Palliative pulmonary artery banding versus anatomic correction for congenitally corrected transposition of the great arteries with regressed morphologic left ventricle: Long-term results from a single center

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Objective: We aimed to compare the long-term results between palliative pulmonary artery banding and anatomic correction for congenitally corrected transposition of the great arteries with regressed morphologic left ventricle.

Methods: From 2003 to 2012, 40 consecutive patients underwent first-stage pulmonary artery banding. The second-stage operation—double switch—was performed in 15 patients (double-switch group). The other 25 patients retained pulmonary artery banding without further operation (pulmonary artery banding group). In-hospital mortality, long-term mortality, and heart function were studied as primary outcomes.

Results: The median time of follow-up was 3.4 ± 0.7 years (range, 6 months–9.5 years). Overall survival rate was 66.7% in the double-switch group versus 96.0% in the pulmonary artery banding group ($P = .03$). The ratio of New York Heart Association functional class I–II (80.0% vs 95.9%; $P = .02$) and the mean functional left ventricle ejection fraction ($51.4\% \pm 9.6\%$ vs $61.0\% \pm 6.4\%$; $P = .01$) were higher in the pulmonary artery banding group at follow-up. In univariate analysis, age at pulmonary artery banding was the only risk factor for late deaths (odds ratio, 7.30; $P = .01$) and left ventricle dysfunction (odds ratio, 4.77; $P = .03$) after the double switch. For patients who experienced prolonged pulmonary artery banding, mean oxygen saturation was $95\% \pm 3.1\%$ and the trans-banding pressure gradient was 46.9 ± 21.5 mm Hg.

Conclusions: In patients with congenitally corrected transposition of the great arteries with deconditioned morphologic left ventricle pulmonary artery banding may be considered an ideal procedure because it allows left ventricle training while improving tricuspid regurgitation. Compared with the double-switch procedure after pulmonary artery banding, prolonged palliative pulmonary artery banding provided a lower mortality rate and indicated better cardiac function. (*J Thorac Cardiovasc Surg* 2014;148:1566–71)

Congenitally corrected transposition of the great arteries (ccTGA) is characterized by the combination of atrioventricular and ventriculoarterial discordance. The morphologic left ventricle (mLV) and morphologic right ventricle (mRV) support the pulmonary and systemic circulations, respectively. The mRV is not ideally suited for the long-

term maintenance of the systemic circulation. In time it may fail under these conditions because of its anatomic and physiologic substrate. The major manifestation of mRV dysfunction is tricuspid regurgitation (TR), which is associated with increased morbidity and mortality in patients with ccTGA.

Surgical approaches for ccTGA include conventional and anatomic repair. It has become apparent that the long-term outcomes of conventional repair, whereby the right ventricle remains in the systemic circulation, are not satisfactory.^{1–5} As such, the lesion itself is far from corrected. True correction, in terms of restoring the mLV to the systemic circulation, has been achieved by double-switch (DS) operation.

The success of DS procedures depends on the ability of the left ventricle to support systemic circulation. In the absence of unrestrictive ventricular septal defect and pulmonary arterial hypertension, the mLV will be deconditioned and cannot undertake the workload of systemic circulation. Pulmonary artery banding (PAB) is considered to be the ideal method for training mLV function. If the

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Abbreviations and Acronyms

ccTGA	= congenitally corrected transposition of the great arteries
DS	= double switch
mLV	= morphologic left ventricle
mRV	= morphologic right ventricle
NYHA	= New York Heart Association
PAB	= pulmonary artery banding
TR	= tricuspid regurgitation

function of the mLV is strong enough to be the main blood pump after PAB, the DS procedure will be done safely. This 2-stage strategy is now considered the optimal choice for patients with a deconditioned mLV. However, deterioration in left ventricle function in trained groups of patients has been reported, and there is concern that this will be a significant long-term problem.⁶ Is it better to enroll patients who have a regressed mLV in a program of retraining of the left ventricle followed by a DS procedure than to perform palliative PAB alone? We followed all patients who underwent PAB (with or without the second-stage DS) to compare the outcomes between DS and PAB as the long-term palliative procedure.

