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**LONG TERM COMPARITIVE ANALYSIS OF SINGLE  
VENTRICLE PHYSIOLOGY PATIENTS FOLLOWING  
BIDIRECTIONAL GLENN SHUNT WITH OR WITHOUT  
ANTEGRADE PULMONARY BLOOD FLOW**



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**In Partial Fulfillment of the Requirement for the Degree of  
M.Ch. in Cardio Vascular and Thoracic Surgery 2019-2021**

**Under the guidance of**

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# DECLARATION

I, **Dr. Prashanth M. Harsur**, hereby declare that this thesis titled “**LONG TERM COMPARITIVE ANALYSIS OF SINGLE VENTRICLE PHYSIOLOGY PATIENTS FOLLOWING BIDIRECTIONAL GLENN SHUNT WITH OR WITHOUT ANTEGRADE PULMONARY BLOOD FLOW**” has been prepared by me under the capable supervision and guidance of

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Date:10/8/2021

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FLOW”**

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# **TITLE**

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# **INTRODUCTION**

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Bidirectional Glenn is a palliative procedure and a basic step towards total cavopulmonary connection. Preserving confluence of pulmonary arteries, obtaining bilateral pulmonary blood flow and leaving options open for any subsequent procedures. The bidirectional Glenn shunt is the second in a series of three staged surgeries to reconstruct a single ventricle heart, in situations where corrective bi-ventricular surgery or cardiac transplantation are not feasible

The bidirectional Glenn shunt procedure involves rerouting circulation such that the superior vena cava (SVC) drains into the right pulmonary artery. This results in deoxygenated blood returning from the head and upper body directly routed to the pulmonary arteries for oxygenation by the lungs, to some extent reducing the ventricular workload. Since the blood passing from the SVC into the pulmonary arterial system flows bidirectionally to both right and left lungs, it is called a bi-directional Glenn procedure.

The Glenn procedure was introduced in 1958 by William Glenn and modifications to the procedure were published by Dr. Azzolina in 1973. The original description by Dr. Glenn allowed communication only between the right pulmonary artery and the SVC, whereas the modified technique had the SVC connecting at or before the bifurcation between the right and left pulmonary arteries.

The bidirectional Glenn procedure (BDG) is used in the staged surgical management of patients with a functional single ventricle. Controversy exists regarding whether accessory pulmonary blood flow (APBF) should be left at the time of BDG to augment systemic saturation or be eliminated to reduce volume load of the ventricle. The present study is a retrospective review of patients undergoing BDG that was conducted to assess the influence of APBF on survival rates.

The data available on the use of Bidirectional Glenn with APBF is unclear, the advantages are higher oxygen saturation, lower mortality, favourable effects on cardiac functions, prevention of arteriovenous fistulas and a better growth of pulmonary arteries if compared with BDG with pulmonary artery interruption. patients who have undergone BDG with APBF for univentricular heart repair maintain circulation of hepatic factors into pulmonary arterial system to prevent pulmonary arteriovenous malformations and presence of APBF would result in raised pulmonary artery pressure volume load on the single ventricle . Hence weighing the advantages over disadvantages of both the procedures ie with antegrade flow and the other with pulmonary artery interruption in BDG single ventricle .we believe the need of review of literature with the above retrospective studies.

## ABBREVIATIONS

APBF - Antegrade pulmonary blood flow

AVCD - Atrioventricular canal defect

AVVR - Atrio Ventricular Valve Regurgitation

BDG - Bidirectional Glenn

CCTGA - Congenitally Corrected Transposition of Great Arteries

DILV - Double Inlet left ventricle with pulmonary stenosis/pulmonary hypertension

DORV - Double Outlet Right Ventricle with pulmonary stenosis/pulmonary hypertension

ECHO - Echocardiography

HLHS - Hypoplastic Left Heart Syndrome

PA, IVS - Pulmonary atresia with Intact Ventricular septum and Hypoplastic right heart variants

PA, VSD - Pulmonary atresia with Ventricular septal defect

PAB - Pulmonary Artery Banding

SV - Single Ventricle

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## **REVIEW OF LITERATURE**

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CLASSIC GLENN SHUNT; Anastmosis between the transected distal end of the RPA and the side of the SVC, which is ligated distal to the anastmosis resulting in blood flowing to only 1 lung, Hence the glenn was modified where the SVC is connected at or before the bifurcation between the right and left pulmonary arteries.

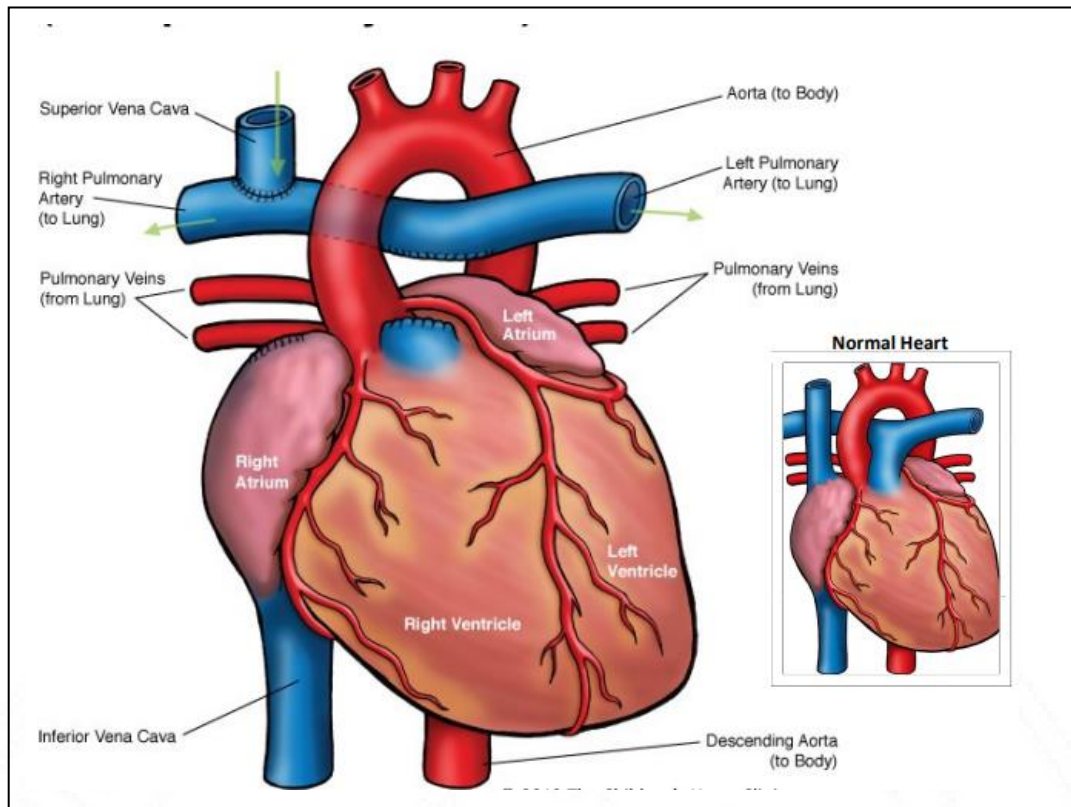
But it has its own advantages; long term results of the classic glenn anastomosis in patients not suitable for complete repair are generally satisfactory. About 85% survive atleast 10 years after creation of shunt, which usually remains patent that length of time. kopf and colleagues reported only 50% are still functional 20 years postoperatively with 10 and 20 year survival at 84% and 66% respectively

The word palliate originates from latin “palliare” which means masking or lessening of an effect. A palliative surgery generally is the one which provides symptomatic relief but leaves the pathophysiology uncorrected. A palliative operation is not a correction or repair.

Principles of superior and total cavopulmonary Cavo shunts;

- 1) The Goal of surgical palliation in single-ventricle lesions is to separate the systemic and pulmonary circuits, resulting in normal or near normal oxygen saturation.
- 2) Cavo Pulmonary shunts divert the systemic venous return directly into the pulmonary vascular bed, providing more “effective” pulmonary blood flow and reduce the volume load on the single ventricle

Though the Cavo pulmonary shunt improves the cyanosis and unloads the single ventricle, the elevated PVR in neonates, preclude their use in neonates until 3 months of age.



In patients with Single ventricle physiology, The dominant ventricle provides both the Systemic and Pulmonary output and remains the major driving force for both the systemic and pulmonary circulation. Patients with univentricular or biventricular atrioventricular(AV) connections can be functionally univentricular, Irrespective of the anatomy, the restoration of a normal preload and optimizing the after load to the dominant ventricle is the postulate in the management of these complex congenital heart diseases.

The bidirectional Glenn (BDG) anastomosis is the 2nd step in a staged palliation in preparation for a later total cavopulmonary connection (TCPC). The blood from superior vena cava (SVC) is routed to right pulmonary artery (PA). It reduces the ventricular load of the systemic ventricle and the blood is directed to the pulmonary artery which helps in the growth of the pulmonary arteries. It can also be performed as the final palliation in older patients/ in borderline right ventricles/Ebsteins anomaly as part of 1.5 ventricle repair. Majority of the patients undergo TCPC (Fontan procedure) in later stage which unloads the systemic ventricle further and direct the systemic venous blood totally to the pulmonary arteries. The surgery involves routing of the blood from inferior vena cava (IVC) to the PA. It is currently recommended by the age of 1.5 to 4 years. This staged approach gives the ventricle the time to adapt and help ventricle remodeling

### **Advantages of Bidirectional Glenn Shunt**

- 1) Superior Cavopulmonary shunt; Directs the desaturated SVC blood exclusively into the Pulmonary arteries, such that systemic to pulmonary artery shunt is not needed which leads to dramatic reduction in ventricular workload.
- 2) BDG provides an opportunity to correct abnormalities before fontan i.e AV Valve regurgitation, anomalous pulmonary venous connection, sub aortic obstruction
- 3) Second stage palliation allows ventricular remodeling which necessarily occurs with acute reduction in volume overload. Thus, ventricular mass and function return to normal before TCPC.

### **Disadvantages of Bidirectional Glenn Shunt**

- 1) Increases surgical risk of an additional procedure
- 2) Inadequate pulmonary artery growth under conditions of low pulmonary blood flow
- 3) Development of Aorto pulmonary collaterals in response to low pulmonary blood flow and cyanosis.
- 4) Formation of intrapulmonary Arterio Venous malformation.

# SINGLE VENTRICLE

The term single ventricle was described by chemineau in 1699, which stated “it’s a heart composed of two auricles but only one ventricle”.

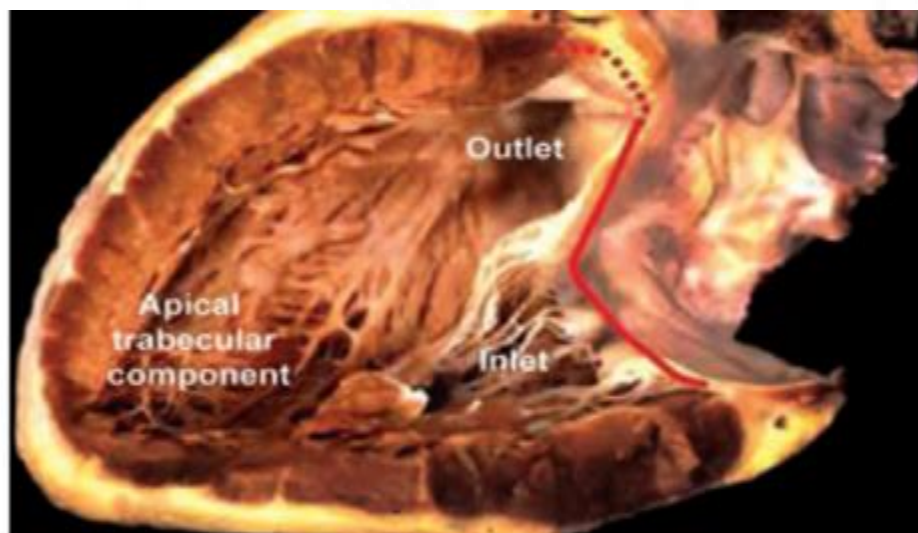
The nomenclature of univentricular heart is still controversial, the term single and common ventricle were used interchangeably by Abott, Taussig and Edwards. Maurice published a paper on single or primitive ventricle in 1969.

