The Yasui Operation: A Single Institutional Experience Over Thirty Years

Christina L. Greene, MD, Brandi Scully, MD, Steven J. Staffa, MS, Mariana Chavez, MD, Kevin G. Friedman, MD, Pedro del Nido, MD, Luis G. Quinonez, MD, Sitaram M. Emani, MD, Christopher W. Baird, MD.

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The Yasui Operation: A Single Institutional Experience Over Thirty Years

- 25 Patients from 1989-2021
- 19 Primary Yasui & 6 Staged
- Median age at OR 11 days and weight 3kg
- Follow up 96% at 5 years with 92% Survival

The Yasui operation can be performed with low morbidity and mortality in patients with two acceptable sized ventricles and aortic atresia or interrupted aortic arch with severe LVOTO.

Despite some burden of re-operation for conduit changes, mid-term re-operation for LVOTO is not common and ventricular function is preserved.

*LVOTO = Left Ventricular Outflow Tract Obstruction
The Yasui Operation: A Single Institutional Experience Over Thirty Years

Christina L. Greene\textsuperscript{1} MD, Brandi Scully\textsuperscript{1}, MD, Steven J. Staffa\textsuperscript{2}, MS, Mariana Chavez\textsuperscript{1}, MD, Kevin G. Friedman\textsuperscript{3}, MD, Pedro del Nido\textsuperscript{1}, MD, Luis G. Quinonez\textsuperscript{1}, MD, Sitaram M. Emani\textsuperscript{1}, MD, Christopher W. Baird\textsuperscript{1}, MD.

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Word Count: 3,417

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GLOSSARY OF ABBREVIATIONS

AA: Aortic Atresia
DKS: Damus-Kaye-Stansel
ECMO: Extra-corporeal Membrane Oxygenation
IAA: Interrupted Aortic Arch
ICU: Intensive Care Unit
LVOTO: Left Ventricular Outflow Tract Obstruction
OR: Operating Room
RV-PA: Right Ventricle to PA
VSD: Ventricular Septal Defect

CENTRAL PICTURE (90/90 characters with spaces)
Freedom from reoperation for LVOTO was 91% a median of 5 years after the Yasui operation.

CENTRAL MESSAGE (197/200 characters with spaces)
The Yasui operation can be performed with low morbidity and mortality, despite some burden of conduit reoperation, in patients with two acceptable sized ventricles and AA or IAA with severe LVOTO.

PERSPECTIVE STATEMENT (395/405 characters with spaces)
This is the largest series of Yasui operations with the longest follow up. A rarely performed repair, unfamiliarity with this approach hinders its widespread application as the first-choice solution to LVOTO, VSD and two adequately sized ventricles. Concerns persist regarding its safety and long-term durability. We report a 92% survival with a 91% freedom from LVOTO reintervention at 5 years.
OBJECTIVE: The Yasui operation was introduced in 1987 for patients with two adequate ventricles, a ventricular septal defect (VSD) and aortic atresia (AA) or interrupted aortic arch (IAA). Despite promising early outcomes, left ventricular outflow tract obstruction (LVOTO) remains a long-term concern. The purpose of this study is to report our institutional experience with the Yasui operation.

METHODS: We retrospectively reviewed all patients undergoing the Yasui operation between 1989 and 2021. Results are reported as median with interquartile range.

RESULTS: 25 patients underwent a Yasui operation (19 primary), at 11 days (7-218) of life and weight of 3 kg (2.8-4.1). Fundamental diagnosis was VSD/IAA in 11 patients and VSD/AA in 14. Follow-up was 96% (24/25) at 5 years (1.4-14.7) with 92% survival. Freedom from LVOTO re-operation was 91% at late follow-up with 2 patients requiring baffle revision at 6 and 9 years. Latest echocardiogram showed 100% of patients had normal biventricular function and 87% (20/23) less than mild LVOTO at 5 years (2.3-14.9). Diagnosis, aortic valve morphology, and material used were not predictors of LVOTO. Freedom from RV-PA conduit re-operation was 48% at a median of 5 years (1.4-14.7). Conduit type was not a predictor of reintervention.

CONCLUSIONS: The Yasui operation can be performed with low morbidity and mortality in patients with two acceptable sized ventricles and AA or IAA with severe LVOTO. Despite some burden of re-operation, mid-term re-operation for LVOTO is not common and ventricular function is preserved.

