

# Long-term outcomes of mitral valve replacement in patients weighing less than 10 kg

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## Research article

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# Abstract

**Background:** The techniques of mitral valve repair (MVP) in children have been well established and provide acceptable long-term outcomes; certain pediatric patients require mitral valve replacement (MVR) after an unsuccessful MVP. The outcomes of MVR in pediatric especially in the patients weighing are not always favorable. This study aimed to measure long-term outcomes of MVR at our institute.

**Methods:** Nine young children weighing less than 10 kg underwent MVR from November 2006 to April 2019. Their mean age was  $11.88 \pm 11.29$  months and mean body weight was  $6.83 \pm 2.56$  kg at the time of initial MVR. Four patients (44.4%) had undergone at least one previous cardiac surgical procedure prior to MVR. Several surgical techniques were used to implant mechanical bileaflet prostheses.

**Results:** All patients received bileaflet mechanical prostheses. The surgical technique varied among the patients with valves implanted intra-annularly (n = 5), supra-annularly (n=1), or supra-annularly with a tilt (n = 3). The valve size/weight ratio ranged from 2.11 to 5.00. After a mean follow-up period of  $80.67 \pm 63.37$  months, the survival rate was 66.67%. One (11.1%) patient underwent an immediate revision MVR after initial MVR for the preprosthetic leak. No patients required surgical reintervention for the development of left ventricular outflow tract obstruction or permanent pacemaker placement during long-term follow-up.

**Conclusions:** The tailored surgical strategy utilized for MVR in infants resulted in reliable valve function and excellent survival. Although revision is inevitable due to somatic growth, the bileaflet mechanical prostheses displayed appropriate durability.

## Visual Abstract

- Key question (120 characters including spaces)

What should we do for patients with mitral valve diseases weighing less than 10 kg?

- Key findings (120 characters including spaces)

Mechanical valve prostheses might be a good choice.

- Take-home message (140 characters including spaces)

MVR in infants resulted in reliable valve function and excellent survival. The mechanical prostheses displayed appropriate durability.

## Introduction

Mitral valve diseases in children are complex and are always accompanied by various cardiac anomalies, making surgical treatment challenging[1]. Although the techniques of mitral valve repair (MVP) in children have been well established and provide acceptable long-term outcomes, mitral valve replacement (MVR) remains the sole surgical alternative.[2] Because of early calcification and short durability of bio-prostheses, mechanical mitral valve replacement (M-MVR) is the most common choice for the pediatric population, especially for neonates and infants[3]. In these cases, a larger-sized prosthesis valve is implanted into the small annulus, possibly causing high mortality, left ventricular outflow obstruction (LVOTO), complete atrioventricular block postoperatively, pulmonary vein stenosis, low valve durability and need for anticoagulant management postoperatively[4]. During the last century, many techniques and prosthesis have been employed to treat mitral valve diseases in infants and the outcomes of the MVR in the patients weighing 10 kg are not always favorable. To better understand the optimal approach to this complex problem, we retrospectively examined our experience with children less than 3 years old and weighing less than 10 kg who underwent M-MVR.

## Patients And Methods

### Patients

We considered all patients weighing 10 kg or less and younger than 3 years old who underwent MVR with mechanical prostheses at the Second Xiangya Hospital of Central South University in China between November 2006 and April 2019. Data were acquired from hospital records and the institute's cardiac database and were analyzed retrospectively. This study was approved by the Institutional Ethics Committee and written informed consent was obtained from parents or guardians before surgery to allow the use of their data.

### Surgical Technique

All patients underwent median sternotomy and standard cardiopulmonary bypass with bicaval cannulation under moderate hypothermia (range 28 to 32 °C). The mitral valve was exposed through an "L" shaped atrial septectomy (from the entrance of superior vena cava to the front of coronary sinus). M-MVR was performed after unsuccessful mitral valvuloplasty or when the valve was judged to be unsuitable for plasty. The posterior leaflet tissue and subvalvar apparatus of the mitral valve were preserved wherever possible. In patients with infective endocarditis, all valve tissue was excised and sent for bacterial cultures. Valves were implanted in either a supra- or intra-annular position; supra-annular valves were sometimes tilted either anteriorly or posteriorly to optimize positioning. When doing the skirt super-annular MVR, the Dacron conduit was interrupt sutured in the annular position and then the mechanical prosthesis was running sutured to the conduit (Fig.1 and Video). Three patients underwent MVR concomitant with repair of the associated cardiac abnormalities, including ventricular septal defect (VSD) closure (n = 1), ligation of patent ductus arteriosus (PDA) (n = 1), correction of coarctation of the aorta (n = 1). Intraoperative transesophageal echocardiography was used to confirm adequate prosthetic valve function in all cases.