Van Praagh quoted that univentricular heart are those which have a rudimentary or additional incomplete ventricle that lacks a proper atrioventricular connection.

“As per the congenital heart surgery nomenclature a single ventricle anomalies are defined as a heterogeneous group of cardiac malformations that have in common the feature that only one of the chambers within the ventricular mass is capable of supporting independently and/ or in combination the systemic and/or pulmonary circulations”

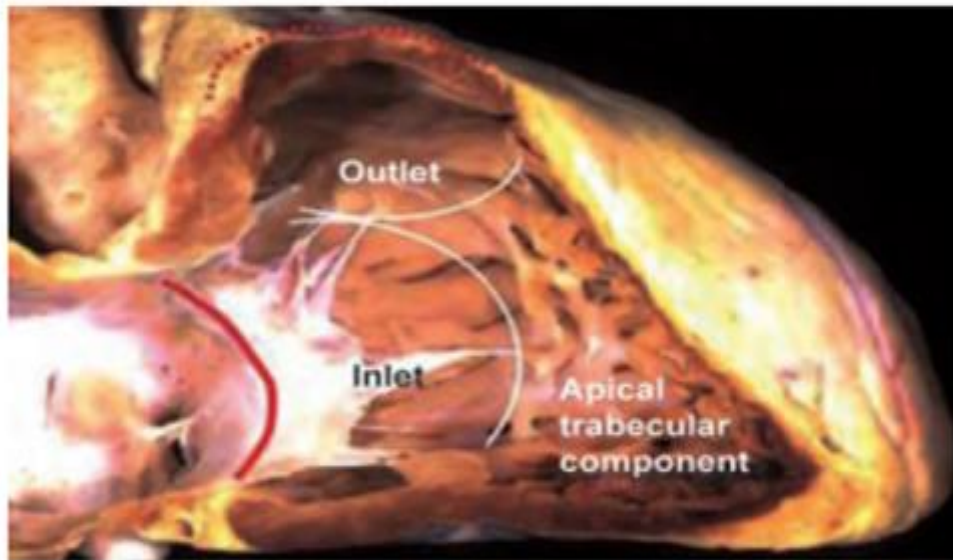
Anderson et al classified univentricular heart

1) Univentricular heart of LV type; where the dominant chamber is of LV morphology and rudimentary chamber had morphological features of RV trabecular zone.



The Figure shows a morphological LV, which is also tripartite. The Solid red line indicates the Atrioventricular junction, while the dotted red line indicates the ventriculoarterial junction

2) Univentricular heart of RV type; where the dominant chamber is of RV morphology and rudimentary chamber had morphological features of LV trabecular zone.

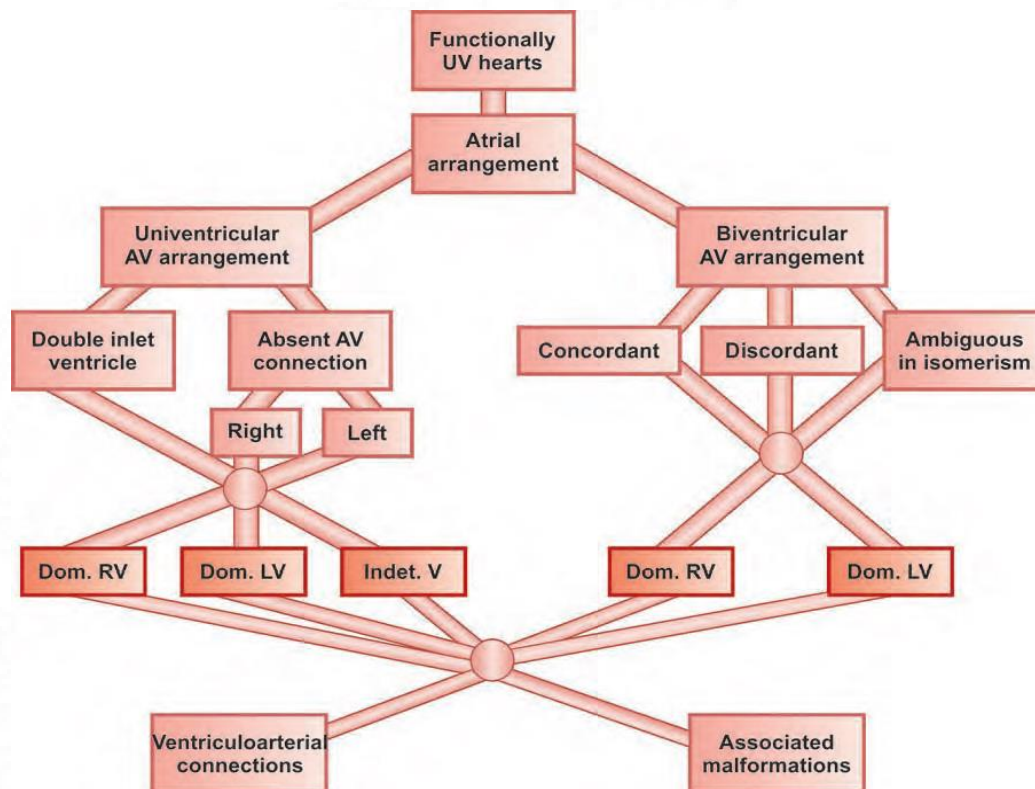


This figure shows a morphological RV, which is tripartite, an inlet, outlet, apical trabecular portions. The apical trabeculations are coarse, the solid red line indicates the atrioventricular junction, while the dotted red lines indicate ventriculoarterial junction

In 1984, Anderson et al responded by introducing the term 'univentricular atrioventricular connection' to describe hearts in which both inlets (whether patent or not) are primarily committed to one dominant ventricle. Thus, according to Van Praagh, a single or common ventricle is one ventricular chamber that receives both the tricuspid and mitral valves or a common atrioventricular valve. So, this definition excludes tricuspid and mitral atresia. Anderson's system likewise emphasizes the nature of the connections between the atrial and ventricular structures, asserting that the unifying criterion for univentricular hearts is that the entire atrioventricular junction is connected to only one chamber in the ventricular mass. A second ventricular chamber, if present, will lack any atrioventricular connection and hence be rudimentary. This system makes the distinction between hearts with a double inlet ventricle versus hearts with absence of an atrioventricular connection, but acknowledges that because a heart with absence of one atrioventricular connection is also a univentricular heart, then tricuspid atresia is among those anomalies associated with a univentricular heart.

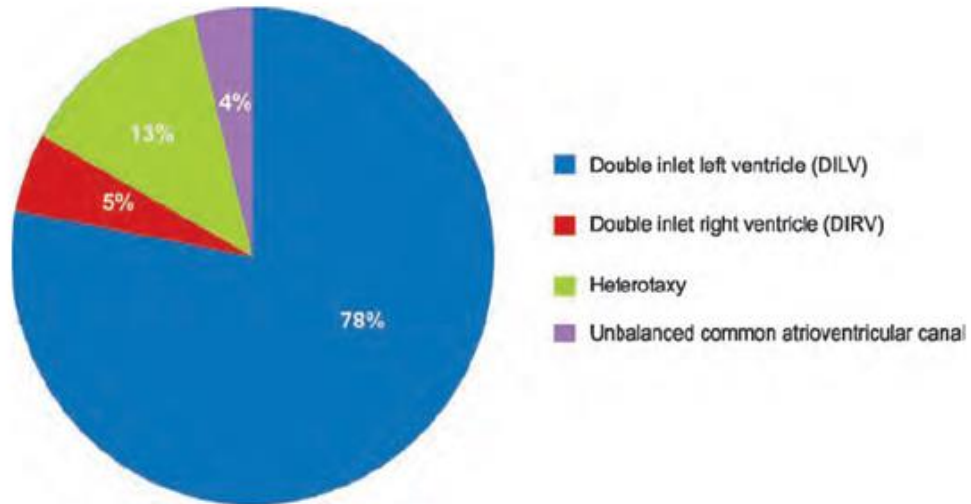
# NATURAL HISTORY

In the largest series of unoperated patients, Moodie et al reported that 70 percent with dominant single left ventricles died before age 16, with an annual attrition rate of 4.8 percent. The natural history is even bleaker for patients with univentricular hearts of right ventricular morphology, with 50 percent survival 4 years after diagnosis. The most common causes of mortality were arrhythmias, congestive heart failure



Schematic representation to show the possible segmental combinations that can result in functionally univentricular heart

Ammash and Warnes reviewed their experience with 13 unoperated adults with univentricular hearts to determine, which characteristics permitted long-term survival. 11 patients had DILV with transposed great arteries, 1 patient had DILV with normally related great arteries and 1 patient had tricuspid atresia. The oldest patient was 66 years old. All had either moderate-to-severe pulmonary stenosis or pulmonary hypertension. The left ventricular ejection fraction was normal (n = 11) or mildly depressed (n = 2) and no patient had more than mild atrioventricular valve regurgitation. Twelve patients reported good functional capacity and worked full- or part-time. Thus, despite the overall grim prognosis in unoperated patients, some adults with DILV, transposition of the great arteries and well-balanced circulations may survive into their seventh decade with acceptable functional capacity and preserved ventricular function.



Autopsy of 60 univentricular heart excluding tricuspid atresia and mitral atresia

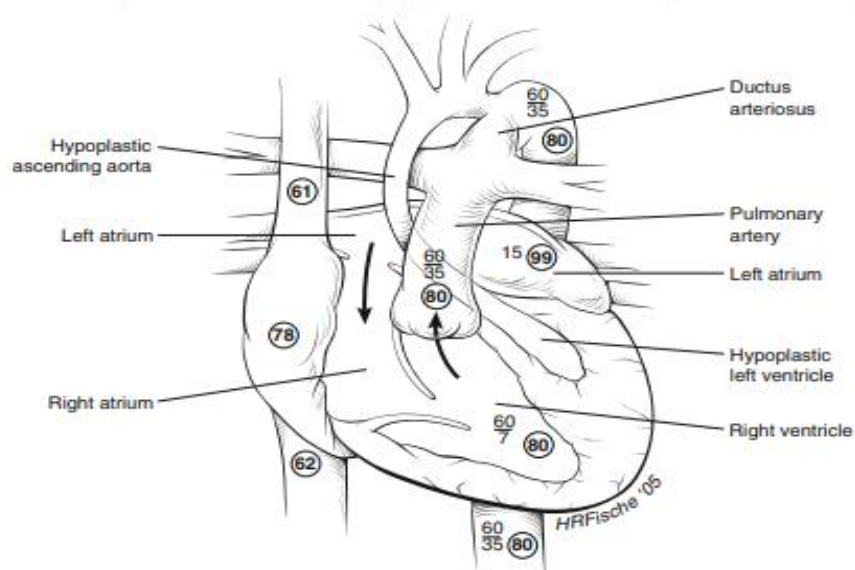
Anatomical variants;

1) HLHS can be anatomically categorized on the basis of atrioventricular (AV) and semilunar valvular morphology into three primary subsets

[a] aortic atresia with mitral atresia (40 %)

[b] aortic stenosis with mitral stenosis (30 %), and

[c] aortic atresia with mitral stenosis (30 %)

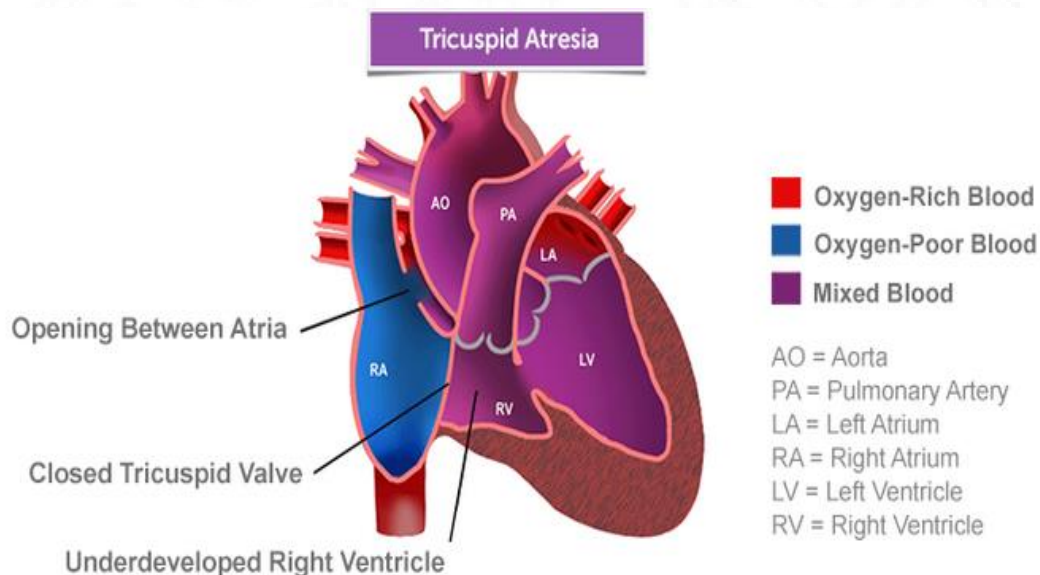


Anatomic features and representative haemodynamic parameters for unrepaired hypoplastic left heart syndrome. Oxygen saturations are enclosed in circles and blood pressures are indicated by standard nomenclature

- 2) Tricuspid Atresia This lesion is defined by atresia of the tricuspid valve but varies in the ventriculo-arterial alignments, presence and size of the ventricular septal defect, and degree of ventricular outflow tract obstruction.

