig 2. Denver Children's Hospital 2005 protocol for the treatment of hypoplastic left heart syndrome (HLHS) patients. (PA = pulmonary artery.)

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Bridge to 2V repair

- Hybrid Stage 1 procedure can be used as a bridge to a two ventricle repair in patients with suboptimal neonatal outcomes in a particular center or diagnosis.
  - e.g. IAA/VSD
- Hybrid Stage 1 can be helpful in the assessment of and decision making in hypoplastic left heart complex patients with a borderline left ventricle.

PEDIATRIC CARDIOLOGY
Volume 28, Number 2, 79-87, DOI: 10.1007/s00246-006-1444-7

ORIGINAL ARTICLE

Hybrid Transcatheter–Surgical Palliation

Basis for Univentricular or Biventricular Repair: The Giessen Experience

Hakan Akintürk, Ina Michel-Behnke, Klaus Valeske, Matthias Mueller, Josef Thul, Juergen Bauer, Karl-Juergen Hagel a Dietmar Schranz

"Using hybrid palliation ….. and observation for left ventricular growth suitable for biventricular repair as well. The actuarial survival rate for patients with BVR is 93%. "

High-risk patients

- Hybrid Stage 1 procedure is an effective palliation for high-risk HLHS patients and the most common indication for a hybrid stage 1.
  - Growing data showing superiority for hybrid approach with prematurity and low birth weight.

Single-ventricle palliation for high-risk neonates: The emergence of an alternative Hybrid stage I strategy

Emile A. Bacha, Suanne Daves, Joel Hardin, Ra-id Abdulla, Jennifer Anderson, Madelyn Kahana, Peter Koenig, Bassem N. Mora, Mehmet Gulecyuz, Joanne P. Starr, Ernerio Alboliras, Satinder Sandhu and Ziyad M. Hijazi

J Thorac Cardiovasc Surg 2006;131:163-171

Conclusion

"The hybrid stage I palliation is a valid option in high-risk neonates. As experience is accrued, it may become the preferred alternative."

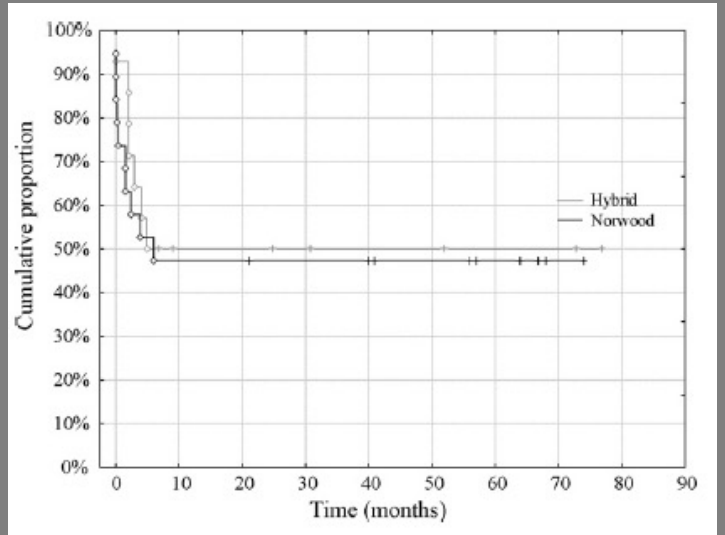

Fig. 3. Kaplan–Meier actuarial survival according to management strategy.

J Thorac Cardiovasc Surg 2010;139:1211-1215

Hybrid procedure as an alternative to surgical palliation of high-risk infants with hypoplastic left heart syndrome and its variants

Prem S. Venugopal, MCh, FRCS, Karyn P. Luna, MD, David R. Anderson, FRCS, Conal B. Austin, FRCS, Eric Rosenthal, FRCP, MRCPCH, Thomas Krasemann, MD, Shakeel A. Qureshi, FRCP*

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Standard-risk patients

- Hybrid Stage 1 procedure has at least equivalent results to traditional approaches for standard risk HLHS patients.

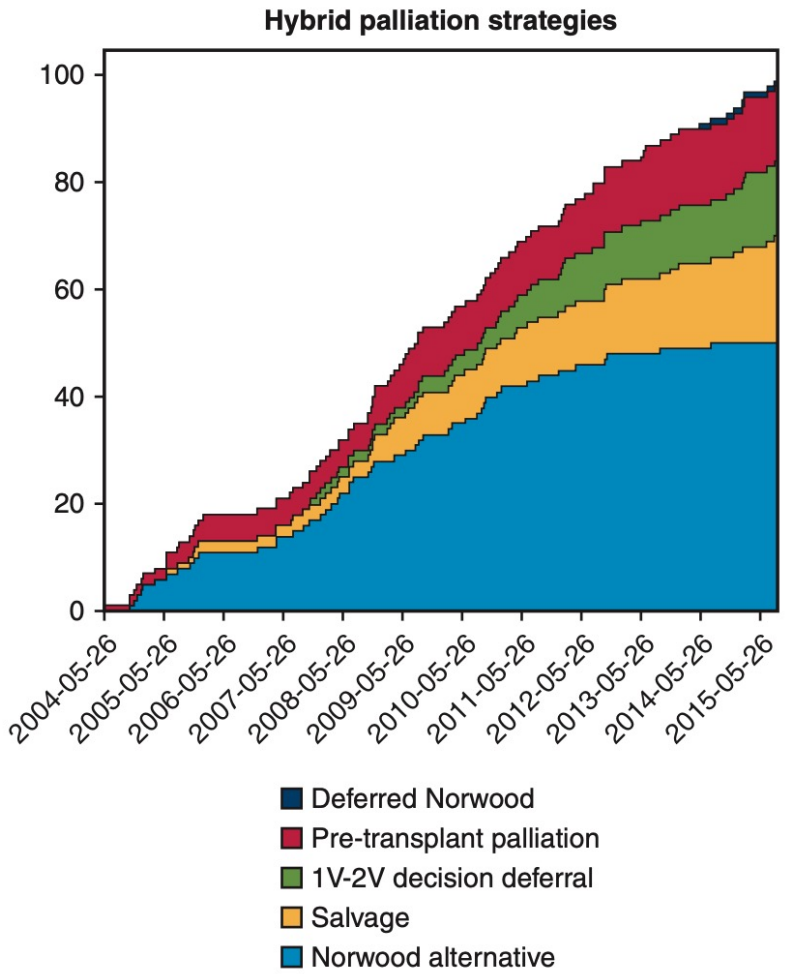


FIGURE 1. Shifting palliation strategies. Cumulative sum plot indicating the pattern of hybrid use over an 11-year period at the Hospital for Sick Children based on palliation strategy (ie, indication). In recent years, there is a decreased trend toward the use of hybrid as a Norwood alternative, whereas deferred Norwood and univentricular-biventricular decision deferral strategies have increased. *1-V*, Univentricular; *2-V*, biventricular.

Wilder T.J. • Caldarone C.A.

Apples to oranges: making sense of hybrid palliation for hypoplastic left heart syndrome.