## Follow-up

Postoperatively, anticoagulation was obtained using sodium warfarin, aiming at an international normalized ratio (INR) of 2.0–2.5. Temporary anticoagulation with intravenous heparin was also used during the 24 hours after the surgery and invasive procedures, aiming at an activated partial thromboplastin time (APTT) of 1.5–2.0 times above baseline.

## Statistical Analysis

The Statistical Package for Social Sciences (SPSS) version 22.0 (IBM) was used for all data analyses. Descriptive statistical analysis was undertaken using continuous data presented as median and interquartile range (IQR) or mean  $\pm$  standard deviation and categorical variables as raw data and/or percentages. Kaplan–Meier survival analysis was used for the prediction of freedom from death and adverse events. Chi-square test were performed to compare outcomes for patients based on the ratio of mechanical prosthesis and weight.

## Result

### Demographics

A total of nine pediatric patients were included in this study; there were three boys and six girls in this cohort. The ages of seven patients were less than 1 year at the initial M-MVR procedure. The mean age at the initial M-MVR was  $11.88 \pm 11.29$  months (range 1 months to 32 months) and mean body weight was  $6.83 \pm 2.56$  kg (range 4.0 to 9.5 kg). Two patients weighing less than 5 kg were diagnosed with severe congenital mitral valve regurgitation and stenosis and were treated with ventilator-assisted respiration before the operation. Mitral valve regurgitation was found in four patients after the AVSD repair, one of which was accompanied by fungal endocarditis after the partial AVSD repair. Three patients were diagnosed with severe mitral valve regurgitation with coarctation (CoA), patent ductus arteriosus, or ventricular septal defect (Table 1). Four (44.4%) patients underwent previous cardiosurgical procedures, of which three underwent partial or complete AVSD repair and one underwent VSD closure and MVP.

### Surgical technique

All patients received bileaflet mechanical prosthetic valves (ATS Medtronic, Minneapolis, Minnesota), with three receiving mitral prostheses and six receiving inverted aortic prostheses. Surgical technique varied between patients with valves implanted intra-annularly ( $n = 5$ ), supra-annularly ( $n = 1$ ), or supra-annularly with a tilt ( $n = 3$ ). The valve size/weight ratio ranged from 2.11 to 5.00 (average  $3.28 \pm 0.91$ ) and there is significant difference between the ratio over 3 and below ( $p = 0.03$ ) for early mortality (Fig.2 and table 2). The cardiopulmonary bypass time was  $154.33 \pm 68.25$  min (range 57 min to 285 min), and the aorta clamp time was  $103.89 \pm 47.94$  min (range 33 min to 173 min). At our institution, patient INRs were strictly monitored at outpatient hematology clinics during follow-up; there were no emergency operations for acute valve thrombosis or a significant event in other series.

## Early and Long-term Follow-up Outcomes

Three patients died 3 months postoperatively; the early survival rate was 66.67%. One died from mycotic endocarditis and the other two died from low cardiac output syndrome (Fig.3). One underwent redo MVR because of perivalvular leak. The postoperative intensive care unit (ICU) stay ranged from 1.8 to 89 days with a median of 8 days. Median duration of postoperative ventilation was 120 hours ranged from 19 to 504 hour (Table 3). Survival was 100% with the other six patients alive after mean follow-up of  $80.67 \pm 63.37$  months. The transvalvular gradient was  $10.5 \pm 1.76$  mmHg (range 8 to 12) and the peak gradient of LVOT was  $5.00 \pm 0.64$  mmHg. No patients required surgical reintervention for the development of left ventricular outflow tract obstruction or permanent pacemaker placement during long-term follow-up (Table 4).