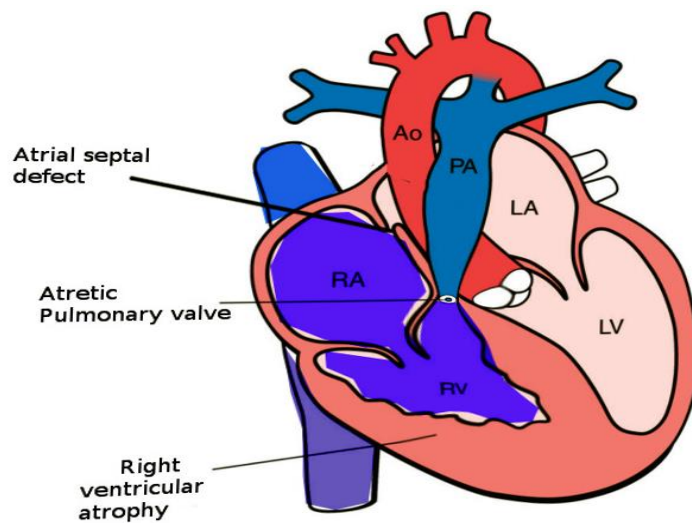
The defect is classified according to the ventricular-great vessels relationship:

- a) Type 1 – normally related great vessels
- b) Type 2 – D-transposed of the great arteries
- c) Type 3 – L-transposed of the great arteries Further classification depends on the presence or absence of ventricular septal defects and ventricular outflow tract obstruction.



- 3) Pulmonary Atresia with Intact Ventricular Septum The spectrum of disease with this abnormality includes variable degrees of hypoplasia of the right ventricle and tricuspid valve stenosis or atresia. Mild forms of the disease with isolated membranous atresia of the pulmonary valve are amenable to biventricular repair.

Patients with tricuspid inflow and a significantly hypoplastic RV cavity will often have significant sinusoids or fistulae that allow communication between the RV and the coronary artery system. When severe, the coronary flow becomes dependent on these sinusoids, and patients with this anatomy have a poor outcome with RV decompression and are not candidates for biventricular repair

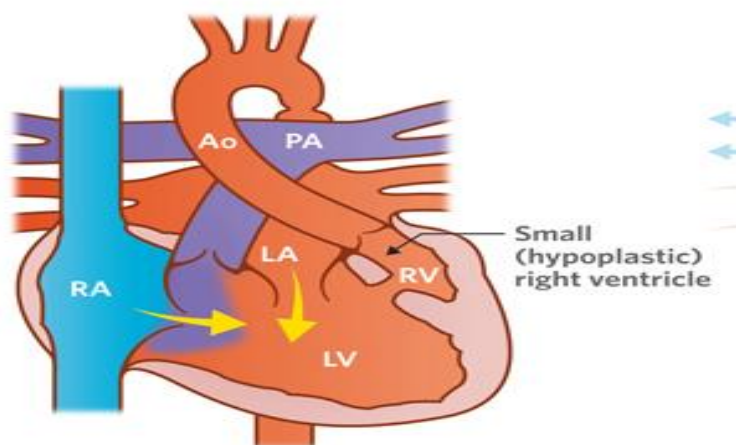


### PULMONARY ATRESIA WITH INTACT VENTRICULAR SEPTUM

- 4) Double Inlet Ventricle The anatomy of double inlet ventricle is characterized by both atria connecting to the single ventricular chamber either via a single or two separate AV valves. Most often, the ventricular morphology is that of a dominant left ventricle which communicates with an outflow chamber via a bulboventricular foramen.




The great vessels can be transposed with ventriculo-arterial discordance (more common) or normally related with ventriculo-arterial concordance (less common, termed “Holmes heart”). A more unusual configuration of double inlet ventricle is that of a single right ventricle with both atrioventricular valves committed to the single RV and both outflow tracts also arising from this ventricle

### Double inlet left ventricle (DILV)



Double inlet (yellow arrows) left ventricle from right and left atriums

5) Unbalanced AV Canal Defect There are no strict criteria for defining unbalanced AV canal defect, although ventricular size and distribution of common AV valve over each ventricle (AVVI) can be used to determine relative imbalance . It can be associated with normal segmental anatomy or variations including situs inversus, L-looping, and heterotaxy syndrome. Trisomy 21 is a common association in patients with normal segmental anatomy and AV canal defect.

A	B	C
<p>Univentricular AV-connection e.g. DILV, DIRV</p>  <p>DILV</p>	<p>Congenital heart defects with absent AV-connection and/or ventricular hypoplasia e.g. TA, PA/VS, MA, HHS</p>  <p>TA with transposed great arteries</p>	<p>Functional univentricular heart e.g. unbalanced AVSD, forms of dTGA/VSD, DORV</p>  <p>Unbalanced AVSD with hypoplastic right ventricle</p>

# CLINICAL FEATURES

1) In the current era, diagnosis is often made in utero by fetal ultrasonography and confirmed by fetal echocardiography. For patients without a prenatal diagnosis, presentation is usually within the first few weeks of life as ductal closure results either in pulmonary or systemic hypoperfusion.

Severe systemic hypoperfusion manifests with poor feeding, tachypnea, hypertension and acidosis. Intestinal malperfusion may result in necrotizing enterocolitis with abdominal distension and bloody stools

2) The clinical features, timing and type of presentation of single ventricle, depends on the associated lesions and degree of outflow obstruction. The most frequent presenting symptom is cyanosis since birth. They can also present for heart murmurs, CHF and neonatal shock.

3) The patients with single ventricle with increased pulmonary blood flow (PBF) present in early infancy with signs and symptoms of typical of large left to right shunts like CHF and failure to thrive. Cyanosis may not be very obvious if the patient has increased PBF. In patients with associated aortic obstruction, the CHF is worsened.

4) In neonates with single ventricle and subpulmonary stenosis/atresia marked cyanosis, metabolic acidosis develops and they become critical as the ductus closes. In patients with mild to moderate pulmonary stenosis, they present like tetralogy of Fallot. They may be relatively asymptomatic, with mild to moderate cyanosis, clubbing and attain adulthood with retarded growth.

5) The LV type of single ventricle patients have a LV type of apical impulse. It can be hyperdynamic in patients with increased PBF. There can be a visible, palpable impulse in the third left intercostal space (due to inverted outlet chamber). The second heart sound is loud and palpable (anterior aorta). The systolic thrill at left sternal border is indicative of subaortic stenosis.

6) The single ventricle of RV type have a subxiphoid RV impulse. There is no impulse in the third left intercostal space as there is no underlying outlet chamber.

7) Aortic component of S2 is loud due to the anterior aorta. The second heart sound is single or narrow split or normally split. In patients with pulmonary hypertension there is no split and it may appear as single S2. The systolic murmur is audible along the mid or lower left sternal

border. The Systolic murmur is decrescendo in patients with increased PBF.

8) A systolic ejection murmur is present in those with subpulmonary stenosis. The murmur vary inversely in length and loudness according to the degree of stenosis. The diastolic murmurs can be heard in patients with single ventricle with increased PBF. There can be an apical mid diastolic rumble due to increased flow across the left atrio ventricular valve.

In patients with pulmonary hypertension, Graham Steell early diastolic murmur of pulmonary regurgitation may be present along the upper left sternal border.

9) On physical examination, weak or absent distal pulses, poor capillary refill, and cool skin tone are common.

10) The chest X-ray may demonstrate pulmonary edema due to congestive heart failure. A less debilitating form of postnatal presentation is development of pulmonary over-circulation due to unrestrictive pulmonary blood flow with or without obstruction to systemic outflow

11) Neonates and infants present with tachypnea, failure to thrive, and are found to have oxygen saturations greater than 90 % suggesting elevated pulmonary to systemic blood flow ( $Q_p/Q_s$ ) ratio. Pulmonary hypoperfusion in patients with ductal dependent pulmonary circulation presents with cyanosis, and chest X-ray will demonstrate origami lung fields.

# HEMODYNAMICS OF SINGLE VENTRICLE

A normal postnatal cardiovascular system consists of a double—pulmonary and systemic circuit, connected in series, powered by a double pump—the ‘right’ and ‘left’ heart. However, in a univentricular heart, the single ventricle has to maintain both the systemic and pulmonary blood circulations, which are not connected in series but in parallel.

There are two main disadvantages:

- 1) Arterial Desaturation and
- 2) Chronic volume overload to the single ventricle. Such chronic volume overload has significant effects on the single ventricle namely:
  - a) Dilatation of atrium and ventricle
  - b) Eccentric hypertrophy
  - c) Spherical remodeling with reorientation of wall fibers
  - d) Annular dilatation causing progressive atrioventricular valve regurgitation

Thus, the hemodynamic problems in univentricular hearts arise from:

- a) Inherent mechanics of a single ventricle (lack of interventricular coupling and volume overload to single ventricle)
- b) Mechanics of morphological RV versus morphological LV
- c) Morphology and functional state of atrioventricular valves
- d) Degree of mixing within single ventricle
- e) Pulmonary vascular resistance (PVR)
- f) Presence and degree of pulmonic or subaortic stenosis

# DIAGNOSIS OF A SINGLE VENTRICLE

## A) ECHOCARDIOGRAPHIC DIAGNOSIS OF UNIVENTRICULAR HEART

The univentricular hearts can be of LV dominance, RV dominance or primitive/ indeterminate morphology. The best view having to evaluate this is parasternal short-axis view.

### Ventriculoarterial Connections

The different connections possible are concordant, discordant, double outlet from main or outlet chamber and single outlet. Nearly 86 percent of univentricular hearts with LV dominance<sup>30</sup> have discordant ventriculoarterial connections. We have to carefully exclude outflow tract obstruction of the great artery arising from the outlet or rudimentary chamber. Only 14 percent of DILV hearts have normally related great arteries called 'HOLMES HEART'

In univentricular hearts of RV dominance, the common pattern is DORV from main chamber or single outlet with pulmonary atresia Atrioventricular Connections; Atrioventricular connections can be of the following three types:

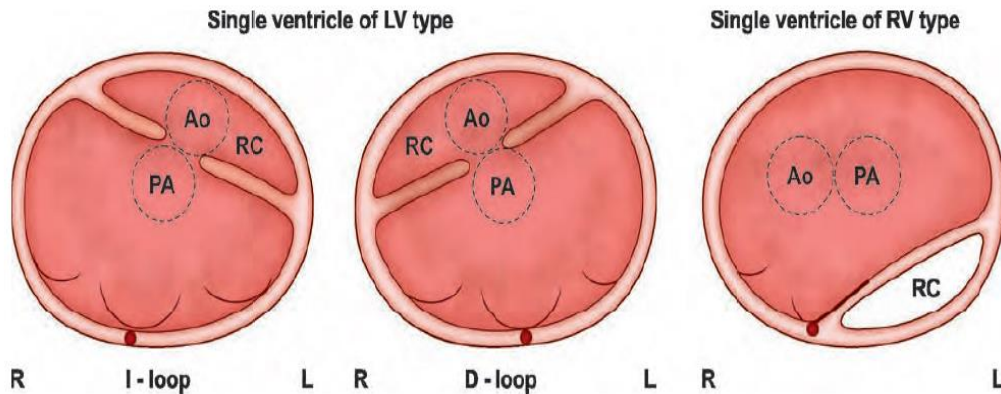
- a. Double inlet.
- b. Absence of an atrioventricular connection.
- c. Straddling atrioventricular valves.

