Impact of Age at Fontan Completion on Postoperative Hemodynamics and Long-Term Aerobic Exercise Capacity in Patients With Dominant Left Ventricle

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PEDIATRIC CARDIAC

Background. Although the Fontan procedure is now being applied to younger patients, the influence of patients' age at the time of surgery on long-term results remains unclear. We investigated whether age at Fontan completion affects subsequent hemodynamics and exercise capacity in patients with a dominant left ventricle followed up for more than 5 years.

Methods. Between January 1990 and December 2001, 68 patients with a dominant left ventricle underwent total cavopulmonary connection (TCPC) at our institute. The survivors routinely underwent postoperative exercise tests and catheterization at 1 year and then every 5 years after TCPC, and were divided into group A (<3 years; n = 32) and group B (≥3 years; n = 33), according to age at time of the Fontan procedure and retrospectively reviewed. We also examined the correlation between age at Fontan and data from postoperative catheterization or exercise tests.

Results. None of the patients died during a follow-up period of 91.2 ± 46.7 months. The postoperative exercise capacity (peak oxygen consumption; % of normal [61.3 ± 11.5 versus 51.9 ± 9.1, $p = 0.0001$]), cardiac index () at 5 years (3.31 ± 0.62 versus 2.86 ± 0.69, $p = 0.0133$) and at 10 years after TCPC (3.24 ± 0.46 versus 2.61 ± 0.65, $p = 0.0194$), and ventricular ejection fraction (%) at 10 years after TCPC (62.1 ± 7.6 versus 53.0 ± 8.0, $p = 0.0131$) were significantly higher in group A. Age at Fontan completion inversely correlated with postoperative peak oxygen consumption ($R = -0.374$, $p = 0.0006$) and cardiac index at 5 years ($R = -0.452$, $p = 0.0003$) and 10 years after TCPC ($R = -0.491$, $p = 0.0072$).

Conclusions. Earlier TCPC is beneficial in the long term from the viewpoint of exercise capacity and hemodynamics among patients with a dominant left ventricle.

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Since the first report of a successful Fontan operation in 1971, this maneuver has been performed with various modifications in patients with single-ventricle physiology [1, 2]. Among these modifications, total cavopulmonary connection (TCPC), introduced by de Leval and colleagues [3] in 1988, is widely accepted as it improves late mortality and morbidity, especially in atrial arrhythmia. We have also used this modification since 1987 at the National Cardiovascular Center, Osaka, Japan.

Although Fontan completion provides near-normal systemic oxygen saturation and reduces ventricular volume overload in patients with single-ventricular physiology, some preoperative factors affect the early and long-term outcome of this procedure [4–7]. The Fontan procedure is now being safely performed in younger patients [8], although how the timing of Fontan completion affects long-term outcome and hemodynamics remains unclear.

The present study investigates whether or not the age at Fontan completion affects the postoperative hemodynamics and exercise capacity of patients with a dominant left ventricle followed up for more than 5 years after Fontan completion.

Material and Methods

Between January 1990 and December 2001, 195 patients underwent TCPC at the National Cardiovascular Center in Osaka, Japan. Of these, a cohort of 65 with a dominant left ventricle was followed up for more than 5 years, and their medical records were retrospectively reviewed. We selected these patients to investigate the impact of age at TCPC completion while excluding the influence of the type of dominant ventricle [10] or Fontan procedure. The Institutional Review Board approved this retrospective chart review and waived the requirement for individual consent.

Patients with a dominant left ventricle with or without a rudimentary right ventricle (right ventricular volume <50% of predicted normal value) were defined as having

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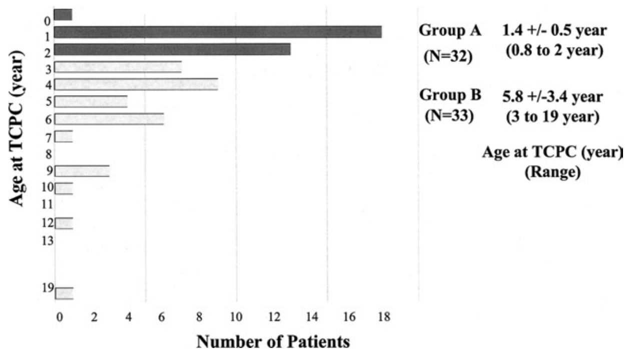

Fig 1. Patients with dominant left ventricle with or without rudimentary right ventricle (ventricular volume <50% of predicted normal value) defined as dominant left ventricular type. These patients were divided into two groups—group A (<3 years of age; n = 32) and group B (≥3 years of age; n = 33)—based on age at total cavopulmonary connection (TCPC).

the dominant left ventricular type and were divided based on age at TCPC into group A (<3 years; n = 32) and group B (≥3 years; n = 33; Fig 1).