## Discussion

MVP is considered to be the current standard of care for the treatment of children with mitral valve abnormalities. Unfortunately, there are certain pediatric patients who will need an MVR instead of an unsuccessful MVP; difficulties for both decision-making and treatment options may arise[5]. The most common indications for MVR in children include rheumatic disease, endocarditis, mitral stenosis in Shone's syndrome or failed auriculoventricular (AV) canal repair. In our studies, over 50% patients were diagnosed with mitral valve disease with infective endocarditis and failed auriculoventricular septal repair. Bioprostheses were not the appropriate choices for MVR in children and infants due to the lack of durability and unavailability of small-sized prostheses. The pulmonary autograft replacement of the MV and Contegra conduit were employed to treat the pediatric patients with small annulae to avoid long-term anticoagulation. However, because of accelerated degeneration and calcification, these technique require long-term follow-up[6, 7]. The Ross II procedure changed one valve problem to two valve problems, similar to the Ross procedure, possibly resulting in early regurgitation due to reduced ability to handle the overload of the left ventricle. Considering their better durability, availability, and hemodynamic performance, mechanical valves are the preferred mitral valve substitute in children.

Historically, MVR in infants has been associated with significant morbidity and mortality and long-term survival is lower than that of infant MV repair[8]. Consequently, surgical techniques and strategies have evolved to optimize outcomes. The reported operative mortality for MVR in infants is 5% to 30% and the 10- and 30-year survival for these patients has been recently reported up to 75%[5] (Table 5). Heart block requiring pacemaker implantation, endocarditis, thrombosis, stroke, an increased ratio of prosthetic size/weight and supra-annular position were all found to be statistically significant predictors of early mortality[9]. In our institute, the early mortality is 33.33% with 100% long-term survival. Among the three patient deaths, one died from a fungal infection and two died from low cardiac output syndrome. Although there were a relatively small number of deaths in our study, we found that smaller annulus, heart failure before the procedure and fungal infections were risk factors for short-term mortality. Previous studies demonstrated that age less than 2 years old at MVR was a risk factor for operative mortality[10]. Rafii et al. found that there was no significant difference in survival between patients aged

less than 2 years and patients aged 2 to 18 years; and age less than 2 years remained a risk factor for reoperation but not for mortality[11]. Bileaflet mechanical prostheses from ATS Medtronic (Minneapolis, Minnesota) were implanted in nine patients in our study. Because the smallest size of available mechanical mitral valve in our institute is 25 mm, six patients were implanted with mechanical aortic valve prostheses. Due to the low profile, excellent hemodynamics and good durability, a bileaflet mechanical valve is the prosthesis of choice in the mitral position in children[12]. Size mismatch between the mechanical prosthesis and mitral valve annular is considered to be a risk factor for operative mortality[13]. Caldarone et al. showed that the prosthesis size-to-patient body weight ratio was  $<2$  and 1-year survival rate was 91%; however, the survival rate was only 61% when the value was  $>4$  and only 37% when the ratio was  $<5$ [1]. In our study, the ratio ranged from 2.1 to 5 and the ratios of the deceased patients were all over 3. This suggests that an appropriate mechanical prosthesis is essential for successful MVR in children.

Multiple surgery techniques were employed in the MVR. The appropriate available mechanical valve was implanted in the annulus if the size matched. Because of the link between the mechanical valve size and freedom from redo MVR, a large mechanical prosthesis was implanted to the smaller annulus, possibly causing atrioventricular block and left ventricle outflow tract obstruction related to valve impingement on surrounding cardiac structures[14]. In the neonate or infant with a small native annulus, implantation of commercially available prosthetic valves in the annular position can be problematic. Placing the prosthesis in a supra-annular position is an alternative, when a more traditional annular implantation is not possible. The prosthetic valve was implanted with interrupted pledgeted polyester sutures with the pledgets on the atrial side of the prosthesis[15]. Previous publications suggested that the early results with supra-annular MVR in children were discouraging and identified it as a risk factor for early mortality because of the reduction of LA volume and compliance and aneurysm formation in the ventricularized segment of LA between the prosthesis and the annulus[2]. One of our patients had valves implanted with a tilt, similar to that described by Moon and colleagues, which involved suturing part of the valve onto the native annulus and the remainder to the left atrial wall or atrial septum. The prosthesis was thereby implanted supra-annularly with a tilt either anteriorly or posteriorly to prevent impingement on the LVOT, pulmonary vein orifices, and conduction tissue. Two weeks later, the patient underwent redo MVR for the periprosthetic leakage and died for acute low cardiac output syndrome. We suggest that implanting the prosthesis supra-annularly with a tilt may have caused the periprosthetic leakage and the immediate redo MVR. Three patients had Dacron Hemashield (Meadox Medicals, Inc, Oakland, NJ) with interrupted sutures sewn to the native valve annulus, after which the prosthetic valve was sewn with running sutures into the conduit. We employed the Dacron conduit that would be softer and provide better hemodynamics than the Gore-Tex conduit. The prosthetic valves were implanted to the conduit follow suturing the pipe to the annulus, which may provide convenience for the surgeon to implant a larger valve in a smaller space, also reducing the occurrence of periprosthetic leakage[16]. The technique of intermittent suture would preserve the growth potential and may provide the possibility for the replacement of a larger mitral valve in the future. It is inevitable that the mitral valve on the annulus will lead to the reduction of the left atrium content, possibly leading to pulmonary vein obstruction or even pulmonary hypertension. In our case, we

