Outcomes of the Arterial Switch Operation in ≤2.5-kg Neonates

Michael Salna, MD,[*] Paul J. Chai, MD,[*] David Kalfa, MD, PhD,[*] Yuki Nakamura, MD,[*] Ganga Krishnamurthy, MD,[†] Jan M. Quaegebeur, MD,[*] Marc Najjar, MD,[‡] Amee Shah, MD,[§] Stephanie Levasseur, MD,[§] Brett R. Anderson, MD, MSc, MBA,[§] and Emile A. Bacha, MD[*]

Although low birth weight is a known risk factor for mortality in congenital heart lesions and may consequently delay surgical repair, outcomes in low-weight neonates undergoing the arterial switch operation (ASO) have not been well described. Our objective was to assess the safety of this procedure in infants weighing ≤2.5 kg at the time of surgery. We retrospectively analyzed outcomes for all neonates undergoing the ASO at our institution from 2005 to 2015. Our primary outcome of interest was major morbidity or operative mortality, assessed as a composite outcome. From 2005 to 2015, 217 neonates underwent the ASO, with 31 (14%) weighing ≤2.5 kg at the date of surgery, and 8 weighing <2.0 kg. Neonates weighing ≤2.5 kg were more likely to be premature than those weighing >2.5 kg, but there was no difference in the age at operation between these groups. Overall, 32 infants experienced a major morbidity or mortality, including 37.5% (n = 3) weighing <2.0 kg, 8.7% (n = 2) weighing 2.0-2.5 kg, and 14.5% (n = 7) weighing >2.5 kg ($P = 0.141$). One infant weighing <2.0 kg (1.1 kg) and 4 infants weighing >2.5 kg died. In multivariable models, odds of major morbidity or mortality were significantly higher for infants weighing <2 kg compared with infants weighing >2.5 kg (odds ratio 3.93, 95% confidence interval 1.04-14.85, $P = 0.044$), but there was no difference between infants weighing 2.0-2.5 kg and those weighing >2.5 kg ($P = 0.225$). The ASO can be performed safely in 2.0- to 2.5-kg neonates and yields results comparable with higher weight infants. Imposed delays for corrective surgery may not be necessary for these low-weight infants with transposition of the great arteries.

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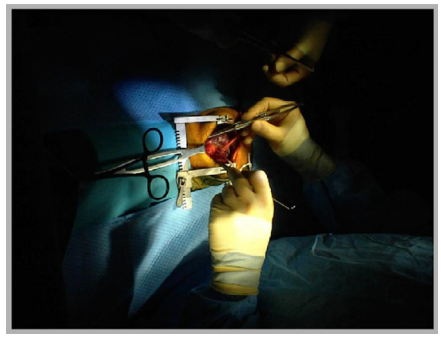
Keywords: Arterial switch operation, Prematurity, Transposition of the great arteries



Intraoperative photo of the arterial switch operation.

Central Message

The arterial switch operation can be safely performed in neonates weighing 2.5 kg. Imposed delays for corrective surgery may not be necessary.

Perspective Statement

Low birth weight and prematurity are known risk factors of mortality in congenital heart disease and may delay corrective surgery. In a retrospective study of 217 infants undergoing the arterial switch operation over 10 years, we found comparable outcomes between neonates weighing 2.5 kg and those weighing >2.5 kg at the date of surgery, even when adjusting for prematurity.

[*]Division of Cardiac, Thoracic and Vascular Surgery, Section of Pediatric and Congenital Cardiac Surgery, NewYork-Presbyterian/Morgan Stanley Children's Hospital, Columbia University College of Physicians and Surgeons, New York, New York
[†]Division of Neonatology, NewYork-Presbyterian/Morgan Stanley Children's Hospital, Columbia University Medical Center, New York, New York
[‡]Department of Surgery, Columbia University College of Physicians and Surgeons, New York, New York
[§]Division of Pediatric Cardiology, NewYork-Presbyterian/Morgan Stanley Children's Hospital, Columbia University Medical Center, New York, New York