KEYWORDS: Yasui, Biventricular Repair, Aortic Atresia, Interrupted Aortic Arch, Left Ventricular Outflow Tract Obstruction
INTRODUCTION

The Yasui operation was introduced in 1987 for patients with two adequate ventricles, a ventricular septal defect (VSD) and aortic atresia (AA) or interrupted aortic arch (IAA). Neontal single stage biventricular repair for IAA/VSD with diminutive aortic valves was plagued by the late development of left ventricular outflow tract obstruction (LVOTO) with nearly half of patients requiring reintervention. Surgical solutions to this unique patient population included single stage palliation with the Norwood operation or biventricular repair with a Ross/Konno/Arch repair. The former commits the patient to a shunted single ventricle physiology when they have two adequate ventricles while the later has a high early mortality rate (33%).

The Yasui operation was developed to address this patient population by creating a Damus-Kaye-Stansel (DKS) connection between the atretic ascending aorta and the pulmonary trunk then baffling the left ventricular outflow through the VSD to the systemic circulation. Pulmonary blood flow is established with a right ventricle to pulmonary artery conduit. The Yasui procedure offers the advantage of a primary or staged bi-ventricular repair, with no shunting and a reliable source of fully oxygenated systemic blood flow. It has been shown to have lower operative mortality in comparison to the Norwood, and equivocal long-term survival ranging from 58% at 5 yrs. to 88% at 10 yrs. Despite promising early outcomes, left ventricular outflow tract obstruction (LVOTO) remains a long-term concern as does the need for conduit revision. Some centers advocate a staged approach as a larger sized conduit can be placed and the post-operative course is more stable, while other centers advocate establishment of two ventricle circulation as early as possible. The purpose of this study is to report our institutional experience with the Yasui operation in the hopes of clarifying some of the ongoing controversies.
MATERIALS & METHODS:

A retrospective chart review was performed to identify all patients who underwent a Yasui operation between September 1989 and May 2021. The study was approved by the institutional review board of Boston Children’s Hospital, 12/21/2019, and patient consent was waived (IRB-P00034147). Patients were identified from the cardiac surgery and cardiology database. Inclusion criteria were all patients undergoing a Yasui operation. A staged Yasui is defined as a primary Norwood procedure followed by septation with a Yasui operation. The patient can be at any stage of the single ventricle palliation including BDG and Fontan, while a primary repair indicates the Yasui as the first operation. Patients being considered for the Yasui operation had two adequate ventricles, a ventricular septal defect (VSD) and aortic atresia (AA) or interrupted aortic arch (IAA). There are no institutional criteria for the Yasui operation and primary repair was pursued in all patients except one who was in extremis and taken for a salvage Norwood. All other staged Yasui patients were referred after receiving the primary palliation at an outside hospital. Primary end points were survival, presence of LVOTO, number of reinterventions and type. A detailed retrospective chart review was performed. Demographic, prenatal, postnatal, echocardiographic, catheterization and operative data were collected from the medical record and analyzed. Follow-up for survival analysis was obtained in 91% of patients.

Surgical Technique

While surgical technique has evolved over the 30 year study period, patients undergoing a Yasui operation were cannulated aorto bi-cavally, underwent moderate hypothermia and received antegrade cardioplegia for a diastolic arrest. DKS was performed in the standard fashion. The location of the ventriculotomy determined the ease of VSD closure/baffle. The closer the
ventriculotomy to the aorta, the easier the baffle, but this places the RV-PA conduit at risk directly behind the sternum. Thus, moving the incision as lateral as possible, toward the LAD, is better for conduit revision but is balanced by the ease of VSD baffle. It is occasionally useful to create a larger ventriculotomy to aid baffle closure then primarily close the portion of the incision underneath the aorta/pulmonary artery before implanting the conduit. Care must be taken to avoid distorting the sub-valvar configuration and causing neo-aortic regurgitation. If there is any concern that the VSD is small and would put the patient at risk for LVOTO, then the VSD is enlarged, even if it is a muscular defect.

Statistical Analysis

Patient and operative characteristics are represented as number (percent) for categorical variables and median and interquartile range for continuous variables. Echo measurements are summarized as mean and standard deviation (SD). Sample sizes are shown for variables with missing data. Univariate Cox proportional hazard regression analysis was used to explore predictors of mortality, LVOTO, reoperation for LVOTO, and conduit reoperation. Results are presented as hazard ratios with 95% confidence intervals (CI) and P values. Multivariable modeling was not performed due to relatively small sample size and number of events. Kaplan-Meier curves were created to estimate freedom from events over time for each outcome, with 95% confidence bands obtained using Greenwood’s formula. The comparison of primary and staged operations was performed using Fisher’s exact test for categorical variables and using the nonparametric Wilcoxon rank sum test for continuous variables. All statistical analyses were performed using Stata (version 16.1, Stata Corp LLC, College Station, Texas) and a two-tailed P < 0.05 was considered statistically significant.
RESULTS

Between 1989 and 2021, 25 patients underwent a Yasui operation (19 primary and 6 staged).

