

Arterial Switch for Transposed Great Vessels With Intact Ventricular Septum Beyond One Month of Age

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Background. Late referral of patients with transposition of the great arteries (TGA) and intact ventricular septum (IVS) is common in China. This study investigates the impact of later age on the arterial switch operation (ASO) performed for TGA-IVS beyond 1 month of age.

Methods. From 2000 to 2011, a total 109 patients with TGA-IVS were referred over 1 month of age. In group A, 78 patients with satisfactory left ventricular (LV) geometry underwent a one-stage ASO. In group B, 31 patients with LV regression underwent a two-stage ASO with prior LV retraining.

Results. The median age at ASO was older in group B (6 months, versus group A 1.9 months; $p = 0.01$). Group A had more frequent patent ductus arteriosus (70.5%, versus group B 38.7%; $p = 0.02$). The in-hospital mortality was similar in both groups (group A 2.6%, group B 9.7%; $p = 0.14$). Late mortality was higher in group B (16%, versus

group A 2.7%; $p = 0.03$), as well as aortic regurgitation rate (group A 9.8% versus group B 33.3%; $p = 0.01$). The median duration of retraining in group B was 18 days. There were no deaths at retraining, although 2 patients required revision of the pulmonary artery banding. The only significant risk factor for late mortality in group B was age at retraining, as continuous variable ($p = 0.04$). Age beyond 3 months at LV retraining was associated with late impaired LV ejection fraction ($p = 0.01$).

Conclusions. The overall outcomes of ASO for TGA-IVS performed beyond 1 month of age are satisfactory. Two-stage ASO has higher late mortality and more neo-aortic regurgitation. Later age at retraining is associated with higher late mortality. Age beyond 3 months at retraining is associated with impaired LV function.

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The arterial switch operation (ASO) is today the treatment of choice for patients born with transposition of the great arteries with intact ventricular septum (TGA-IVS). Late referral of patients with TGA-IVS is common in China. Our strategy at the Fuwai Hospital in Beijing is to favor anatomical repair for nearly all patients with TGA-IVS, including for patients presenting beyond 1 month of age. The LV ability to sustain a systemic function is slowly decreasing after 1 month of age in TGA-IVS. There is an ongoing controversy around the optimal surgery to perform in TGA-IVS seen beyond 1 month of age. Left ventricle (LV) retraining in TGA-IVS was first reported by Yacoub and associates [1] in 1977 before the era of the neonatal switch. In 1989, Jonas and colleagues [2] reported the rapid two-stage switch technique.

Although these technologies had been used for a very long time and applied to a relatively large number of patients, there is little information about late mortality, late LV dysfunction, and neo-aortic valve performance, especially for patients who underwent LV retraining at a later age.

This study reports midterm outcomes of the ASO done beyond 1 month of age, focusing on the two-stage ASO and on the impact of “later age” at LV retraining.

Material and Methods

From January 2000 to August 2011, 477 consecutive dextro-transposition of the great arteries (dTGA) patients (including TGA with ventricular septal defect) underwent an ASO in our institution. We conducted a retrospective study on the 109 consecutive dTGA-IVS or dTGA with restricted VSD (≤ 3 mm on echocardiogram) operated on beyond 1 month of age. Group A includes 78 patients with favorable LV geometry (median age 1.9 months; range, 31 days to 6.8 months) who underwent a one-stage ASO; and group B includes 31 patients (median age 6 months; range, 31 days to 5.2 years) who

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underwent LV retraining followed by a second-stage ASO. No patients underwent previous atrial switch. The Ethics Committee at Fuwai Hospital approved the study and waived the need for patient consent to publish outcome data.