J Thorac Cardiovasc Surg Open. October 15, 2020; ([Epub

NCH Experience to date

- 276 Hybrid Stage 1
- 211 Comprehensive Stage 2
- 131 Fontan s/p hybrid 1

Hybrid Stage 1

NCH Experience
long-term

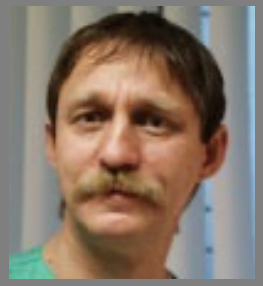
- 82% survival at 5 years
- 78% survival, standard risk pts, at 12 years
  - 65% overall including high risk (97pts)
  - Only 19 pts bridged to two ventricle repair

Hybrid Treatment of HLH-(S): the Giessen experience

Pediatric Heart Center Giessen

Dietmar Schranz

Ina Michel-Behnke

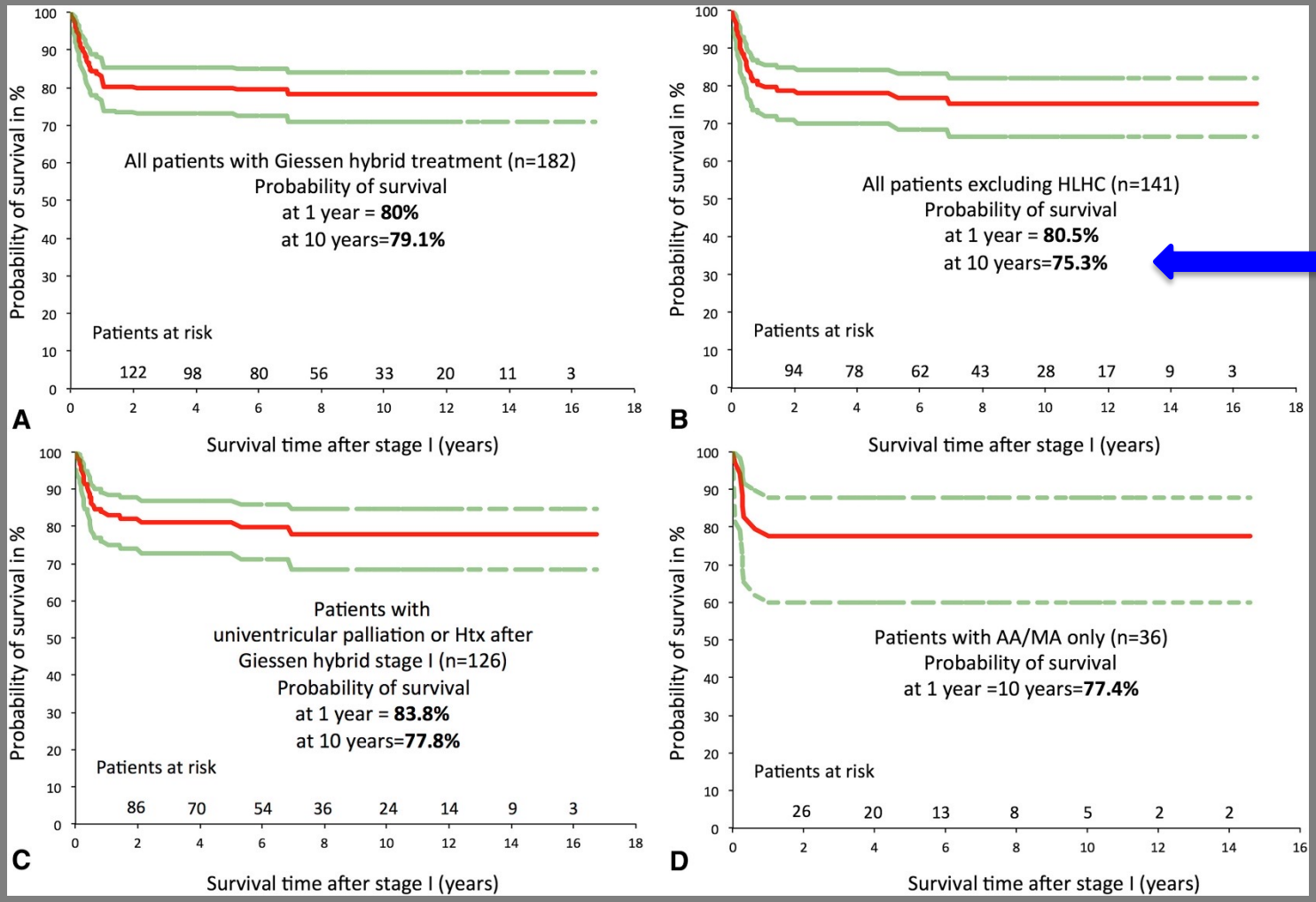


Jürgen Bauer

Hakan Akintürk

JUSTUS-LIEBIG-UNIVERSITÄT GIESSEN

Giessen long-term outcomes



The Journal of Thoracic and Cardiovascular Surgery 2016 151, 1112-1123.e5DOI: (10.1016/j.jtcvs.2015.10.066)
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Smaller brain volumes at two years of age in patients with hypoplastic left heart syndrome - Impact of surgical approach

Walter Knirsch [a,b,*], Kristina N. Heye [a,b,c], Ruth O'Gorman Tuura [b,c], Andreas Hahn [d], Kristina Wetterling [e], Beatrice Latal [b,f], Dietmar Schranz [g], Bettina Reich [g]

