Improving the outcome of high-risk neonates with hypoplastic left heart syndrome: hybrid procedure or conventional surgical palliation?\textsuperscript{a}

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Abstract

Objectives: Despite significant progress, surgical outcome for high-risk patients with hypoplastic left heart syndrome (HLHS) remain suboptimal. The hybrid palliation lessens the initial operative insult and is expected to improve overall survival; however the outcome of this management sequence is unknown. Methods: Retrospective review of all high-risk neonates (prematurity, low birth weight, associated genetic or co-morbid conditions) undergoing initial palliation for HLHS either by hybrid or Stage I Norwood procedure at a single institution between January 2001 and December 2006. The two strategies were compared using survival after stage II as the end-point for outcome. Results: The cohort included 33 patients (14 hybrid and 19 Norwood) with a mean age of 3.8 ± 2.4 days, weight of 2.6 ± 0.6 kg and Aristotle comprehensive score of 18.7 ± 2.5. Aortic atresia was present in 5/14 hybrid and 12/19 Norwood patients. The mean gestational age was 36.8 ± 2.2 weeks, six patients were under 36 weeks in each group. Patients undergoing hybrid palliation had a lower preoperative pH [7.14 ± 0.2 vs 7.25 ± 0.05, \( p = 0.04 \)], higher incidence of organ dysfunction [9/14 (64%) vs 5/19 (26%), \( p = 0.03 \)] and less associated cardiac anomalies [3/13 (21%) vs 13/19 (68%), \( p = 0.009 \)]. Hospital mortality and interstage mortality was 7/33 (21%) and 6/26 (23%) for the entire cohort, without significant differences between the hybrid and the conventional Norwood strategies. Of the original 33 patients only 16 (48.5%) were alive following the second stage procedure (7/14 (50%) hybrid and 9/19 (47.4%) Norwood). Conclusions: Regardless of the type of initial palliation, high-risk neonates with HLHS continue to have decreased survival. Although the hybrid approach reduces the initial surgical insult, important interstage mortality and ongoing morbidity result in survival no different than with conventional surgical palliation.

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1. Introduction

Significant improvement in the management of patients with hypoplastic left heart syndrome (HLHS) has led to increased survival in recent years [1—4]. These improved operative outcomes have resulted in the increasing use of the surgical palliation in patients considered at high-risk, but at the expense of considerable morbidity and mortality. The early success with the hybrid approach reported by Akintuerk et al. have prompted the increasing use of this strategy in order to minimize the deleterious impact of the conventional surgical intervention on high-risk patients [5—7]. In addition, the negative impact of low birth weight and surgical complexity on survival among patients undergoing Norwood palliation or heart transplantation supports the idea that a less extensive initial procedure could improve the outcome in these patients [8]. Here we describe our experience with a contemporary cohort of high-risk HLHS patients who underwent a hybrid or a Norwood procedure as initial palliation and provide a comparison of their mid-term outcome.

2. Material and methods

This is a longitudinal review of all newborns with HLHS or variants considered at ‘high risk’, due to the presence of important associated co-morbid conditions or genetic abnormalities, who were admitted to the Nemours Cardiac Center between January 2001 and December 2006 (n = 33). According to physician recommendation and family preferences, patients underwent conventional Stage I Norwood (19 patients) or ‘hybrid’ ductal stenting and bilateral branch pulmonary artery banding (14 patients).

The two groups in this study were contemporary and non-randomized. Data collection included demographic,
preoperative, operative and postoperative variables, as well as follow-up information obtained during office visits. Aristotle comprehensive score was calculated for each patient in order to adjust the complexity according to specific patient and procedural characteristics prior to initial palliation [9]. Risk factors examined for their potential influence on procedure-related mortality included age, birth weight, weight at surgery, gestational age, multiple pregnancy, prenatal diagnosis, prematurity, lowest preoperative pH, organ dysfunction, comprehensive Aristotle score, diagnosis of HLHS or variant, presence of aortic atresia, additional cardiac diagnosis, and genetic or chromosomal abnormality. Echocardiographic parameters included assessment of ventricular function, A–V valve regurgitation and restriction of pulmonary venous return. Operative mortality was defined as mortality within 30 days or prior to hospital discharge.