Indication for Left Ventricle Retraining and Timing of Second-Stage ASO

As shown in **Figure 1**, LV retraining was indicated according to a combination of different factors: (1) age more than 1 month; (2) an LV mass index less than 35 g/m² (the LV mass was calculated at echocardiography using the formula issued by the American Society of Echography [3] and was then indexed to the body surface area); a single pediatric cardiologist who was blinded to treatment and results made all the measurements); (4) shape of the interventricular septum; all retrained patients had a right to left bulging of the interventricular septum with a “banana” LV shape, designating a low LV pressure; and (5) presence of an atrial septal defect; a patent ductus arteriosus (PDA), a closing VSD, or a LV outflow obstruction can modify the LV inload and afterload, and allow survival beyond 1 month of age in patients with TGA-IVS. The second-stage ASO was performed after the LV mass index had reached 50 g/m², and when the interventricular septum resumed a straight shape, indicating an increased LV pressure.

Surgical Management

LEFT VENTRICLE RETRAINING, PULMONARY ARTERY BANDING WITH MODIFIED BLALOCK-TAUSSIG SHUNT. After median sternotomy and pericardiotomy, the left ventricle and right ventricle pressures were measured by direct manometry,

confirming the low LV pressure and the reduced LV to right ventricle (RV) ratio. The Blalock-Taussig shunt was first performed and implanted between the innominate artery and the right pulmonary artery (PA) branch. When present, the patent ductus arteriosus was ligated. The size of the Gore-Tex (W.L. Gore, Flagstaff, AZ) conduit included 3.5, 4, and 5 mm, based on the body weight. Then a banding of the pulmonary trunk with continuous proximal pressure measurement was performed. The band was placed distally in a way to preserve together the pulmonary valve and the PA branches. The aim of the banding was to achieve an intraoperative LV/RV pressure of one third, between 0.60 and 0.70. All infants showed an anticipated decrease in systemic oxygen saturation, but without the need to change ventilation determinants. Two patients with intact atrial septum underwent a concomitant atrioseptectomy under cardiopulmonary bypass, to improve oxygenation. Inotropic support was always required, including variously, dopamine, milrinone, or epinephrine.

ARTERIAL SWITCH OPERATION. The ASO technique was the same for one-stage and two-stage ASO. The cardiopulmonary bypass techniques included continuous flow with bicaval cannulation, blood prime, and moderate hypothermia. Myocardial protection was achieved with antegrade single-dose blood cardioplegia. The second-stage ASO was made more challenging owing to pericardial adhesions. The Blalock-Taussig shunt was ligated and transected at the beginning of the cardiopulmonary bypass, and the PA trunk was divided at the site of the previous PA band. The Lecompte maneuver was always performed, and the coronary artery translocation was done with liberal mobilization of the coronary artery trunks. The neopulmonary artery was reconstructed with a single pantaloon patch of fresh autologous pericardium to reconstruct the sinuses of Valsalva. Postoperative care included various inotropes, and extubation was achieved based on the quality of the LV function at echocardiogram.

Statistical Analysis

Continuous variables are presented as mean ± SD and or median with minimum and maximum range, and categorical variables are presented as percentage with 95% confidence limits (CL). Time to death and neo-aortic regurgitation are displayed as Kaplan-Meier curves. Contingency tables and the Fisher exact test were applied for discrete variables. Distribution differences of variables between groups were tested by Mann-Whitney U test for the skewed distribution. The level of significance was set at *p* 0.05. Analysis was conducted using SPSS version 17.0 for Windows (SPSS, Chicago, IL).

Results

Results of LV Retraining in Group B

There was no death at LV retraining. The median age was 5.2 months (range, 34 days to 5 years). The median duration of LV retraining (**Fig 2**) was 18 days (range, 1 day