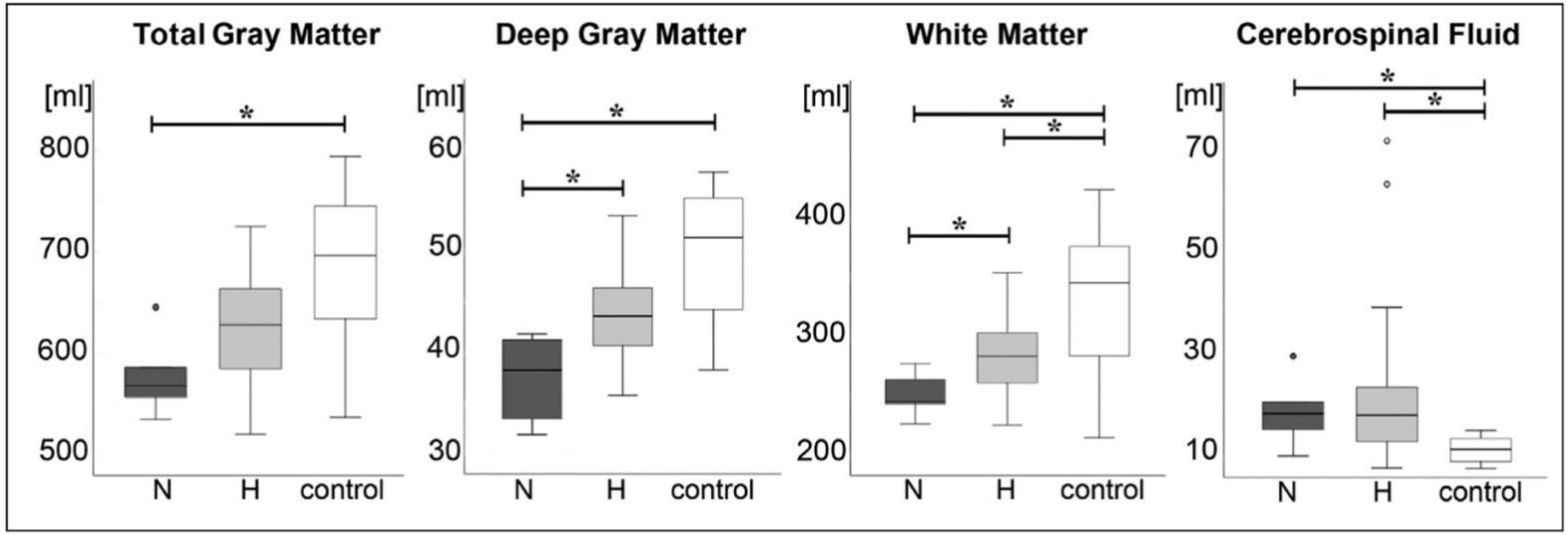

Fig. 1. The graphs show brain volumes of HLHS patients at two to three years of age, with median and interquartile range. Patients received either Hybrid (H, n = 24, light gray bars), Norwood operation (N, n = 5, dark gray bars), or were healthy toddlers (n = 8, control, white bars). Circles represent outliers. Significant differences between patients in deep gray matter volumes, white matter volumes, and cerebrospinal fluid (CSF) are displayed (*<0.05). p-Values by Student's *t*-test or Mann-Whitney *U* test.

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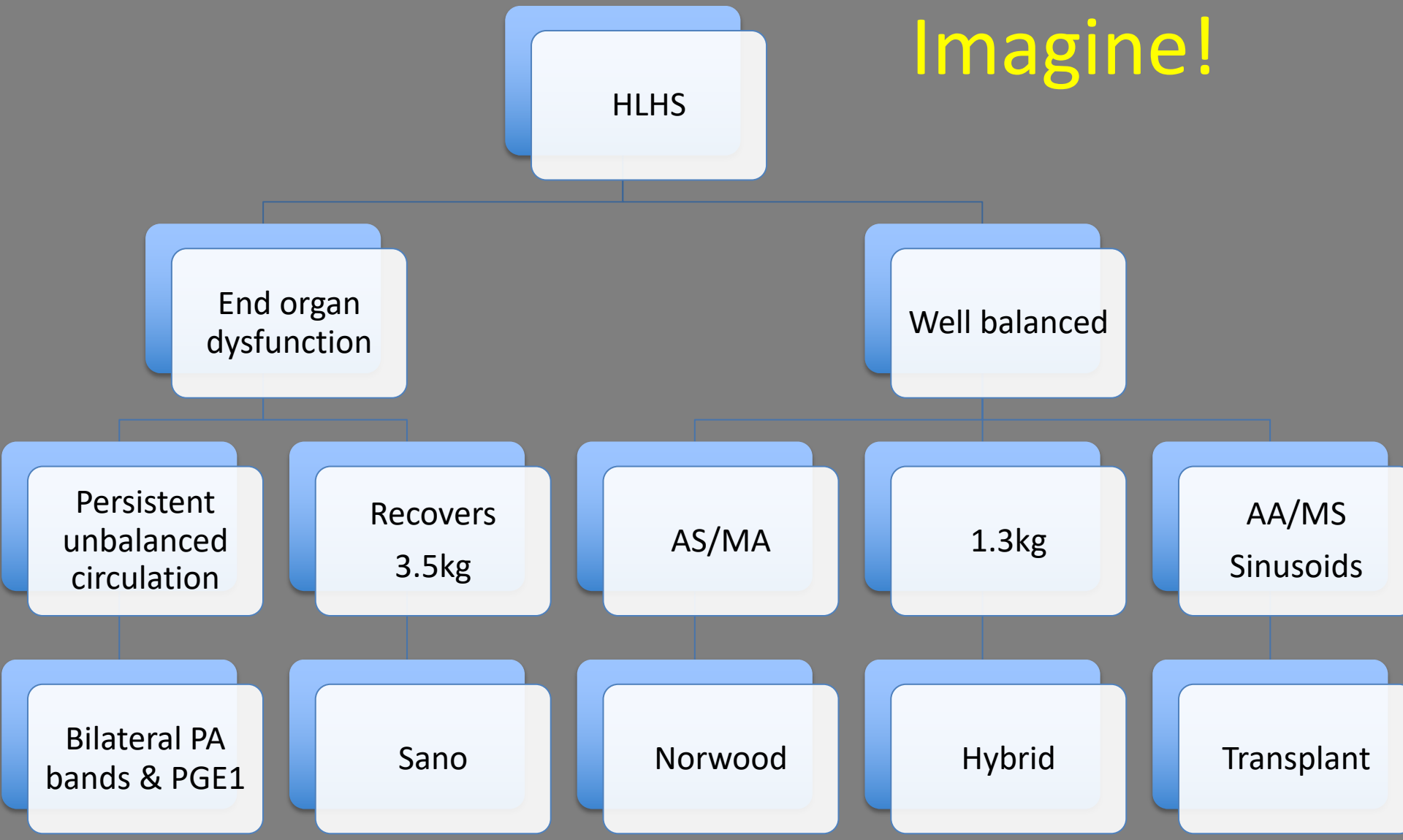
Conclusion - 1

- The Hybrid Approach indications are many, not just for high-risk babies.
- Therefore data is difficult to interpret given varied intentions for hybrid usage, varied patient risk profile, varied procedural/technical elements, differing levels on the learning curve, as well as natural evolution of the hybrid stage 1
- The question is no longer whether or not to use a Hybrid Approach for HLHS, but when best to use it.
- Or more importantly, evolving to more individualized care matching the best procedure to the appropriate subtype of HLHS.

Imagine!

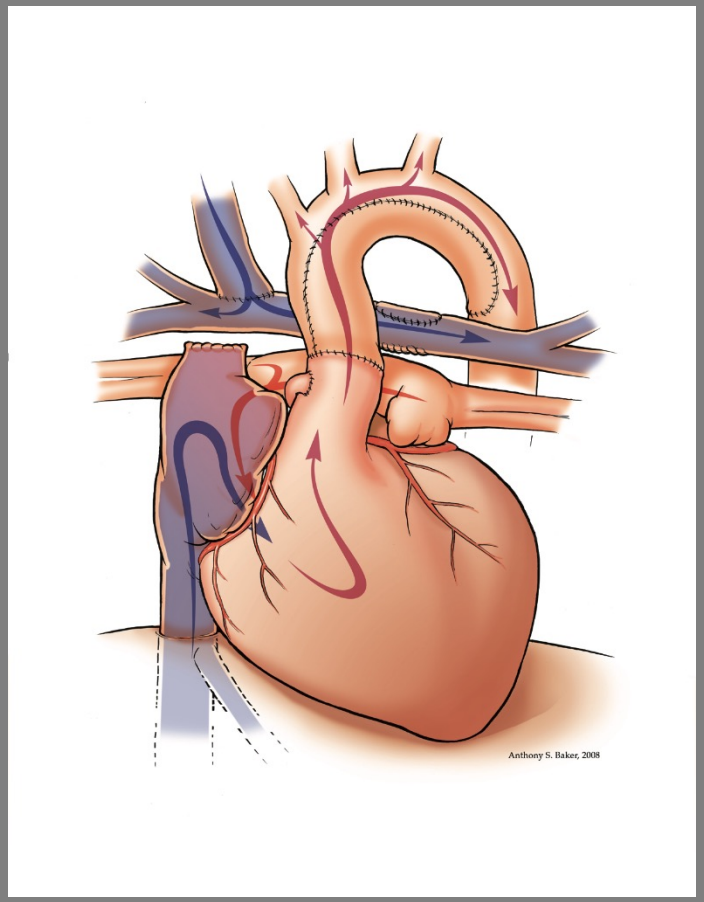

HLHS
End organ dysfunction
Well balanced
Persistent unbalanced circulation
Recovers 3.5kg
AS/MA
1.3kg
AA/MS Sinusoids
Bilateral PA bands & PGE1
Sano
Norwood
Hybrid
Transplant