1) Double Inlet Connections ; The most common univentricular hearts have double inlet connection, which is usually due to both atrioventricular valves draining into a common ventricular chamber (88%) or rarely by a common atrioventricular valve (12%). Usually common atrioventricular valve is associated with heterotaxy syndromes (asplenia or polysplenia). The double inlet is best visualized in short axis and four chamber echocardiographic views. In DILV, there is no intervening inlet septum between the right and left atrioventricular valves; therefore these valves may actually touch one another when they open in diastole (kissing atrioventricular valves) and both valves are in continuity with posterior great artery.

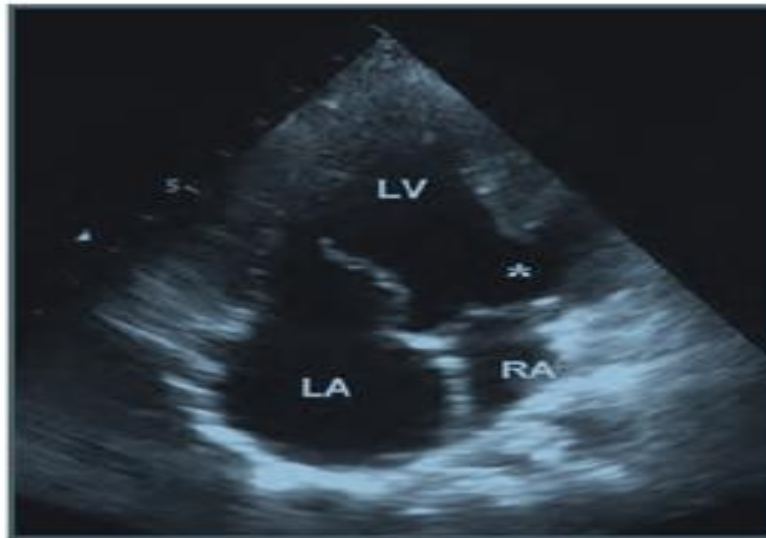
Echocardiographic diagnosis of univentricular hearts

Type	Relation of rudimentary chamber to main chamber	Orientation of trabecular septum	AV valves
LV dominance	Anterior with either D/L loop	Anterior	Posterior to trabecular septum
RV dominance	Posterior	Posterior	Anterior
Primitive	No rudimentary chamber	No trabecular septum	

AV = Atrioventricular; LV = Left ventricle; RV = Right ventricle



- 6) Advanced Cardiac Imaging ; Echocardiography remains the primary imaging modality for patients with single ventricle pathology due to its excellent spatial and temporal resolution, easy accessibility, and its ability to assess the hemodynamic burden of associated anomalies such as arch obstruction via the use of Doppler. However, in selected cases, cardiac computed tomography (CT) and magnetic resonance imaging (CMR) may provide adjunctive data, with CMR preferred when possible for most patients in order to avoid exposure to ionizing radiation. For instance, for patients with pulmonary venous anomalies where echocardiography is unable to clearly delineate the drainage of all pulmonary veins, CT or CMR angiography can provide detailed assessment of the veins and their course. In patients with restricted acoustic windows reducing the sensitivity of echocardiography, CT and CMR can allow visualization of the intra and extracardiac anatomy.



An apical four-chamber echocardiographic view of double inlet left ventricle (LV) showing both mitral and tricuspid valves draining into morphological LV which is dominant. The star (\*) shows the location of the interventricular communication between dominant LV and rudimentary right ventricle (RV)



An echocardiogram in apical four-chamber view showing atretic tricuspid valve (\*), concordant left atrioventricular connection and mild mitral regurgitation. Left ventricle (LV) is dominant

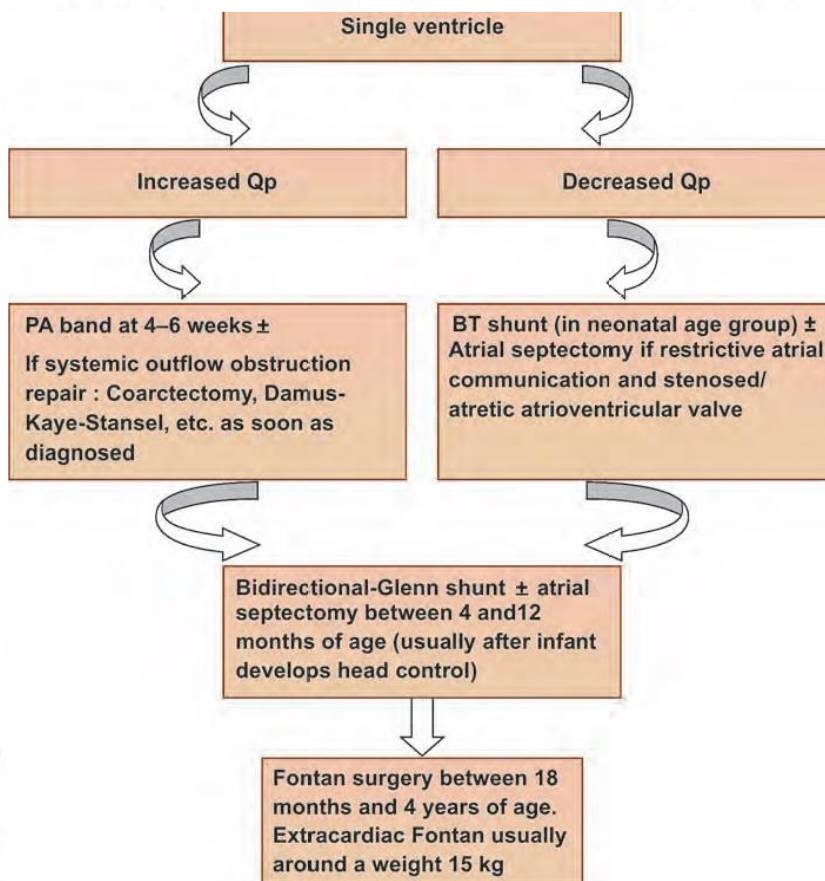
- 7) Cardiac Catheterization Diagnostic catheterization is occasionally necessary in the evaluation of the child with a new diagnosis of single ventricle lesion. Patients with pulmonary atresia and intact ventricular septum deserve catheterization to evaluate the presence of coronary sinusoids and proximal coronary artery atresia or stenosis. Delineation of PA anatomy may be necessary if echocardiography raises suspicion for discontinuous pulmonary arteries. Diagnostic catheterization solely for the purposes of

measuring pulmonary vascular resistance or  $Q_p:Q_s$  is rarely necessary in the neonate, although patients who present beyond infancy with unguarded pulmonary blood flow would benefit from evaluation of pulmonary artery pressures and resistance, particularly if the first procedure contemplated is a cavopulmonary shunt.



# MANAGEMENT STRATEGIES

**Single Ventricle Management** The ultimate goal of this strategy is to utilize the single ventricle for systemic perfusion while depending upon passive drainage of venous return from the upper and lower extremities for pulmonary blood flow. Attainment of this circulation may require staged surgical procedures. The need for neonatal palliation depends upon the state of the systemic and pulmonary perfusion. Typically, palliation in a child 4–6 months of age involves creation of a superior cavopulmonary anastomosis and is termed “second” stage procedure. Finally, between 2 and 4 years of age, creation of an inferior cavopulmonary anastomosis completes the fontan circulation.



Surgical management of single ventricle

# CAVOPULMONARY SHUNT

Conversion from the newborn circulation to the Fontan circulation is a gradual process essentially because of the changes that occur within the lung vasculature and somatic growth during the first months and years of life. PVR is systemic at birth and only comes down to adult levels by the age of six months. The microvasculature of the lungs is also not fully developed for several months, and this is why a systemic shunt is required in a newborn to drive pulmonary blood flow. However, once a child has reached four to six months of age, the PVR has dropped sufficiently that a high-pressure source of blood flow is no longer required. Instead, the SVC blood can be connected directly into the pulmonary arteries – the cavopulmonary shunt. This is a passive shunt that depends entirely on a head of pressure in the systemic veins to drive blood through the pulmonary vasculature as continuous, non-pulsatile flow. This has major advantages over the systemic shunt because it does not place a volume load on the circulation, and it also delivers fully deoxygenated blood to the lungs rather than partially deoxygenated blood. Thus, at the time of cavo-pulmonary shunt, any systemic shunt is usually disconnected, thus removing a volume load from the ventricle and allowing it to function at better loading conditions. The procedure is named after William Glenn, who described the procedure in the 1958 as an end-to-end connection between the SVC and the right PA (i.e. flow to only one lung). This has been superseded by an end-to-side anastomosis, and referred to as the ‘bidirectional Glenn’ shunt to emphasize that flow is to both lungs. The need for maintenance of adequate PBF without the blood getting pumped out from a ventricle was the basis for animal studies. Thus, after a series of animal studies, Dr Glenn reported on end-to-end anastomosis between SVC and distal right PA in 1958. The landmark paper in 1971 by Dr Francois Fontan reported on the complete disconnection of the non functioning ventricle from the circuit with drainage of systemic venous return into the pulmonary vascular bed. The surgical techniques have undergone numerous revisions over the years and the classical Glenn is no longer performed.

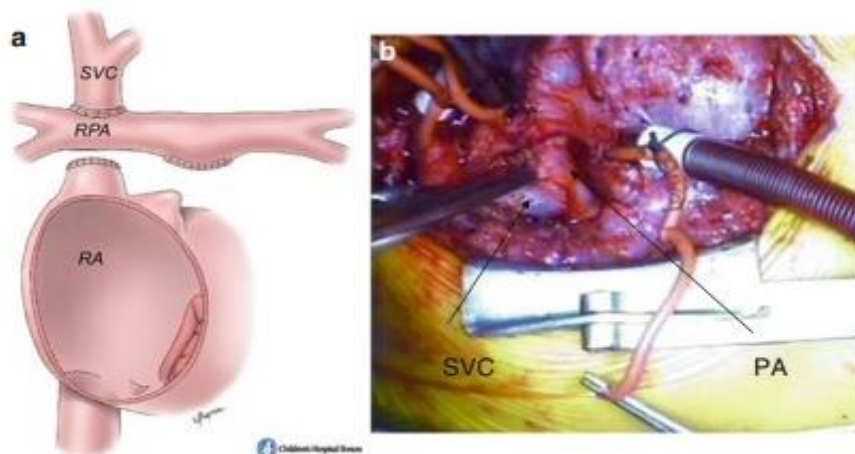
# **BIDIRECTIONAL GLENN SHUNT**

The goals of stage II palliation are to eliminate dependency of pulmonary blood flow upon systemic circulation and create upper body venous drainage into the pulmonary circulation as a prelude to total cavopulmonary shunting. The resistance of the pulmonary circulation decreases over the first several months of life, thus permitting adequate pulmonary blood flow with venous pressure alone as the driving force. The bidirectional Glenn procedure involves separation of the superior vena cava from the right atrium, and anastomosis to the right PA and also but prepares the anatomy for subsequent Fontan procedure by creation of atrial pulmonary connection and intraatrial patch exclusion of the remaining atrium from the superior cavopulmonary anastomosis. The advantage of the bidirectional Glenn procedure is the ability to perform the operation without the use of cross-clamp.

The second stage procedure is performed between 4 and 6 months of age unless clinical scenario (desaturation) dictates earlier operation. Centers have demonstrated safety in patients as young as 2 months of age, although hospital lengths of stay are prolonged in the patients under 4 months of age . The preoperative evaluation should exclude the presence of PA and aortic arch obstruction, elevated pulmonary vascular resistance and restrictive interatrial communication.

