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Research Article

Use of Three-Dimensionally Printed Cardiac Models for Strategic Determination in Complex Double Outlet Right Ventricle

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Abstract

Background: We evaluated the influence of anatomical characteristics of complex Double Outlet Right Ventricle (DORV) and the use of three-dimensionally printed cardiac model (3DM) on the selection of one of the two surgical strategies, Single Ventricular Palliation (SVP) versus Left Ventricular Recruitment as a systemic ventricle (LVR).

Methods: Retrospective review of 100 patients of DORV with LVR precluding factors (i.e. remote Ventricular Septal Defect [VSD], Left Ventricular [LV] hypoplasia, Mitral Valve [MV] straddling, and Tricuspid Valve [TV] interposition in the baffle course) was performed. Since 2015, 3DMs have been made for 26 patients in whom pre-operative debate on surgical strategies could not reach an agreement.

Results: Initially, 50 patients were deemed suitable for LVR, and 50 patients were regarded as SVP candidates. Among the 50 patients with initial LVR strategy, there was no strategic crossover toward SVP. Among the 50 patients with initial SVP strategy, there were 15 strategic crossovers while 35 patients remained in the SVP arm. On logistic regression analysis, LV hypoplasia (OR 5.16, $p = 0.002$), MV straddling (OR 11.94, $p = 0.003$), and no use of 3DM (OR 4.35, $p = 0.042$) were identified as predictors of final SVP strategy. Among the 50 patients with initial SVP strategy, predictors of strategic crossover toward LVR were TV interposition in the baffle course (OR 4.66, $p = 0.041$) and utilization of 3DM (OR 8.99, $p = 0.006$).

Conclusions: LVR can be facilitated by comprehensive preoperative anatomical assessment using 3DM in the treatment of DORV with LVR precluding factors.

Keywords: Double outlet right ventricle; Three-dimensionally printed cardiac model; Single ventricle palliation; Left ventricular recruitment

Abbreviations: 3D: Three Dimensional; 3DM: Three-Dimensionally Printed Cardiac Model; BDG: Bidirectional Glenn Operation; CT: Computed Tomography; DORV: Double Outlet Right Ventricle; LVOTO: Left Ventricular Outflow Tract Obstruction; LVR: Left Ventricular Recruitment As A Systemic Ventricle; MV: Mitral Valve; PBF: Pulmonary Blood Flow; SVP: Single Ventricular Palliation; TV: Tricuspid Valve; VSD: Ventricular Septal Defect

Introduction

Three-Dimensional (3D) printing of the heart has become a widely used diagnostic modality for the treatment of congenital heart disease in recent times [1-4]. Since structural malformations in complex congenital heart diseases show heterogeneous features, it is principal to understand patient-specific pathophysiology of the anomalies to establish an optimal treatment strategy [5]. Comprehensive assessment of internal cardiac structures is important especially in Double Outlet Right Ventricle (DORV). Because DORV is manifested as extreme anatomical variability, selection of optimal therapeutic strategy can also be challenging, with potential options ranging from simple intracardiac rerouting to single ventricular Palliation (SVP) [6]. Although several anatomical risk factors precluding anatomical repair recruiting the Left Ventricle (LV) as a systemic ventricle (i.e. non-committed Ventricular Septal Defect [VSD], severe Mitral Valve [MV] straddling, left ventricular hypoplasia, multiple VSDs…) have been suggested [7], determination of surgical strategy for each patient is not always straightforward and is more frequently dependent on personal experiences of individual cardiologists and cardiac surgeons [8,9]. Despite the promising early outcomes after

SVP, LVR has remained as a preferable approach, given the long-term consequences of SVP. We hypothesized that the candidacy for LVR in complex DORV can be extended with the aid of Three-Dimensionally Printed Cardiac model (3DM).

Methods

Patients

From January 2008 to June 2018, 294 consecutive patients were diagnosed as having DORV in our institution. Ninety patients with concomitant atrioventricular septal defect, discordant atrioventricular connection (i.e. congenitally corrected transposition of great arteries, double inlet right or left ventricle, criss-cross heart), or atresia of one atrioventricular valve were excluded. In remaining 204 patients, 102 patients who did not have any LVR precluding complex features, such as remote VSD, both great arteries completely arise from the right ventricle (200% DORV) [10], restrictive VSD, huge or multiple VSDs, LV outflow tract obstruction, ventricular hypoplasia, atrioventricular valve straddling, and tricuspid valve interposition in potential baffle course were excluded, and two patients who died before the definite determination of surgical strategy were also excluded. Consequently, 100 patients with DORV who were allocated to one of the two treatment strategies during immediate postnatal period constituted the study cohort (Figure 1A).