Comprehensive Stage 2 Challenge

- We need to think of the Hybrid Approach as 3 important elements; Hybrid Stage 1, the Comprehensive Stage 2, and the inter-stage period between them.
- Close collaboration between surgery and interventional cardiology teams is imperative throughout the Hybrid Stage 1, Comprehensive Stage 2, and inter-stage phases to optimize outcomes.
- Beware of infrequent usage of the Hybrid Stage 1 which limits experience with subsequent management strategies creating a perpetual learning curve.

Comprehensive Stage 2 Procedure

- PDA stent removal
- Aortic arch reconstruction
- Ascending Ao anastomosed to MPA
- MPA to Aorta anastomosis
- PA debanding, possible LPA reconstruction
- Bidirectional Glenn
- Atrial septectomy
- At 4-6 months of age
- Can be performed on bypass without a period of circulatory arrest, without any aortic cross-clamping, and even without blood transfusion



Comprehensive Stage 2

60	ASD creation/enlargement	2.5	4
*2170	Hybrid Approach "Stage 1", Stent placement in arterial duct (PDA)	2.5	4
80	Atrial septal fenestration	2.6	4
480	Valve closure, Tricuspid (Exclusion, Univentricular approach)	2.6	4
*2160	Hybrid Approach "Stage 1", Application of RPA and LPA bands	2.6	4
1660	Damus-Kaye-Stansel procedure (DKS) (Creation of AP anastomosis without arch reconstruction)	2.9	5
*2200	TAPVC repair + Shunt - Systemic to pulmonary	3	5
*2180	Hybrid Approach "Stage 1", Stent placement in arterial duct (PDA) + application of RPA and	3.1	5
900	Transplant, Heart and lung	3.2	5
1060	Congenitally corrected TGA repair, Atrial switch and Rastelli	3.2	5
1050	Congenitally corrected TGA repair, Atrial switch and ASO (Double switch)	3.4	5
****2755	Conduit insertion right ventricle to pulmonary artery + Intraventricular tunnel left ventricle to neoaorta + Arch reconstruction (Rastelli and Norwood type arch reconstruction) (Yasui)	3.6	5
*2150	Hybrid approach "Stage 2", Aortopulmonary amalgamation + Superior Cavopulmonary anastomosis(es) + PA Debanding + Without aortic arch repair	3.6	5
870	Norwood procedure	4	5
2140	Hybrid approach "Stage 2", Aortopulmonary amalgamation + Superior Cavopulmonary anastomosis(es) + PA Debanding + Aortic arch repair (Norwood [Stage 1] + Superior Cavopulmonary anastomosis(es) + PA Debanding)	4.1	5
**2220	Truncus + IAA Repair	5	5

Comprehensive Stage 2 at NCH

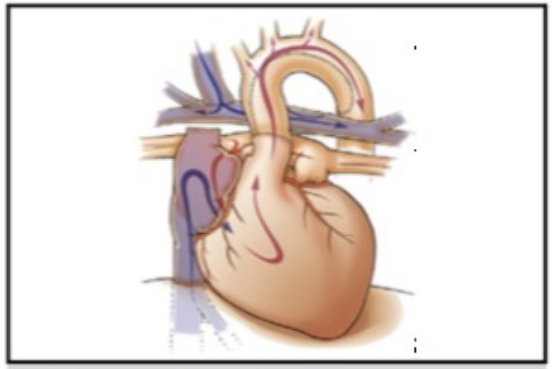
Improved outcomes with the comprehensive stage 2 procedure after an initial hybrid stage 1

Mark Galantowicz, MD,[a,b,d] and Andrew R. Yates, MD[a,c,e]

ABSTRACT

Objective: To report our improving institutional experience with the hybrid alternative surgical strategy for the management of hypoplastic left heart syndrome, in which hybrid stage 1 is followed by a comprehensive stage 2 procedure (removal of patent ductus arteriosus stent and pulmonary artery [PA] bands, aorta and PA reconstruction, Damus–Kaye–Stansel, atrial septectomy, Glenn).

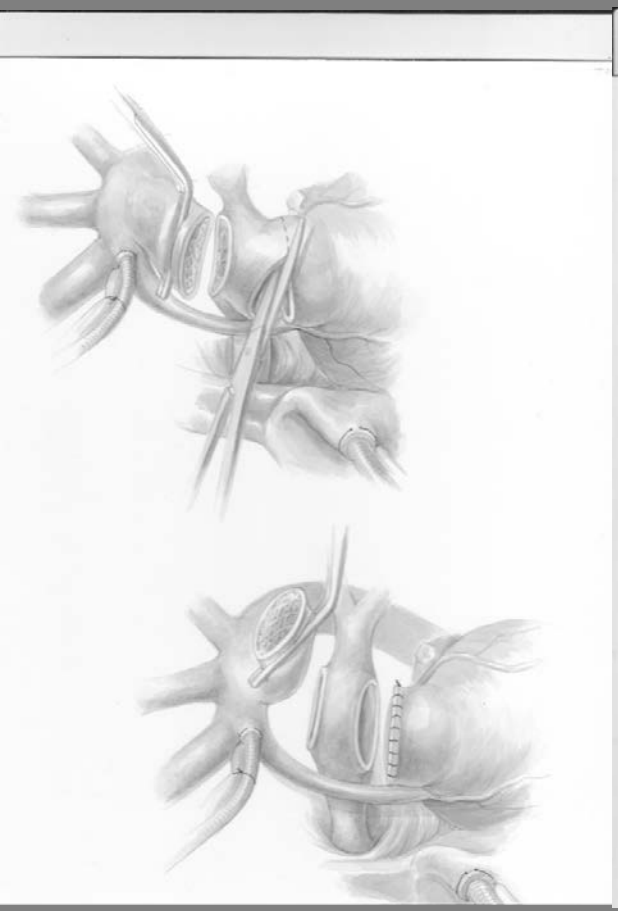
Methods: In this Institutional Review Board–approved retrospective review of all patients undergoing a comprehensive stage 2 procedure between January 2002 and December 2014, data were compared between the pre-protocol group