It is common for patients to develop aortopulmonary collaterals in the interstage period, although management of collaterals with coil occlusion prior to second stage differs among institutions

# SURGICAL TECHNIQUES



Bidirectional Glenn procedure

Procedure; Glenn shunt are performed through a median sternotomy. To perform a bidirectional Glenn procedure, cardiopulmonary bypass is achieved with neo-aortic arch cannulation and separate right-angle inferior and superior vena cavae cannulas. Alternatively, a single cannula is placed in the right atrium, and the superior vena cava is vented and occluded during the anastomosis. The aortopulmonary shunt is ligated and divided at the time of initiation of cardiopulmonary bypass. If there is any stenosis of the pulmonary artery secondary to the prior shunt or patch, it is repaired with patch augmentation. The azygous vein is ligated and divided. The superior vena caval flow is controlled with a snare, and a vascular clamp is placed at the junction of the superior vena cava and right atrium. The superior vena cava is transected and anastomosed in an end-to-side fashion to the superior aspect of the right pulmonary artery. The cardiac end of the transected superior vena cava is then oversewn.

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## **AIMS, OBJECTIVES AND METHODOLOGY**

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**Aim:** To assess whether the Anetgrade flow carries any advantages over the subset of patients without Antegrade flow in univentricular physiology patients.

**Hypothesis:**

We hypothesise that patients with antegrade flow have higher saturations, comparatively bigger PA sizes; assesement of CATH pressures pre fonatn may be same.

**Objectives:**

- 1) To assess advantages and disadvantages of antegrade pulmonary blood flow in post op Bidirectional Glenn patient with single ventricle
- 2) To compare pulmonary artery size prior to fontan completion
- 3) To Assess the Survival of patients following Bidirectional Glenn shunt

**Materials and Methods:**

**Design:** Retrospective cohort and cross sectional study of patients who underwent BIDIRECTIONAL GLENN SHUNT in our institute between January 2006-December-2019

**Setting:** A tertiary referral centre, a university level hospital, single-centre (Sree Chitra Tirunal Institute for Medical Sciences and Technology-SCTIMST)

**Division of Subsets:** The two Subsets in the Cohort for the convenience of study is divided into two groups i.e.

- a) Group A: Patients with Antegrade pulmonary blood flow
- b) Group B: Patients without Antegrade pulmonary blood flow

**STATISTICAL METHODS:**

PA Pressures, Saturation, RPA and LPA Sizes were considered variables. Antegrade Pulmonary Blood Flow was considered as primary explanatory variable.

All Quantitative variables were checked for normal distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro-wilk test was also conducted to assess normal distribution. Shapiro wilk test p value of >0.05 was considered as normal distribution.

For normally distributed Quantitative parameters the mean values were compared between study groups using independent sample t-test (2 groups). The change in the quantitative parameters, before and after the intervention was assessed by paired t-test (In case of two time periods)

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.(1)

1. IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.



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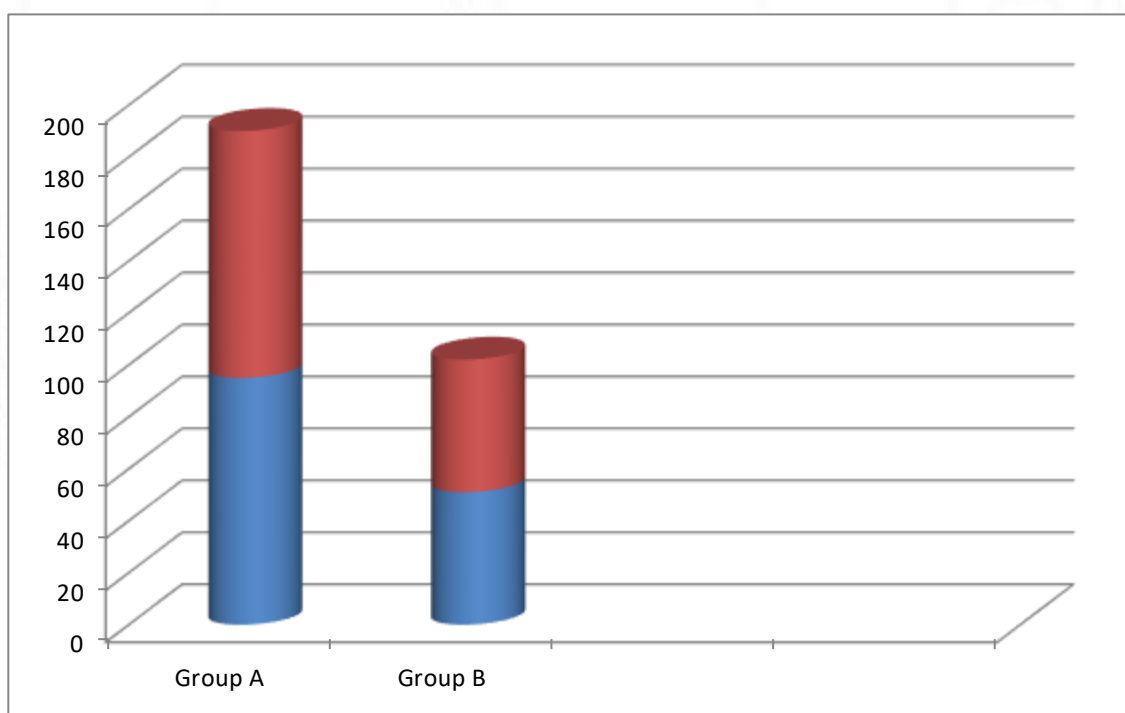
## **RESULTS**

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1) There were a total of 263 patients who underwent BDG from 2006-2019 with univentricular physiology. Out of these 144 patients who underwent BDG underwent both CATH Study and CT imaging and met the requirement of the cohort and fulfilled the inclusion criteria (who were waiting for TCPC or already had undergone TCPC). Out of that 144 patients 93 patients were grouped into Group A i.e. they had antegrade pulmonary blood flow and 51 patients did not have antegrade pulmonary blood flow i.e. Group B

**Table 1: Descriptive analysis of Antegrade Pulmonary Blood Flow in the study population (N=144)**

<b>Antegrade Pulmonary Blood Flow</b>	<b>Frequency</b>	<b>Percentage</b>
Present(Group A)	93	64.58%
Absent(Group B)	51	35.42%

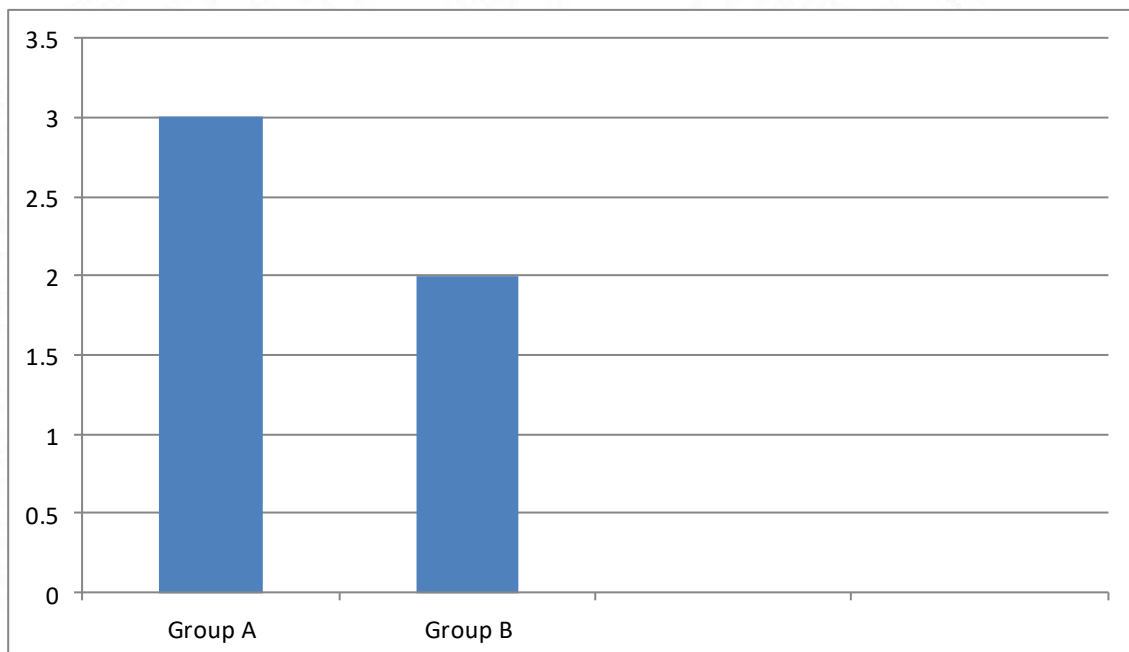


2) Age: The Median age at which the Group A Patients was 3.2 years. When group B is taken into account. The mean age is considerably early as expected with mean age at 2 years.

**Table 2: Comparison of the age at which the patients underwent BDG in the cohort**

Parameter	Antegrade Pulmonary Blood Flow (Mean± SD)		P value
	Patients with APBF (N=93) Group A	Patients without APBF (N=51) Group B	
Age at BDG	3.19 ± 3.55	2.01 ± 2.14	0.032

**Figure 2: Bar chart of comparison of Age at BDG between Group A and Group B(N=144)**

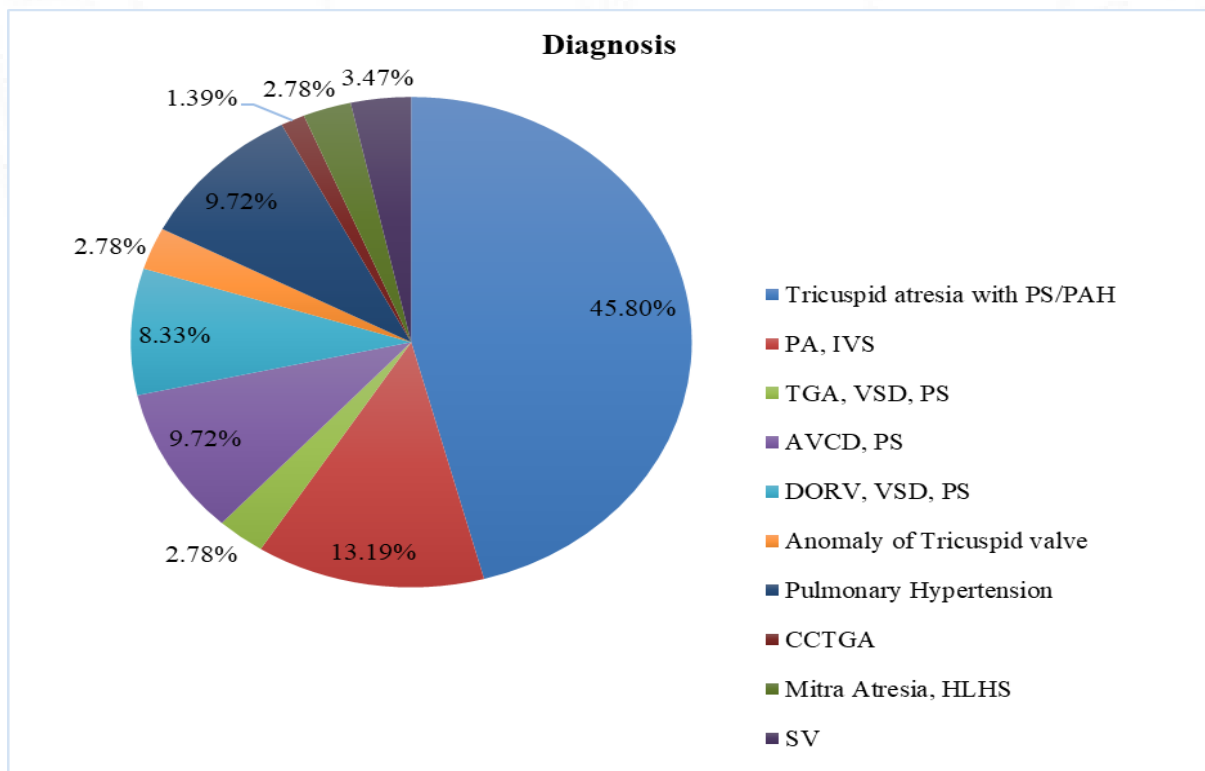


3) Diagnosis around the cohort:

Out of 144 patients in the cohort the majority of them belonged to tricuspid atresia(45.8% and n=66), followed by pulmonary atresia with intact septum (13% with n=19), AVCD,DILV,DORV were the other anomalies in the cohort(AVCD-9.7% with N=14,DILV-9.7%,DORVwith 8.33% and N=12),rest other patients were TGA-5 ,Mitral atresia-4,large VSD which amounts to single ventricle-5 ,with least number of patients belonging to CCTGA.