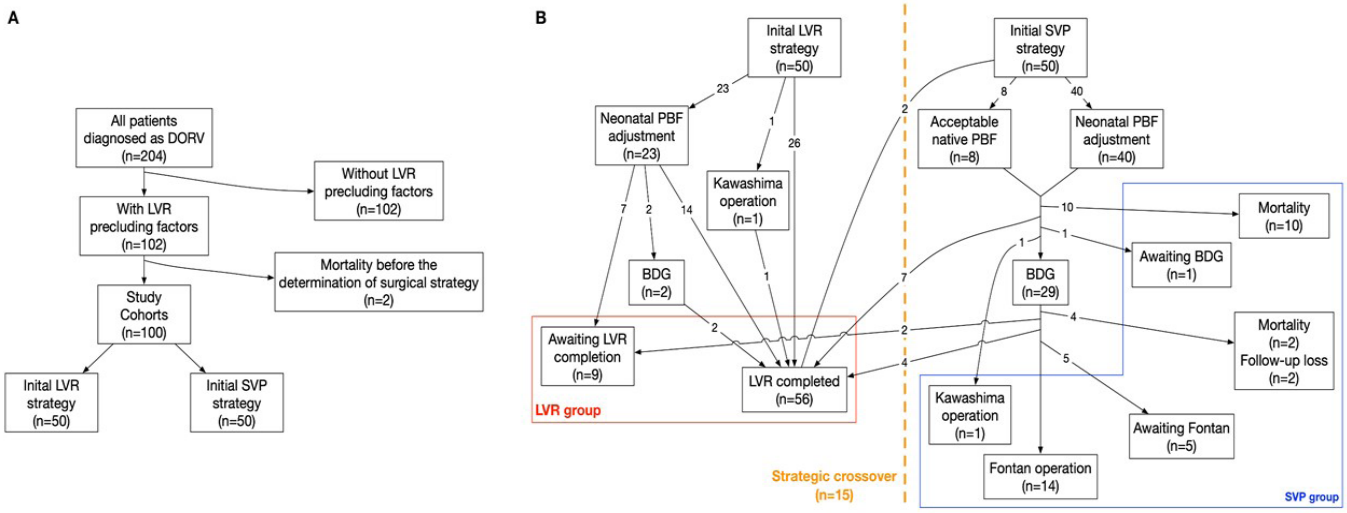

Figure 1A: (A) Selection of study cohort (n = 100) from 204 patients with DORV, and (B) clinical courses of the 100 patients with initial SVP strategy (n = 50) or initial AR strategy (n = 50). DORV = double outlet right ventricle; LVR = let ventricular recruitment as a systemic ventricle; SVP = single ventricular palliation; PBF = pulmonary blood flow; BDG = bidirectional Glenn operation

Determination of treatment strategy at initial presentation

Initial treatment plan was established by thorough discussion among the cardiologists, radiologists, and surgeons based on the patient's echocardiographic findings, catheterization data, magnetic resonance imaging, Computed Tomography (CT) images, and 3DMs since 2015. With these diagnostic modalities, patients were allocated for initial treatment plan either to LVR arm (n = 50) or to SVP arm (n = 50). There were 15 patients with strategic crossover from SVP to LVR in the course of staged palliation, and surgical strategy was finalized as SVP in 35 patients and LVR in 65 patients (Figure 1B).

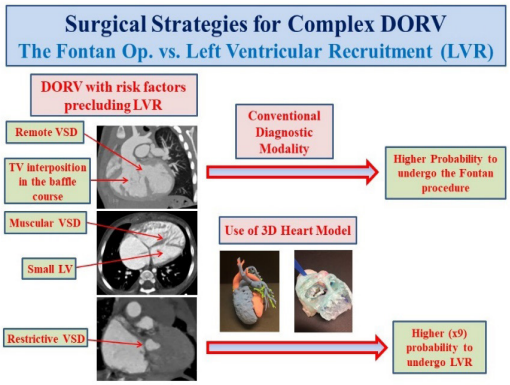

Figure 1B: Surgical Strategies.