The end-points investigated were: (1) hospital survival after initial palliation, (2) interstage mortality and (3) survival after Stage II procedure. The study was approved by the local institutional review board and the need for consent was waived.

The anatomic diagnosis of HLHS was based on two-dimensional echocardiography and required the presence of aortic valve atresia or hypoplasia, hypoplasia or absence of the left ventricle and a ductus-dependent systemic circulation with retrograde flow in the aortic arch. Tricuspid valve function and right ventricular function were evaluated qualitatively using two echocardiographic views (subcostal and apical four chambers) by two independent observers. Right ventricular and tricuspid valve dysfunction was considered significant if moderate or greater. Obstruction of pulmonary venous return was considered significant if a mean gradient greater than 5 mmHg was present on Doppler interrogation at the level of the interatrial septal communication or anomalous pulmonary venous connection.

2.1. Initial palliation

Technical aspects of the initial hybrid (off-pump) palliation have been reported previously [7]. In summary, via median sternotomy, branch pulmonary artery banding was performed using 3.5 mm Gore-tex (W.L. Gore, Newark, DE) rings preceding stent deployment. Tightness of the bands was usually adjusted over a 2.5 mm coronary probe placed alongside the branch pulmonary artery to achieve an arterial oxygen saturation of about 80%. Stenting of the ductus arteriosus was performed through a sheath placed directly into the proximal main pulmonary artery. Stent size and positioning was based on a lateral angiogram through the sheath. Balloon-expandable stents (8 mm × 10 mm pre-mounted and 8 mm × 17 mm [Palmaz-Genesis, Cordis, Miami, FL]) and self-expandable (7 mm × 20 mm [Protégé GPS, ev3, Plymouth, MN]) stents were used. Choice of stent was largely influenced by ductal anatomy and availability.

The adequacy of the atrial septal communication was determined based on hemodynamic and echocardiographic data. If the atrial septal communication was thought to be restrictive after the branch pulmonary artery banding, a balloon atrial septotomy or deployment of an atrial septal stent was performed. Adequacy of the distal arch opening at the confluence with the ductus arteriosus was evaluated with color Doppler echocardiogram. Flow acceleration or narrowing of the color Doppler jet was considered a contraindication for stenting among patients with aortic atresia. Routine echocardiographic assessment was performed on admission to the intensive care unit and weekly until discharged.

Conventional Stage I Norwood was performed using deep hypothermic cardiopulmonary bypass and a period of circulatory arrest as previously reported [3]. Aortic arch reconstruction was performed using pulmonary artery homograft. According to the surgeon’s preference, the source of pulmonary blood flow was a modified Blalock-Taussig shunt in 3 patients and a right ventricle to pulmonary artery conduit in 16 patients. The latter was usually chosen if coronary artery anomalies were present.

At the time of hospital discharge, all patients had a 12-lead electrocardiogram, chest X-ray and echocardiographic assessment. Criteria for hospital discharge included appropriate caloric intake (≥120 cal/kg per day) associated with weight gain for three consecutive days. All patients were discharged on 10 µg/kg of digoxin QD and 1 mg/kg of furosemide BID.

2.2. Interstage follow-up

Outpatient follow-up including an echocardiogram was performed at 2–4-week intervals or earlier depending on the clinical condition. Patients in the hybrid group were referred for elective complete hemodynamic, angiographic, and echocardiographic evaluation at 12 weeks or earlier if a hemodynamic issue was suspected and at 16 weeks in the Norwood group.

2.3. Stage II procedure

Stage II after conventional Stage I Norwood consisted of hemifontan procedure. In addition, a left bidirectional Glenn was performed if a left SVC without a bridging vein was present. The Stage II surgical reconstruction following hybrid palliation was an extensive procedure and consisted of amalgamation of the proximal ascending aorta with the main pulmonary artery, removal or resection of the ductus/stent complex, aortic arch reconstruction, atrial septectomy (±removal of atrial septal stent), removal of the branch pulmonary artery bands with arterioplasty if necessary, and superior cavopulmonary connection.