MATERIALS AND METHODS

Patients

Forty consecutive patients underwent PAB with or without the second-stage DS at Fuwai Hospital from January 2003 through December 2012. All patients were diagnosed with ccTGA without left ventricular outflow tract obstruction. The second-stage DS was performed in 15 patients (DS group) and palliative PAB was regarded as the ending procedure in the other 25 patients (PAB group). This study was approved by the Ethics Committee at Fuwai Hospital. They gave us their approval to waive the need for patient consent for publishing follow-up data about these patients. Follow-up information was completed in all patients. The median time of follow-up was 3.4 ± 0.7 years (range, 6 months-9.5 years).

Clinical Protocols and Surgical Techniques

All patients had objective evidence of TR and mRV dilation. PAB was used as an interim measure to both train the mLV for future DS and relieve the TR. The target mLV:mRV pressure ratio after PAB was 0.50-0.75 irrespective of the patient's age, underlying diagnosis, or baseline left ventricular pressure. The DS procedure was performed only when the mLV was considered to be well conditioned. Assessment for suitability for DS procedure was by means of transthoracic echocardiography and/or cardiac catheterization. Criteria for second-stage DS included mLV pressures $>75\%$ of systemic pressure for at least several months, less than moderate ventricular dysfunction, and less than moderate mitral regurgitation. The mLV mass index and mass:volume ratios were not calculated and not used in decision making.

PAB

Access was obtained via median sternotomy. The mLV and mRV pressures were measured by direct manometry before PAB. The PAB procedure was performed on the pulmonary trunk away from the pulmonary valve with the use of a polytetrafluoroethylene band (Gore-Tex, W. L. Gore &

Associates, Inc, Flagstaff, Ariz). The aim of banding was to achieve an intraoperative mLV pressure 0.50-0.75 of the systemic pressure.

DS

The DS approach was made through the previous incision for PAB. Ventricular septal defect repair was performed transatrially, through the aorta or through the right ventricle. The Senning procedure was used for atrial switch in all DS patients. The Lecompte maneuver was generally performed if the great arteries were not located side by side. Sinotubular junction plasty of the neo-aorta was performed to repress root dilation. Tricuspid valvuloplasty was performed simultaneously in 3 patients.

Data Collection

Patient demographics and clinical data were obtained from our local database. Ventricle function and size were assessed by echocardiography. A single cardiologist reviewed all previous echocardiograms and performed independent measurements. In-hospital mortality was defined as both 30-day mortality and death any time after operation but before discharge. Follow-up mortality was defined as death after 30 days or after discharge if length of hospital stay was >30 days. Reoperation included only reoperations on the heart and excluded secondary closure of the sternum and revision for bleeding or mediastinitis. Valvular regurgitation was considered substantial when documented as moderate or severe. mLV dysfunction was defined as mLV ejection fraction $<60\%$.

Statistical Analysis

Results are presented as mean $\pm$ standard deviation for continuous variables with normal distribution, as median and range for variables with non-normal distribution, and as frequency and percent for categorical variables. Time to death and neo-aortic regurgitation at follow-up are displayed by Kaplan-Meier curves. Comparisons of variables were made using the Student *t* test, the χ^2 test, or the Fisher exact test, as appropriate. Multivariate analysis could not be performed because the ratio of events per variable was too small. The level of significance was set at $\alpha = 0.05$. Analysis was conducted using SPSS version 17.0 (IBM-SPSS Inc, Armonk, NY) for Windows.

RESULTS

Patient Population and Anatomic Characteristics

The study group consisted of 23 men and 17 women. The median age at PAB of these patients was 3.1 years (range, 2 months-10 years), and their median weight at banding was 11.5 kg (range, 5.1-22.0 kg). In this cohort, 28 patients (70.0%) had a patent ductus arteriosus (≤ 3 mm on echocardiogram), 22 patients (55.0%) had an additional restrictive ventricular septal defect with no hemodynamic significance. TR was present in all patients, including 7 mild, 14 moderate, and 19 severe. One patient had dextrocardia. There were no pre-PAB procedures. The baseline data for these 2 groups are shown in [Table 1](#).