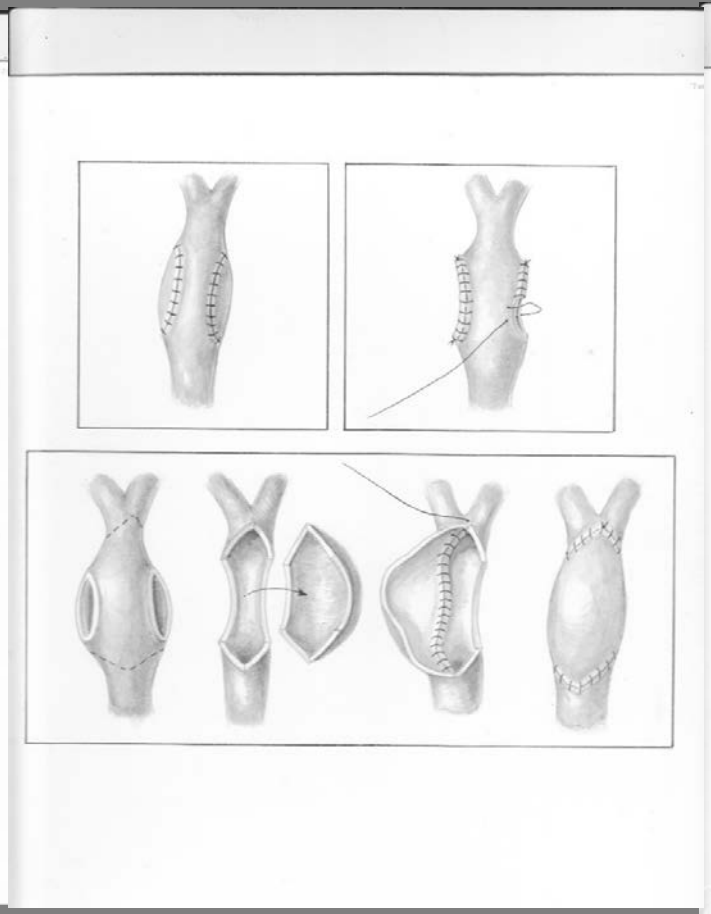


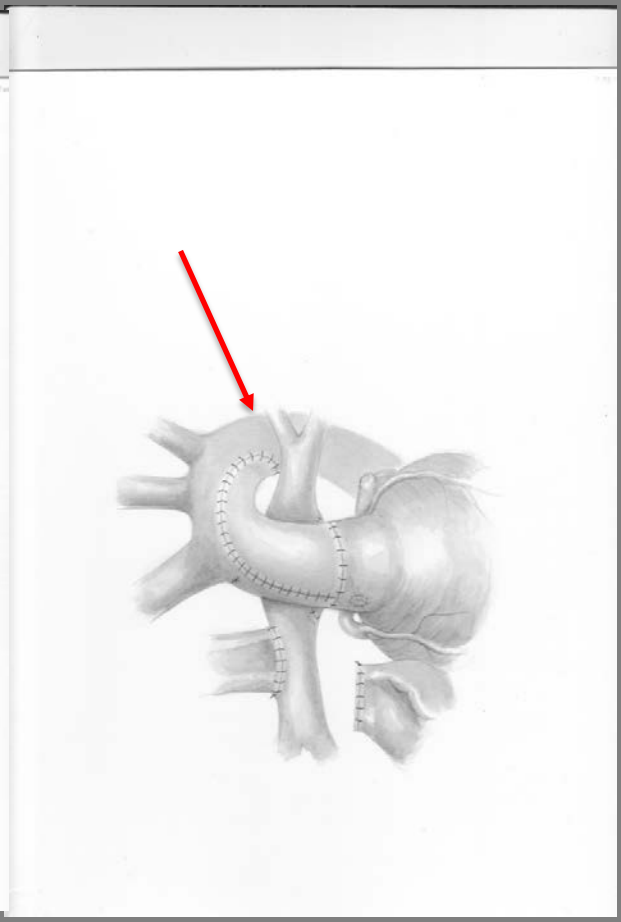
Comprehensive stage 2 procedure.