did not find the existence of pulmonary hypertension. We believe that the larger left atrium has sufficient space for buffering and grasping the height of the Dacron conduit that can effectively avoid this complication.

Redo valve replacement is inevitable following infant MVR because of somatic growth. The duration has been reported to be  $8.6 \pm 6.6$  years in children <5 years of age at initial MVR and 7.3 years following infant MVR[17]. The most common reported indication for early redo valve replacement is excessive pannus formation, particularly in infants and young children. valve type, size, and positioning were thought to optimize longevity of the implanted prosthesis and maximize time until redo MVR[18]. As presented in our follow-up results, the transvalvular gradients of implanted mechanical aortic valve and mitral valve demonstrated no significant differences. Studies indicated that choosing a mechanical valve larger than 19 mm could considerably delay the redo MVR[5], due to valve size  $\geq 19$  mm. There were no redo MVRs for somatic growth in our cohort.

There are several limitations in this study. First, it was a single-centre study, and therefore may be subject to selection bias. For this reason, we instituted strict inclusion and exclusion criteria. Multi-centre studies are needed to validate our findings. Besides that, study is limited by its retrospective design and the relatively small patient population.

## Conclusion

In terms of long-term outcomes, MVR is an adequate remedial procedure for MVP in infants and young children whose weight is less than 10 kg. The ratio between size of mechanical prosthesis and weight and mycotic endocarditis are risk factors for patients undergoing mechanical MVR. The size of mechanical valve over 19 mm can avoid redo MVR for 10 years or more. The skirt super-annular may reduce the mortality associated with MVR with a mismatched ratio.

## Abbreviations

Mitral Valve Repair (MVP)

Mitral Valve Replacement (MVR)

Mechanical Mitral Valve Replacement (M-MVR)

Supra-Annul Mitral Valve Replacement (SMVR)

Skirt Supra-Annul Mitral Valve Replacement (SSMVR)

Left Ventricular Outflow Obstruction (LVOTO)

International Normalized Ratio (INR)

Activated Partial Thromboplastin Time (APTT)

Statistical Package for Social Sciences (SPSS)

Interquartile Range (IQR)

Intensive Care Unit (ICU)

Auriculoventricular (AV)

Mitral Valve Regurgitation (MR)

Mitral Valve Stenosis (MS)

Ventricular Septal Defect (VSD)

Patent Duct Arteriol (PDA)

Infective Endocarditis (IE)

Partial Atrioventricular Septal Defect (PAVSD)

Complete Atrioventricular Septal Defect (CAVSD)

Coarctation (CoA)

Pressure Gradient (PG)

Mean Pulmonary Artery Pressure (mPAP)

## Declarations

- Ethical Approval and Consent to participate

This study was approved by the Institutional Ethics Committee and written informed consent was obtained from parents or guardians before surgery to allow the use of their data.

- Consent for publication

Written informed consent for publication was obtained from all participants

- Availability of supporting data

The data sets supporting the results of this article are included within the article and its additional files.

- Competing interests

There's no competing interests for this study.

- Funding

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2.National key research and development project[2016YFC1101002]

3.Major Scientific and Technological Projects for collaborative prevention and control of birth defects in Hunan Province[2019SK1010]

- Authors' contributions

Dr Can Huang, Zhongshi Wu, and Haoyong Yuan developed the idea of the study, participated in its design and coordination and helped to draft the manuscript. Ting Lu and Yilun Tang contributed to the acquisition and interpretation of data. Yifeng Yang and Jinlan Chen provided critical review and substantially revised the manuscript. All authors read and approved the final manuscript.