Early Outcomes After PAB

There was no death in either group after PAB. The pressure gradient trans-banding was 53.2 ± 11.1 mm Hg, although the mLV:mRV pressure ratio increased from 0.31 ± 0.15 to 0.63 ± 0.16 immediately after banding (0.63 ± 0.14 in PAB group vs 0.65 ± 0.17 in DS group; $P = .89$). No patient required removal of the band for

TABLE 1. Patient characteristics in the 2 groups

Patient characteristic	DS group (n = 15)	PAB group (n = 25)	P value
Age at PAB	3.0 y (3 mo-10 y)	2.0 y (2 mo-8 y)	.392
Weight at PAB (kg)	13.0 (5.2-19.3)	11.4 (5.1-22.0)	.598
Male gender	8 (61.5)	15 (75.0)	.461
PDA	11 (84.6)	17 (85.0)	1.000
VSD without hemodynamic significance	9 (69.2)	13 (65.0)	1.000
Tricuspid regurgitation			.513
Mild	3 (20.0)	4 (16.0)	
Moderate	5 (33.3)	9 (36.0)	
Severe	7 (46.6)	12 (48.0)	
mLV:mRV systolic pressure ratio before training	0.31 ± 0.09	0.32 ± 0.08	.837

Data are presented as median (range), n (%), or median ± standard error. DS, Double switch; PAB, pulmonary artery banding; PDA, patent ductus arteriosus; VSD, ventricular septal defect; mLV, morphologic left ventricle; mRV, morphologic right ventricle.

PAB. One patient required tightening of the band (rebanding) early after the initial procedure. Another 2 patients required late rebanding. The interval between initial PA banding and rebanding was 10 days, 6.9 months, and 13.7 months, respectively. No early left ventricle systolic/diastolic dysfunction was noted. No patients requiring early rebanding underwent late rebanding. Fifteen patients underwent DS. The duration of training for patients in the DS group who achieved anatomic repair was 17.2 months (range, 1 week-36.1 months). The mean mLV:mRV pressure ratio before DS was 0.80 ± 0.04 . The reason for absence of DS was mLV less response in 15 patients (ie, far from well-prepared mLV was noted by echocardiography evaluation; mLV:mRV pressure ratio at latest follow-up was not available because these 15 patients did not undergo cardiac catheterization), prolonged family preparation in 6 patients, and concomitant illness in 4 patients. Early after banding, mRV ejection fraction improved from $50.8\% \pm 11.7\%$ to $63.3\% \pm 8.1\%$ ($P = .04$). Improvement in TR can be viewed in Figure 1.

FIGURE 1. Improvement in tricuspid regurgitation. PAB, Pulmonary artery banding.

Perioperative Outcomes of DS

In the DS group, there was no early death after DS procedure. No reoperation, reintervention, extracorporeal membrane oxygenation, or permanent pacing were required during the early postoperative period. All patients were in New York Heart Association (NYHA) functional class I-II and no mLV dysfunction was detected at discharge. More information on perioperative outcomes of DS procedure is available in Table 2.

Follow-up Outcomes

At follow-up there were 5 deaths in the DS group. Three were because of mLV failure. The other 2 died of sudden death and pulmonary infection, respectively. In univariate analysis, age at PAB was a risk factor for late death (odds ratio [OR], 7.30; $P = .01$) and left ventricle dysfunction after DS procedure (OR, 4.77; $P = .03$), whereas pre-DS mLV:mRV pressure ratio was not (OR, 2.40; $P = .56$ for late deaths and OR, 5.05; $P = .22$ for left ventricle dysfunction). The pre-DS mLV:mRV pressure ratio of the 3 patients who experienced late death caused by mLV dysfunction was 0.78, 0.76, and 0.77, respectively. There was no difference in pre-DS mLV:mRV pressure ratio found among these 3 patients who died and other patients (0.77 ± 0.01 vs 0.82).

TABLE 2. Perioperative variables of double-switch (DS) procedure

Variable	DS group (n = 15)
Inotropes/ventilation before DS	0
CPB time (min)	163 ± 41
Aortic crossclamp time (min)	104 ± 37
Delayed sternal closure	3 (20)
LA pressure at ICU arrival (mm Hg)	8.1 ± 0.8
Ventilation time (h)	53.3 ± 39.0
ICU stay time (d)	4.4 ± 3.1
Postoperative length of stay (d)	19.9 ± 10.9
Peritoneal dialysis	0

Data are presented as n (%) or mean ± standard deviation. CPB, Cardiopulmonary bypass; LA, left atria; ICU, intensive care unit; DS, double switch.

FIGURE 2. Kaplan-Meier curves for mortality. PAB, Pulmonary artery banding; DSO, double switch operation.

± 0.04; $P = .99$). In the PAB group, 1 follow-up death was noted (recurrent pulmonary infection). The overall survival rate was higher in the PAB group (66.7% in DS group vs 96.0% in PAB group; $P = .03$). The estimated survival rate from the time of operation was 100% at 1 year, 71.4% at 2 years, and 47.6% at 3 years in the DS group, whereas it was 96.0% at 1, 2, and 3 years in the PAB group (Figure 2).