2.4. Statistical analysis

Data are presented as medians (ranges) or means (±standard deviation) and as a count with percentages where appropriate. Continuous variables were compared using a Mann–Whitney test and Student’s t-test. Fisher’s exact test and Chi-square were used for dichotomous and categorical variables. Comparison of clinically relevant factors was performed to determine any significant differences between treatment groups. Univariate analysis of risk factors for mortality at different time points for the entire cohort and each subgroup, as well as Cox hazard and logistic regression were performed. Kaplan–Meier survival curves using single and cumulative end-points for death were stratified by type of initial palliation. Analysis was performed based on intention to treat.
3. Results

Patient characteristics are illustrated in Table 1. No significant differences between groups were observed regarding age at the time of intervention, surgical weight, presence of genetic or chromosomal anomalies, Aristotle comprehensive score, incidence of low birth weight or prematurity. Patients in the hybrid group had a lowest recorded preoperative pH and had a higher incidence of organ dysfunction, while patients who underwent a Norwood procedure had more associated cardiac diagnoses, including a greater degree of AV valve regurgitation, restrictive or anomalous pulmonary venous drainage, coronary anomalies and dysrhythmias. Patient distribution and outcome according to each strategy are shown in Fig. 1. One cross-over occurred in a patient who underwent a hybrid procedure after a late diagnosis associated with NEC and a grade II intracerebral bleed. Six weeks after initial palliation, excessive pulmonary blood flow was documented the patient underwent a Norwood procedure and subsequently a second stage.

3.1. Hybrid group

There were two hospital deaths, a 900 g newborn with a progressively restrictive ASD, underwent surgical atrial septectomy and died of NEC and multisystem organ dysfunction. The second death involved a 2.2 kg premature newborn with multiple congenital anomalies including a single kidney, who developed sudden hemodynamic collapse 5 days after successful palliation. Although the patient recovered without neurologic sequelae, the patient died due to progressive renal dysfunction.

Three additional patients died during the interstage period. A sudden death occurred in a 10-week-old premature newborn, who underwent successful initial palliation followed by surgery for necrotizing enterocolitis. Autopsy study revealed no residual anatomic lesions. A second death involved a patient with Ellis Von Crevald syndrome, restrictive lung disease and persistent renal failure, several months after successful hybrid palliation. A third patient presented at 3.5 months post-hybrid procedure with persistent infectious colitis, which led to necrotizing enterocolitis and subsequent death.

Two operative deaths occurred after Stage II reconstruction, one in a patient with complex transposition unusual ductal and arch anatomy who suffered a cerebral hemorrhage in the perioperative period, the second involved a patient who suffered significant disruption of the left pulmonary artery associated with severe hypoxemia, bleeding and coagulopathy.

3.2. Norwood group

There were five operative deaths, two in patients with coronary anomalies and a diminutive aorta, one in a 1.8 kg patient with obstructed total anomalous pulmonary venous drainage and supraventricular tachycardia, one in a 1.3 kg patient with renal dysfunction and thrombocytopenia and another in a 2.3 kg premature newborn with VACTERL syndrome and renal dysfunction. In addition there were three interstage deaths, two sudden events in patients with aortic atresia and history of postoperative supraventricular tachycardia, both with unrevealing post-mortem studies. The third in a patient who received a right ventricle to pulmonary artery conduit and presented with a severe cyanotic spell at the age of 4 months. Stage II mortality involved a patient with history of a pulmonary vein stenosis, dysmorphic features and urologic abnormalities who developed fungal septicemia. The second patient was a former 2.4 kg newborn with aortic atresia and Adams Oliver syndrome, who underwent Stage II at 10 weeks of age due to progressive hypoxemia, which was complicated by important myocardial ischemia leading to a hypoxic CNS injury after cardiac arrest.

3.3. Outcomes

Table 2 shows the mortality associated with each stage according to strategy. Hospital mortality following initial palliation was 21.2% for the entire cohort. The Norwood group had more operative deaths, and the hybrid strategy