Operative Procedures

Fifty patients in the SVP arm underwent initial palliation based on the hemodynamic characteristics, principally on the degree of pulmonary blood flow (PBF). Twenty-one patients with excessive pulmonary blood flow were initially managed either with pulmonary artery banding (n = 20) or Norwood-type repair (n = 1). Nineteen patients with insufficient pulmonary blood flow were managed with systemic-pulmonary shunt (n = 16; right modified Blalock-Taussig shunt in 13, left modified Blalock-Taussig shunt in 3), stent insertion in the ductus arteriosus (n = 2), or surgical pulmonary valvotomy (n = 1). No initial palliation was performed for 8 patients whose pulmonary blood flow was deemed appropriate. In the remaining 2 patients with remote VSD, there was a strategic crossover towards LVR in the operating theater because intra-cardiac baffling appeared to be technically feasible. As a second stage palliation, Bidirectional Glenn Operation (BDG) was performed in 29 patients and 1 patient is awaiting BDG. One patient with left atrial isomerism and inferior vena cava interruption underwent Kawashima operation as a definitive palliation. Seven patients had strategic crossover towards LVR and 10 patients died prior to BDG. Among the 29 patients with BDG, 14 patients completed entire palliative operation with extracardiac conduit Fontan operation and 5 patients are awaiting Fontan operation. Six patients had strategic crossover towards LVR prior to Fontan operation. There were 2 early mortalities after BDG and 2 patients were lost to follow-up.

Among the 50 patients in the initial LVR arm, 23 patients underwent palliation (pulmonary artery banding in 14, systemic-pulmonary shunt in 6 [right modified Blalock-Taussig shunt in 4, left modified Blalock-Taussig shunt in 1, and central shunt in 1], Norwood-type operation in 2, and right ventricle to pulmonary artery conduit insertion in 1). Two patients underwent BDG and 1 patient with inferior vena cava interruption underwent Kawashima operation prior to LVR. Forty-three patients completed LVR and 7 patients are awaiting repair. Among the 15 patients with strategic crossover from the SVP arm, 13 patients completed LVR and 2 patients are awaiting repair. Thus, 56 patients (43 from initial LVR arm, 13 with strategic crossover from initial SVP arm) have completed LVR. One and a half ventricle hemodynamics was established in 7 patients (3 from initial LVR arm, 4 patients with strategic crossover from initial SVP arm after BDG). Among the 56 patients with completed LVR, intraventricular baffling was done toward aortic valve in 45 patients (to the native orthotopic aortic valve in 40, to the posteriorly tranlocated aortic valve upon modified Nikaidoh procedure in 5) and toward pulmonary valve in 11 patients (in combination with arterial switch operation in 10, with modified Yasui operation in 1). Surgical management for the reconstruction of right ventricular outflow tract comprised conventional right ventricular outflow widening with or without pulmonary valvotomy or branch pulmonary artery angioplasty in 23 patients, right ventricle to pulmonary artery conduit insertion in 11 patients, utilization of anteriorly translocated pulmonary artery upon modified Nikaidoh operation in 5 patients. In 17 patients, no surgical intervention was performed for the reconstruction of right ventricular outflow tract.

Three-Dimensional Printing

Entire 3DM manufacturing processes are 1) Acquisition of high quality CT images, 2) 3D reconstruction of blood pool, 3) Segmentation and coloring of reconstructed images, 4) Acquisition of the cavitary data along the surface of reconstructed blood pool, 5) Data processing to STL format, and 6) Actual 3D printing [11]. High quality CT images were obtained by electrocardiogram-gated, breath tracking cardiac CT with contrast media (Somatom Definition Flash, Siemens, Erlangen, Germany). Images of intra-cardiac structures were obtained by thresholding algorithm of contrast enhanced blood pool, and surface of the 3DM was smoothed manually by the attending radiologists. Using this reconstructed intra-cardiac structure, we made two different models: rigid model and soft model. Rigid model is a replica of entire cardiac structure with adjacent great vessels and made for general anatomical comprehension, while soft model is the reconstruction of cavitary surface of the blood pool and made for the understanding of the special relationship between the anatomical structures. This cavitary wall model had 1 mm-thickness with soft material for better manipulation and surgical simulation. All models were made in real size of the patients' heart except for one model from an adult patient which was reduced by 1/4 magnification. Rigid models were made of gypsum-like material (VisiJet PXL Core powder, VisiJet PXL clear binder and color bonds; 3D Systems, Rock Hill, SC, USA) using Projet 460 printer, and soft models were made of rubber-like resin (TangoPlus FullCure resin, Stratasys Ltd., Eden Prairie, MN, USA) using Objet Connex Series printer. CT image reconstruction and 3D

printing required about 1 to 2 weeks after CT examination, depending on the size of the models. Entire 3DM manufacturing processes are illustrated in Figure 2.