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Address reprint requests to Emile A. Bacha, MD, Division of Cardiac, Thoracic and Vascular Surgery, Columbia University College of Physicians and Surgeons, NewYork-Presbyterian Morgan Stanley Children's Hospital, 3959 Broadway, Suite 274, New York, NY 10032. E-mail: eb2709@cumc.columbia.edu

INTRODUCTION

Low birth weight and prematurity are recognized risk factors of mortality for congenital heart surgery.[1,2] As a result, intervention may be deferred in low-weight infants until a certain weight is achieved before proceeding with corrective surgery. Imposed delays, however, have not been found to confer benefit but rather increase preoperative morbidity.[3-5] A growing body of literature suggests that low weight should not be a contraindication to surgery and that these infants can be operated on safely with good results.[1,6,7] With continuing improvements in prenatal diagnostics and the management of premature and small for gestational age newborns in neonatal intensive care units, the demand for surgical intervention of congenital heart lesions early in life for low-weight infants will likely increase.

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Over the last 2 decades, the arterial switch operation (ASO) has been perfected as the surgical correction of choice for children with transposition of the great arteries (TGA) with now negligible mortality in full-term neonates. However, there have been few reports addressing the issue of infant size in this population. The objective of the present study was to assess the overall feasibility and safety of performing the ASO in neonates weighing ≤2.5 kg.

METHODS

Patients

A retrospective cohort study was performed using clinical data for all infants undergoing the ASO at the NewYork-Presbyterian/Morgan Stanley Children's Hospital, Columbia University Medical Center, between January 2005 and January 2015. Infants with or without ventricular septal defects and Taussig-Bing anatomy were included. Patients who were >6 months of age at the time of repair or those who underwent Rastelli operation, Nikaidoh procedures, or a double switch were excluded. The present study was approved by the Institutional Review Board of Columbia University Medical Center with waiver of informed consent.

Perioperative and Operative Procedures

All infants were cared for pre- and postoperatively in our neonatal cardiac intensive care unit, managed by both a pediatric cardiologist and a neonatologist and cardiac neonatal nurses. All infants <32 weeks' gestation at our institution undergo regular, routine head ultrasounds. Any infant who undergoes a balloon septostomy also undergoes preoperative brain magnetic resonance imaging to determine if a delay of cardiopulmonary bypass (CPB) is necessary. Additional postoperative imaging is done in the event of focal neurologic concerns.

All operations were performed by 1 of 5 surgeons. All operations were performed under hypothermic CPB, and del Nido cardioplegia at 20 cc/kg was used to minimize fluid load. The majority of patients underwent a brief period of circulatory arrest. The aorta was transected at the midascending portion, whereas the pulmonary trunk was divided just before the bifurcation. Coronary buttons were mobilized and reimplanted into the proximal neoaortic sinuses. The Lecompte maneuver was routinely performed after coronary reattachment, and the neoaortic and neopulmonary anastomoses were performed sequentially. In TGA-ventricular septal defect cases, the ventricular septal defect was almost always closed transatrially with a patch. The sternum was not routinely left open.

Risk Factors

The primary risk factor of interest was weight at surgery (in kilogram). Other variables considered included sex, age at operation (in days), gestational age (as a continuous variable), prematurity (<37 weeks' gestation), antenatal diagnosis, year of surgery (to reflect surgical era), CPB, cross-clamp and circulatory arrest times, TGA subtype (intact ventricular septum, ventricular septal defect, or Taussig-Bing anomaly), abnormal coronary artery anatomy (defined as those other than the most common subtype, by Leiden criteria, in our cohort), and concomitant arch repair. Cardiac anatomy was determined preoperatively by echocardiography and confirmed by the surgeon at the time of repair. Normal coronary anatomy was defined as a left anterior descending artery and circumflex artery arising from a single ostium in sinus 1 and a right coronary artery arising from a single ostium in sinus 2. Intramural coronaries and all other patterns were defined as abnormal.