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hybrid (n = 14)</th>
<th>Norwood (n = 19)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (days)</td>
<td>4.3 ± 3.4</td>
<td>3.5 ± 1.6</td>
<td>0.96</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>2.6 ± 0.6</td>
<td>2.7 ± 0.4</td>
<td>0.77</td>
</tr>
<tr>
<td>ACS</td>
<td>19.3 ± 3.1</td>
<td>18.3 ± 2.6</td>
<td>0.46</td>
</tr>
<tr>
<td>Asc Ao (mm)</td>
<td>3.2 ± 1.7</td>
<td>2.7 ± 1.0</td>
<td>0.13</td>
</tr>
<tr>
<td>Lowest pH</td>
<td>7.14 ± 0.2</td>
<td>7.29 ± 0.05</td>
<td>0.040</td>
</tr>
<tr>
<td>Ao atresia</td>
<td>6 (43%)</td>
<td>12 (63%)</td>
<td>0.15</td>
</tr>
<tr>
<td>Additional cardiac factors</td>
<td>3 (21.4%)</td>
<td>13 (68.4%)</td>
<td>0.009</td>
</tr>
<tr>
<td>Organ dysfunction</td>
<td>9 (64%)</td>
<td>5 (26%)</td>
<td>0.03</td>
</tr>
<tr>
<td>Genetic/chromosomal</td>
<td>3 (21.4%)</td>
<td>4 (21.8%)</td>
<td>0.78</td>
</tr>
<tr>
<td>LBW (&lt;2.5 kg)</td>
<td>5 (35.7%)</td>
<td>6 (31.5%)</td>
<td>0.54</td>
</tr>
<tr>
<td>Prematurity (&lt;36 weeks)</td>
<td>4 (28.5%)</td>
<td>4 (21%)</td>
<td>0.46</td>
</tr>
</tbody>
</table>

Asc: ascending; Ao: aorta; ACS: Aristotle comprehensive score; LBW, low birth weight.

Fig. 1. Patient distribution and outcome.
was associated with a higher interstage mortality, though neither of these differences reached statistical significance. Univariate analysis of patient and procedural variables identified prematurity ($p = 0.004$) and low birth weight ($p = 0.002$) to be associated with early death. Alternatively, when the end-point analyzed was cumulative mortality along the management sequence including Stage II palliation, low birth weight ($p = 0.01$) and presence of organ dysfunction ($p = 0.05$) were associated with poor outcome.

The Cox proportional hazard curve (Fig. 2) demonstrates an important initial hazard phase in the first 6 months, followed by a plateau phase without additional attrition including 12 patients followed beyond 30 months. Kaplan–Meier survival using both early and cumulative death end-points stratified by type of palliation, demonstrated no difference in survival along the staging process (Fig. 3).

Logistic regression analysis of patient and procedural variables revealed that low birth weight was the only risk factor predictive of early and overall mortality ($p = 0.004$ OR 6.55; 95% CI: 94–45.6).

3.4. Comment

Despite considerable improvement in the outcome of the Stage I Norwood in the recent years, this form of surgical palliation for small newborns with significant medical issues still carries a substantial risk. Since the description of a less extensive approach by Gibbs and Wren [10,11], a more refined and collaborative effort to implement the ‘hybrid’ approach has offered an alternative form of palliation while minimizing the intervention and avoiding the exposure to cardiopulmonary bypass. In addition, the report of a successful combined Stage II surgical reconstruction by Akintuerk et al. [5] has opened the path from hybrid palliation towards a Fontan circulation and this approach continues to gain interest. To date, the hybrid strategy has been applied to a broad range of patients based on institutional preferences and expertise, yet comparative data regarding the outcome of high-risk patients along the staging process is lacking.

Increased awareness of interstage mortality as an important contributor to patient attrition, the increased risk of associated co-morbidities and the challenging technical aspects of the Stage II reconstruction, require a longitudinal and comprehensive analysis to gauge the overall success of any management strategy in these patients. Our data demonstrates that the outcome of high-risk patients with HLHS can be influenced in the short term by the initial hybrid intervention. However, when the outcome sought includes completion of the second stage, this does not appear to be influenced by the strategy chosen for initial palliation, but rather by variables known to have negative impact on outcome (i.e. low birth weight and associated non-cardiac morbidity). Our experience confirmed the idea that a lesser intervention can be effective and well-tolerated, nevertheless early mortality was not eliminated and remained associated to technical issues in the extremely small premature newborn and the natural course of organ dysfunction.

In this cohort, without significant differences for age, weight, gestational age and Aristotle comprehensive score between strategies, the Norwood approach exhibited a higher hospital mortality. In fact, four of the six low birth weight newborns in this group died after the initial surgery. This observation concurs with the negative impact of low weight on survival after Stage I Norwood [1–3], increased risk for interstage death and early transition to a cavopulmonary shunt. These facts support the notion that the hybrid approach could somehow improve the early outcome of these patients [8].