Age at the time of OR was 11 days (6.5-218) and weight was 3.1 kg (2.8-4.2). Gestational age was 39 weeks (35-39). 56% of patients were male (n=14) and 24% of patients were pre-mature (<37 weeks). Six had known genetic disorders (4 DiGeorge, 1 Elastin Gene Defect and 1 Chromosome 5 deletion). Fundamental diagnosis was VSD/IAA in 11 patients and VSD/AA in 14 (11 hypoplastic arch and 3 double outlet right ventricle). All patients had a VSD; 92% (23/25) had a posterior malalignment VSD and two had a muscular VSD. Additional diagnoses include sub-aortic stenosis (7), bicuspid aortic valves (6), unicuspid aortic valves (3), right sided aortic arch (2) and aberrant right (8) and left (2) subclavian arteries. Six patients had undergone the Norwood pathway with three having progressed to a bi-directional Glenn and one to a Fontan at the time of Yasui.

Complete pre-operative echocardiographic data was obtained in 12 patients (Table 1).

Cardiopulmonary bypass time was 264 min (191-297), cross clamp time was 195 min (110-221), circulatory arrest time was 18 min (16-39), selective antegrade perfusion time was 90.5 min (66-115), and patient temperature was 18°C (18-23). The VSD was enlarged in 4 patients when there was concern for LVOTO. VSD/Baffle was constructed of autologous pericardium (52%) or Dacron (20%) most commonly. Aortic Arch Reconstruction was performed in 16 (64%) patients and was most often constructed of thick pulmonary homograft (7), aortic homograft (4) or Dacron (3). All patients had an RV-PA homograft conduit (12 pulmonary, 13 aortic) with a median size of 11 mm (9-12). Immediate post bypass echocardiogram showed no residual LVOTO. All but two patients were found to have good biventricular function. The chest was left open in 19/23 (83%) patients and closed at 4 days post-operatively (3-6). Two patients required
ECMO in the perioperative period. One had a Protamine reaction with arrest and was transitioned to ECMO in the OR. The second bled post-operatively and was transitioned to ECMO for recovery of his metabolic status. Early re-operation occurred in 7 patients: 3 for bleeding, 2 for residual VSD, 1 for wound infection and 1 for pacemaker placement. Time to extubation was 7 days (5-16), ICU length of stay was 18 days (7-33), and total hospital length of stay was 26 days (18-46).

Follow-up was obtained in 96% (24/25) of patients at a median of 5 years (1.4-14.7) with 92% survival (Figure 1). There was one in-hospital death from multi-organ failure and 1 patient died of an unknown cause 1.5 years post-operatively. Freedom from LVOTO re-operation was 91% (21/23) at last follow-up with 2 patients requiring baffle revision and VSD enlargement at 6 and 9 years (Figure 2). Original diagnosis was AA/VSD in these two patients. One was staged and had their VSD enlarged at the time of Yasui, while the other was a primary Yasui where the VSD was originally felt to be adequate. Latest follow-up echocardiogram showed 100% of patients had normal biventricular function and 87% (20/23) had less than mild LVOTO at 5 years (2.3-14.9) (Figure 3). On latest follow-up echo, AV annular growth was observed in 78% (7/9) of patients, all of whom had aortic atresia, a median of 5 years post op (median z-score 5.1). Two patients with IAA had stably small AV annuli with a median z-score of -4.6. No pre-operative factors were associated with increased LVOTO or survival (Table 2). Freedom from RV-PA conduit re-operation was 48% at 5 years (1.4-14.7) with 13 patients requiring conduit replacement at 4 years (2-8) (Figure 4). Size of initial conduit replacement was 20 mm (17-23). Neither size nor type of conduit was predictive of conduit reintervention.

Cohort size and event rate was insufficient to compare primary vs staged repairs for the primary outcomes. Comparison of operative and post-operative outcomes was performed and
found length of open chest (17 vs 2 days, \( p=0.042 \)) and ICU length of stay (23 vs 8 days, 
\( p=0.017 \)) to be significantly different between the two groups (Table 3).
DISCUSSION

The Yasui operation provides a two-ventricle solution to a single ventricle physiology. The combination of AA or IAA with VSD and two adequately sized ventricles can be safely managed with either a single ventricle or two ventricle approach with acceptable early survival. Concerns exist regarding subsequent development of LVOTO, the need for LVOT reintervention and the burden of conduit replacement. We evaluated our experience over the past 30 years with the Yasui operation in order to address some of these concerns.