- 4% mortality

Comprehensive Stage 2

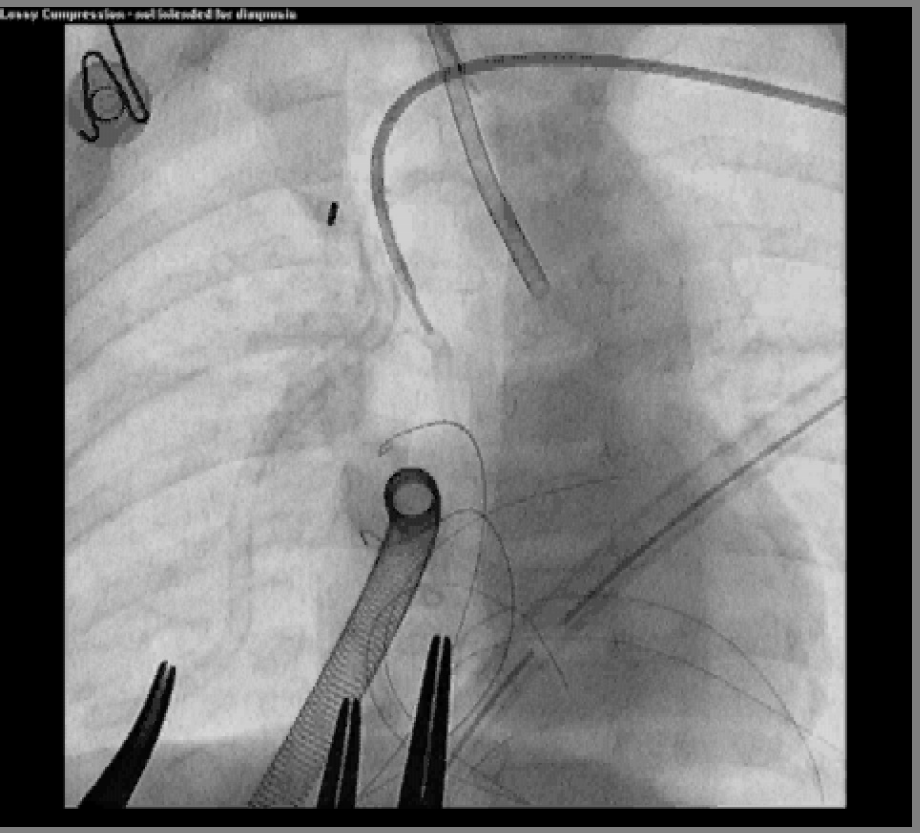


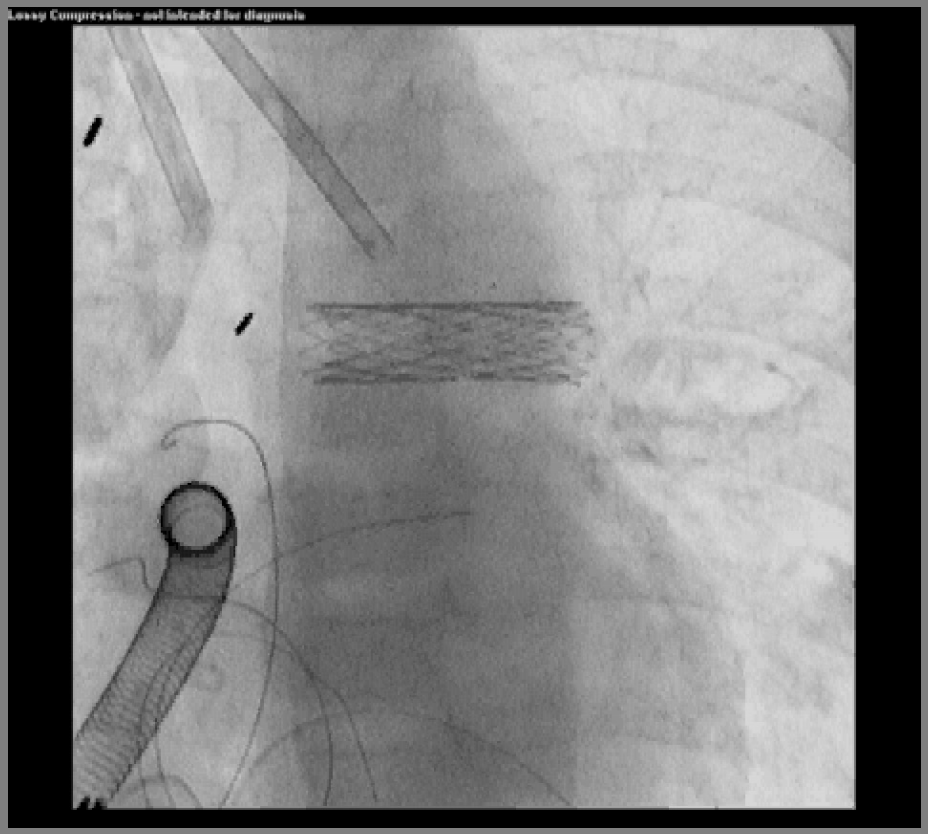




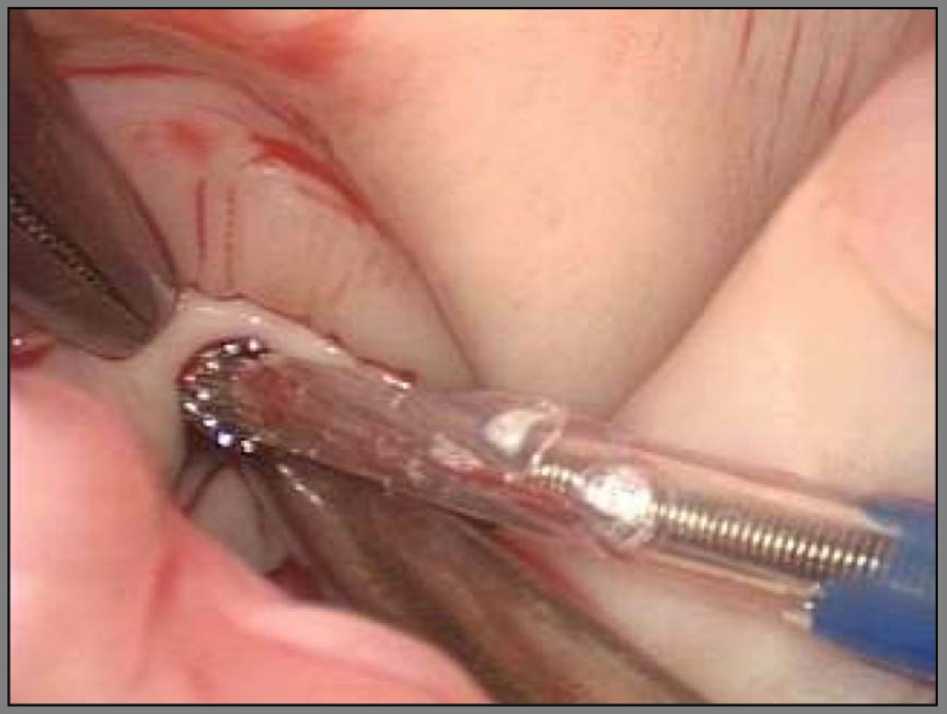
Comprehensive Stage 2 Exit Angiogram

Exit Angiogram with Hybrid PA stenting





Pre-emptive Hybrid LPA stenting during the Comprehensive Stage 2



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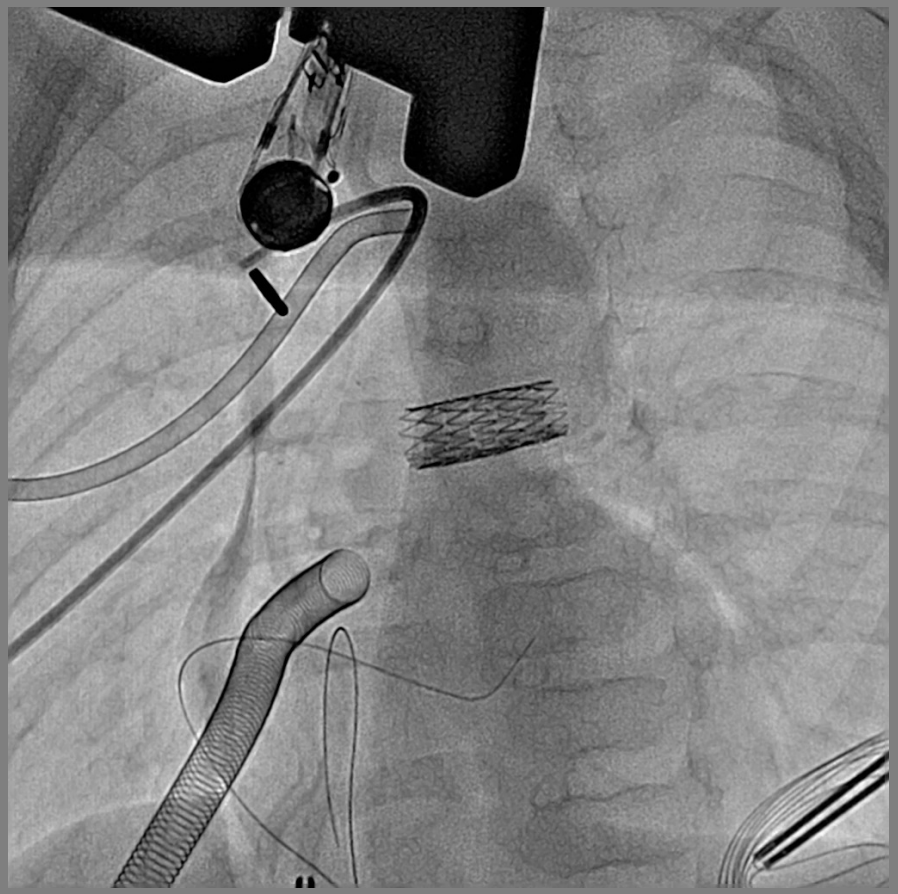
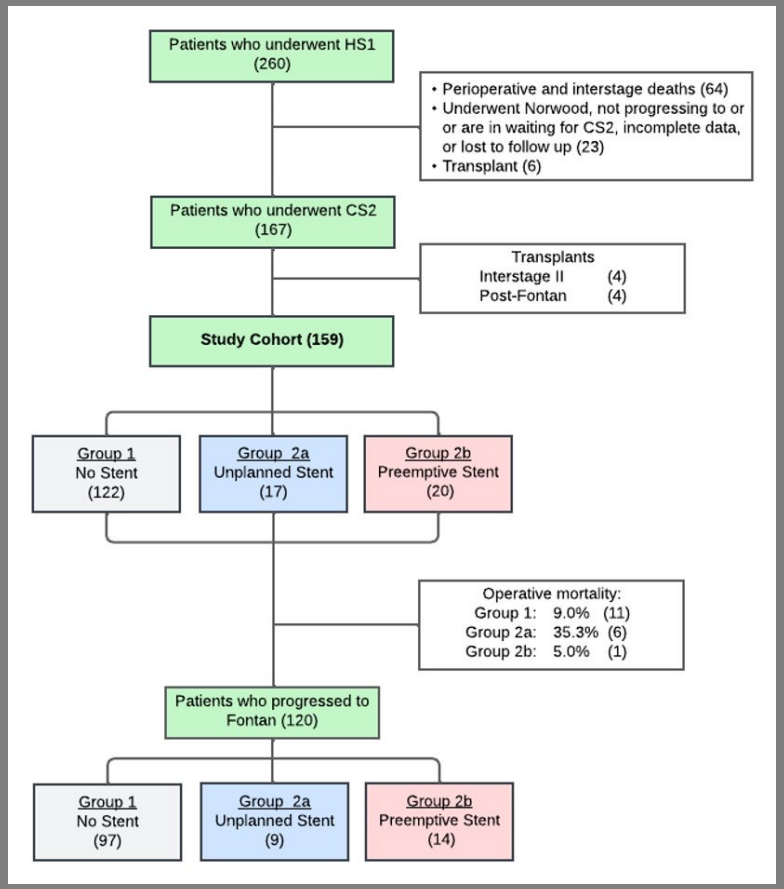
Completion Angiogram



