

Medium and Long-Term Outcomes of Fontan Operation

Paweena Chungsomprasong MD*,
Jarupim Soongswang MD*, Apichart Nana MD*,
Kritvikrom Durongpisitkul MD*, Daungmanee Loahaprasitiporn MD*,
Chodchanok Vijansorn MD*, Somchai Sriyodchartti MD**

* Division of Pediatric Cardiology, Department of Pediatrics, Faculty of Medicine Siriraj Hospital,
Mahidol University, Bangkok, Thailand

** Division of Cardiothoracic Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital,
Mahidol University, Bangkok, Thailand

Background: The Fontan operation had been proposed as the final palliative surgery in the patients with single ventricle physiology. Even though modifications of the operation were developed to improve outcomes, long-term complications remain significant with time. The present study reviewed long-term survival rate, morbidities associated with time, and risk factors during the follow-up period after Fontan operation.

Material and Method: A retrospective study was conducted. Every patient who underwent the Fontan operation at Siriraj Hospital between January 1987 and December 2007 and had available data was included in the present study. The data was collected until the most recent follow-up in December 2008. Demographic data, diagnosis, echocardiographic data, cardiac catheterization data, surgical data, type of modified Fontan procedure, and perioperative data were collected. The follow-up clinical data, cardiac investigation data, complications, and management were also collected and analyzed.

Results: Survival rates were 88.7%, 85.3%, and 83.8% at 1 year, 5 years, and 10 years, respectively. The median follow-up time was 4.75 years (0-17.45). The 10-years survival rate of tricuspid atresia, single ventricle and the heterotaxy syndrome were 94.5%, 79%, and 83.3%, respectively, which were not significantly different ($p = 0.09$). The 10-years survival rates of the patients that underwent lateral tunnel, extracardiac conduit and atriopulmonary connection were 80.7%, 88% and 84.3%, respectively. A mean pulmonary artery pressure of more than 18 mmHg was the only factor that affected the survival rate after Fontan surgery ($p = 0.008$). The incidence of postoperative arrhythmia was 7.9%. Age at operation, diagnosis, type of operation, fenestration, systemic EDP, or PVR before operation did not significantly affect the survival rate. Diagnosis and type of surgery did not affect long-term outcome regarding arrhythmia, re-intervention, systemic atrioventricular valve regurgitation, and systemic ventricular dysfunction. Patients post Fontan operation had good survival rate.

Conclusion: Cardiac diagnoses were not significantly different in the medium and long-term survival rate of post Fontan patients, freedom from arrhythmia, re-intervention and systemic atrioventricular regurgitation. Types of Fontan operation did not affect long-term survival rate or long-term complications. Mean pulmonary artery pressure of more than 18 mmHg was the only risk factor to the survival rate.

Keywords: Fontan operation, Outcome, Complication

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The incidence of cyanotic heart diseases with single-ventricle physiology was 0.05-0.1 per 1,000 live births or about 1% of congenital heart diseases⁽¹⁾. Prior to the Fontan operation era, this subset of patients had progressively low quality of life and died before being 20 to 30 years old.

The Fontan operation was first reported in 1971. The principle was to connect the systemic venous system directly to pulmonary arteries in the patients with functional single ventricle physiology. This has been widely accepted as the final palliative surgery to salvage this subset of patients since then. There have been many modified Fontan operations to improve the surgical outcome, such as atriopulmonary connection, total cavopulmonary connection, lateral tunnel and lastly extracardiac conduit. Despite the improvements in surgical techniques reduce perioperative mortality and outcomes, the long-term morbidities have still

Correspondence to:

Soongswang J, Division of Pediatric Cardiology, Department of Pediatrics, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.

Phone: 0-2419-5672

E-mail: sjsw@mahidol.ac.th

been the matters of concern, such as arrhythmia, ventricular failure, atrioventricular valve regurgitation and thromboembolic events, etc. Many studies demonstrated long-term survival and complications of the patients after Fontan operation⁽²⁻⁵⁾. It has been suggested that the proper selection of the patients will lead to the excellent outcomes. The studies of long-term outcomes in Thailand of post Fontan operation were limited. The present study aims to evaluate the long-term survival rate, morbidities, and time-dependent risk factors during the follow-up period.