- Acknowledgements

Not applicable

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## Tables

Table 1. Patients list

NO.	Sex	Age	Weight	Diagnosis	Procedure	VALVE (SIZE)	Ratio	Redo	Clapping	Bypass	Intube	ICU Stay	PG 1week post	Ealy Death
1	F	9	9	MR, Post CAVSD Repair	SSMVR	19	2.11	N	173	285	66	3.3	8	N
2	M	3	5.5	MR, VSD	SMVR	19	3.45	Y	125	185	336	14		Y
3	F	3	4.7	MS, MR	SSMVR	19	4.0	N	104	121	124	10	12	N
4	F	1	3.8	Post MVP, MR	MVR	19	5	N	160	209	48	2		Y
5	F	12	7	IE, MR, Post PAVSD Repair	MVR	21	3	N	56	95	504	89		Y
6	F	21	9	MR, PDA	MVR	25	2.7	N	33	57	19	1.8	12	N
7	M	2	4	MS, MR	SSMVR	16	4	N	124	171	384	20	12	N
8	F	32	9.5	MR, Post PAVSD Repair	MVR	25	2.6	N	104	155	72	7	10	N
9	M	24	9	MR, CoA	MVR	25	2.7	N	56	111	120	8	9	N

Age (months), Clapping, Bypass, Intube and ICU Stay (min), Weight(kg) Size(mm), PG(mmHg), F=Female, M=Male, N=NO, Y=Yes, Ratio= valve size/weight, MR=Mitral valve regurgitation, MS=Mitral valve stenosis, VSD=Ventricular septal defect, PDA=Patent duct arteriol, IE=infective endocarditis, PAVSD=Partial artroventricular septal defect, CAVSD=Complete artroventricular septal defect, CoA=Coarctation, MVP=Mitral valve repairment, MVR=Mitral valve replacement, SMVR=Supra-annul mitral valve replacement, SSMVR=Skirt supra-annul mitral valve replacement, PG=Pressure gradient

Table 2. Comparison of the survival between ratio  $\geq 3$  and below

	Death	Survival	P value
Ratio $\geq 3$	3	2	P=0.03
Ratio < 3	0	4	

Table3. Patients character list

Age at operation	11.88 ± 11.29 months (range 1 months to 32 months)
Weight at operation	6.83± 2.56 kg (range 4.0 to 9.5 kg)
Interval from original ration	80.67 ± 63.37 months
The cardiopulmonary bypass time	154.33 ± 68.25 min (range 57 min to 285 min)
The aorta clamp time	103.89 ± 47.94 min (range 33 min to 173 min)
Duration of ventilation	Median 120 hours [ranged from 19 to 504 hour]
Duration of ICU stay	Median 8 days [ranged from 1.8 to 89 days]