Although the hybrid approach could delay the extensive reconstructive procedure, allowing time for the small patient to gain weight and grow, this appeared to be only applicable to premature newborns. The difficulties with growth and development observed in the post-Norwood population also

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Mortality by stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Hybrid ($n = 14$)</td>
</tr>
<tr>
<td>Initial palliation</td>
<td>2 (14.3%)</td>
</tr>
<tr>
<td>Interstage deaths</td>
<td>3 (21.4%)</td>
</tr>
<tr>
<td>Stage II</td>
<td>2 (14.3%)</td>
</tr>
<tr>
<td>Total</td>
<td>7 (50%)</td>
</tr>
</tbody>
</table>

Fig. 2. Cox proportional hazard for the entire cohort.

Fig. 3. Kaplan–Meier actuarial survival according to management strategy.
were observed in hybrid patients, who at the time of stage II reconstruction were well below the 15th percentile for weight, despite appropriate caloric intake. This should not constitute an unexpected finding, particularly in a population which exhibited important co-morbidities and in some cases an important hemodynamic burden.

Follow-up data demonstrated that patients undergoing the hybrid procedure had a tendency to higher interstage mortality. Recent studies including a meta-analysis have suggested that Norwood procedure with a right ventricle to pulmonary artery conduit results in a lesser number of interim deaths [12–15]. The hybrid procedure, much like a systemic-to-pulmonary artery shunt, establishes a connection between the systemic and pulmonary circulations at the arterial level allowing for diastolic run-off away from the systemic and coronary beds. In addition, the technical challenges associated with the appropriate banding of the branch pulmonary arteries and opening of a restrictive interatrial septal communication in small patients can result in hemodynamically important residual lesions, which have been thought to contribute to unexpected mortality prior to the second stage [16].

Mortality associated with Stage II reconstruction was similar between groups. This is probably related to a combination of patient and procedural variables with emphasis on the challenging nature of the reconstruction following the initial hybrid intervention and the severity of the co-morbid conditions. Although improvement could be expected by refinement of technical aspects of the Stage II reconstruction, the negative impact of existing medical conditions is more difficult to contain and perhaps could only be altered by changes in patient selection.

Analysis of this cohort demonstrated that patients undergoing the Norwood palliation frequently had other associated cardiac anomalies, a lower incidence of end-organ dysfunction and a tendency to have a smaller ascending aorta. Although under certain circumstances (i.e. obstructed anomalous pulmonary venous drainage or a restrictive atrial septal defect not amenable to catheter intervention) an open surgical approach is necessary, it is possible that in the presence of a coronary anomaly or cardiac dysrhythmias, a less invasive approach could be advantageous.

Alternatively, patients in the hybrid strategy commonly had a history of exposure to a lower pH and exhibited a higher incidence of end-organ dysfunction. Even though the hybrid approach achieved the desired hemodynamic palliation, it was commonly the residual organ dysfunction which interfered with the ability of these infants to cope with the subsequent palliation, leading to significant morbidity and in some cases mortality beyond the initial palliative procedure, as demonstrated in this cohort. It should be noted that the significant influence of these co-morbid conditions might also limit the usefulness of the hybrid approach as a preamble to cardiac transplantation, therefore restricting the therapeutic options available for these patients.

Our results demonstrate high-risk patients with HLHS managed with either a Stage I Norwood or hybrid approach exhibit significant attrition along the staging process. This appears related to the presence of serious co-morbidities, in addition to the potential for residual hemodynamic issues and the incremental technical challenge of implementing this strategy among very small and premature newborns. Our experience not only concurs with the report by Bacha et al. [6] on the management of high-risk HLHS patients, but also is not too dissimilar to the early reports using this strategy in patients otherwise considered good candidates for conventional surgical palliation [17,18]. Despite significant enthusiasm to implement the hybrid approach in high-risk patients, follow-up data demonstrates that the procedural risk and morbidity are somewhat shifted along the staging process but not eliminated. Based on this observation, a comprehensive evaluation from the time of initial palliation leading to the Fontan circulation will be necessary before a meaningful comparison between new strategies and the conventional surgical palliation can be made. As the number of high-risk patients in need of Norwood-type palliation continues to increase, it is possible that optimal management may come from a combination of the current strategies available, the choice and its timing determined by the most relevant clinical issues.