Does Pre-emptive LPA stenting effect Fontan outcomes.

Presented at the 2022 AATS meeting



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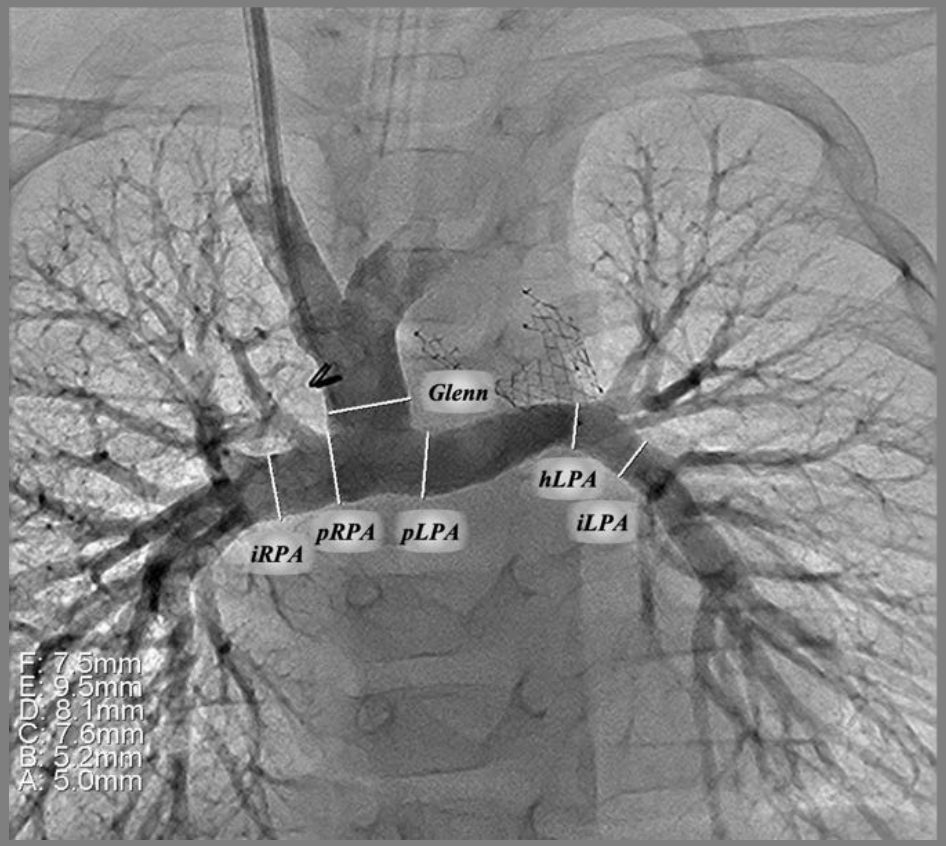
Operative characteristics at the Comprehensive Stage 2

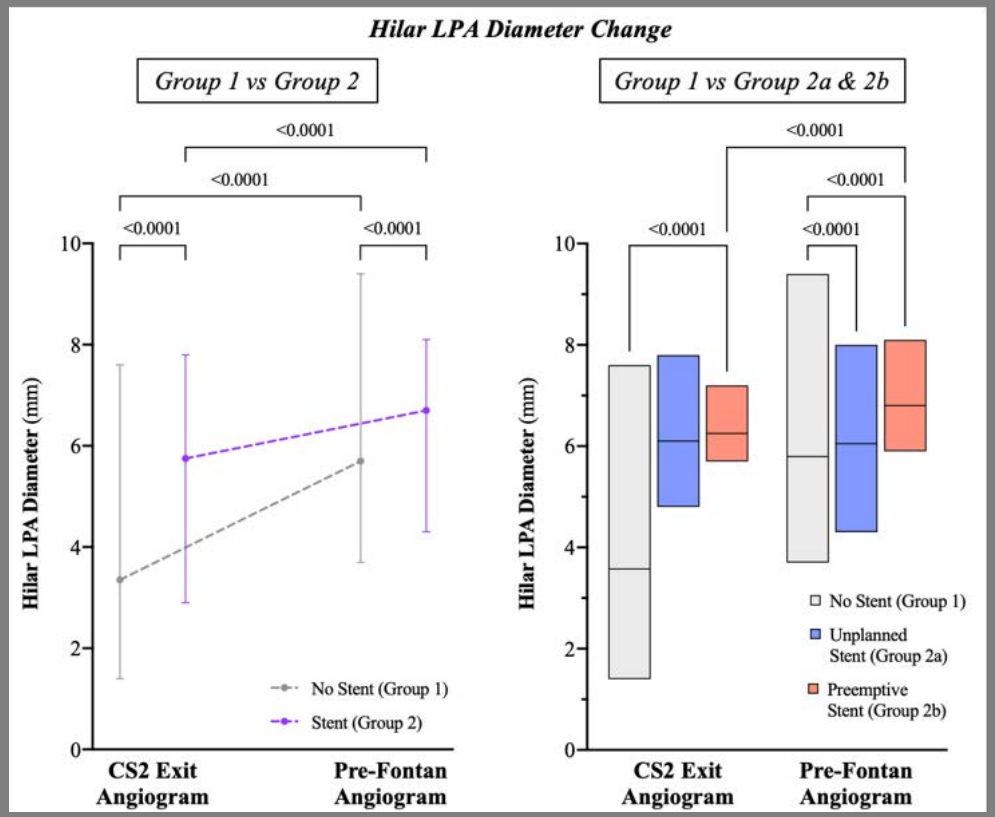
Parameter	Group 1	Group 2	Group 2a	Group 2b
	No Stent	**Stent**	**Unplanned**	**Preemptive**
Weight (kg)	6.24 (± 1.18)	6.42 (± 0.80)	6.36 (± 0.63)	6.47 (± 0.94)
Age (m)	5.89 (± 1.83)	5.55 (± 0.94)	5.58 (± 0.97)	5.58 (± 0.97)
CBP Time (min)	277.61 (± 58.41)	259.14 (± 70.08)	303.29 (± 74.24)	221.60 (± 37.90)
XC Time (min)	54.35 (± 48.47)	30.92 (± 33.14)	42.06 (± 34.93)	21.45 (± 29.12)
DHCA Time (min)	3.52 (± 13.82)	7.92 (± 23.76)	12.12 (± 28.03)	4.35 (± 19.45)
Length of Stay (day)	23.53 (± 38.48)	25.88 (± 28.48)	34.82 (± 27.72)	18.28 (± 27.52)
In-hospital Operative Mortality	**9.0% (n=11/122)**	**18.9% (n=7/37)**	**35.3% (n=6/17)**	**5% (n=1/20)**