Primary Outcomes

The primary outcome of interest was a composite of operative mortality or major morbidity. Mortality was defined as death before discharge or within 30 postoperative days if discharged before 30 days. Major morbidity was defined in accordance with criteria established by the Society of Thoracic Surgeons and included postoperative mechanical circulatory support, renal failure requiring temporary or permanent dialysis, neurologic deficit persistent at discharge, heart block or other arrhythmia requiring permanent pacemaker placement, phrenic nerve injury or diaphragmatic paralysis, and unplanned reintervention before hospital discharge.[8] In exploratory univariable analyses, we examined postdischarge cardiac reintervention (defined as an interventional catheterization or surgery) at the last known follow-up.

Statistical Analysis

All statistical analyses were performed with Stata software, version 13 (StataCorp LP, College Station, TX). Clinical and demographic variables are presented using standard summary statistics, including mean ± standard deviation or median and interquartile range (IQR), depending on the normality of distribution for continuous variables, and the frequencies and proportions for categorical variables. Associations between operative weight and major morbidity or mortality were first assessed using locally weighted scatter plot smoothing to determine if it was most appropriate to model weight as a continuous variable (either linear or log transformed), a dichotomous variable split at 2.5 kg as has historically been done, or a 3-level discrete separation (separating patients weighing <2.0 kg from those weighing 2.0-2.5 kg), as newer literature has suggested. A 3-level discrete separation was determined to be most appropriate. To assess associations between independent variables and each of the measured outcomes, chi-square and Fisher exact tests were used for categorical variables and analysis of variance and Mann-Whitney *U* tests were used for continuous variables. Associations between independent variables and major morbidity or mortality were then explored using multivariable logistic modeling. Model selection was performed using the Akaike information criterion, with a smaller Akaike information criterion representing a better model. Because prematurity and operative weight were highly associated (given the short preoperative lengths of stay), a decision was made to exclude prematurity from the final model. Interactions between weight, prematurity, bypass time, and operation

subtype were tested. To account for multiple procedures performed by the same surgeon, model-based confidence intervals (CIs) were constructed and hypothesis testing was performed using robust standard errors and clustering by surgeon. In exploratory analyses, surgeons were also tested as fixed effects.

RESULTS

A total of 217 infants underwent the ASO at our institution from January 2005 to January 2015 (Fig. 1) with a median weight at surgery of 3.2 kg (range: 1.1-4.8 kg, IQR 2.8-3.5 kg). There were 31 infants weighing ≤2.5 kg at the time of surgery, 8 weighing <2.0 kg, and 1 <1.5 kg. Although there was no difference in the age at operation between infants weighing 2.0-2.5 kg vs >2.5 kg (median 6 days [IQR 3-8] vs 6 days [IQR 4-7], $P = 0.814$), the median age at operation was 5 days older for infants weighing <2.0 kg (median 11 [IQR 6-22]) vs those weighing ≥2 kg ($P = 0.016$). There were no significant differences in anatomical subtype or coronary anatomy between weight categories (Table 1).

One surgeon performed 54.4% (n = 118) of the cases, including 58.0% (n = 18) of cases in infants weighing ≤2.5 kg and 37.5% (n = 3) of cases in infants weighing <2.0 kg. The rest of the cases were divided roughly evenly between 3 of the 4 remaining surgeons (with only 5 cases performed by the 1 surgeon who joined our practice shortly before the study period ended). There were no significant differences in the proportion of low-weight cases each surgeon performed (≤2.5 kg, $P = 0.107$; <2.0 kg, $P = 0.373$) or in overall outcomes between surgeons ($P = 0.684$).

There were 29 neonates born at <37 weeks' gestation, comprising 13% of the total sample. Weight category was highly associated with prematurity, with 100% (n = 8) of infants weighing <2.0 kg being premature, 30.4% (n = 7) of infants weighing 2.0-2.5 kg being premature, and only 5.9% (n = 11) of infants weighing >2.5 kg being premature ($P < 0.001$).