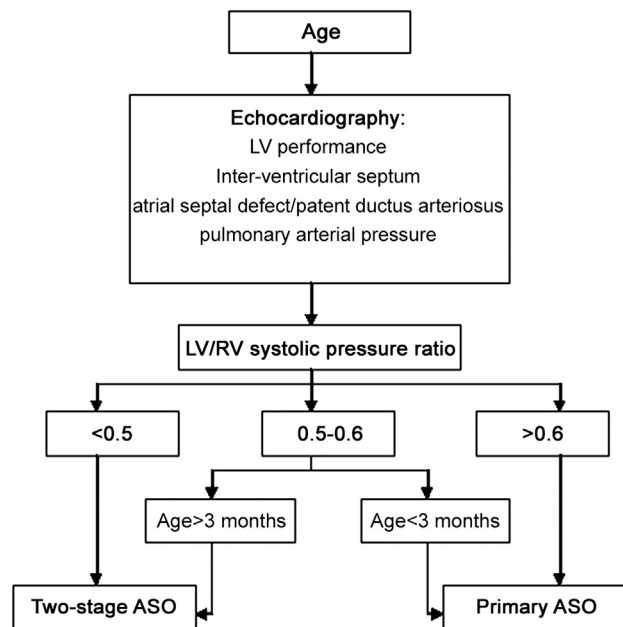


Fig 1. Protocol of left ventricle (LV) retraining. (ASO = arterial switch operation; RV = right ventricle.)

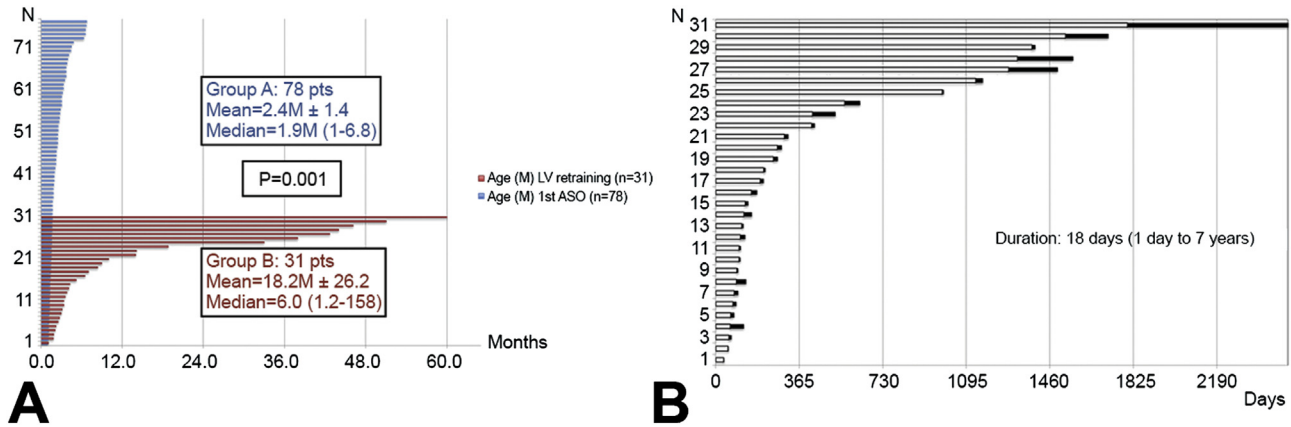


Fig 2. Age at arterial switch operation (ASO). (A) Age at ASO between group A (blue) and group B (red). (B) Duration of retraining and age at ASO in group B.

to 7 years). The median LV mass index was 26 g/m² (range, 13 to 31 g/m²). The median LV/RV systolic pressure ratio was 0.36 (range, 0.16 to 0.62). Two patients required revision of a too-tight PA banding with low oxygen saturation. At the time of the second stage ASO, the LV mass index raised to median 57 g/m² (range, 51 to

70 g/m²) and the LV/RV systolic pressure ratio raised to 0.62 (range, 0.55 to 0.70).

Results of One-Stage ASO in Group A

As shown in Table 1, the mean age at one-stage ASO was 2.4 ± 1.4 months. A PDA was present in 70.5%, a factor