Our institutional policy allows Fontan completion in 1-year-old children. The reason for older Fontan completion in the present study was mainly delayed consultation from other institutions. Our standard maneuver since 1997 has been to establish extracardiac TCPC without cardiopulmonary bypass when feasible.

In accordance with our institutional policy, all Fontan candidates underwent cardiac catheterization before surgery and this was repeated in survivors at 1 (n = 64 patients), 5 (n = 63), and 10 (n = 30) years after TCPC to assess Fontan circulation. Patients also underwent additional cardiac catheterization if clinically indicated.

The morphology of the dominant ventricle was determined by ventriculography (direct injection into the ventricle), and the ventricular volume was calculated using Simpson's rule. The ventricular ejection fraction was calculated as the ratio of the stroke volume to the end-diastolic volume (%). The end-diastolic volume was divided by the body surface area for standardization, and the values are presented as ratios (% of normal value). The central venous pressure and end-diastolic pressure of the systemic ventricle were measured (mm Hg) at the time of catheterization. The cardiac index was also measured using the Fick principle from the oxygen consumption and oxygen content in the systemic and pulmonary blood.

All patients whose data were investigated (58 patients) underwent a total of 79 exercise tests at 12.1 ± 4.1 years of age (range, 6 to 24) as described [9], on a motor-driven, programmable treadmill (Q-5000 System; Quinton, Seattle, WA) and peak oxygen consumption (peak VO_2) was measured. Peak VO_2 values are also expressed as ratios (%) of the predicted normal values (% peak VO_2), and were standardized by body weight, height, and age at the time of exercise test, as well as by sex. Controls comprised data from a cohort of 65 male and 60 female patients aged 5 to 24 years described by Ohuchi and colleagues [9]. The distributions of the values obtained

Table 1. Background of Patients

	Group A	Group B	*p* Value
Number of patients	32	33	
Age at TCPC (years)	1.4 ± 0.5 (0.8 to 2)	5.8 ± 3.4 (3 to 19)	< 0.0001
Weight at TCPC (kg)	9.0 ± 1.6	16.9 ± 8.4	< 0.0001
Main cardiac anomaly			
TA/TS	20 (63%)	14 (42%)	
UVH	8 (25%)	14 (42%)	
PA/IVS	4 (13%)	0 (0%)	
Others	0 (0%)	5 (15%)	
Atrial arrangement			
Normal	31 (97%)	28 (85%)	
Heterotaxy	1 (3%)	5 (15%)	0.1968
Right isomerism	1 (3%)	3 (9%)	
Left isomerism	0 (0%)	2 (6%)	
mPAP before TCPC (mm Hg)	13.7 ± 4.6	14.1 ± 5.2	0.7770
Rp before TCPC (Um^2)	2.1 ± 0.9	2.1 ± 0.8	0.8019
PAI before TCPC (mm^2/m^2)	333 ± 84	360 ± 169	0.4553
EF before TCPC (%)	63.7 ± 8.4	59.4 ± 10.6	0.0652
EDV before TCPC (% of normal)	193.1 ± 53.1	181.0 ± 61.0	0.3843
Cardiac index ($L/min/m^2$)	3.1 ± −0.7	3.6 ± 1.2	0.0017
Follow-up period (years)	7.6 ± 3.8	8.3 ± 3.7	0.4449
Number of patients followed up for >10 years	13 (41%)	15 (45%)	

EDV = end-diastolic volume of systemic ventricle; EF = ejection fraction of systemic ventricle; mPAP = mean pulmonary arterial pressure; PAI = pulmonary artery index; PA/IVS = pulmonary valve atresia with intact ventricular septum; Rp = pulmonary arterial resistance; TA/TS = tricuspid valve atresia/tricuspid valve stenosis; TCPC = total cavopulmonary connection; UVH = univentricular heart.

are given as means ± SD, and p less than 0.05 was considered statistically significant. Correlations between continuous parameters were determined by simple regression analysis (StatView-J4.02; Abacus Concepts, Berkeley, CA). Differences in exercise cardiopulmonary variables between the two groups were compared using an unpaired Student's t test and the analysis of variance. The group distribution of heterotaxy or type of TCPC was compared using the χ^2 test. The rate of freedom from reoperation was estimated using the Kaplan-Meier method, and differences in these rates between the groups were assessed using the log-rank test.