Material and Method

Every patient who underwent the Fontan procedure between January 1987 and December 2007 at Siriraj Hospital was recruited in the present retrospective study. Only 139 from 146 patients were included due to unavailable data. All medical records of the patients were retrospectively reviewed. The collected data were the diagnoses, echocardiographic, cardiac catheterization, surgical, age at modified Fontan procedure, type of modified Fontan procedure, perioperative, follow-up (functional class, current clinical and hemodynamic status), the intervention or reoperation and complications. Data was collected until the most recent follow-up in December 2008. The questionnaire was sent out to get data from the patients or the caregiver of patients who were lost to follow-up for longer than one year. Survival rate and freedom from re-intervention, arrhythmias, systemic atrioventricular valve regurgitation and systemic ventricular dysfunction according to diagnoses and types of Fontan operation were analyzed using the Kaplan-Meier method and compared by log-rank statistics. A $p < 0.05$ was considered statistically significant. Interval started from the time at Fontan surgery and patient-year was accrued until death or last follow-up. Censoring occurred at the last follow-up visit.

Results

Patients

One hundred thirty nine patients (90 males and 49 females) who underwent the modified Fontan procedure with available postoperative data were included in the present study. The median age at presentation was 4.7 years (0 - 23.8 years). The cardiac malformations were as follows: tricuspid atresia, 41 cases (29.5%); single ventricle, 78 cases (56.1%); heterotaxy syndrome, 18 cases (12.9%); and hypoplastic left heart syndrome in two cases (1.4%) (Fig. 1).

Hemodynamic data at pre Fontan operation period, operative data and follow-up data are shown in Table 1 and 2. The median age at operation was 8.7 years (1.67-32.72 years). The age at operation were divided into three groups: less than 4 years, 27 cases

Table 1. Demographic data, echocardiographic data, hemodynamic data and operative data of the patients with Fontan operation

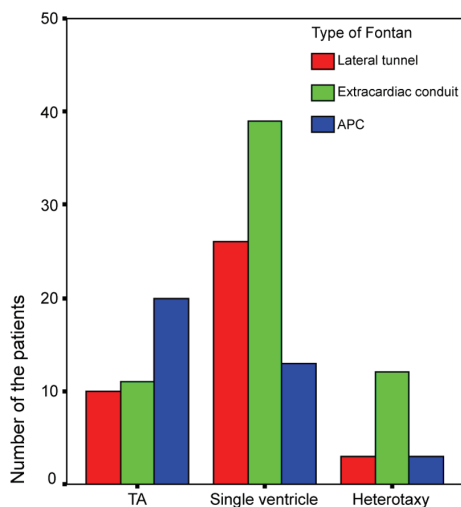
Characteristic	All Fontan (n = 139)
Age at operation (years)	
< 4	27 (19.7%)
4-10	53 (38.7%)
> 10	57 (41.6%)
Echocardiography data	
Morphology of systemic ventricle	
Left	47 (55.3%)
Right	24 (28.2%)
Mixed	14 (16.5%)
Atrioventricular valve	
Common AVV	61 (74.4%)
Two AVV	21 (25.6%)
Cardiac catheterization data	
PAP (mmHg)	
< 15	53 (50.5%)
15-18	34 (32.4%)
> 18	18 (17.1%)
PVR (Wood.unit.m ²)	
< 2	42 (60%)
2-4	24 (34.3%)
> 4	4 (5.7%)
McGoan ratio	
< 1.5	3 (3.7%)
1.5-1.8	10 (12.2%)
> 1.8	69 (84.1%)
Systemic EDP	
< 12	75 (67%)
12-15	30 (26.8%)
> 15	7 (6.3%)
Operation	
Bidirectional Glenn operation before Fontan	
Yes	98 (83.8%)
No	19 (16.2%)
Type of operation	
Atriopulmonary connection	36 (25.9%)
Lateral tunnel	39 (28.1%)
Extracardiac conduit	64 (46%)
Fenestration	
No	113 (83.1%)
Yes	23 (16.9%)