Table 1. Patient Characteristics and Outcomes Between Group A and Group B

Variables	Group A 1-stage ASO, n = 78	Group B 2-stage ASO, n = 31	p Value
Patient characteristics			
LV geometry	Satisfactory	Impaired	NA
Mean age at ASO, months	2.4 ± 1.4	18 ± 26.2	<0.01
Median age at ASO, months (range)	1.9 (1-6.8)	6.0 (1.2-158)	<0.01
Median weight at ASO, kg	5.3 (4.2-8.8)	6.2 (4-34)	0.09
Patent ductus arteriosus (%)	55 (70.5)	12 (38.7%)	0.02
Hemodynamically restrictive VSD <3 mm (%)	16 (20.5)	5 (16.1%)	0.19
LV outflow tract obstruction	0	0	NA
Aortic arch obstruction	0	0	NA
Coronary anatomy (%)			
1LCx2R	25 (81)	58 (74.4)	0.33
1L2RCx	2 (7)	6 (7.7)	0.31
1LR2Cx	1 (3)	4 (5.1)	0.38
1LRCx	1 (3)	2 (2.6)	0.44
2LRCx	2 (7)	8 (10.3)	0.26
Cross-clamp time, minutes	98.9 ± 22.1	122.9 ± 35.8	0.06
Median age at retraining, months (range)	NA	5.2 (34 days-5 yrs)	NA
Duration of retraining, days (range)	NA	18 (1 day-7 yrs)	NA
Median LV mass index, g/m ² (range)	NA	26 (13-31)	NA
Median LV/RVSP ratio before training	NA	0.36 (0.16-0.62)	NA
Outcomes			
In-hospital mortality (%)	2/78 (2.6)	3/31 (9.7)	0.14
Lost to follow-up (%)	3/76 (3.9)	3/28 (10.7)	0.51
Late mortality (%)	2/73 (2.7)	4/25 (16.0)	0.03
Significant neo-aortic regurgitation (%)	7/71 (9.8)	4/21 (19.0)	0.04
LVEF, %	67 ± 9	63 ± 6	0.69

ASO = arterial switch operation; LV = left ventricle; LVEF = left ventricular ejection fraction; NA = not applicable; RVSP = right ventricle systolic pressure; VSD = ventricular septal defect.

protective for LV performance. The in-hospital mortality was 2.6% (95% CL: 0.4% to 7.8%) and the late mortality was 2.7% (95% CL: 0.4% to 7.8%), with 2 deaths related to impaired LV function. The mean follow-up was 3.8 years (range, 6 months to 6.9 years) with 3 patients lost to follow-up. There were 7 significant late neo-aortic regurgitations (9.8%). The mean left ventricular ejection fraction (LVEF) was 67% ± 9%.

Compared with group B patients, group A patients have a younger age at ASO (18 months versus 2.4 months, $p = 0.001$; Fig 2), lower late mortality (4 of 25 versus 2 of 76, $p = 0.032$), and less late aortic regurgitation (19.0% versus 9.8%, $p = 0.032$).

Results of Second-Stage ASO in Group B

Mean age at second stage ASO (Table 1) was older than in group A, at 18 ± 26.2 months ($p = 0.001$; Fig 2A), as well as the PDA present was less than group A, 12 (38.7%). The in-hospital mortality was similar ($p = 0.138$). Cross-clamp times were similar ($p = 0.06$), but longer in group B owing to adhesions and not to more complex coronary anatomy. Two in-hospital deaths were caused by septicemia, and the other was caused by low cardiac output syndrome. Follow-up was complete in 25 patients (89.3%) and ranged from 6 months to 7.6 years (mean 4.3 years). The late mortality was higher (16%; 95% CL: 5.4% to 53.1%); the causes were pneumonia in 2, sudden death in 1, and unknown in 1. However, the LVEF of 4 late deaths was only 50%, 54%, 50%, and 52%, respectively. Overall survival for the total study population of group B was 89.3% at 6 months, and 75.0% at 1 year and 5 years. Age at LV retraining, as a continuous value, was the only risk factor for late mortality ($p = 0.04$). The data are shown in Figure 3.

LV Retraining Beyond 3 Months of Age

All the in-hospital mortality, late mortality, and at least moderate neo-aortic regurgitation were observed in

patients who had their LV retrained beyond 3 months of age. So we further compared the outcome between the less than 3 months of age group and the greater than 3 months group. There were 7 patients in the less than 3 months group and 24 patients in the more than 3 months group, with 3 patients lost to follow-up. The data are presented in Table 2 and Figure 4. Estimated overall survival for the more than 3 months population (including in-hospital mortality) was 85.7% at 6 months, 66.7% at 1 year, and 66.7% at 5 years.