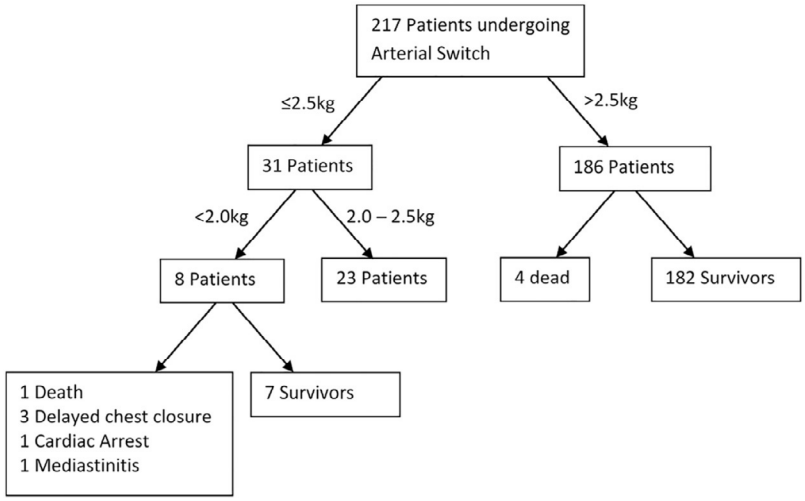


Figure 1. Schematic of all patients undergoing the arterial switch operation from 2005 to 2015, stratified by operative weight.

Table 1. Characteristics and Outcomes of Patients Who Underwent the Arterial Switch Patients Stratified by Operative Weight

	Overall (n = 217)	<2.0 kg (n = 8)	2.0-2.5 kg (n = 23)	>2.5 kg (n = 186)	*P* Value
Sex (male)	133 (61.3)	2 (25.0)	16 (69.6)	115 (61.9)	0.093
Age at operation (d)	6 (4-8)	11 (6-22)	6 (3-8)	6 (4-7)	0.052
Premature birth (<37 wk)	26 (12.0)	8 (100.0)	7 (30.4)	11 (5.9)	<0.001*
Antenatal diagnosis	136 (62.7)	5 (62.5)	17 (73.9)	114 (61.3)	0.801
TGA subtype					0.420
TGA, intact ventricular septum	123 (58.5)	5 (62.5)	11 (47.8)	107 (56.6)	
TGA, ventricular septal defect	70 (32.2)	3 (37.5)	11 (47.8)	56 (30.1)	
Taussig-Bing anomaly	24 (11.0)	0 (0.0)	1 (4.4)	23 (12.4)	
Coronary anatomy (1LCx-2R)	131 (59.5)	4 (50.0)	7 (30.4)	107 (57.5)	0.423
Intraoperative characteristics					
Bypass time (min)	140 (120-166)	144 (125-170)	136 (116-180)	140 (120-165)	0.805
Aortic cross-clamp time (min)	82 (71-100)	81 (71-103)	87 (71-103)	82 (71-99)	0.879
Circulatory arrest time (min)	9 (5-23)	7 (5-17)	6 (4-18)	9 (5-24)	0.104
Concomitant arch repair	30 (13.6)	0 (0.0)	6 (26.1)	24 (12.9)	0.157

Data are presented as median (IQR) or n (%).
*Denotes *P* value <0.05.

Premature neonates were more likely to be older than full-term infants at the date of operation (median age 8 days [IQR 5-16 days] vs 6 days [IQR 4-7 days], $P = 0.012$).

Mortality or Major Morbidity

Overall, 32 infants experienced a major morbidity or mortality, including 37.5% (n = 3) weighing <2.0 kg, 8.7% (n = 2) weighing 2.0-2.5 kg, and 14.5% (n = 7) weighing >2.5 kg (see Fig. 2). One infant weighing <2.0 kg (1.1 kg) and 4 infants weighing >2.5 kg died. There were no other operative mortalities. Two patients underwent early reintervention during hospitalization with a pulmonary arterioplasty for suprasystemic right ventricular pressures and a revision of the right coronary button for refractory ventricular dysfunction, respectively. The latter patient subsequently underwent reoperative repair of the pulmonary artery bifurcation for stenosis. For additional details on specific morbidities, see Table 2.