To the authors knowledge, this is the largest published series of Yasui operations (n=25) with the longest follow up (33 years).\textsuperscript{4-6} A rarely performed repair, unfamiliarity with this approach hinders its widespread application as the first-choice solution to LVOTO, VSD and two adequately sized ventricles and concerns persist regarding its safety and long-term durability. We report a 92% survival with a 91% freedom from LVOTO reintervention and 48% freedom from conduit reintervention at a median of 5 years (1.4-14.7). This corroborates the assertion that the Yasui operation is a safe two-ventricle solution to AA or IAA, VSD and two adequately sized ventricles.\textsuperscript{5,6}

Additionally, concerns regarding the need for early LVOT reintervention are alleviated. The majority of patients (86\%) did not have LVOTO at 5 years, and those that did (n=3) reported less than mild LVOTO. All patients were found to have preserved bi-ventricular function at follow-up. The lack of LVOTO is likely attributed to careful patient selection. While all patients had diminutive aortic annuli (median Z-score -4.7) they all also had apex forming left ventricles and normal sized mitral valves (median Z-score -0.15). Thus, when applied to the appropriate patient population, the Yasui operation can be performed with minimal risk of recurrent LVOTO.\textsuperscript{10}
The need for conduit reintervention is significant with almost half of patients requiring conduit replacement at 5 years. When evaluated against the reintervention rate for the alternative solutions (Norwood or Ross/Konno/Arch repair), the Yasui compares favorably. In the Norwood pathway, most patients will undergo a minimum of three operations with the first occurring as early as 4 months of age. The Ross/Konno/Arch repair has the same burden of conduit replacement but suffers from a high early mortality rate (33%).\textsuperscript{5,6,11-13} So, while there is a burden of reintervention for conduit replacement in the Yasui operation which is unavoidable, the need for reintervention is on par or less than the other surgical alternatives.

Given our small sample size of staged repairs, we were unable to compare the primary outcomes of freedom from LVOTO, freedom from reintervention for LVOTO, freedom from conduit change and survival for primary vs staged patients. We did find however that patients who were initially staged had their chest closed sooner and had faster ICU length of stays as suggested by Nakano et al.\textsuperscript{6} This is logically attributed to the older age and greater weight at staged repair. It is erroneous to conclude that staged repair is safer or better based on these findings as the two patient populations have too many confounding factors precluding direct comparison. Additionally, the added risk of undergoing single ventricle palliation with the inherent interstage mortality must also be considered. Some advocate pulmonary artery banding (PABs) as an alternative to the Norwood to delay decision-making regarding the need for Yasui or standard biventricular repair.\textsuperscript{6} No patients in our series were managed with PABs. Of the six patients that were staged, 5 presented after undergoing single ventricle palliation at an outside hospital and one underwent a salvage Norwood as they were in extremis. It is our assertion that if patients can be repaired safely as neonates and avoid a shunted physiology that is better for their overall prognosis.\textsuperscript{5,10}
While this study confirms the findings of previous investigations, it is a single center retrospective review of a rare operation with a small sample size and is subject to all the biases and limitations of a retrospective chart review.

In conclusion, the Yasui operation can be performed with low morbidity and mortality in patients with two acceptable sized ventricles and AA or IAA with severe LVOTO. Despite some burden of re-operation, mid-term re-operation for LVOTO is not common and ventricular function is preserved. A primary Yasui operation avoids the morbidity and mortality associated with a shunted single ventricle palliation and can be performed safely with durable result in select patient populations with AA or IAA, severe LVOTO and two acceptable sized ventricles (Figure 5).
REFERENCES