**Descriptive analysis of Diagnosis in the study population (N=144)**

Tricuspid atresia with PS	66	45.8%
PA, IVS	19	13.19%
TGA, VSD, PS	4	2.78%
AVCD, PS	14	9.72%
DORV, VSD, PS	12	8.33%
Anomaly of Tricuspid valve	4	2.78%
DILV	14	9.72%
CCTGA	2	1.39%
Mitra Atresia, HLHS	4	2.78%
Large V.S.D mounting toSV	5	3.47%

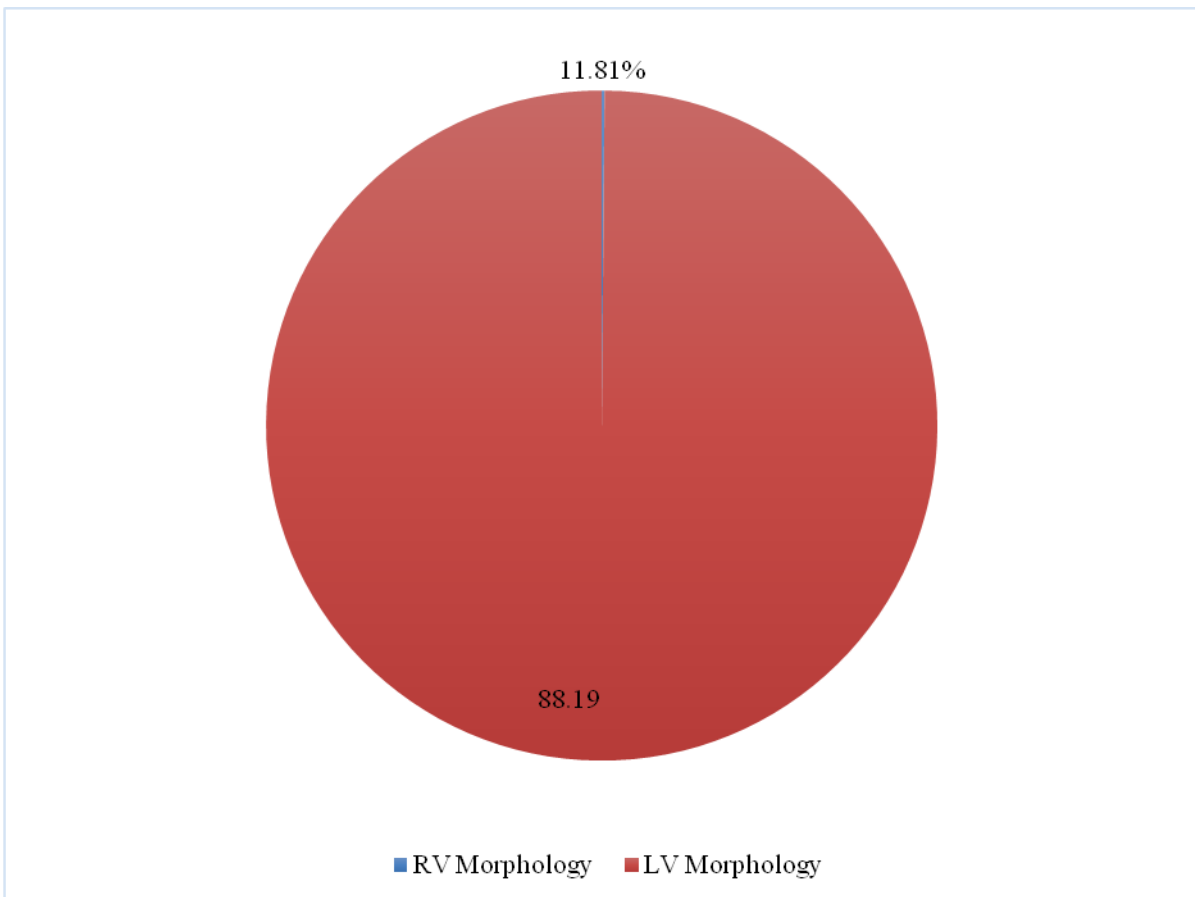


4) Cohort group with dominance of ventricle

- 1) LV DOMINANCE – 89%
- 2) RV DOMINANCE-11%

Most of the patients in the cohort belonged to Tricuspid Atresia and maximum of the lesions were right sided, hence majority of the patients had the left ventricle to be dominant ventricle, 89% was Left dominance.

Parameter	Frequency	Percentage
RV Morphology	17	11.81%
LV Morphology	127	88.19

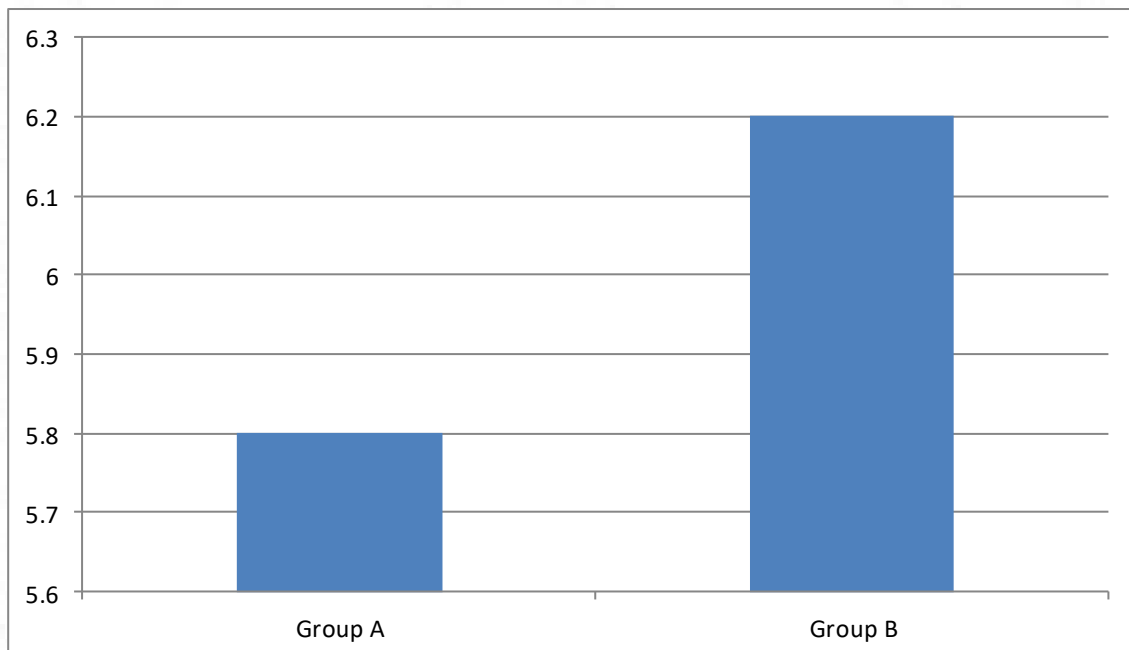


5) Hospital Stay: In our cohort the presence or absence of antegrade flow did not have any impact on the way the patient behaved post operatively .the duration of hospital stay was unaltered and both the subsets were discharged on post-operative day 5 or day-6 .in our cohort patients with concomitant surgeries like PA banding altered the duration. Patient having to stay for longer duration when they underwent additional PA banding along with BDG.

**Table 5: Comparison of mean of post op day of discharge between Group A and Group B(N=144)**

Parameter	Antegrade Pulmonary Blood Flow (Mean± SD)		P value
	Patients with APBF (N=93) Group A	Patients without APBF (N=51) Group B	
Post op day of discharge	5.83 ± 1.03	6.27 ± 1.8	0.060

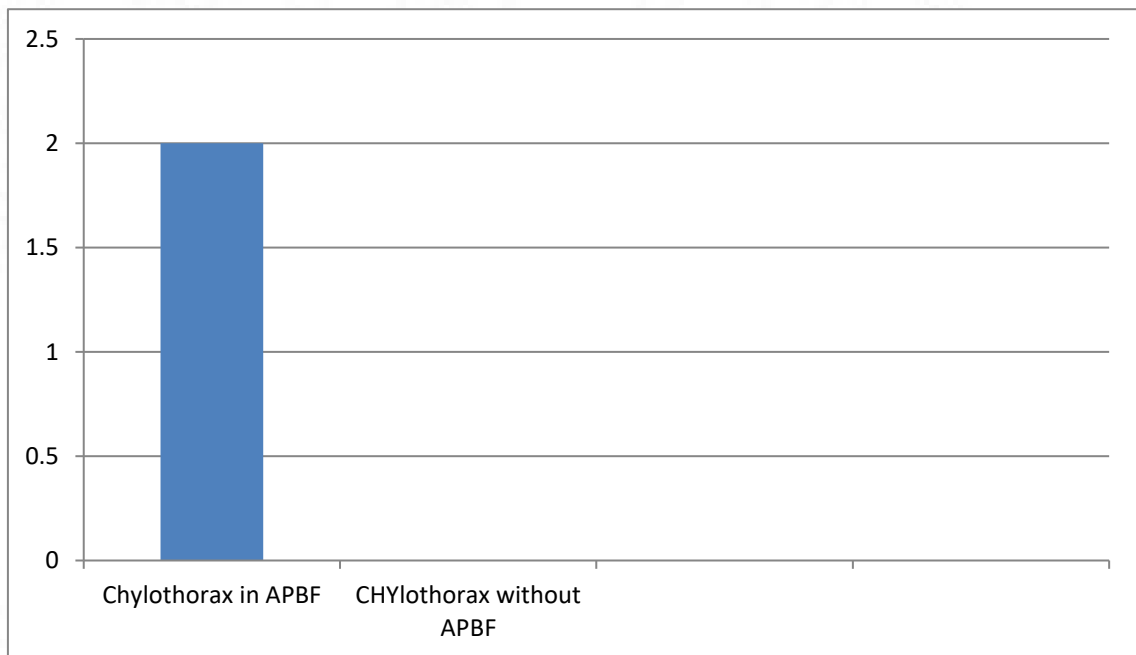
**Figure 5: Bar chart of post op day of discharge between Group A and Group B (N=144)**



6) Chylothorax: Analyzing the post operative complications between Group A & Group B, when we assessed the two subsets in regard with the number of patients presenting with chylothorax .post operatively we found very good results with almost 99% of patients being free from chylothorax irrespective of the Antegrade blood flow, with only 2 patients in the Group A (With antegrade blood flow) presenting with chylothorax