3.5. Limitations

The non-randomized and retrospective nature of this study, the limited number of subjects, and the homogeneity of the cohort regarding high-risk conditions may limit the potential for meaningful statistical analysis for unaccounted factors. Due to the consistent and uniform operative management of these patients, no inferences could be drawn regarding potentially important determinants of outcome, such as perfusion strategy, timing of surgery, etc. The lack of specific risk-adjustment variables for the hybrid procedure and subsequent stage II reconstruction limit the usefulness of the Aristotle comprehensive score as a tool to establish a fair comparison of risk and performance.

Acknowledgements

We would like to thank Drs William I. Norwood and John D. Murphy for their contribution in the care of some of these patients, and Ms Julie Simons and Jacek Kolcz, MD for their assistance with the statistical analysis.

References

Appendix A. Conference discussion

Dr W. Brown (Birmingham, United Kingdom): I won’t go over all the things that you have said because you have indicated some of the problems with the paper; the retrospective nature, small numbers, difficulty in applying statistics to that group of patients. I would like to say that in our experience, with the introduction of the 3.5 shunt and the RV-PA conduit, we see changes in our outcome with our patients, and I would hope that one would expect to see a similar impact on this hybrid approach if it was to become successful so that we would have an improvement now for an actuarial survival curve at 1 year from 55% to just under 80%. I’m not sure that we will see that with this hybrid approach. However, we will wait to see and I’m sure the jury is still out. You haven’t really shown any improvement overall at stage II. The results are the same, however you apply them. That’s fair enough. They are a very difficult group of patients.

What I would like to ask you is to comment on a few practical issues. The first thing is that we have huge problems with necrotizing enterocolitis and ongoing sepsis in low-output patients. Have you seen or would you expect to see any improvement in that? I’m particularly concerned that there’s still diastolic run-off in these patients with the bands, so maybe the hemodynamics, particularly to the myocardium, might not be so well improved. And then there are two practical issues; the complexity and the difficulty of stage II reconstruction and the selection of patients who have severe coarction of the aorta, which I often find difficult to evaluate preoperatively. So you may think there is not so much of a coarctation, with adequate retrograde flow around the arch, but at operation that is quite severe, and presumably over the timing of the stenting may progress. So the incidence of that co-morbidity of ongoing low output associated with NEC and infection and then the practical issues of stage II reconstruction and the selection of patients who have a coarctation which I think can be difficult to evaluate.

Dr Pizarro: First, in reference to necrotizing enterocolitis and sepsis, let me say that an important number of these patients actually underwent a hybrid procedure because of these issues. They had a late diagnosis and some present with an acute abdomen, which required a surgical intervention. Under these circumstances we explained to family it would be best to perform a palliative procedure that would improve the hemodynamic profile with a lesser intervention and allow them to have the necessary treatment to resolve the acute problem. Among these patients there was no mortality and all patients recovered. This illustrates some of the clinical scenarios when we thought a hybrid approach would offer an advantage over the conventional surgical approach.

You raised a very important point, which is the fact that these patients have a physiology, which is quite similar to a patient with a systemic-to-pulmonary artery shunt in the sense that there is important diastolic run-off that will be variable according to the adequacy or inadequacy of the bands. As a matter of fact, sudden or unexpected death occurred in the interstage period in some of those patients. Absence of residual anatomic lesions on post-mortem examination suggests that short of a rhythm disturbance, which could have been primary, these events could have been related to the precarious coronary blood supply and limited reserve afforded by these patients.

Regarding the stage II surgery, it requires a very extensive reconstruction. There has been an evolution regarding some technical aspects of the operation. However a number of questions remain, for example, what is the best way to manage the ductal stent during the arch reconstruction? Do you try to peel it away? Do you resect it? Do you cut through it and then just do the reconstruction? These issues are still part of the learning curve. I would mention that these technical aspects had some influence on the deaths with had during this intervention, therefore important room for improvement exists here. It remains in the back of our minds remains the question about the timing of the stenting may progress. So the incidence of that co-morbidity of coarctation which I think can be difficult to evaluate.

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