Comment

Compared with group B patients, group A patients have a younger age at ASO (2.4 versus 18 months, $p < 0.01$) and more frequent PDA (70.5% versus 38.7%, $p = 0.02$). Both of those factors were protective for the LV performance. The in-hospital mortality, late mortality, significant neo-aortic regurgitation, and LVEF were satisfactory in group A. Moreover, the late mortality and significant neo-aortic regurgitation were lower in group A. These encouraging results were consistent with those of Sarris and colleagues [4] and indicated that the primary ASO may be done uneventfully even at the age of 3 to 4 months. The largest retrospective study of primary ASO is reported by Kang and colleagues [5] in which 275 neonates younger than 21 days were compared with 105 infants (age range, 21 to 185 days) undergoing primary ASO for TGA-IVS. They found no significant difference in terms of in-hospital mortality (5.5% versus 3.8%) or need for mechanical LV support (3.6% versus 5.7%) between the early and late ASO groups, respectively.

However, the LV retraining undoubtedly remains the choice for patients with unfavorable LV geometry. Lacour-Gayet and coworkers [6] suggested that the indication for LV retraining was based on a combination of factors including age greater than 1 month, a “banana

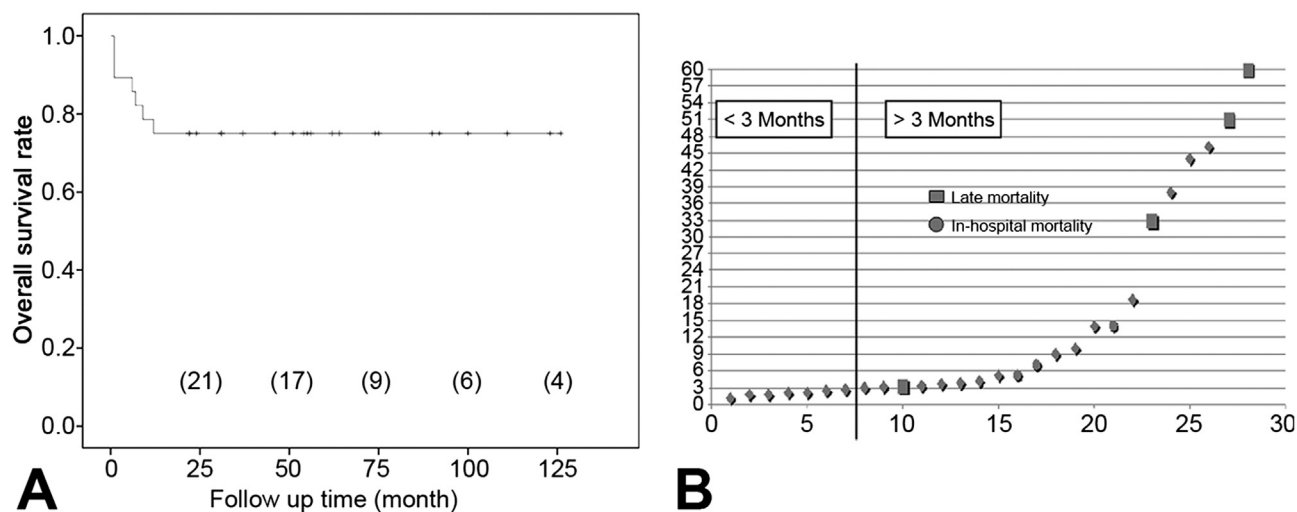


Fig 3. Mortality of arterial switch operation (ASO) in patients who underwent retraining. (A) Kaplan-Meier curves for mortality; numbers of patients at risk are in parentheses. (B) Late mortality (squares; circles indicate in-hospital mortality) and age at retraining (without patients lost to follow-up). Age at left ventricle retraining, as continuous value, was the only risk factor for late mortality ($p = 0.04$).