AVV = atrioventricular valve; PAP = pulmonary artery pressure; PVR = pulmonary arterial vascular resistance; EDP = end diastolic pressure

Table 2. Cardiac catheterization data, operative data and post Fontan operation follow-up data

	Number of patients	Mean \pm SD	Median (minimum-maximum)
Cardiac catheterization data			
MPAP (mmHg)	105	15.19 \pm 7.79	13.00 (7-67)
PVR (Wood.unit.m ²)	70	1.75 \pm 1.28	1.56 (0.04-6.83)
QP:QS	85	1.37 \pm 0.88	1.10 (0.16-5)
Ventricle EDP (mmHg)	112	9.32 \pm 3.52	10.00 (3-18)
McGoon ratio	82	2.22 \pm 0.57	2.10 (1.35-4-7)
Duration prior surgery (years)	99	1.09 \pm 1.05	0.77 (0.1-5.7)
Operative data			
Bypass time (min)	115	120.51 \pm 47.53	112.00 (36-326)
Aortic cross clamp time (min)	77	46.43 \pm 27.64	50.00 (1-122)
Age at operation (years)	137	9.76 \pm 6.40	8.73 (1.67-32.72)
Follow-up data			
Follow-up time (years)	139	5.26 \pm 4.34	4.76 (0-17.45)

MPAP = mean pulmonary artery pressure; PVR = pulmonary vascular resistance; QP:QS = pulmonary blood flow: systemic blood flow; EDP = end diastolic pressure

**Fig. 1** Demonstrates types of the modified Fontan surgery in different groups of single ventricle physiology

(17.9%); 4-10 years, 53 cases (38.7%); and more than 10 years, 57 cases (41.6%). The patients underwent three types of the modified Fontan procedure: atrio-pulmonary connection, 36 cases (25.9%); lateral tunnel technique, 39 cases (28.1%); and extracardiac conduit, 64 cases (46%).

Mortality

Of the initial 139 patients, 20 cases (14.8%) passed away during the follow up period. Survival rates

were 88.7%, 85.3%, 83.8% and 74.3% at 1 year, 5 years, 10 years and 15 years, respectively, as in Fig. 2.1. The 10 years survival rate of tricuspid atresia, single ventricle and the heterotaxy syndrome were 94.5%, 79% and 83.3%, respectively, as shown in Fig. 2.2, which were not significantly different ($p = 0.09$). Survival rate of the patients who underwent lateral tunnel were 84.1%, 80.7% and 80.7%, extracardiac conduit were 90.1%, 88% and 88% and atrio-pulmonary connection 88.2%, 84.3%, and 84.3% at 1 year, 5 years and 10 years, respectively, as in Fig. 2.3. Mean pulmonary pressure was the only factor that affected the survival rate ($p = 0.008$) as in Fig. 2.4. Age at operation, diagnosis, type of operation, fenestration, systemic EDP or PVR before operation did not significantly affect survival rate.

Complications

The complications during the follow-up period (median 4.76 years) were arrhythmia, 11 cases (7.9%); venovenous collateral vessels, eight cases (5.8%); arterial collateral vessels, eight cases (5.8%); thromboembolic event, two cases (1.4%); Fontan leakage, four cases (2.9%); and Fontan pathway obstruction, three cases (2.22%). Almost all post operation arrhythmias were atrial arrhythmia (atrial flutter five cases, atrioventricular block four cases, atrial tachycardia one case, and premature ventricular contraction one case). The freedom from arrhythmia in each group of diagnosis and types of operation were not significantly different (Fig. 3.1, 3.2) as well as freedom to re-intervention (Fig. 4). The systemic