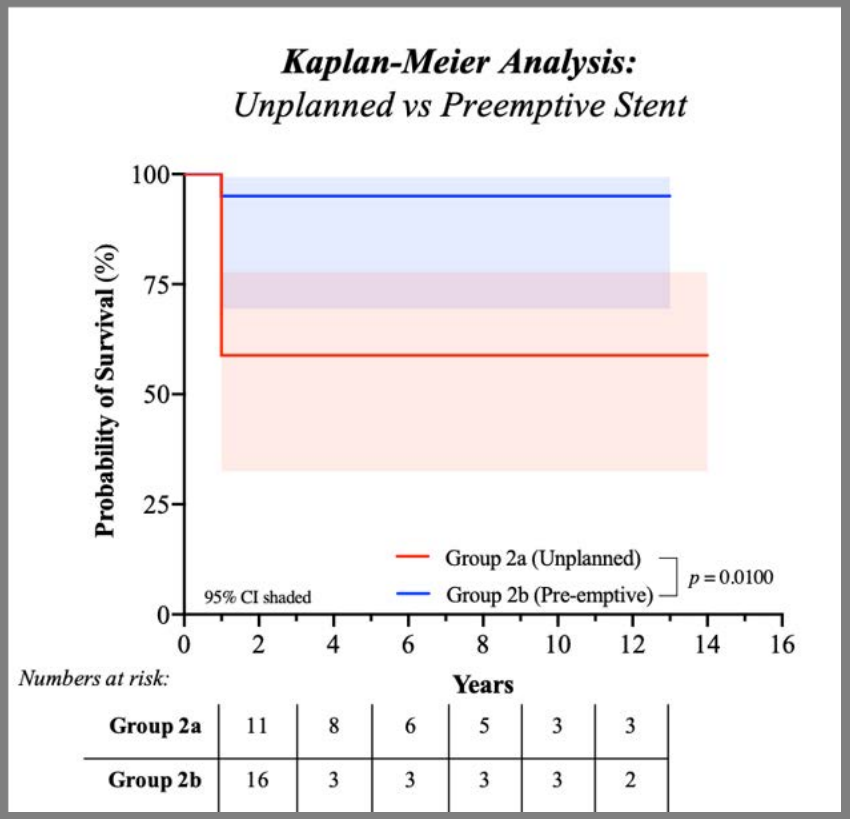
Pulmonary Artery Growth



Region of Interest	Group 1 *No Stent*	Group 2 *Stent*	*p value*
CS2 Exit			
pRPA	4.10 ± 1.40	4.20 ± 1.20	0.697415
iRPA	4.70 ± 1.60	5.60 ± 1.40	**0.012789**
pLPA	5.70 ± 1.50	6.50 ± 1.80	0.072793
hLPA	3.60 ± 1.10	6.20 ± 0.60	**<0.000001**
iLPA	5.50 ± 1.70	6.20 ± 1.60	0.072793
Pre-Fontan			
pRPA	7.70 ± 1.60	7.90 ± 1.70	0.875415
iRPA	8.50 ± 9.40	7.70 ± 1.60	0.850918
pLPA	6.80 ± 1.10	6.70 ± 1.10	0.875415
hLPA	5.80 ± 1.10	6.40 ± 0.80	**0.00563**
iLPA	6.20 ± 1.30	5.90 ± 0.90	0.46939

Results





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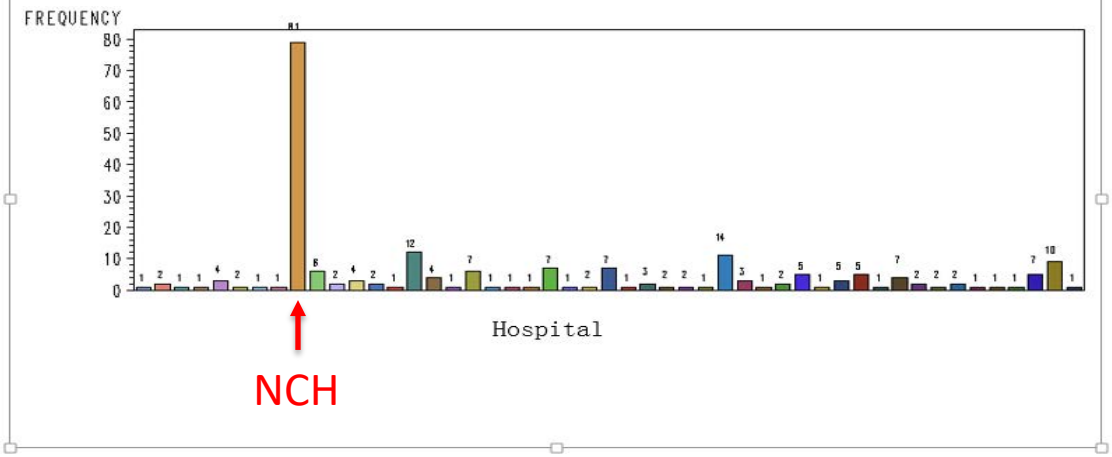
3 days post-Comprehensive Stage 2

Comprehensive Stage 2 at all centers

Ann Thorac Surg. 2018 May;105(5):1455-1460. doi: 10.1016/j.athoracsur.2017.11.046. Epub 2017 Dec 19.

Hybrid Palliation: Outcomes After the Comprehensive Stage 2 Procedure.

Cua CL[1], McConnell PI[2], Meza JM[3], Hill KD[3], Zhang S[3], Hersey D[2], Karamlou T[4], Jacobs JP[5], Jacobs ML[5], Galantowicz M[2].



Pic: Frequency of Patients receiving comprehensive stage II procedure as primary procedure across each center.

- 209 pts from 49 centers (81 pts from NCH)
- 12.4% mortality overall (4% NCH)

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Comprehensive Stage 2 Challenge

- Many surgical studies demonstrate improved outcomes related to volume, this is increasingly true as complexity/risk increases
- Therefore in the management of HLHS each program should go to their strengths as a team and be sure to have the volume to emerge from a perpetual learning curve.

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Thank You

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