Table 4. Follow up for the latest echocardiograf examination

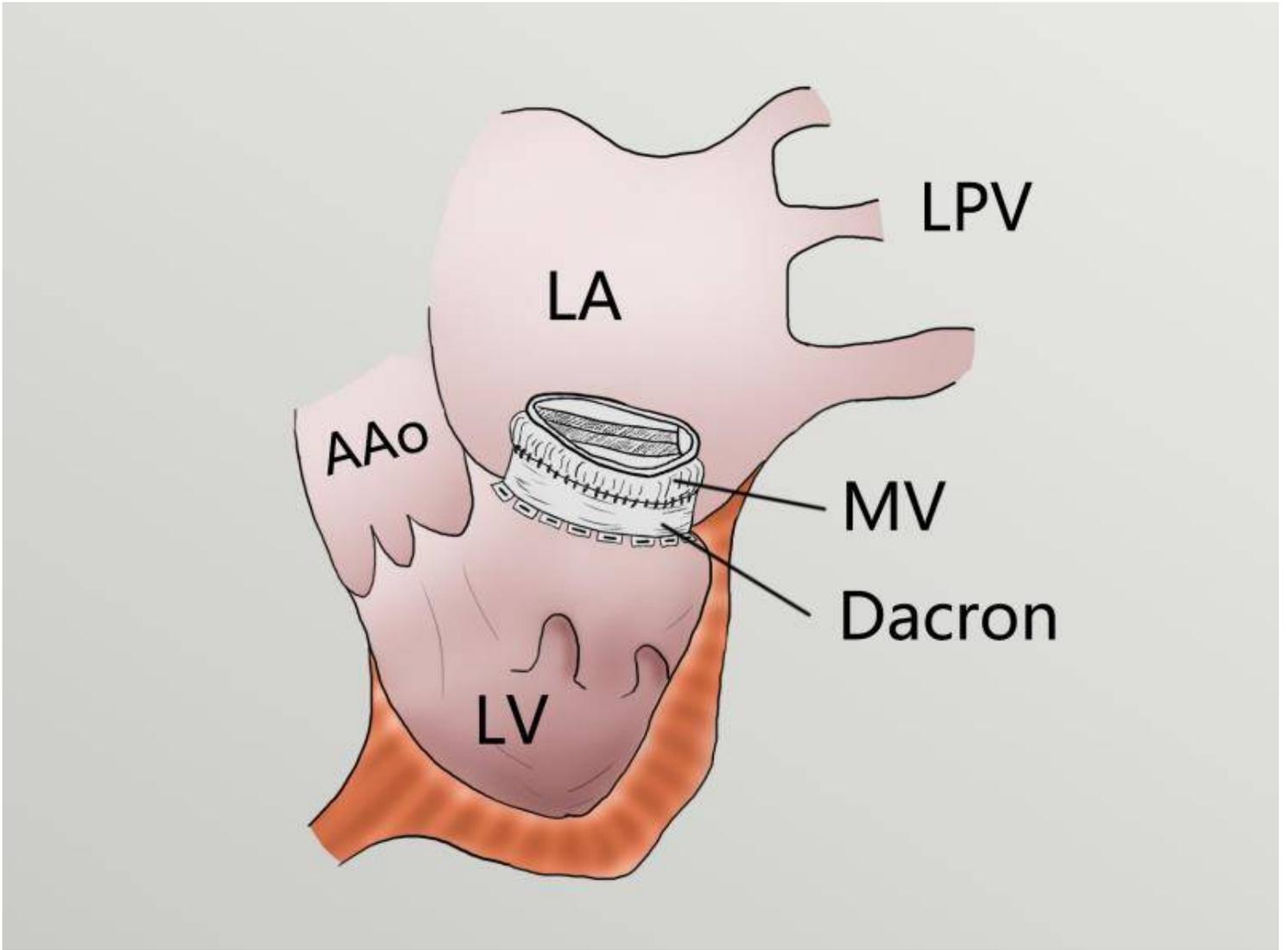
Patients	Follow Up	PG(LVOT)	PG( MV)	mPAP
1	8	5	8	20
3	32	5	11	16
6	108	6	12	20
7	36	5	12	18
8	144	5	11	17
9	156	4	10	16

Follow up (months), MV=Mitral valve, PG=Pressure gradient, LVOT=left ventricular outflow tract, mPAP=mean pulmonary artery pressure

Table 5. Literature review of long-term survival and freedom from redo MVR after MVR