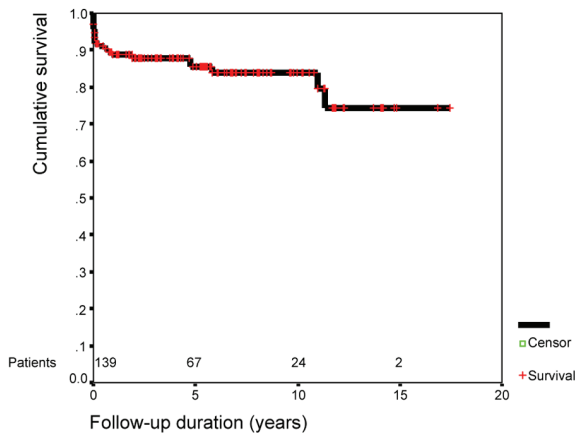


Fig. 2.1 Kaplan-Meier curve of survival rate in post operative modified Fontan patients

ventricular dysfunction was defined as an ejection fraction of less than 50%. Freedom from fair systemic ventricular dysfunction and atrioventricular valve regurgitation in each group of diagnoses and types of modified Fontan operation are shown in (Fig. 5, 6), respectively. Tricuspid atresia had the highest freedom rate from systemic ventricular dysfunction (92.8%) at 10 years post operation.

Discussion

Palliative surgery to correct obstructive systemic blood flow, restrictive pulmonary blood flow, obstructed pulmonary venous return and obstructed interatrial communication has been proposed to maintain adequate systemic blood flow and oxygenation in single ventricle physiology. In patients with excessive pulmonary blood flow, pulmonary artery banding to prevent increased pulmonary vascular resistance before undergoing the Fontan operations is essential. The Fontan operation may be done in a single step or staged operations with a bidirectional Glenn and then a modified Fontan operation, without change in perioperative mortality⁽⁶⁾.

The pre-operation data is essential in selecting the appropriated patients for better outcome⁽⁷⁾. In a previous study, at Siriraj Hospital, it was found that abnormal pulmonary venous drainage, atrioventricular valve regurgitation and systemic ventricular morphology were risk factors of the midterm outcome⁽⁸⁾. There were studies showing that mean pulmonary pressure of more than 18 mmHg was associated with significantly lowest survival rate^(9,10), which were consistent with the finding in the present study. The diagnosis, type of

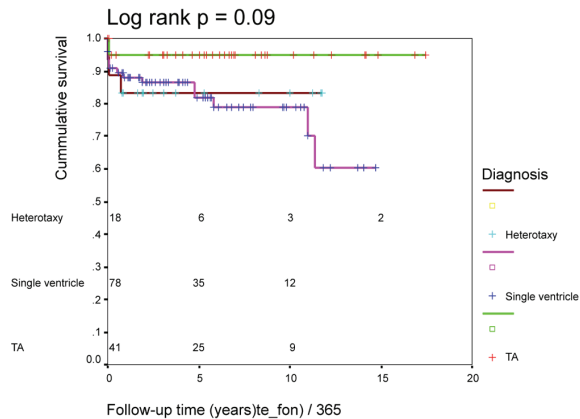


Fig. 2.2 Kaplan-Meier curve of survival rate in post operative modified Fontan based on the diagnosis

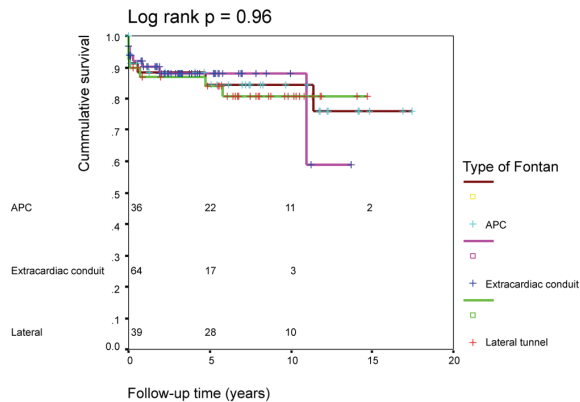


Fig. 2.3 Kaplan-Meier curve of survival rate in post modified Fontan patients operation based on the surgical technique