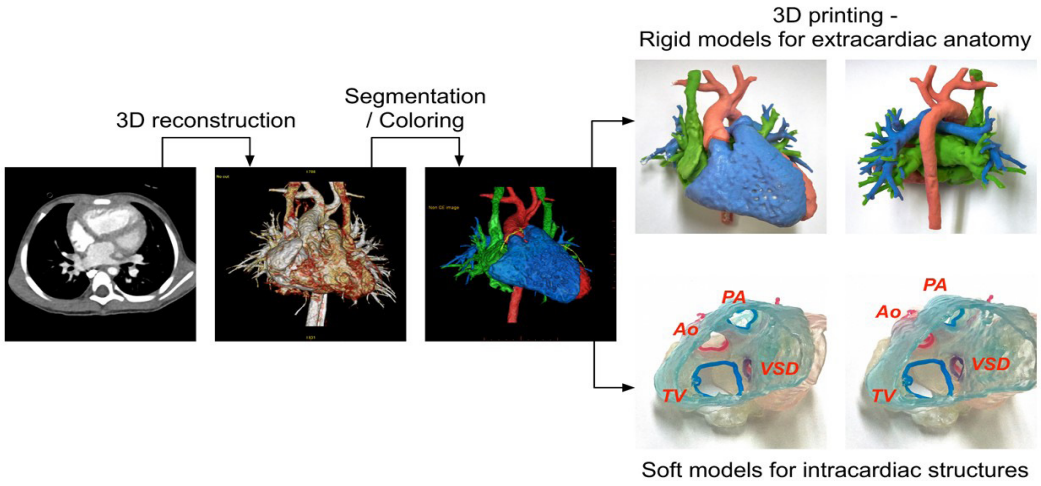

Figure 2: Three-dimensional printing process for the production of cardiac models. 3D: Three-Dimensional; Ao: Aorta; PA: Pulmonary Artery; TV: Tricuspid Valve; VSD: Ventricular Septal Defect

Statistical Analysis

Categorical variables are presented as numbers with percentages, and continuous variables are presented as mean with standard deviation or median with Interquartile Range (IQR) or entire range according to the distribution of data. Kolmogorov-Smirnov method was used for verification of normal distribution. Kaplan-Meier survival estimate with log-rank test were used for analysis of time to adverse events. Risk factors for final destination to the SVP arm (35/100) and predictors of strategic crossover from the SVP arm to LVR arm (15/50) were identified with logistic regression analysis. Variables for univariable analysis included patient's demographic data, year of registration, LVR precluding features, associated anomalies, and the use of 3DM. Variables with a p-value less than 0.1 on univariable analysis were used for multivariable analysis. A p-value less than 0.05 was considered statistically significant. All statistical analyses were conducted using SPSS Statistics version 25 (IBM, Armonk, NY, USA) or R software version 3.5.1 (www.r-project.org).

Results

Determinants of final SVP and strategic crossover

Among the 100 patients of entire study cohort, 35 patients eventually remained in the SVP arm after repeated evaluation in each step of the Fontan track. Significant determinants for final SVP strategy were LV hypoplasia (OR 5.16, 95% CI 1.83 to 14.55, p = 0.002), MV straddling (OR 11.94, 95% CI 2.39 to 59.76, p = 0.003), and preoperative use of 3DM turned out to lower the probability to remain in the SVP arm (OR 0.23, 95% CI 0.05 to 0.95, p = 0.042) (Table 1). In the 50 patients with initial SVP arm, there were 15 patients with strategic crossover towards LVR in the course of Fontan track. Tricuspid valve interposition within the potential baffle course (OR 4.66, 95% CI 1.07 to 20.37, p = 0.041) and preoperative use of 3DM (OR 8.99, 95% CI 1.90 to 42.49, p = 0.006) were identified as predictors of strategic crossover from the SVP arm towards LVR arm (Table 2).