Table 2. Baseline Data and Outcomes Between Less Than 3 Months and More Than 3 Months in Group B

Variables	<3 Months Group	>3 Months Group	p Value
Patient characteristics			
Male (%)	5 (71.5)	19 (79.1)	0.67
Presence of PDA (%)	2 (28.5)	10 (41.6)	0.85
Hemodynamically restrictive VSD <3 mm (%)	1 (14.3)	4 (16.7)	1.00
Complex coronary anatomy (%)	2 (28.7)	4 (16.7)	0.65
Median LVMI before retraining, g/m ² (range)	27 (13–31)	27 (15–31)	0.60
Median LV/RVSP ratio before training	0.38 (0.12–0.60)	0.37 (0.16 to 0.62)	0.91
Duration of retraining, days (range)	14 (7 days–1 yr)	20 (1 day–7 yrs)	0.56
Median LV/RVSP ratio at ASO	0.61 (0.55–0.70)	0.63 (0.55–0.67)	0.88
Median LV mass index at ASO, g/m ²	60 (53–70)	56 (51–67)	0.92
Results			
In-hospital mortality (%)	0 (n = 7)	3 (12.5%, n = 24)	0.99
Lost to follow-up (%)	0 (n = 7)	3 (14.3%, n = 21)	0.99
Late mortality (%)	0 (n = 7)	4 (22.2%, n = 18)	0.55
Significant neo-aortic regurgitation (%)	0 (n = 7)	4 (28.5%, n = 14)	0.26
LVEF, %	69 ± 4 (n = 7)	54 ± 8 (n = 14)	0.01

ASO = arterial switch operation; LVMI = left ventricle mass index; LVEF = left ventricular ejection fraction; PDA = patent ductus arteriosus; RVSP = right ventricle systolic pressure; VSD = ventricular septal defect.

shape" LV, and mainly, LV mass less than 35 g/m². For the patients in group B, we have a full-fledged strategy to retrain the LV, regarding multiple factors (Fig 1).

Corno and associates [7], Wernovsky and colleagues [8], and Jonas and associates [2] found that the LV mass index, RV/LV wall thickness ratio, LV to RV pressure ratio, LV mass and volume, and mass to volume ratio increased significantly after retraining. Although the LV was prepared well, drawbacks such as relatively high mortality, impaired cardiac function, and the high incidence of neo-aortic regurgitation still perplexed us.

Boutin and colleagues [9] found that the LV of transposed infants had the ability to hypertrophy rapidly, achieving a plateau within 7 days after PA banding. But in our cohort, LV could not meet the criteria for second-stage ASO several days after retraining in some patients, so the ASO was arranged 3 to 6 months later until they got well conditioned. Our findings were consistent with those of the Yacoub study [1]. The huge discrepancies in the interval time (1 day to 7 years) between PA banding and ASO was observed in our study population. In the patient whose duration was 1 day, the preoperative LV performance was not far from meeting the criteria for ASO, the acquisition of LV mass was rapid, and all the variables were suitable for ASO at 1 day after the retraining. Moreover, several patients had delayed ASO with prolonged duration of retraining due to economic constraints. Even so, the interval time between PA banding and ASO was not correlated with mortality in the univariate analysis.

Follow-up of this two-stage approach has revealed impaired LV systolic performance [6, 10], an increased incidence of neo-aortic regurgitation [10–12], and RV outflow tract obstruction [13] compared with the primary arterial switch. In our cohort, the in-hospital and late mortality were acceptable. Absence of reoperation may be confounded by small sample and short follow-up

periods. Both mortality and reoperation were consistent with results from other centers.

Age at retraining, as a continuous value, was the only risk factor for late mortality in the retrained patients ($p = 0.04$). Meanwhile, all the deaths were observed in patients who underwent LV retraining beyond the age of 3 months. So we directly compared the outcomes between the age of more than 3 months and less than 3 months. Although the difference in mortality was not statistically significant, this result indicated that age at retraining was an independent risk factor, which was in accordance with the conclusion by Boutin and colleagues [9]. Furthermore, the follow-up study by Poirier and associates [14] of 39 patients with TGA who underwent LV retraining and anatomic correction for systemic RV dysfunction after atrial rerouting showed that age significantly increased the probability of anatomic correction failure. There were no differences of retraining duration, LV mass index, and LV/RV systolic pressure ratio, which indicates that age at retraining is an independent factor for neo-aortic regurgitation after these confounding factors ruled out.