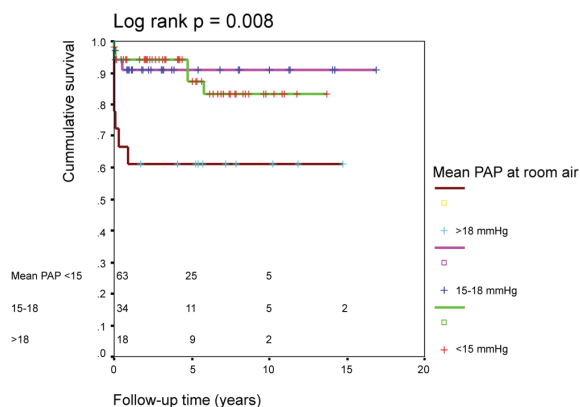


Fig. 2.4 Kaplan-Meier curve of survival rate in post modified Fontan patients based on mean pulmonary pressure

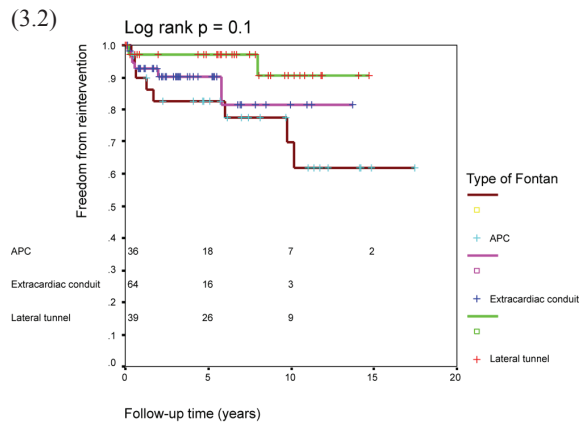
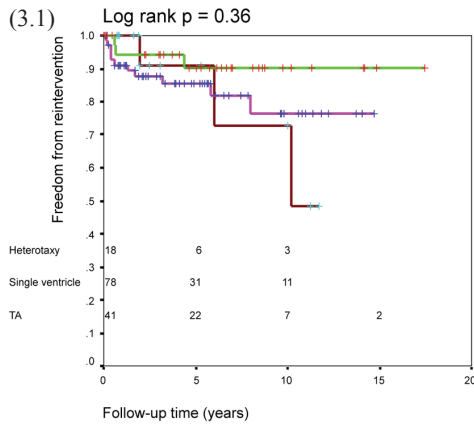


Fig. 3 Freedom from arrhythmia based on diagnoses (3.1) and the surgical techniques (3.2)

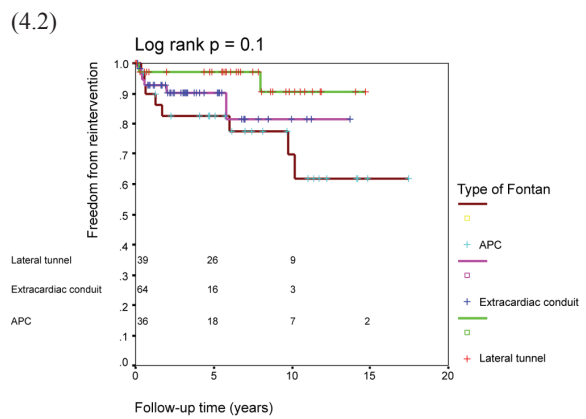
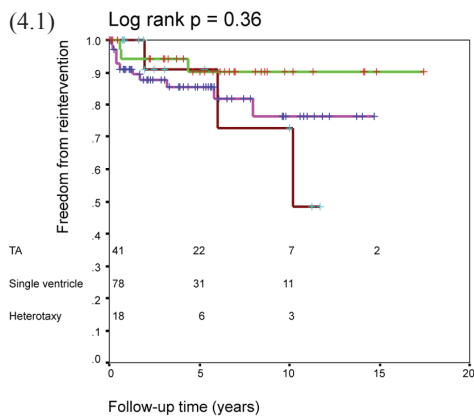