Results

Groups A and B were aged 1.4 ± 0.5 years (range, 10 months to 2 years) and 5.8 ± 3.4 years (range, 3 to 19), respectively ($p < 0.0001$), and weighed 9.0 ± 1.6 and 16.9 ± 8.4 kg, respectively ($p < 0.0001$) at the time of TCPC. The mean pulmonary arterial pressure, pulmonary arterial resistance, and pulmonary arterial index immediately before TCPC did not significantly differ between the two groups; only cardiac index was higher in group B (Table 1). The mean follow-up periods in groups A and B were 7.6 ± 3.8 and 8.7 ± 3.7 years, respectively ($p = 0.4449$; not statistically different).

The major cardiac defect was tricuspid atresia or stenosis in 34 patients (groups A and B, n = 20 and n = 14, respectively), univentricular heart (left ventricle type) in 22 (groups A and B, n = 8 and n = 14, respectively), pulmonary atresia with intact ventricular septum in 4 (all in group A), and others in 5. The atrial arrangement was normal in 59 patients (groups A and B, n = 31 and n = 28, respectively), isomerism of the right atrial appendages in 4 (groups A and B, n = 1 and n = 3, respectively), and left isomerism in 2 (both in group B). The distribution of neither cardiac defects nor heterotaxy statistically differed between the groups.

Table 2. Operative Maneuvers

	Group A	Group B
Approach to TCPC		
Staged	8 (25%)	10 (30%)
Primary	24 (75%)	23 (70%)
Fenestration	2 (6%)	2 (6%)
TCPC method		
Intra-atrial channel	11 (34%)	13 (41%)
Extracardiac channel (on CPB)	6 (19%)	5 (15%)
Extracardiac channel (off CPB)	15 (47%)	15 (45%)
Simultaneous surgical procedure at TCPC		
Pulmonary artery plasty	11 (34%)	9 (27%)
DKS procedure	3 (9%)	4 (12%)
Atrioventricular valve repair	1 (3%)	2 (6%)
Relief of LVOT stenosis	1 (3%)	1 (3%)
Repair of TAPVC	0 (0%)	1 (3%)

CPB = cardiopulmonary bypass; DKS = Damus-Kaye-Stansel; LVOT = left ventricular outflow tract; TAPVC = total anomalous pulmonary venous connection; TCPC = total cavopulmonary connection.

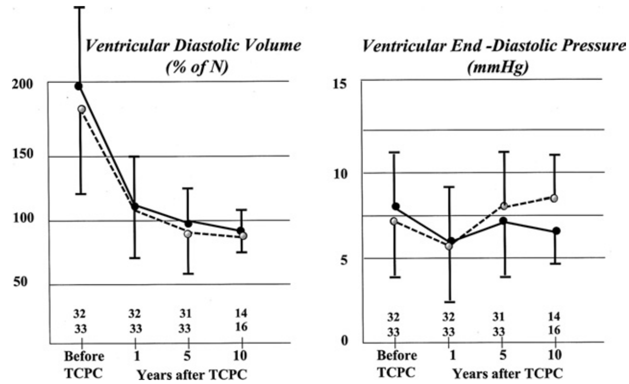

Fig 2. Changes in ventricular end-diastolic volume (% of normal value) and ventricular end-diastolic pressure (mm Hg) before and at 1, 5, and 10 years after total cavopulmonary connection (TCPC) in group A (solid circles) and in group B (open circles). Groups did not significantly differ.