**Table 6: Descriptive analysis of Chylothorax after BDG in the study population (N=144)**

Chylothorax after BDG	Frequency	Percentage
Group A	2	1.39%
Group B	142	98.61%



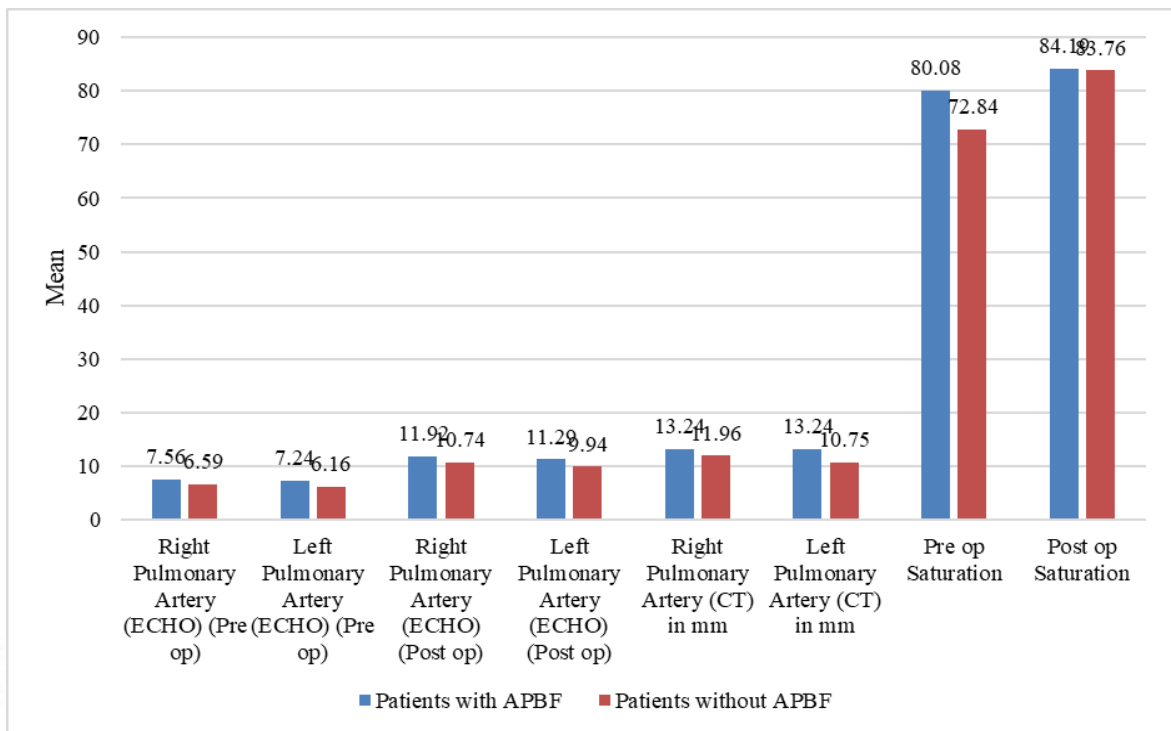
7A a) RPA SIZE (ECHO):

RPA Sizes whether Pre op or Post op assessed with Echo, the Sizes of RPA were better in Group A and the growth of RPA sizes were better in patients with Antegrade flow, with statistical significance in the cohort. The median RPA size of 7.5 mm preoperatively had a median increase in the size of the RPA up to 11.9mm in Group A , in comparison with Group B the median RPA sizes at 10.7 from pre op size of 6.5mm,with difference of 1.2mm.

b) RPA CT Sizes: The scenario with the CT imaging was much similar in the cohort with the good sizes of RPA preoperatively and also better gain in RPA sizes post operatively in patients in Group A with median size of 7.5mm preoperatively with increase in the median size up to 13.2mm in the cohort. But in the subset of Group B, the gain in the RPA size was comparatively less with pre op median size at 6.5mm with post op median size at 11.2mm, with almost 2mm difference in the two groups

**Table 7: Comparison of PA sizes, Pre op and post op Saturation in the study population (N=144)**

Parameter	Antegrade Pulmonary Blood Flow (Mean ± SD)		P Value
	Patients with APBF (N=93)	Patients without APBF (N=51)	
Right Pulmonary Artery (ECHO) (Pre BDG)	7.56 ± 2.50	6.59 ± 2.17	0.0214
Left Pulmonary Artery (ECHO) (Pre BDG)	7.24 ± 2.37	6.16 ± 2.24	0.0085
Right Pulmonary Artery (ECHO) (Pre fontan)	11.92 ± 3.87	10.74 ± 3.21	0.0658
Left Pulmonary Artery (ECHO) (Pre fontan)	11.29 ± 3.32	9.94 ± 3.40	0.0220
Right Pulmonary Artery (CT) in mm	13.24 ± 4.29	11.96 ± 3.91	0.0804
Left Pulmonary Artery (CT) in mm	13.24 ± 8.89	10.75 ± 3.50	0.0568
Pre op Saturation	80.08 ± 7.31	72.84 ± 6.91	<0.001
Post op Saturation	84.19 ± 5.18	83.76 ± 4.59	0.6219

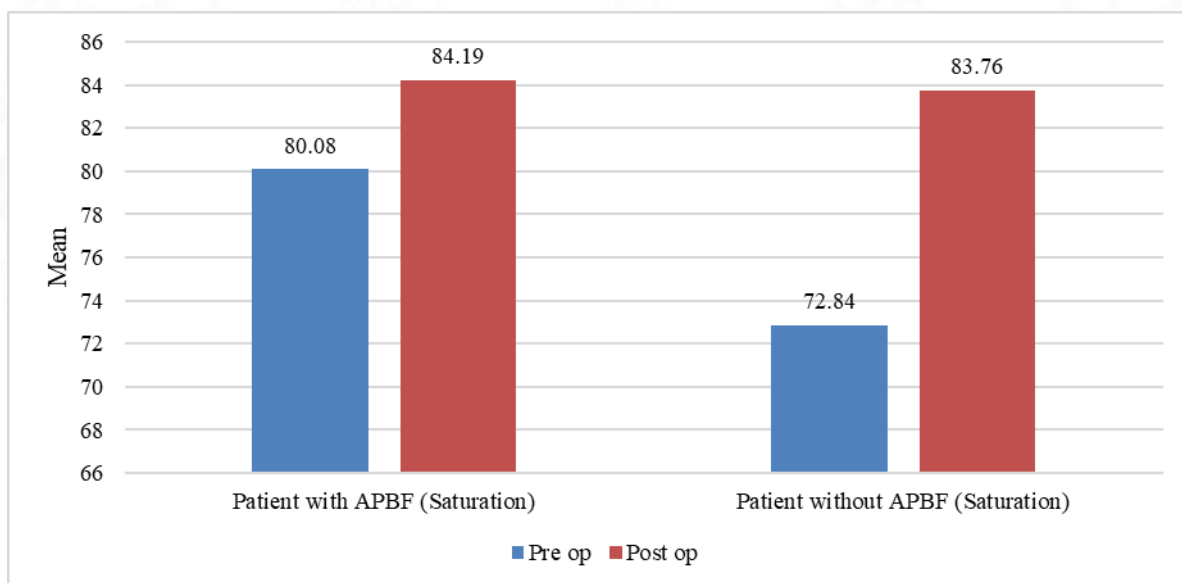


7B) LPA SIZE: The Scenario with the LPA in cohort was not much different, when the pre op and Post Op sizes were assessed, it was much similar to the RPA variations.

a ) ECHO ; Evaluation by Echo left us to the same inference, where the patients with antegrade flow had better LPA sizes compared to the patients without antegrade flow ,the pre op median size of the patients was 7.2mm and post op was 11.2 with a significant increase of 4mm in Group A. In patients Group B the pre op mean sizes of the LPA was 6.5mm and post op size at 9.9 with a gain of 3mm.

b) CT SIZES: The CT sizes in the cohort in the two subgroups were in accordance with ECHO, CT Sizes was greater in patient with APBF. In patients with APBF the mean LPA size was 7.2mm pre op and went upto 13.2mm post op ,with an average gain of 6mm in each patient. The gain in the other group( ie subset without antegrade flow )was 4mm on a average

**Figure7B: Column Bar chart for Comparison of Saturation pre op and post op with and without Antegrade Pulmonary Blood Flow in the study population (N=144)**

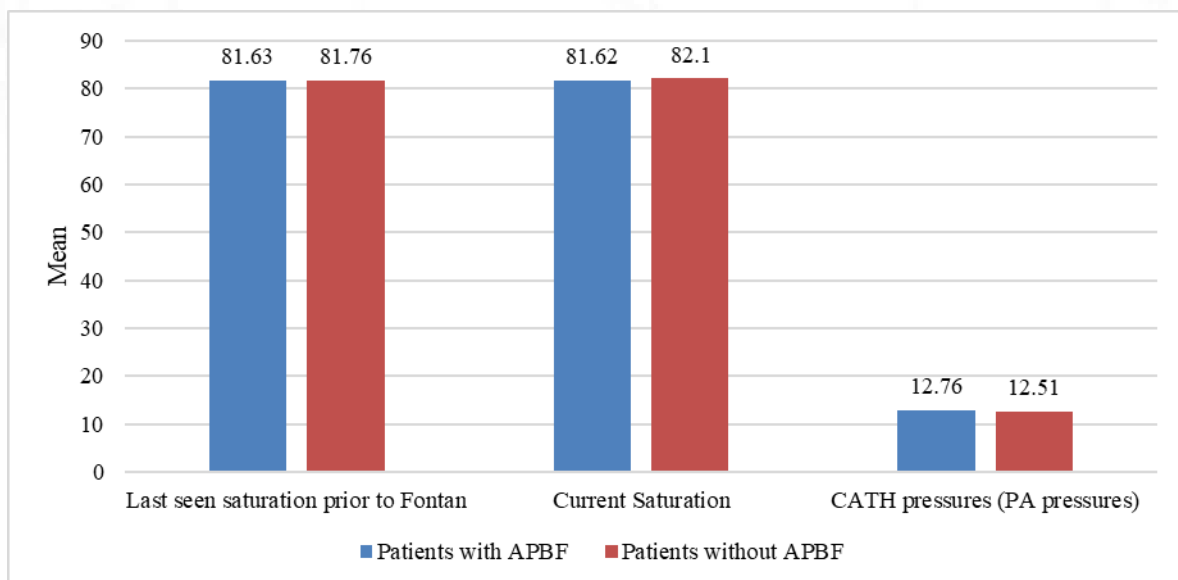


8) Saturation: The pre op Saturations when taken into account in both the Groups, in Group A the baseline pre op saturations were low and such patients as expected presented earlier due to evident cyanosis and the saturations getting better post op, but the patients Group A had better saturations pre op or post op .

**Table 8: Comparison of CATH Pressures, Saturation prior to Fontan, in Group A and Group B (N=144)**

Parameter	Antegrade Pulmonary Blood Flow (Mean ± SD)		P Value
	Patients with APBF (N=93)	Patients without APBF (N=51)	
Last seen saturation prior to Fontan	81.63 ± 5.31	81.76 ± 5.24	0.8877
Current Saturation	81.62 ± 5.28	82.10 ± 4.84	0.5962
CATH pressures (PA pressures)	12.76 ± 2.15	12.51 ± 2.82	0.5465

**Figure 8: Column bar chart for Comparison of parameters in patients with and without Antegrade Pulmonary Blood Flow (N=144)**



9) Cath study:

One of the important pre requisites for the end stage surgery (Fontan procedure) in single ventricle Physiology patients, is the assessment of PA pressures prior to fontan, candidates ideal for fontan should have ideal PA pressures. Hence we assessed the impact of APBF on PA pressures, we could Infer that the presence or absence of APBF did not have impact on PA pressures.

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# DISCUSSION

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It's a Cohort of Various anatomical variation with a wide Spectrum of disease ranging from Tricuspid atresia to HLHS but physiologically a Single ventricle.

The Glenn shunt is usually done after 3 months. Patients who have Single ventricle physiology has adequate source of pulmonary flow in patients with APBF. These Patients are usually protected with Higher PA pressure due to the avascular bed but at the cost of saturation, but usually they maintain adequate saturations. According to the Cohort we could state that, patients with APBF usually did not require early palliation and BDG could be done on elective basis and the other subset without antegrade flow required early palliation before 6 months of age. In patients where pulmonary flow was unrestricted, PA banding was done with BDG. Early BDG in the cohort were performed for patients having cyanotic spells. There were 19 patients (5%) who underwent BDG before 6 months of age, out of which 4(2.6% of total cohort) had the surgery within 4 months of age.

According to the Cohort the majority diagnostic criteria belongs to Tricuspid atresia which eventually ended up into TCPC and the mortality rate is much lower may be attributed to the TA group. This data is quite contrasting to data from the western world, where the SV palliation is done for HLHS

1) Age; The term Single ventricle is a wide spectrum of disease with wide anatomic variations from tricuspid Atresia to HLHS syndrome .In our Cohort the age at which patients underwent BDG varied from as Early as 2 months to as late as 18 years of life. The extreme variation in the age can be attributed to The presence of Antegrade blood flow , Group B patients had severe cyanosis and presented earlier and also the Patient with unrestricted pulmonary blood flow presented with H/O failure before 1 year of life and also the Advances in imaging with early antenatal diagnosis has been the major contributing factor in patients without symptoms. In Our cohort study the median age group where the patients underwent BDG is around 3.2 years in Group A patients in contrast to patients in Group B who needed early surgery with Median age of 2 years which can be attributed to presenting symptoms like cyanosis or cyanotic spells.