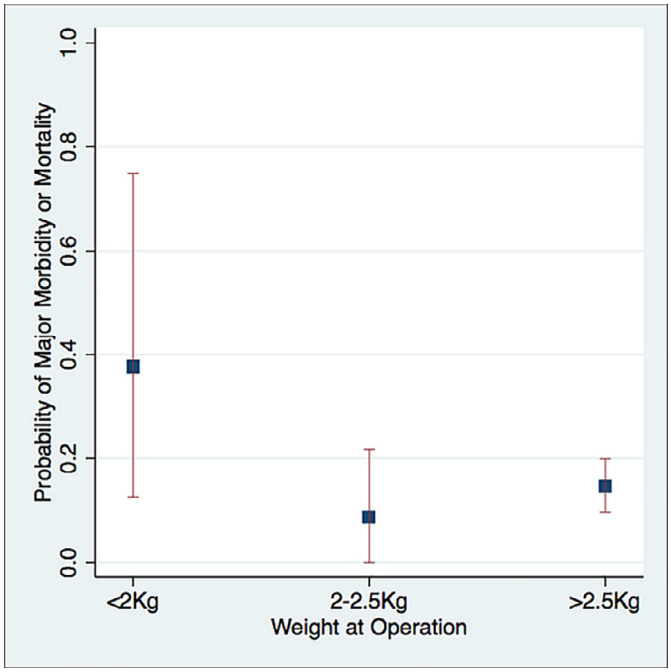


Figure 2. Major morbidity or mortality among infants undergoing the arterial switch operation, stratified by operative weight. (Color version of figure is available online.)

In the multivariable models, the odds of major morbidity or mortality were higher for infants weighing <2 kg compared with infants weighing >2.5 kg (odds ratio 3.93, 95% CI 1.04-14.85, $P = 0.044$). There was no difference in the odds of major morbidity or mortality when comparing infants weighing 2.0-2.5 kg with those weighing >2.5 kg ($P = 0.225$). Longer bypass times and Taussig-Bing anomaly were also associated with increased odds of the composite outcome (see Table 3). There was a significant interaction between bypass time and Taussig-Bing procedures. There was no significant interaction between prematurity and operative weight. In sensitivity analyses excluding patients with Taussig-Bing anomaly, results were similar, with children weighing <2 kg having 3.96 times the odds of major morbidity or mortality (95% CI 1.04-15.09, $P = 0.044$) and no significant difference in the odds of major morbidity or mortality when comparing infants weighing 2.0-2.5 kg with those weighing >2.5 kg ($P = 0.314$).

Postdischarge Outcomes

Follow-up data were available for 129 patients beyond 30 postoperative days, including 57% (n = 4/7) of surviving infants weighing <2.0 kg, 87.0% (n = 20/23) of surviving infants weighing 2.0-2.5 kg, and 57.7% (n = 105/182) of surviving infants weighing >2.5 kg ($P = 0.014$). Among those with available data, the median follow-up duration did not differ between weight categories. Among these patients, 22.5% (n = 29) underwent cardiac reintervention after discharge, with no significant differences across weight categories ($P = 0.903$). The majority of these (82.8%, n = 24/29) patients were for branch pulmonary artery stenosis. Of these, 70.1% (n = 17) were addressed surgically via patch reconstruction (the rest were treated via a catheter-based approach). There were no differences in approach across weight categories ($P = 1.000$). Of the 24 patients requiring reintervention for pulmonary artery stenosis, 62.5% (n = 15) had primary patch reconstruction during the initial ASO. Other late cardiac reinterventions included

Table 2. Details on Postoperative Outcomes of Patients Who Underwent the Arterial Switch Stratified by Operative Weight