Among patients who underwent two-stage ASO, the LVEF was lower in the more than 3 months group at latest echocardiography. Furthermore, the direct cause of death may not be cardiac function impairment, but the decreased LVEF was noted in the majority of deaths. Strikingly, both the capacity of LV hypertrophy and the myocyte performance decreased with increasing age [15]. Postoperative myocardial ischemia is a strong confounding factor. There were no symptoms, signs, or electrocardiography factors indicating coronary anastomosis complication at follow-up. Reduced coronary flow reserves, where the rapid LV hypertrophy after banding may induce subendocardial ischemia, may mainly impair diastolic function. In group B, no early diastolic dysfunction was noted. However, we failed to provide

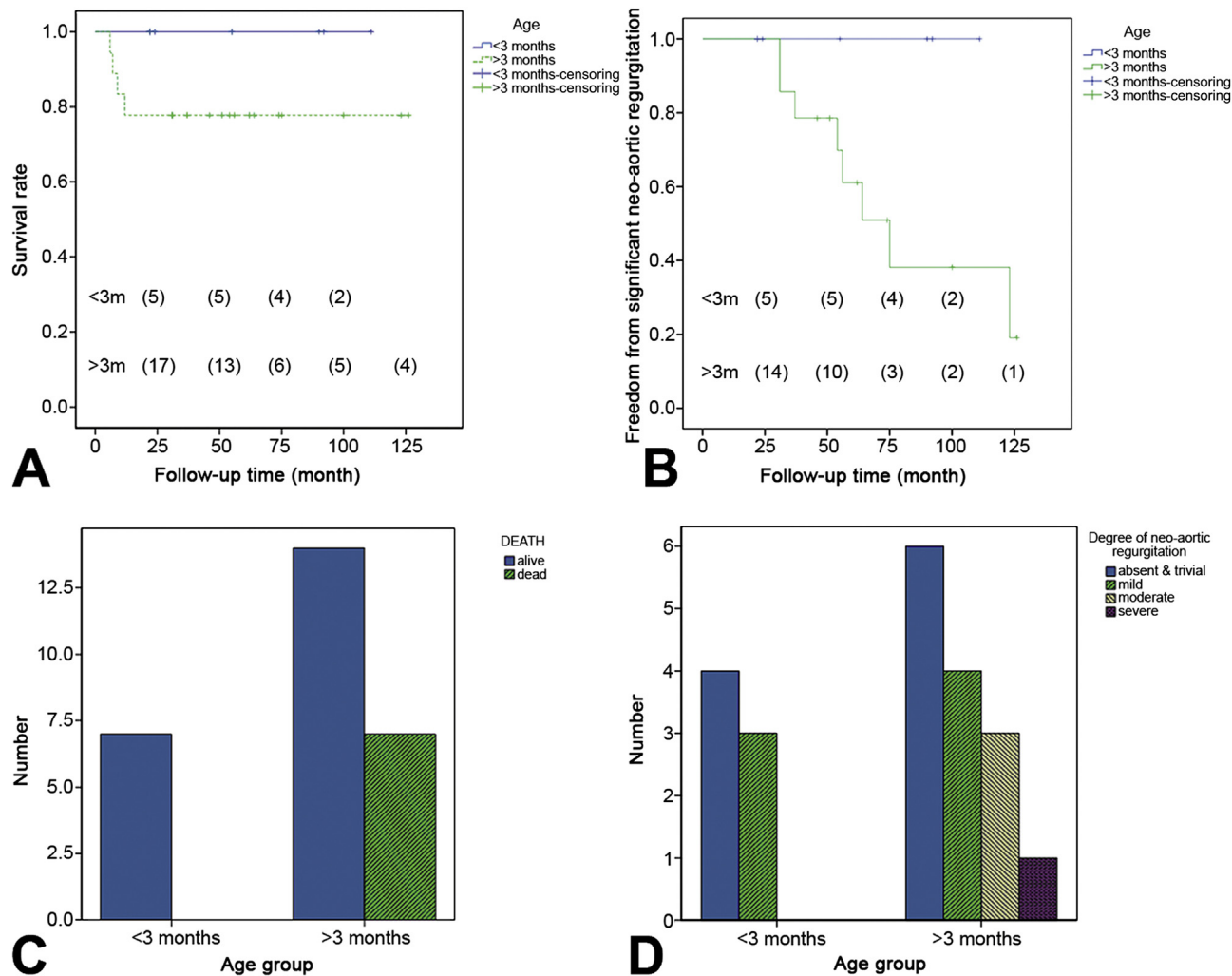


Fig 4. Outcomes between groups. (A) Kaplan-Meier curves for mortality; numbers of patients at risk are in parentheses. (Blue lines = >3 months group; Green lines = <3 months group; Cross = censoring.) (B) Kaplan-Meier curves for significant neo-aortic performance; numbers of patients at risk are in parentheses. (Blue lines = >3 months group; Green lines = <3 months group; Cross = censoring.) (C) Mortality. (Blue bars = alive; green bar = dead.) (D) Significant neo-aortic performance. (Blue bars = absent or trivial; green bars = mild; gray bar = moderate; purple bar = severe.)

diastolic function at ASO, which may be a confounding factor. Poirier and Mee [16] have shown myocardial edema on magnetic resonance imaging shortly after banding, which is believed to be a precursor of fibrosis.

Boutin and colleagues [17] pointed out the LV function falls acutely owing to afterload excess or depressed contractility but recovers rapidly as compensatory hypertrophy occurs, but we did not note any early LV function impairment after PA banding. The method of PA banding was to achieve an initial LV/RV systolic pressure ratio around 0.66 in our cohort. Bonnet and associates [18] and Corno and colleagues [19] have described their early results with a telemetric adjustable FloWatch pneumatic device in which tightening and loosening are regulated by an external control unit. DiBardino and coworkers [20] and Sekarski and coworkers [21] also provided a similar adjustable PA band for staged LV retraining. The most important advantages are its gradually adjusting of band