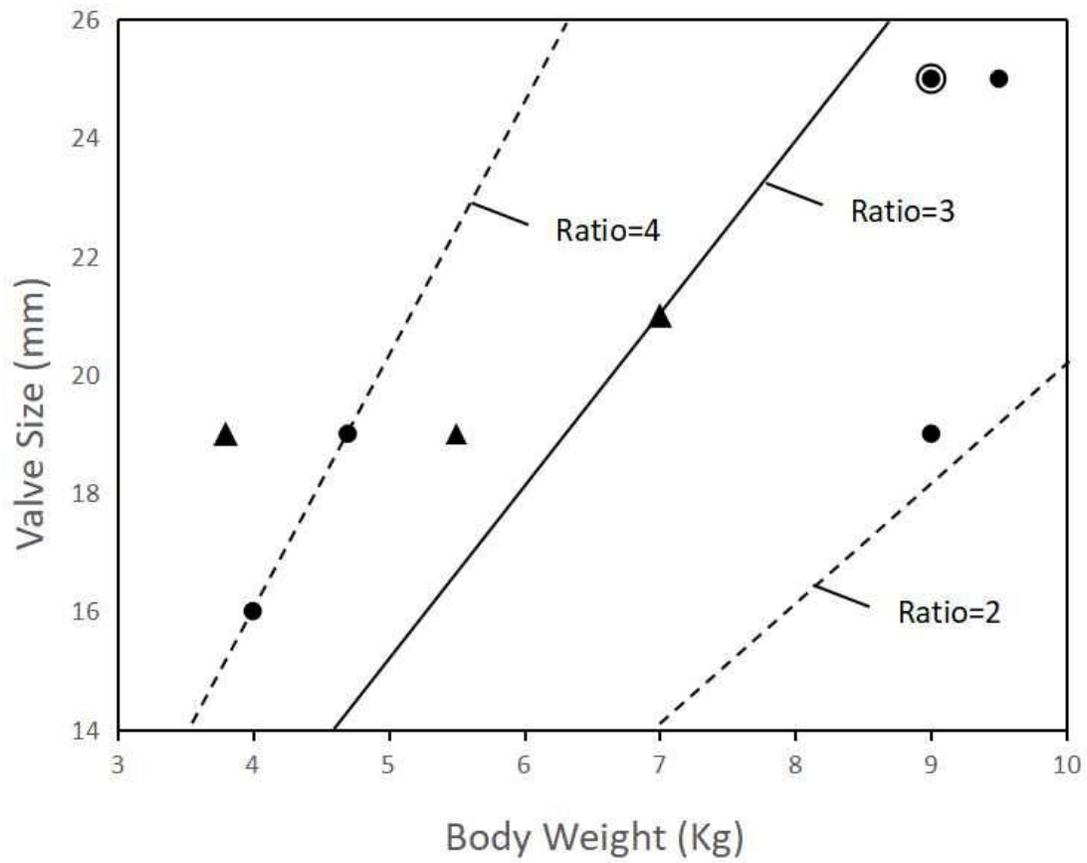
Studies	Cases	Age	Follow up	Survival rate	Free from Redo MVR
Mater, Kathryn. 2019. Australia <sup>9</sup>	22	Mean age 6.8±4.1 months	6.2±4.4 years	100%	86.1% at 1 years, 80.7% at 5 years and 21.2% at 10 years
Raffaele Giordano. 2015. Italy <sup>2</sup>	7	Mean age 13.3±11.2 months	67.1±34.8 months	100%	71.4%
Christopher A. Caldarone .2015. USA <sup>1</sup>	139	Mean age 1.9±1.4 years	Median 6.2 years	74%	
Jiyong Moon. 2015. Japan <sup>20</sup>	18	Mean age 4.0 ± 1.8 months	4.5 ± 3.8 years	89.1%	57.8% at 10 years
John W. Brown. 2012. USA <sup>18</sup>	97	Median age 8 years	12.8 ±10.1 years	71%	94% at 1 year, 82% at 5 years, 71% at 10 years, and 63% at 20 and at 35 years
Hyung-Tae Sim. 2012. Korea <sup>21</sup>	19	Mean age 7.6 ± 5.5 years	76 ± 56 months	100%	94.7 ± 5% at 10 years
Daniela Y. Rafifii. 2011. USA <sup>11</sup>	18	Median age 1.2 years	Median 5.4years	82%	69% at 5 years and 40% at 10 years
Kirk R. Kanter. 2011. USA <sup>22</sup>	15	Mean age 337 ± 412 days	4.3 ±2.8 years,	84%	69% at 5 years and 21% at 10 years
BahaaldinAlsoufi. 2010. Canada <sup>22</sup>	79	Median age 24 months	4.1±3.7 years	62%	
ElifSeda Selamet Tierney. 2008. USA <sup>8</sup>	118	Median age 16.3 months	Over 30 years	56%	72% at 5 years and 45% at 10 years
J. S. Sachweh. 2007. Germany <sup>23</sup>	17	Mean age 4.3±4.3 years	9.1 ± 6.6 years	94.1%	93.4% at 1 year 89.0% at 5 and 10 years
Wolfram Beierlein. 2007. UK <sup>24</sup>	54	Median age 3.0 years	Median 9.2 years	33%	45.3% at 5 years and 17.3% at 10 years
Hunaid A. Vohra. 2007. UK <sup>12</sup>	24	Mean age 1.4±1.3 years	Median 7.5 years	75.7%	
Naoki Wada. 2005. Japan <sup>25</sup>	18	Mean age 1.02±0.72 years	3.3± 3.5 years	68.9%	87.1% at 5 years and 69.6% at 10-years