Table I: Pre-Operative Echocardiographic Measurements

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>Mean z score (SD)</th>
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<tr>
<td>Aortic Valve Annulus</td>
<td>4.1 (± 2.3) mm</td>
<td>-4.2 (± 2.0)</td>
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<tr>
<td>Mitral Valve Annulus</td>
<td>11 (±0.34) mm</td>
<td>0.68 (± 1.6)</td>
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<tr>
<td>LV Mass</td>
<td>7.7 (± 6.8) g</td>
<td>-1.96 (± 1.88)</td>
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<tr>
<td>Aortic Root Diameter</td>
<td>0.7 (± 0.3) mm</td>
<td>-1.8 (± 2.2)</td>
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<tr>
<td>Ascending Aorta Diameter</td>
<td>0.4 (±0.8) mm</td>
<td>-2.9 (± 3.7)</td>
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<td>Hazard Ratio</td>
<td>95% CI</td>
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<tr>
<td>Female</td>
<td>1.4</td>
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<td>Age at surgery (years)</td>
<td>0.79</td>
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<td>Weight at surgery (kg)</td>
<td>0.38</td>
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<td>Aortic Z-Score</td>
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<td>Mitral Z-Score</td>
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<tr>
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<td>LV Mass Z-Score</td>
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<td>AA Z-Score</td>
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<td>Arch Reconstruction</td>
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<td>RV-PA Conduit Size (mm)</td>
<td>0.86</td>
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<td>Material RV-PA</td>
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<tr>
<td>Pulmonary</td>
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<tr>
<td>CPB time (minutes)</td>
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<td>Cross clamp time (minutes)</td>
<td>1.04</td>
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<tr>
<td>Circ Arrest time (minutes)</td>
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<td>(0.93, 1.19)</td>
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<td>SACP (minutes)</td>
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<tr>
<td>Days intubated</td>
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<td>ICU LOS (days)</td>
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<tr>
<td>Total Hospital LOS (days)</td>
<td>1.01</td>
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Table 3: Comparison of Primary vs Staged Operations

<table>
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<th>Primary (n=19)</th>
<th>Staged (n=6)</th>
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<td>CPB time (minutes)</td>
<td>279 (246, 334)</td>
<td>191 (151, 264)</td>
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<td>Cross clamp time (minutes)</td>
<td>201 (127, 227)</td>
<td>106 (82, 204)</td>
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<tr>
<td>Circ Arrest time (minutes)</td>
<td>18 (16, 47)</td>
<td>22 (5, 39)</td>
<td>0.693</td>
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<tr>
<td>Chest left open</td>
<td>17 (89.5%)</td>
<td>2 (40%)</td>
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<td>Days intubated</td>
<td>9.1 (5.8, 18.2)</td>
<td>5.3 (4, 7)</td>
<td>0.121</td>
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<tr>
<td>ICU LOS (days)</td>
<td>23 (12, 38)</td>
<td>8 (6, 13)</td>
<td>0.017*</td>
</tr>
<tr>
<td>Total Hospital LOS (days)</td>
<td>34 (19, 54)</td>
<td>21 (14, 26)</td>
<td>0.072</td>
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</tbody>
</table>

Data are presented as n (%) or median (interquartile range).
P values were calculated using Fisher's exact test or the Wilcoxon rank sum test.
*Statistically significant.
FIGURE LEGEND

Figure 1: Survival after Yasui operation over time. Survival was 92% a median of 5 years post-operatively (1.4-14.7). There were two deaths: one in-hospital and one at 1.5 years post-operatively. Shaded areas represent the 95% confidence interval.

Figure 2: Freedom from LVOTO reoperation over time showed 91% of patients to be free of LVOTO reintervention at a median of 5 years post-operatively. Two patients underwent LVOT reoperation at 6 and 9 years post-operatively. Shaded areas represent the 95% confidence interval.

Figure 3: Freedom from LVOTO over time. Eighty-six percent of patients had no LVOTO by most recent echocardiogram with three patients found to have mild LVOTO. All patients had preserved biventricular function. Shaded areas represent the 95% confidence interval.

Figure 4: Freedom from conduit reintervention over time. Forty-eight percent of patients were found to require conduit reintervention at 5 years with 75% of patients requiring conduit reintervention by 10 years. Shaded areas represent the 95% confidence interval.

Figure 5: Graphical Abstract summarizing the findings of this single institutional experience with the Yasui operation over the past thirty years.
Reoperation for LVOTO after Yasui

<table>
<thead>
<tr>
<th>Time (years)</th>
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<td>6-10</td>
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<td>21-25</td>
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<td>26-30</td>
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</table>

Freedom from Reoperation for LVOTO:
- 0% 25%
- 25% 50%
- 50% 75%
- 75% 100%
Figure 3

Freedom from LVOTO

Time (years)

Number at risk

25 13 8 5 3 2 1
The Yasui Operation: A Single Institutional Experience Over Thirty Years

- 25 Patients from 1989-2021 • 19 Primary Yasui & 6 Staged • Median age at OR 11 days and weight 3kg • Follow up 96% at 5 years with 92% Survival

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