Fig. 4 Freedom from re-intervention based on diagnoses (4.1) and the surgical techniques (4.2)

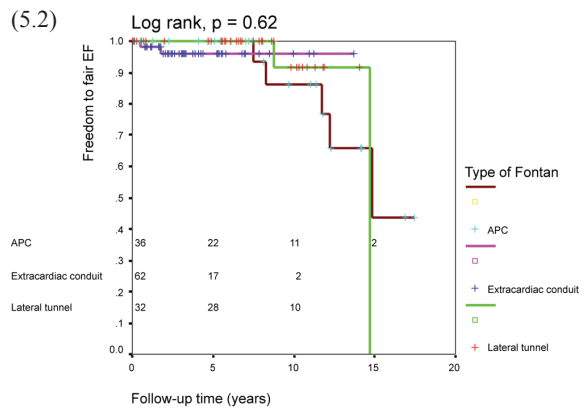
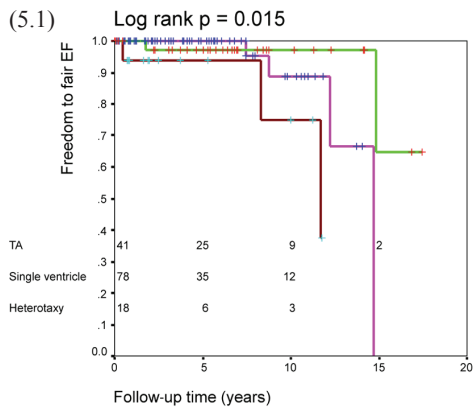


Fig. 5 Freedom from systemic ventricle dysfunction base on diagnoses (5.1) and the surgical techniques (5.2)

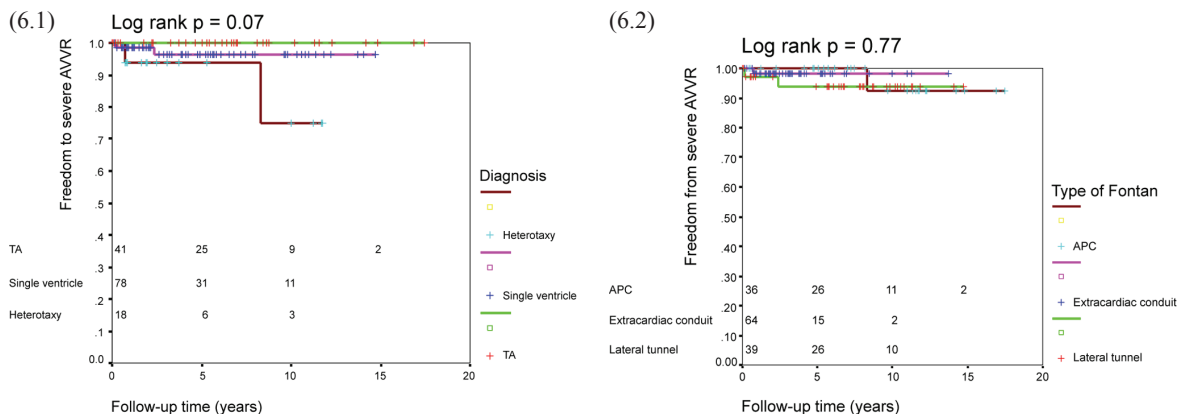


Fig. 6 Freedom from atrioventricular regurgitation based on diagnoses (6.1) and the surgical techniques (6.2)

operation, systemic ventricular EDP, and pulmonary vascular resistance did not affect the overall survival. This could be explained by and confirm the strict selection criteria for modified Fontan surgery in Siriraj Hospital. The present study showed that heterotaxy syndrome was not a risk factor of post Fontan mortality, which was also demonstrated in another study⁽¹¹⁾. This might be due to the small number of this group of patients and because the more severe patients expired prior to the Fontan operation. In Thailand, there was a report that patients with tricuspid atresia or pulmonary atresia with intact ventricular septum had a survival rate of 92% and 87% at 1 year and 4 years, respectively⁽¹²⁾. However, those with the heterotaxy syndrome and hypoplastic left ventricle syndrome were found to have poor prognosis with survival rates of 69% and 42% at 1 year and 4 years, respectively⁽²⁾. The present study also showed that age at operation did not affect the overall survival rate. However, there was a report which showed that age more than 18 years was the risk factor for late mortality⁽²⁾.