Table 2 summarizes operative maneuvers. All 65 patients underwent TCPC. Eighteen of them had previously undergone bidirectional cavopulmonary Glenn anastomosis as a staged approach (groups A and B, n = 8 and n = 10, respectively), before TCPC. We established TCPC by intra-atrial channel in 24 patients or by extracardiac redirection in 41 of them. The ratios of the TCPC method (intra-atrial channel or extracardiac redirection) did not statistically differ between the groups ($p = 0.8681$). The diameter of the extracardiac graft ranged from 16 mm to 24 mm. Fenestration was reconstructed in 4 patients (n = 2 per group) at the time of TCPC. Of these, the fenestration spontaneously closed in 2 patients, and the remainder underwent catheter device closure or surgical intervention within 5 years after TCPC. Oxygen saturation remained above 90% at the time of the exercise test or cardiac catheterization in all patients.

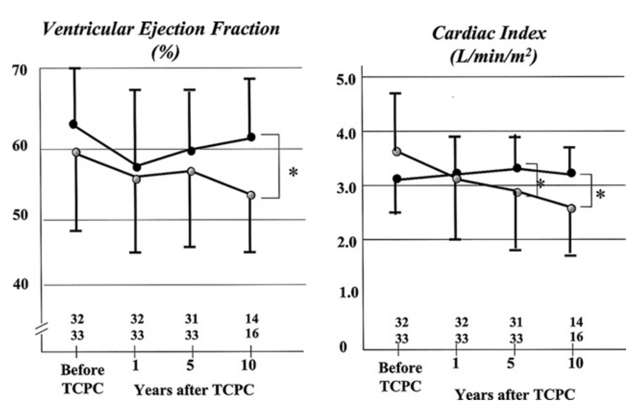

Fig 3. Changes in ventricular ejection fraction (%) and cardiac index (L/min/m²) before total cavopulomnary connection (TCPC) and at 1, 5, and 10 years thereafter. Cardiac index was higher in group A (solid circles) than in group B (open circles) at 5 years (3.3 ± versus 2.9 ± 0.7 L/min/m²; $p = 0.0133$) and at 10 years (3.2 ± 0.5 versus 2.6 ± 0.7 L/min/m²; $p = 0.0194$) *after TCPC.*

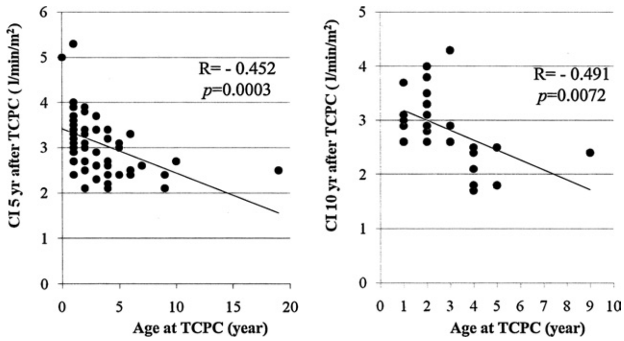

Fig 4. Age at total cavopulmonary connection (TCPC) weakly and inversely correlated with cardiac index at 5 years (R = −0.452, p = 0.0003) and 10 years (R = −0.491, p = 0.0072) after TCPC.

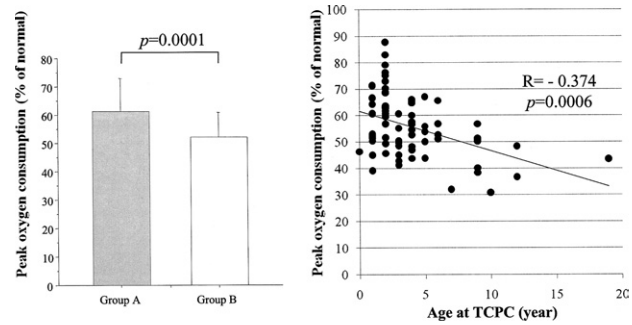

Fig 6. Postoperative exercise capacity (peak oxygen consumption [% of normal]). This value was significantly higher in group A than in group B (61.3 ± 11.5 versus 51.9 ± 9.1; p = 0.0001). Age at Fontan completion and peak oxygen consumption also were inversely correlated (R = −0.374, p = 0.0006). (TCPC = total cavopulmonary connection.)