## Figures



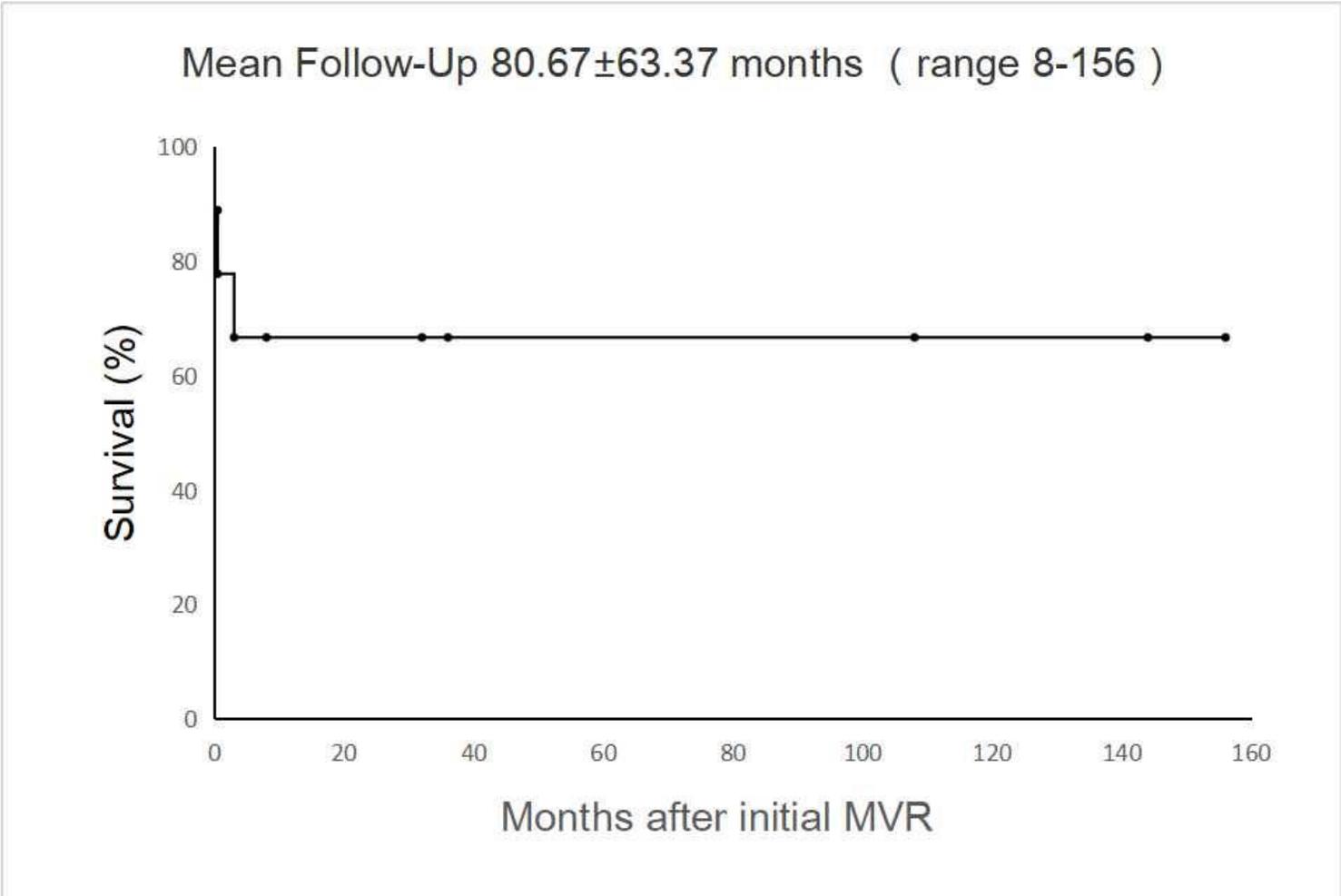
**Figure 1**

Valves implanted supra-annularly with a tilt



**Figure 2**

The patients Ratio between valve size/body weight



**Figure 3**

Kaplan-Meier analysis of survival

### Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Video.mp4](#)