	Univariable analysis				Multivariable analysis		
	OR	95% CI	p		OR	95% CI	p
Sex	0.99	0.43 to 2.27	0.98		NA		
Year of initial registration	0.89	0.79 to 0.99	0.029		NA		
200% DORV	0.55	0.23 to 1.34	0.19				
Remote VSD	1.01	0.44 to 2.31	0.98				
Restrictive VSD	1.43	0.30 to 6.78	0.65				
Multiple VSD	0.61	0.2 to 1.85	0.38				
Common ventricle	6.00	0.6 to 60.00	0.13				
LVOTO	2.54	0.64 to 10.16	0.19				
Aortic arch obstruction	1.29	0.42 to 3.97	0.66				
RVOTO	2.25	0.97 to 5.21	0.058		NA		
LV hypoplasia	5.24	1.99 to 13.80	0.001		5.16	1.83 to 14.55	0.002
RV hypoplasia	2.95	0.47 to 18.58	0.25				
MV straddling	6.12	1.51 to 24.86	0.011		11.94	2.39 to 59.76	0.003
TV straddling	1.74	0.73 to 4.14	0.21				
TV interposition into baffle course	1.10	0.38 to 3.12	0.85				
Heterotaxy	0.92	0.22 to 3.94	0.91				
3DM	0.25	0.08 to 0.81	0.020		0.23	0.05 to 0.95	0.042

DORV: Double Outlet Right Ventricle; VSD: Ventricular Septal Defect; LVOTO: Left Ventricular Outflow Tract Obstruction; RVOTO: Right Ventricular Outflow Tract Obstruction; LV: Left Ventricle; RV: Right Ventricle; MV: Mitral Valve; TV: Tricuspid Valve; 3DM: Three-Dimensionally Printed Cardiac Model

Table 1: Determinants of single ventricular palliation strategy.

	Univariable analysis				Multivariable analysis		
	OR	95% CI	p		OR	95% CI	p
Sex	1.17	0.35 to 3.93	0.80		NA		
Year of initial registration	1.17	0.97 to 1.42	0.10		NA		
200% DORV	4.85	0.56 to 42.26	0.15				
Remote VSD	3.00	0.72 to 12.53	0.13				
Restrictive VSD	2.67	0.47 to 15.08	0.27				
Multiple VSD	1.50	0.31 to 7.28	0.62				
Common ventricle	0.76	0.07 to 7.98	0.82				
LVOTO	0.43	0.05 to 4.02	0.46				
Aortic arch obstruction	0.74	0.13 to 4.19	0.74				
RVOTO	0.76	0.23 to 2.58	0.66				
LV hypoplasia	0.18	0.04 to 0.93	0.041		NA		
RV hypoplasia	< 0.001	NA	0.99				
MV straddling	0.52	0.10 to 2.80	0.45				

TV straddling	1.31	0.39 to 4.44	0.66				
TV interposition within baffle course	4.57	1.23 to 16.94	0.023		4.66	1.07 to 20.37	0.041
Heterotaxy	2.67	0.47 to 15.08	0.27				
3D printing	8.86	2.07 to 37.90	0.003		8.99	1.90 to 42.49	0.006
DORV: Double Outlet Right Ventricle; VSD: Ventricular Septal Defect; LVOTO: Left Ventricular Outflow Tract Obstruction; RVOTO: Right Ventricular Outflow Tract Obstruction; LV: Left Ventricle; RV: Right Ventricle; MV: Mitral Valve; TV: Tricuspid Valve; 3DM: Three-Dimensionally Printed Cardiac Model							

Table 2: Predictors of strategic crossover among the patients with initial SVP strategy (n = 50).

Mortalities and reinterventions

There were 5 surgical mortalities and 1 late death after the completion of LVR, and 6 surgical mortalities and 6 inter-stage mortalities (4 after the initial palliation, 2 after the BDG) in the course of SVP (Figure 1). Overall survival since first hospital registration was better in patients with final LVR strategy (n = 65) than those with final SVP strategy (n = 35) (88.8% vs. 64.6% at 5 year; log-rank p = 0.002; Figure 3A). When the survival rates of the patients who completed staged operation either with LVR (n = 56) or SVP (n = 14) were compared, however, there was no significant inter-group difference (88.9% in LVR strategy vs. 100% in SVP strategy at 5 year; log rank p = 0.19; Figure 3B). Eight patients underwent reinterventions after LVR (3 LV outflow tract relief, 3 permanent pacemaker insertion, 1 remnant VSD closure, 1 pulmonary valve replacement, and 1 tricuspid valve repair). Two patients underwent reinterventions after SVP (1 LV outflow tract relief, 1 pericardiostomy). Freedom from reoperation or catheter-based reintervention was not significantly different between the two groups (82.4% in LVR strategy vs. 81.7% in SVP strategy at 5 year; log rank p = 0.91; Figure 3C).