None of patients died during follow up. Late complications developed in 9 patients: persistent cyanosis due to intra-atrial baffle leak or systemic-to-atrial venous communication in 4, atrial tachycardia in 1 (intra-atrial channel TCPC), sick sinus syndrome in 2 (intra-atrial channel TCPC in 1, extracardiac TCPC in 1), recurrent nerve palsy in 1, and ventricular tachycardia in 1. Nine patients required reoperation after Fontan completion: closure of intra-atrial baffle leakage or fenestration in 3, relief of subaortic stenosis in 2, replacement of atrioventricular valve for regurgitation in 1, Fontan revision (from intra-atrial rerouting to extracardiac redirection) for intra-atrial baffle leakage in 1, and permanent pacemaker implantation in 2. The rate of freedom from reoperation 10 years after TCPC was 86.3% in group A and 87.1% in group B (no significant difference).

Although ejection fraction did not significantly differ between the two groups at 1 and 5 years after TCPC (p = 0.7033 and p = 0.1973, respectively), ejection fraction values were significantly higher in group A than in group B at 10 years after TCPC (62.1% ± 7.6% versus 53.0% ± 8.0%; $p = 0.0131$). End-diastolic volume and end-diastolic pressure did not significantly differ. The central venous pressure at 1 year (10.3 ± 1.7 mm Hg versus 11.8 ± 2.0 mm Hg; $p = 0.0030$) and at 5 years (10.3 ± 2.6 mm Hg versus 11.7 ± 2.8 mm Hg; $p = 0.0440$) years after TCPC was significantly lower in group A, although values did not significantly differ at 10 years after TCPC (10.6 ± 1.8 mm Hg versus 11.5 ± 2.2 mm Hg; $p = 0.2373$). The cardiac index was also higher in group A than in group B at 5 years (3.3 ± 0.6 $L \cdot min^{-1} \cdot m^{-2}$ versus 2.9 ± 0.7 $L \cdot min^{-1} \cdot m^{-2}$; $p = 0.0133$) and at 10 years (3.2 ± 0.5 $L \cdot min^{-1} \cdot m^{-2}$ versus 2.6 ± 0.7 $L \cdot min^{-1} \cdot m^{-2}$; $p = 0.0194$) after TCPC (Figs 2 and 3). Age at TCPC and cardiac index weakly and inversely correlated at 5 years (R = −0.452, $p = 0.0003$) and 10 years (R = −0.491, $p = 0.0072$) after TCPC (Fig 4). To match age at catheterization, we compared the mean cardiac indexes between 10 and 15 years of age, and found that it was significantly higher in group A (3.1 ± 0.5 versus 2.6 ± 0.5 $L \cdot min^{-1} \cdot m^{-2}$; $p = 0.0008$; Fig 5).

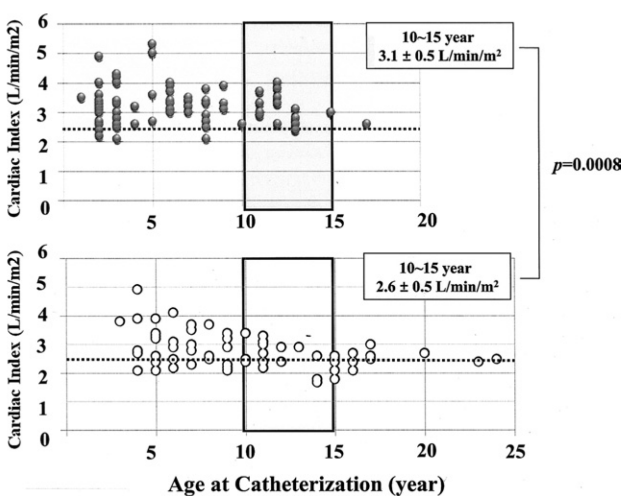

Fig 5. Serial changes in cardiac index after total cavopulmonary connection (TCPC). The upper and lower graphs show groups A and B, respectively. Mean cardiac index between 10 and 15 years old was significantly higher in group A than in group B (3.1 ± 0.5 versus 2.6 ± 0.5 L/min/m^2; p = 0.0008).

The postoperative peak oxygen consumption was significantly higher in group A (61.3% ± 11.5% versus 51.9% ± 9.1% of normal; $p = 0.0001$). Age at Fontan completion also correlated inversely with peak oxygen consumption (R = −0.374, $p = 0.0006$; Fig 6).