In long-term follow-up, thromboembolic event was found to affect the survival rate⁽¹⁰⁾. A study demonstrated venous thrombosis 92% at 1 year, 90% at 3 years, 84% at 8 years, and 82% at 10 years⁽¹³⁾. The present study found the thromboembolic event to be less frequent than the previous study, this might be due because the Asian people have less prevalence of thromboembolic event compared to the caucasians, and most of the patients in the present study routinely received low dose aspirin and might therefore be under detection.

The prevalence of postoperative cardiac arrhythmias in the present study was 7.9%, which was

less than another study⁽³⁾. This might be due to decreased number of patients during the long-term follow-up period as well as insensitive tools for detection of arrhythmia. Patients with extracardiac Fontan have been demonstrated to have a lower incidence of atrial tachyarrhythmia and bradyarrhythmias than the patients with lateral tunnel Fontan⁽¹⁴⁾. Compared to extracardiac Fontan, lateral tunnel Fontan had a significantly higher rate of early postoperative sinus node dysfunction (45% vs. 15%), supraventricular tachycardia (33% vs. 8%), and need for temporary postoperative pacing (32% vs. 12%)⁽¹⁵⁾. However, the present study found no difference in freedom from arrhythmia in each group of the diagnoses categories and types of surgery. In the authors' experience, medications such as amiodarone and flecainide played a role as the most effective antiarrhythmic drug in long-term control of supraventricular arrhythmia. Electrophysiologically guided ablation of an arrhythmogenic substrate has become more successful in the patients with single ventricle physiology either prior to or after the modified Fontan surgery, and must be considered when medical therapy is ineffective and to avoid long-term side effects.

The incidence of systemic ventricular dysfunction depended on the diagnosis. Tricuspid atresia had less incidence of systemic ventricular dysfunction which implied that left morphologic ventricle, as systemic ventricle, was better than right morphologic ventricle⁽⁴⁾. In contrast, the present study demonstrated no different systemic ventricular dysfunction dependent on diagnosis. This could be explained by the small number of patients with systemic

ventricular dysfunction. There was a report that showed that post-Fontan patients had diminished systolic function as well as diastolic function⁽¹⁶⁾. The mean myocardial performance index in the single-right ventricle patients was also significantly higher than controls.

Protein-losing enteropathy (PLE) is a late complication after the Fontan procedure that responds poorly to the present treatment protocol due to unknown causes and not well understood pathophysiology. The prevalence had been reported ranging from 2.5% to 10%, with a 5-year survival rate post onset of approximately 50%. The risk factors of PLE were longer cardiopulmonary bypass time and single-right ventricle anatomy^(17,18). There was no report of PLE in the present study, which could be underestimated from loss of follow-up patients.

Conclusion

The medium and long-term survival rate of the patients with post-modified Fontan operation at Siriraj Hospital was acceptable and comparable to other institutes in Western countries. The diagnoses and types of Fontan operation did not significantly affect the medium and long-term survival rate of post Fontan patients. Mean pulmonary artery pressure more than 18 mmHg was a risk factor of the survival rate after Fontan surgery. Postoperative arrhythmia was 7.9%. Risk factors of postoperative arrhythmia, re-intervention, and atrioventricular regurgitation were not significantly different in each group of diagnoses and types of modified Fontan operation. The long-term complications of these patients remain the crucial problems.

Limitations

This study has the retrospective nature of data collection. The lost to follow up patients may lead to overestimating the survival rate and underestimating the complications during the follow-up period. Prospective data collection and recruitment of more patients as well as a longer follow-up period are essential for better long-term predictions concerning this patient group.

Potential conflicts of interest

None.