The NYHA functional class I-II (80.0% in the DS group vs 95.9% in the PAB group; $P = .02$) and the mean systemic ventricular ejection fraction ($51.4\% \pm 9.6\%$ in the DS group vs $61.0\% \pm 6.4\%$ in the PAB group; $P = .01$) were higher in the PAB group. There was no significant difference ($P = .83$) for the incidence of TR between the DS group and the PAB group. More information is available in Table 3.

At latest follow-up, significant aortic regurgitation and supraventricular tachyarrhythmia was identified in 3 and 1 patients in the DS group, respectively. No venous pathways, left ventricular outflow tract obstruction, or right ventricular outflow tract obstruction was noted. For patients who did not undergo the anatomic repair, the mean trans-banding

pressure gradient was 46.9 ± 21.5 mm Hg and the mean ± standard deviation oxygen saturation was $95\% \pm 3.1\%$.

DISCUSSION

Long-term outcomes were compared between palliative PAB and anatomic correction in patients with ccTGA with deconditioned mLV using proper statistical methods. We found that the palliative PAB provided a lower mortality rate and indicated better cardiac function.

The long-term outcome of patients with ccTGA after conventional surgical approach is unsatisfactory.¹⁻⁵ For patients in whom there is a coexisting ventricular septal defect or subpulmonary obstruction, many centers now follow a strategy that restores the mLV to the systemic position, either with a DS procedure or an atrial switch with a Rastelli reconstruction where necessary. Good results have emerged from many centers using this approach, and it represents a serious alternative to conventional repair.⁷⁻¹¹

The patients in our study were in a more complex group. In the absence of an unrestrictive ventricular septal defect or subpulmonary obstruction, the mLV works against the low-resistance pulmonary vascular bed, whereas the mRV contends with high-resistance systemic circulation. Typically, the mLV has a reduced ventricular volume and wall thickness and may be squashed by the volume-loaded mRV.¹² Patients with deconditioning of the mLV need to be identified and considered for training to sustain the systemic pressure by means of PAB.

PAB has been demonstrated to train the left ventricle effectively, so all patients in our cohort were referred for PAB with an intention to move subsequently to anatomic repair. In all patients, the gradient over the banding increased to 53.2 ± 11.1 mm Hg, whereas the mLV:mRV systolic pressure ratio increased from 0.31 ± 0.15 to 0.63 ± 0.16 immediately after banding. Twenty-five patients' mLV (62.5%) were judged to be well retrained and 15 patients (37.5%) underwent the anatomic repair. These results are consistent with the results found by Winlaw and colleagues.¹³ Lacour-Gayet and colleagues¹⁴ pointed out some cellular changes and molecular alterations that resulted from stimulation of the left ventricle.

Clinicians are frequently impressed that patients with ccTGA and pulmonary outflow obstruction fare better than those without. It has unequivocally been established that PAB has several beneficial effects in patients with mRVs acting as the systemic ventricle, such as improved RV function, stabilized TR, and delayed cardiac transplantation. In addition, PAB may even be used as palliation.^{15,16} In our cohort, the morphologic TR and mRV ejection fraction improved significantly after PAB. Theoretically, PAB increases the afterload of the mLV and effects a shift of the interventricular septum back toward the midline position, inducing the mRV to become less spherical. This

TABLE 3. Outcomes between groups

Outcome	DS group (n = 10)	PAB group (n = 24)	P value
Tricuspid regurgitation			.83
Mild	4 (40.0%)	10 (50.0%)	
Moderate	2 (20.0%)	4 (25.0%)	
Severe	0	0	
Systemic ventricular ejection fraction	$51.4\% \pm 9.6\%$	$61.0\% \pm 6.4\%$	<.01
New York Heart Association functional class I-II	80.0%	95.9%	.02
Long-term survival rate	66.7%	96.0%	.03

DS, Double switch; PAB, pulmonary artery banding.

left ventricle interference moves the attachment of the septal leaflet of the tricuspid valve and improves tricuspid valve coaptation, thereby reducing regurgitation. As a result, right ventricle preload is reduced with improvement of right ventricle dilation and systolic function.¹⁵

For 25 patients who did not undergo anatomic repair, the survival rate, systemic ventricular function, TR, and NYHA functional class were satisfactory at latest follow-up. The only late death was caused by pneumonia without cardiac reasons. The relatively good trans-banding pressure gradient and oxygen saturation could indicate that the banding was not too tight and required no loosening. These encouraging results suggest that PAB may be left in place as long-term palliative treatment, which is consistent with the study by Cools and colleagues.¹⁷ Although there was an important concern about long-term functional capacity and exercise tolerance, NYHA functional class was better in palliative PAB patients at follow-up.