Comment

Pulmonary vascular development and maturation are essential for successful Fontan completion, because the Fontan circulation does not exert driving pressure for pulmonary circulation produced by the ventricle. Therefore, earlier Fontan operations had been considered a risk factor for early mortality [11], and the ideal timing of Fontan operation remains controversial. Moreover, some investigators have suggested that growth of the pulmonary vascular bed might be adversely affected by early conversion to nonpulsatile blood flow, which means that Fontan completion in infants or small children would increase mortality and morbidity rates.

However, more recent approaches to Fontan completion include volume-unloading surgery at a younger age to reduce the adverse effects of prolonged ventricular volume overload on ventricular function. Furthermore, recent reports have demonstrated safe Fontan completion during the first year of life independently of anatomical diagnosis without additional morbidity or mortality [8, 12]. Regarding the size of the pulmonary artery, Adachi and colleagues [13] have reported that a preoperative and postoperative small pulmonary artery does not affect midterm outcomes of the Fontan operation. We found no significant difference in long-term mortality and morbidity rates between older and younger groups, indicating that the Fontan procedure can be safely completed without increasing these rates over the long term.

Another possible disadvantage of earlier Fontan completion is the smaller material graft for extracardiac TCPC. The ideal size of the extracardiac graft for Fontan circulation remains unclear, and many surgeons prefer intracardiac redirection for younger patients undergoing the Fontan procedure. We applied a 16-mm graft to 15 patients during the extracardiac Fontan procedure, and these grafts have not required any revisions. Therefore, we do not consider that the Fontan operation in younger patients is disadvantageous from this perspective.

One further issue regarding earlier Fontan operations cannot be ignored. Long-term follow-up has revealed several problems because Fontan circulation affects the function of organs such as the kidneys, liver, intestine, and lungs [14, 15]. These problems might develop sooner in patients who had undergone the Fontan procedure in earlier age. Although we did not encounter such complications during the present study, patients should nevertheless be carefully followed up, particularly with respect to these issues.

Earlier Fontan completion has several theoretical advantages in terms of minimizing the effect of persistent cyanosis, the potential for paradoxical embolization, and the duration of chronic volume overload of the single ventricle [16].

Long-standing cyanosis and volume overload to the ventricle are believed to cause progressive ventricular fibrosis by inducing histopathologic changes, which must result in both systolic and diastolic dysfunction. Since ventricular dysfunction is more frequent after later definitive repair in patients with tetralogy of Fallot or other cyanosis-related diseases, age at the time of Fontan completion might influence cardiac contractility over the long term. Therefore, earlier elimination of cyanosis and volume overload can enhance cardiac performance and subsequently improve the exercise capacity of Fontan patients. We found here that the ventricular ejection fraction and cardiac indexes were significantly higher at 5 and 10 years after the Fontan procedure had been completed in younger patients. Age at the time Fontan completion inversely correlated with cardiac index at 5 and 10 years thereafter. These results suggest that earlier Fontan completion helps to maintain ventricular contractility, prevent the progression of ventricular dysfunction, and provide a higher ejection fraction and cardiac index.

Furthermore, the hemodynamics in Fontan circulation depend not only on cardiac contractility but also on pulmonary circulation and function, and the growth of respiratory and skeletal muscles is considered to be an important factor affecting Fontan circulation. For these reasons, we postulate that earlier elimination of hypoxia allows better growth of respiratory and skeletal muscles, which would subsequently increase the cardiac index and exercise capacity, especially at 5 and 10 years after the Fontan procedure. However, this hypothesis remains to be proven. Pulmonary vascular development might also affect cardiac output in the Fontan circulation, but we did not assess the pulmonary vasculature in this study. Therefore, further studies should investigate the relationship between age at Fontan completion and lung pathology.

Aerobic exercise capacity is a useful indicator of postoperative status, and it can be used to predict the prognosis of congenital heart disease in adult patients [17, 18]. Thus, a high exercise capacity might predict a better long-term prognosis. Others have found that exercise capacity estimated based on peak oxygen consumption is impaired owing to a limited ability to increase cardiac output during exercise [19, 20]. Cardiac catheterization data (such as cardiac index and ejection fraction) provide information only about “static” status, but exercise capacity might predict the dynamic functional status of the Fontan circulation. We found an inverse relationship between age at the time of the Fontan operation and peak oxygen consumption. These findings also support the notion that earlier Fontan completion is beneficial for the long-term exercise capacity and hemodynamics of patients with a dominant left ventricle.