	Overall (n = 217)	<2.0 kg (n = 8)	2.0-2.5 kg (n = 23)	>2.5 kg (n = 186)
Operative mortality	5 (2.3)	1 (12.5)	0 (0.0)	4 (2.2)
Major morbidity	29 (13.4)	2 (25.0)	2 (8.7)	25 (13.4)
Mechanical circulatory support	3 (1.4)	1 (12.5)	1 (4.4)	1 (0.5)
Dialysis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Persistent neurologic deficit	3 (1.4)	0 (0.0)	1 (4.4)	2 (1.1)
Pacemaker placement	7 (3.2)	0 (0.0)	0 (0.0)	7 (3.8)
Diaphragmatic paralysis	5 (2.3)	0 (0.0)	0 (0.0)	5 (2.7)
Unplanned reintervention	2 (0.9)	1 (12.5)	0 (0.0)	1 (0.5)
Late reintervention*	29/129 (22.5)	1/4 (25.0)	5/20 (25.0)	23/105 (21.9)
Postdischarge mortality (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Data are expressed as n (%).
*Surgical or catheter-based intervention after discharge.

Table 3. Univariable and Multivariable Associations With Major Morbidity or Mortality

Univariable Analysis	*P* Value	Multivariable Model		
		Odds Ratio	95% CI	*P* Value
Operative weight (kg)	0.141			
<2		3.93	1.04-14.85	0.044
2-2.5		0.52	0.19-1.49	0.225
>2.5		REF	REF	NA
Sex (male)	0.304			
Premature birth (<37 wk)	0.076			
Antenatal diagnosis	0.244			
TGA subtype	0.018‡			
TGA, intact ventricular septum		REF	REF	NA
TGA, ventricular septal defect		1.25	0.77-2.89	0.502
Taussig-Bing anomaly		22.38	1.13-6.88	0.007
Abnormal coronary anatomy*	0.074			
Bypass time (min)†	0.005‡	1.15	1.09-1.22	<0.001
Aortic cross-clamp time (min)	0.226			
Circulatory arrest time (min)	0.903			
Concomitant arch repair	0.782			
Taussig-Bing bypass time	NA	0.86	0.80-0.93	<0.001

NA, not applicable; REF, reference.
*1LCx-2R vs other.
†Odds ratio for bypass time is reported as the effect per 10-minute change in bypass time.

pacemaker placement (n = 1), pacemaker generator replacement in patients who underwent postoperative pacemaker placement (n = 2), and pericardiocentesis (n = 1). Taussig-Bing anomaly was associated with a higher incidence of late reintervention (52.9% vs 17.9%, $P = 0.001$). No other patient characteristic was associated with late reintervention.

DISCUSSION

In this retrospective cohort study, we found that the ASO may be safely performed in infants weighing 2.0-2.5 kg, without significant increase in mortality or major morbidity. Low weight has traditionally been considered a risk factor for early mortality in congenital cardiac surgery and may thereby prompt delays in surgical repair until a certain weight is achieved.[2,9-11] However, there is growing evidence that this delay to gain an arbitrary weight does not beget better outcomes.[1] As surgeons gain experience operating on low-weight infants, complex operations can be performed safely and with comparable outcomes in infants of normal weights.[12] Mortality and major morbidity then, seems to depend more on patient-specific factors such as the type of lesion.

There remains considerable concern in operating on neonates weighing <2.0 kg. Roussin et al identified an operative mortality of 16% in their cohort weighing <2.0 kg,[13] and Fricke et al recently reported a 50% mortality rate in their cohort of 10 neonates weighing <2.0 kg.[14] While our study only had 1 patient weighing <2.0 kg who died (in a 1.1 kg neonate), even with a sample size of 8 patients, we were able to detect statistically significant differences in outcomes in this extremely low-weight cohort compared with a cohort of children weighing >2.5 kg. Although there are large CIs around the magnitude of this association, our data suggest that observed differences in outcomes are not likely to be the result of chance alone. Future research should focus on this challenging demographic.