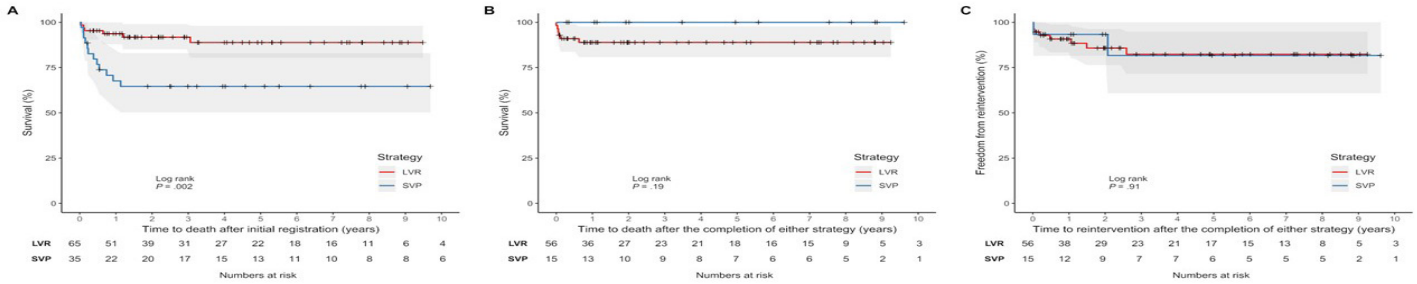

Figure 3: Kaplan-Meier survival estimates according to the initial surgical strategy (A), after the completion of AR or SVP (B), and freedom from reintervention after the completion of AR or SVP (C). LVR: Let Ventricular Recruitment as A Systemic Ventricle; SVP: Single Ventricular Palliation

Influence of 3DM

Among the patients who completed LVR (n = 56), median cardiopulmonary bypass time and aortic cross-clamping time in the patients with (n = 13) or without (n = 46) the preoperative use of 3DM were not significantly different (cardiopulmonary bypass time: 170 min vs 176 min, p = 0.82, aortic cross-clamping time: 106 min vs 108 min, p = 0.96). Since the introduction of preoperative use of 3DM in patients with DORV in 2015, 3DMs were made in 26 patients, of whom strategic crossover from initial SVP to LVR took place in 8 patients. Detailed information and strategic changes of the 26 patients with preoperative 3DM are summarized in Table 3 and Figure 4.

No.	Initial plan	Anatomical features	Current status
1	LVR	LVOTO	2V repair
2	LVR	Remote VSD, 200% DORV	Repair awaiting
3	SVP	Mitral valve straddling, Remote VSD	Fontan awaiting

4	LVR	LVOTO, Remote VSD	Repair awaiting
5	SVP	Mitral valve straddling, Multiple VSD	2V repair
6	LVR	Restrictive VSD, 200% DORV	2V repair
7	LVR	LVOTO, Remote VSD	Repair awaiting
8	SVP	Remote VSD, 200% DORV	Repair awaiting
9	LVR	TV straddling, Remote VSD	2V repair
10	LVR	Remote VSD, 200% DORV	2V repair
11	LVR	Remote VSD	2V repair
12	LVR	Multiple VSD, Remote VSD	2V repair
13	SVP	Remote VSD, 200% DORV	Repair awaiting
14	LVR	200% DORV	2V repair
15	LVR	LVOTO, Remote VSD	2V repair
16	SVP	Left isomerism, TV interposition in baffle course, Restrictive VSD, Remote VSD	2V repair
17	SVP	LV hypoplasia, TV straddling, Multiple VSD, Remote VSD	2V repair
18	LVR	Remote VSD, 200% DORV	2V repair
19	SVP	TV interposition in baffle course, TV straddling, Remote VSD, 200% DORV	Fontan awaiting
20	SVP	TV straddling, remote VSD	2V repair
21	SVP	TV straddling, Multiple VSD, Remote VSD	Fontan awaiting
22	SVP	LV hypoplasia, MV straddling, Remote VSD	Fontan awaiting
23	SVP	MV straddling, 200% DORV	1 & 1/2 repair
24	LVR	Remote VSD, 200% DORV	1 & 1/2 repair
25	LVR	Remote VSD, 200% DORV	1 & 1/2 repair
26	SVP	TV interposition in baffle course, TV straddling, remote VSD, 200% DORV	2V repair

DORV: Double Outlet Right Ventricle; LVR: Left Ventricular Recruitment As A Systemic Ventricle; SVP: Single Ventricular Palliation; 2V: Biventricular; LV: Left Ventricular; LVOTO: Left Ventricular Outflow Obstruction; VSD: Ventricular Septal Defect; MV: Mitral Valve; TV: Tricuspid Valve

Table 3: Summary of patient's status with three-dimensionally printed cardiac model.