Of course, excessive extension of the age-related indication is limited because of the unique features of the Fontan circulation, and Fontan completion during neonatal life or early infancy is not ideal. Earlier TCPC should not be promoted in patients with considerable risk factors, but should rather be recommended for patients who are good candidates for Fontan circulation.

Study Limitations

This study has several limitations. The study was retrospective and the timing of Fontan completion was not random, indicating potential for selection bias. However, the backgrounds of the two groups of patients were similar except for body weight at the time of the procedure. The ages at routine postoperative catheterization differed, and age at catheterization might also affect the ejection fraction. Although age at catheterization might correlate with ventricular ejection fraction [21], not all results support this notion. We limited this study to patients with a dominant left ventricle. Thus, patients with a dominant right ventricle and with a biventricular heart should be further investigated.

In conclusion, we investigated the influence of age at TCPC on the exercise capacity and hemodynamics of patients who underwent a Fontan operation. Our study demonstrated that earlier Fontan completion is safe, that late outcome is satisfactory, and that age at the time of the Fontan operation significantly affects the cardiac index, ejection fraction, and peak oxygen consumption over the long term.

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DISCUSSION

DR CHRISTOPHER A. CALDARONE (Toronto, Ontario): My compliments on your slides where you showed how your patient population was selected. That was a very effective way to do it. One thing that wasn't clear though is, was there an era effect in the choice of lateral tunnel versus extracardiac Fontans? And was that a factor in terms of the later determinations of exercise capacity?

DR SHIRAISHI: We analyzed the operative data, such as operative maneuver or another operation, but we have no significant difference between such groups.

DR CALDARONE: And was there a change in difference in heart rate and achievable heart rate between the two groups during exercise testing?

DR SHIRAISHI: During the exercise test, heart rate was not significantly different in change.

DR PETROS V. ANAGNOSTOPOULOS (Phoenix, AZ): Two questions. One, how did you decide to perform the Fontan procedure in patients younger and older than 3 years? How do you make the decision when you're going to do the Fontan. And two, in the patients younger than 3 years old, how many patients had conduits that were 16 mm or less when you utilized the extracardiac conduit technique? And did you have to come back and revise them?

DR SHIRAISHI: For the first question, our institutional policy for the timing of the Fontan completion has gradually become earlier than before, so the earlier age Fontan patients exist predominantly in the earlier period of this study cohort. And the other reason for the older age operation is the delayed consultation from another institution. But our recent institutional policy is about 1 or 2 years old.

And for the second question, less than 3 years old in group A, the size of the extracardiac conduit was16 mm or 18 mm. And we have no experience of the revision.

DR FRANK A. PIGULA (Boston, MA): Can I just clarify? Your institutional bias is to do the Fontans at what age? What age do you prefer to do the Fontan, 1 to 2 years of age?

DR SHIRAISHI: Our recent institutional policy is 1 year old.

DR PIGULA: Did you see any further advantage? You stratified these patients into less than 3 years of age and more than 3 years of age. And so did you look and see if there is any further advantage into the 1- or 2-year-old versus the 3-year-old at the time of their Fontan?

DR SHIRAISHI: We compared 1-year-olds and 2-year-olds, but there was no significant difference.

DR CHRISTIAN PIZARRO (Wilmington, DE): Those were very interesting data, but I don't know if I missed some part of your presentation. Did any of these patients have an intermediate bidirectional Glenn, or you went directly from initial palliation or no palliation to a Fontan?

DR SHIRAISHI: In both groups, about 30% of the patients had undergone the bidirectional Glenn before the TCPC.

DR PIZARRO: Now, were you able to look specifically of the effect on exercise in the patients who had a previous bidirectional Glenn? Because data from Steve Paridon in the Children's Hospital demonstrated that volume unloading, really, it's what appears to matter. And therefore, in the patients who had volume unloading by an intermediate stage, the impact of age at the time of completion on exercise would be really told by looking at those patients. Therefore, just by looking at patients who had Fontan completion without intermediate stage, you would expect, based on Paridon's data, that the patients who were unloaded earlier would be better, which is what you have shown.

DR SHIRAISHI: In this study, our primary Fontan completion is predominant, so we did not compare the staged approach and primary Fontan.

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