The fate of the retrained left ventricle after DS procedure for ccTGA remains a refractory problem. The group from Birmingham reported deterioration in mLV function in the trained group of patients after anatomic repair.⁶ In our cohort, late mortality, systemic ventricular function, and NYHA functional class were significantly deteriorated in the anatomic repair group compared with the palliative PAB group. In addition, the majority of late deaths (80%; 3 as a result of low cardiac output and 1 sudden death) in the anatomic group were in relation to poor cardiac performance. As some research has suggested, PAB may cause myocardial necrosis, fibrosis, and reduced ventricular work index.¹⁸ Imposition of a pressure overload induces both myocyte hyperplasia and hypertrophy rapidly, but the angiogenesis increases slowly and deficiently, which causes subendocardial ischemia. The placement of a looser band with lower initial left ventricle:right ventricle ratio (in the order of 50%) may be a clinical alternative and provide better postanatomic repair mLV performance. However, Sharma and colleagues¹⁹ concluded that less-aggressive banding techniques are associated with decreases in mLV function after DS procedure. Outcomes of these techniques remain controversial and further investigation is required.

The time and degree of PAB may directly influence outcomes after anatomic repair. In our study, the baseline data about these factors showed no difference between the 2 groups.

Myers and colleagues²⁰ recently reported their experience with the use of PAB in retraining the left ventricle in ccTGA. Late left ventricle dysfunction was significantly more frequent in older patients, both at PAB and at anatomic repair, with cut-off values of age 2 and 3 years, respectively. Within weeks after birth, a myocyte can no longer undergo mitosis, resulting in a fixed number of myocytes.¹⁸ When a child becomes older, his or her heart can hypertrophy in

response to physiologic challenges, but may do so in an ultimately maladaptive fashion. In our study population, age at PAB was a risk factor for late deaths ($P = .01$) and left ventricle dysfunction ($P = .03$) after DS. Early PAB during infant periods may avoid long-term events, but our clinical data was too limited to evaluate this.

There is a trend that pre-DS mLV:mRV pressure ratio in the 3 deaths caused by mLV dysfunction was lower than survivors (0.77 ± 0.01 vs 0.82 ± 0.04 ; $P = .09$). However, the pre-DS mLV:mRV pressure ratio, as a continuous value, was not a risk factor for late death and left ventricle dysfunction after DS procedure in univariate analysis. The small sample size might be the reason. As a result, we cannot offer any guidance as to the suitable subgroup in whom the DS procedure should be pursued regarding mLV performance. We believe there might be an intrinsic correlation between mLV performance and late outcomes. Further multicenter study must be undertaken.

Some studies²¹ have recently identified PAB before DS operation as a risk factor for the development of aortic root dilation and aortic regurgitation after DS. Neo-aortic regurgitation has been recently reported as a factor contributing to late left ventricle dysfunction in patients undergoing DS procedure.^{22,23} In our study, 3 patients (30%) after DS repair had significant aortic insufficiency, and their mLV ejection fraction was 52%, 49%, and 55% at follow-up, respectively. But no correlation could be established between aortic insufficiency and mLV dysfunction due to the very small sample size.

Limitations

Limitations of our study include its single-institution and retrospective nature, and the sample size is relatively small. Magnetic resonance imaging-based techniques, which may provide a better assessment of left ventricle mass, was unavailable. Optimal timing and degree of PAB remain perplexing, so all patients were managed individually and not according to a favorable treatment protocol. However, the baseline data between the 2 study groups were not different. Objective assessments of functional capacity (eg, cardiopulmonary exercise testing) are needed in future studies.

CONCLUSIONS

In ccTGA patients with regressed mLV, PAB may be an ideal procedure because it allows LV training in those undergoing anatomic repair while improving or stabilizing right ventricle function and TR in others. Compared with PAB followed by DS operation, prolonged palliative PAB provides a lower mortality rate and indicates better cardiac function. The timing of PAB must be carefully considered. Further follow-up is warranted with a focus on exercise tolerance.

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