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ผลการรักษาระยะกลางและระยะยาวหลังการผ่าตัดฟอนแทน

ปวีณา จิงสมประสงค์, จารุพิมพ์ สูงสว่าง, อภิชาติ นานา, กฤตยวีกรม ดุรงค์พิศิษฎ์กุล, ดวงมณี เลหาประสิทธิพร, ชดชนก วิจารสรณ์, สมชาย ศรียศชาติ

ภูมิหลัง: การผ่าตัดฟอนแทนเป็นการผ่าตัดเพื่อรักษาผู้ป่วยโรคหัวใจพิการแต่กำเนิดที่มีหัวใจห้องล่างเพียงห้องเดียวหรือไม่สามารถผ่าตัดให้ใช้หัวใจห้องล่างได้ทั้งสองห้องได้ แม้ว่าจะมีการพัฒนาเทคนิคการผ่าตัดเพื่อผลการรักษาที่ดีขึ้น แต่ผลแทรกซ้อนระยะยาวยังคงเป็นปัญหา การศึกษานี้ศึกษาถึงอัตราการรอดชีวิตระยะยาว ภาวะทุพพลภาพ มีความสัมพันธ์กับระยะเวลาหลังการผ่าตัด และปัจจัยเสี่ยงในช่วงการติดตามหลังการผ่าตัดฟอนแทน

วัตถุประสงค์และวิธีการ: การศึกษาย้อนหลังในผู้ป่วยที่ได้รับการผ่าตัดฟอนแทนที่โรงพยาบาลศิริราชตั้งแต่เดือนมกราคม พ.ศ. 2530 ถึง เดือนธันวาคม พ.ศ. 2550 ติดตามผู้ป่วยจนถึงเดือนธันวาคม พ.ศ. 2551

ผลการศึกษา: พบว่าอัตราการรอดชีวิตหลังการผ่าตัดคือ 88.7%, 85.3%, 83.8% ที่ 1 ปี, 5 ปี และ 10 ปีตามลำดับ อัตราการรอดชีวิตที่ 10 ปีของผู้ป่วย Tricuspid atresia, single ventricle, และ heterotaxy syndrome คือ 94.5%, 79%, และ 83.3% ตามลำดับ ซึ่งไม่มีความแตกต่างทางสถิติ ($p = 0.09$) อัตราการรอดชีวิตที่ 10 ปีของผู้ป่วย ที่ได้รับการผ่าตัด lateral tunnel, extracardiac conduit และ atriopulmonary connection คือ 80.7%, 88% และ 84.3% ตามลำดับ ความดันโลหิตในปอดที่มากกว่า 18 มิลลิเมตรปรอทก่อนการผ่าตัด เป็นปัจจัยเดียวที่มีผลต่ออัตราการรอดชีวิต ภาวะหัวใจเต้นผิดจังหวะพบได้ 7.9% อายุที่ได้รับการผ่าตัด, การวินิจฉัย, ชนิดของการผ่าตัด, fenestration, systemic EDP และ pulmonary vascular resistance ไม่มีผลทางสถิติต่ออัตราการรอดชีวิต การวินิจฉัย และชนิดของการผ่าตัด ไม่มีผลต่อผลการรักษาระยะยาว, ภาวะหัวใจเต้นผิดจังหวะ, reintervention, ลิ้นหัวใจรั่ว และการทำงานของเวนทริเคิลที่ลดลง

สรุป: การวินิจฉัยชนิดของหัวใจไม่มีผลต่อผลการรักษาระยะกลางและยาว, ระยะเวลาที่เกิดหัวใจเต้นผิดจังหวะ, reintervention และลิ้นหัวใจรั่วหลังการผ่าตัดฟอนแทน ชนิดของการผ่าตัดไม่มีผลต่ออัตราการรอดชีวิต และภาวะแทรกซ้อนในระยะยาว ความดันโลหิตในปอดที่มากกว่า 18 มิลลิเมตรปรอทเป็นปัจจัยเดียวที่มีผลต่ออัตราการรอดชีวิต