The adverse effects of prematurity on congenital cardiac surgical outcomes have been well described.[15,16] We have previous reported that gestational age was more impactful than birth weight on in-hospital mortality in the Norwood procedure for infants with hypoplastic left heart syndrome.[17] Surgical weight poses technical challenges that can be overcome with improved surgical techniques. In contrast, prematurity poses physiological challenges with immature organ systems more prone to intra- and postoperative dysfunctions. Notably, however, delays of arterial switch for TGA were associated with significantly increased morbidity and cost.[18] In this investigation, birth at <37 weeks was not associated with worse outcomes, although the methods were not designed to explore this in detail.

Despite advances in pulmonary artery reconstruction, supravalvar pulmonary stenosis remains one of the most common postoperative complications, occurring in at least 18.6% of our patients with available follow-up data. This finding is consistent with previous reports that have ranged from 5.1% to up to 56% of cases.[19-21] This result is thought to be due to a variety of reasons, including anastomotic scar formation, tension on anastomotic sites from inadequate mobilization of the neopulmonic root and pulmonary artery, or the more traditional use of a pantaloon pericardial patch for the anastomosis between the neopulmonic root and the pulmonary artery.[20,21] There is discordant literature regarding the use of pericardial patch reconstructions. Some reference accelerated patch calcification and inadequate growth potential compared with the surrounding tissues.[22] Although we do not have precise patch size

details on our low-weight neonates, it is possible that disproportionately large patches used in smaller patients may predispose to the development of stenosis necessitating long-term reintervention.

Limitations

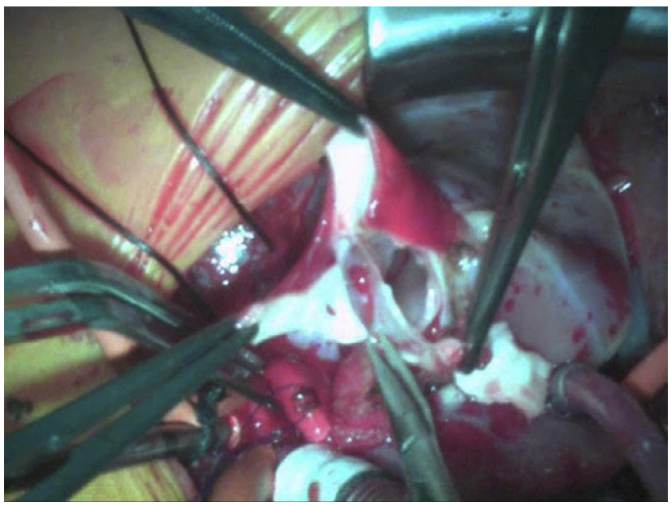
There are several limitations to this investigation. The retrospective nature of the present study subjects it to limitations inherent in all observational investigations. Furthermore, data were derived from a single, high-volume institution, which may limit generalizability. Our infants were managed pre- and postoperatively in a specialized cardiac neonatal intensive care unit and were all operated on by 1 of 5 surgeons with an uneven case distribution (54% operated on by a single surgeon). Moreover, we do not have data on those infants who electively pursued palliative care or who were turned down for surgical repair because of other complications. Most importantly, the 2.0-kg weight was chosen arbitrarily; we do not have sufficient power to examine other potential cut points below this threshold. Finally, because many of our patients are referred to us from around the world and return to their primary cardiologists for long-term care, our follow-up data are limited, limiting our ability to draw meaningful inferences regarding long-term outcomes and time-related events.

CONCLUSION

The ASO may be safely performed by experienced surgeons on neonates weighing 2.0-2.5 kg without differences in overall outcomes compared with those weighing >2.5 kg. Imposed delays for corrective surgery may not be necessary for these low-weight infants with TGA.

SUPPLEMENTARY MATERIAL

The following is the supplementary data to this article:



Video 1. Arterial switch operation techniques in a low-weight neonate.

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