tightening, which conforms to the physiologic processes. Their results have demonstrated a significant reduction in early deaths, need for reoperation, inotropic support, and early acute adverse events, without compromising on the degree of desired gradients. However, no early LV systolic/diastolic impairment and different LV/RV systolic pressure ratio between two groups was noted. In addition, there was no correlation between the LV/RV systolic pressure ratio at ASO and mortality. So we cannot easily speculate that an adjustable PA band would provide better outcomes.

The presence of a PA band may result in subsequent distortion and regurgitation of the neo-aortic valve. The pulmonary valve was also exposed to the higher pressure after PA banding. In our study, there was more neo-aortic regurgitation in group B, who underwent previous PA banding. Even more, all significant neo-aortic regurgitation in retrained patients were noted in the more than 3

months group. On the one hand, the root of the PA cannot gradually expand owing to lack of stimulation by pressure, which in turn results in a more unfavorable mismatch between the anatomic pulmonary root and the ascending aorta. Blume and Wernovsky [22] reported that the turbulence of the blood, caused by a mismatch of the neo-aortic root and the ascending aorta, led to neo-aortic regurgitation. On the other hand, although there were no apparent morphologic and histologic differences between the aortic and pulmonary valves in newborn infants [23], the elastic fibrous tissue in the pulmonary valve shrinks and becomes weaker under the lower pressure of pulmonary circulation with aging [24].

Limitations of this study include its single institution, small sample size, and retrospective nature. The choice of a cutoff of 3 months for investigating the age effect of two-stage ASO was mainly determined by the preliminary results, which must be investigated in further prospective study. The number of patients not included in the follow-up could influence the interpretation of the results.

In conclusion, overall outcomes of ASO undertaken for TGA-IVS beyond 1 month of age are satisfactory. Two-stage ASO is associated with higher late mortality and more neo-aortic regurgitation. Later age at retraining is associated with higher late mortality. Age beyond 3 months at retraining is associated with impaired LV function. Further follow-up is needed.

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