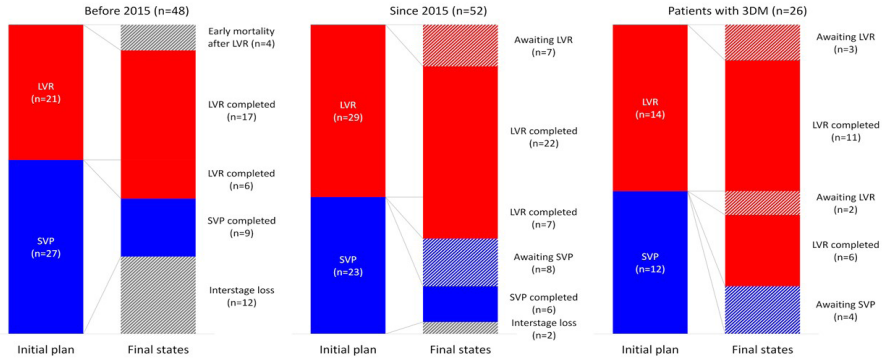

Figure 4: Comparison of the initial and final surgical strategies according to the eras before (A) and after (B) the introduction of 3DM, and in patients with 3DM (C). LVR: Let Ventricular Recruitment As A Systemic Ventricle; SVP: Single Ventricular Palliation; 3DM: Three-Dimensionally Printed Cardiac Model.

Comments

In this study, we found potential benefit of 3DM usage in the determination of surgical strategy favoring LVR in patients with complex DORV. Although MV straddling and LV hypoplasia were identified as LVR precluding factors in this study, absolute contraindications (or indications) for LVR is still controversial [7,8,12]. In practice, LVR precluding factors manifest themselves as a spectrum rather than discrete features (i.e. remoteness of the VSD, degree of LV hypoplasia, extent of the subvalvular apparatus encroachment into the course of intracardiac baffling…). The difficulties in delineating a subset not amenable to LVR may be attributed not only to non-standardized and inconsistent assessment of each morphologic feature but to the differences in individual surgeon's ability to overcome these obstacles. Therefore, comprehensive and standardized preoperative assessment of intra-cardiac structures is crucial to formulate an optimal surgical strategy for each patient [13,14]. In this regard, utilization of 3DM may be beneficial to reach a consensus on optimal surgical strategy for each patient and to predict potential complications related to the LVR [15-18]. Compared to the 3-dimenstionally reconstructed images on two-dimensional displays [19], 3DM provides real 3-dimensional spatial relationship with tactile sensation [20].

In this study, there was no surgical mortality in 26 patients with 3DM. However, extension of candidacy for LVR in patients with multiple risk factors may lead to higher postoperative mortality and morbidity, including the development of LV outflow tract obstruction and atrioventricular block [12,21]. In the previous studies, use of 3DM has been also known to be advantageous for the surgical training and preoperative simulation [1,22-24]. However, 3DM still has limitations. Because it is made from the still images of CT, 3DM cannot elucidate cardiac movement and function. Changes in intracardiac dimensions and function of the cardiac valves according to the cardiac cycle, regional ventricular wall motion, and exact attachment of fine chordae and subvalvar apparatus can be better visualized by echocardiography [25]. Secondly, direct measurement of cardiac structures from 3DM can be erroneous because imaging data from cardiac CT undergo multiple processing before the reconstruction of 3DM. Last limitation is time and cost [26]. Acquisition of sophisticated radiologic images, conversion of imaging data to a 3D format, and 3D printing process are time-consuming procedures. Therefore, it may not be an appropriate diagnostic modality for the patients who require urgent operation.

Conclusion

LVR can be facilitated with comprehensive preoperative anatomical assessment using the 3DM in patients with complex DORV. However, LVR is still challenging in patients with LV hypoplasia and MV straddling.

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