A retrospective study By Jae Suk Baek ET al in 2021 for patients who underwent BDG from 2000-2015 as an interim palliation for a single ventricle physiology patients which excluded patients who underwent kawashima or Norwood procedure ,total of 279 patients were taken out of which 202 patients had Antegrade pulmonary blood flow . APBF was terminated in 110 patients and 92 patients continued to have APBF.The impact of APBF was assessed. The Conclusion was the patients who underwent BDG had a median age group was 8 months and median weight was 7.8 kgs. Chylothorax was more in patients with APBF, Such patients had more hospital Stay with ICD dependant Drainage for the chylothorax and also had more rate of readmissions. In patients without antegrade blood flow the Saturations initially after BDG was low but slowly improved prior to fontan, But the saturation was higher in patients with patients having APBF when compared to the patients without APBF. Overall transplant-free survival was worse in the antegrade pulmonary blood flow group, hence concluded Maintaining antegrade pulmonary blood flow at bidirectional Glenn shunt was beneficial for higher oxygen saturation and increase in the pulmonary artery size before Fontan operation. However, it did not favour overall transplant-free survival with a sustained higher risk of death or transplant until the elimination of antegrade pulmonary blood flow.

In other study by Orlando Petrucci and others to assess the feasibility of BDG in patients below 3 Months of age, a total of 169 patients who underwent BDG between 1998- 2007 were considered, 20 Patients less than 3 months were considered and other 149 patients were above 3 months. In the group Below 3 months the length of ICU Stay ,ventilatory support and hospital Stay was longer in younger Group (I e patients who underwent BDG below 3 months) but the saturations prior to discharge, the saturations prior to fontan was similar both the early and late mortalities were similar between the two groups. Hence they concluded that BDG is safe in patients below 2 months of age, with early and late mortality similar to BDG done in patients in

later age group. (its in comparisom with article 10 in bibliography)

2) Saturations: The varied anatomical spectrum from a right sided lesion like the commonest tricuspid to the rarely presenting HLHS in our cohort study (i.e Tricuspid atresia patients occupied 45% of the cohort and only two patients included HLHS of the total 144) irrespective of the diagnosis ,the Saturations were better in patient with antegrade flow( both pre op and post op) and they presenting to the hospital at later stages in life (few were diagnosed accidentally ,ie during evaluation for a murmur), the rational being patients with antegrade flow had saturations which were just adequate to mask the effect of cyanosis and patients without antegrade flow often presented earlier with appreciable cyanosis or history of cyanotic spells at earlier part of life .From our Cohort we could infer that Group A patients had better pre op Saturations then Group B who had poor Saturations ,few patients not feasible for life and had to undergo emergency BDG. Our cohort is in accordance with other studies like Michele A. Frommelt and others in 1995,where they retrospectively studied 43 patients who underwent BDG in Children's Hospital of Wisconsin with Anatomic diagnosis included double inlet left ventricle (14 patients), tricuspid atresia (8 patients), pulmonary atresia with intact septum (6 patients), single right ventricle (5 patients), hypoplastic left heart (3 patients), unbalanced atrioventricular septal defect (3 patients), and other complex lesions (4 patients). They then divided the patients into two groups for analysis. Group 1 were patients who had undergone BDG without antegrade blood flow (22 patients) and the other group included BDG with APBF (21 patients). Patient age at the time of BD ranged from 6 months to 12 years, with group 1 patients being younger. Group 2 patient (ie patients who have undergone BDG with Antegrade flow) had higher oxygen saturations than did group 1 patient. There was no statistical difference in both groups when compared in regard with hospital stay and chylothorax .There was 1 early death due to severe ventricular dysfunction and 1 late death due to sepsis. Five patients in group 2 were readmitted to the hospital for drainage of a large chylothorax compared with none in group 1.

Hence the study concluded that with an additional source of pulmonary blood flow after bidirectional glenn shunt have higher oxygen saturations, and are at risk for the late development of a chylothorax The study compared (reference no:22 in bibliography)

3) PA SIZES: The assessment of the PA sizes were based on two modalities i.e. with Echo and CT Imaging. The comparative analysis of PA Sizes both pre op and post op were done across the Cohort. Both the Preop and post op sizes were comparatively greater in patients with APBF, with higher saturations and with very less patients presenting with Chylothorax (only 2 patients in 93) . the other Group without antegrade flow had less saturations and no patients presenting with chylothorax, but the PA Sizes were smaller pre operatively and the growth in PA sizes Post BDG was lesser compared to patients with APBF Though not much of statistical difference. This confers with our hypothesis and also with various other studies, like the study by Davide F. Calvaruso and others in 2008. A series of 246 patients, from three joint institutions in Italy, having univentricular heart with restricted but not critical pulmonary blood flow received a bidirectional Glenn shunt with APBF. All patients were studied according to their progression, or not, to Fontan operation. Two hundred and eight (84.5%) patients underwent bidirectional cavopulmonary anastomosis as primary palliation. Twenty patients with previous pulmonary artery banding were also considered for the study. Patients who had received additional pulmonary blood flow through a previous systemic to pulmonary artery. Shunt for the critical pulmonary blood flow was excluded. The study concluded that there was no in hospital deaths and the Follow-up was complete at 100%. Mean follow-up was 4.2 to 2.8 years. During the Study period 73 patients were considered optimal candidates, underwent Fontan completion for increasing cyanosis and (or) hematocrit and (or) fatigue with exertion. Three patients expired after Fontan. The remaining 173 patients are alive with initial palliation. All patients were still well palliated with arterial oxygen saturation at rest about 90%. And bidirectional Glenn with antegrade pulmonary blood flow may be an excellent temporary palliation prior to a Fontan operation, which can be performed at the onset of symptoms. Bidirectional Glenn may also be the best possible palliation for a suboptimal candidate for Fontan. The smaller PA sizes can account for lower saturations which explains patients without antegrade Pulmonary blood flow post op or pre op had lower saturations of oxygen and both the pre op and Post op PA sizes were less without antegrade flow ,this rationale is also explained in a study by Sunitha. J. Ferns and others where 212 patients were studied who had undergone BDG from 2000-2010, of those 103 patients were retrospectively reviewed and divided into two groups (70 with antegrade flow and rest 33 without antegrade flow) Group A and Group B did not have much differences in oxygen saturations post op but Group A had better saturations prior to fontan ,better PA Sizes with Group A mean PA sizes of 18 mm and Group B sizes of 16mm.(reference no: 1 in bibliography)

4) Hospital Stay; According to the our Cohort the Hospital stay was not influenced by presence or absence of Antegrade pulmonary blood flow, which is contradictory to other studies which interprets patient with APBF had longer duration of stay in hospital which presented with chylothorax, but our cohort the hospital stay was prolonged due to other concomitant procedures like PA band, but not significant. Our Cohort in Group A had 2 patients presenting with Chylothorax and the hospital stay was prolonged, our cohort may be falsely interpreting due to only 2 patients presenting with chylothorax. When compared with other studies like Sunitha.j et al in 2012 studied Records of 212 patients undergoing staged single ventricle palliation during a 10-year period were retrospectively reviewed. Of those, 103 were selected.

Conclusion was that Demographics and pre- and intraoperative variables were comparable for both groups. Oxygen saturations immediately after the bidirectional Glenn in the 2 groups were similar with not much of difference. The total length of hospital stay was higher because of chylothorax and need for ICD Drainage in group A. There was no difference in the number of diuretics or oxygen requirement upon discharge between groups.

5) Cath study; The Important Pre requisite for a fontan completion is the assessment of PA pressures By cardiac catheterization and the ideal PA pressure of less than 15 decides the outcome of a fontan. When our cohort was taken into consideration and the assesement of PA pressures, the presence or absence of Antegrade pulmonary blood flow had no relation with the PA pressures, the mean PA pressure was almost same across the cohort .our cohort is in accordance with a Chinese study by Tao Yan in 2017, where Records of 112 consecutive patients who had a BDG procedure during a 10-year period were reviewed retrospectively. The patients were divided into 2 groups based on whether APBF occurred following the BDG procedure (APBF group, n = 81) or not (non-APBF group, n = 31). The median age at the BDG procedure was 6 years in the APBF group and 5.5 in the non-APBF group. Follow-up data were obtained for patients at the BDG stage and for those who had undergone the Fontan completion. Both oxygen saturation levels and pulmonary pressure were higher in the APBF group immediately after the BDG procedure. At the pre-Fontan measurement, there was no significant difference in mean pulmonary artery pressures between the groups. Fifty-nine patients underwent the Fontan completion (43 from the APBF group and 16 from the non-APBF group) procedure with a median age of 1.2 (APBF group) and 1.4 (non-APBF group) years after the BDG procedure. No significant differences between groups were observed in arterial oxygen saturation levels, incidence of systemic atrioventricular valve regurgitation or ventricular dysfunction in survivors at the last follow-up visit.

6) Mortality; the overall mortality was unaffected within the subgroups and the low rate of mortality may be attributed to the majority of cohort having Tricuspid atresia. A retrospective study of classical Glenn patients at a follow up of 50 years was reported by Zahr et al in 2016. Median overall survival was 43 years and the survival following the Glenn shunt was 31.4 years. There were 46 deaths, 7 were in the post-operative period and 39 late deaths.

Bidirectional Glenn Shunt with Antegrade Pulmonary blood flow may be a good long-term palliation prior to Fontan completion. Calvaruso et al reported a series of 246 patients having univentricular heart who underwent BDG with additional source of APBF. Two hundred and eight (84.5%) patients underwent BDG as primary palliation. Twenty patients with previous PA band were also included in the study. There were no deaths in the hospital. During a mean follow-up of 4.2 years, 73 patients underwent Fontan completion with a mortality rate of 4.1%. Remaining 70.3% patients were alive with initial palliation with arterial saturation around 90% at rest. Seventy-one palliated patients out of the 173 patients awaiting Fontan (28.8%) were considered less than ideal candidates for TCPC. Double inlet LV, Tricuspid atresia and Double outlet right ventricle constituted 42%, 17% and 10% of the cohort respectively.

A series of 149 patients by Mainwaring et al showed that both perioperative and late mortality was higher when BDG was performed with preservation of APBF. They concluded that elimination of APBF conferred a long-term survival benefit. In their study, patients with preserved APBF had an operative mortality rate of 5.4% and late mortality of 15.1%. The respective figures for those without APBF were 2.2% and 4.4% of patients.

In other study by Davide F. Calvaruso and others in 2008 in a cohort of 246 patients as BDG with Antegrade flow as a definitive palliation, for a patient with univentricular heart without critical pulmonary blood flow underwent bidirectional cavopulmonary shunt with additional forward pulmonary blood flow. All patients were assessed according to their progression to Fontan operation. Two hundred and eight patients underwent bidirectional cavopulmonary anastomosis as primary palliation. Twenty patients with previous pulmonary artery banding were also included in the study. No in-hospital death occurred. Follow-up at 100%. Mean follow-up was 4.2 -2.8 years (range, 6 months to 7 years). During the observational period 73 patients, considered optimal candidates, underwent Fontan completion for increasing cyanosis and (or) hematocrit and (or) fatigue with exertion. Three patients expired after total cavopulmonary connection. The remaining 173 patients are alive with initial palliation. All patients were still well palliated with arterial oxygen saturation at rest about 90%. They came to a final conclusion that bidirectional Glenn with antegrade pulmonary blood flow can be an excellent temporary palliation prior to a Fontan operation, which can be performed at the onset of symptoms. BDG may also be the best possible palliation for a suboptimal candidate for Fontan.

## LIMITATIONS

This is a Cohort of retrospective study of the data of the patients operated. The collection of data depended upon the accurate documentation of the anatomical diagnosis, preoperative and post-operative evaluation and the surgical details.

It's a single centre design study where the anatomical variations may be different. Though every effort was made to contact the patient or the relatives, it is possible that patients lost to follow up may have died and could falsely suggest a lower overall mortality rate. Patients from neighboring states were difficult to be contacted either through phone or letters.

The mortality may be different or may reflect falsely because the majority of the cohort patients belonged to tricuspid atresia group and basically LV dominant patients have more life expectancy compared to RV dominance patients. The hospital stay may also be falsely interpreted because majority of them had no complications.

## CONCLUSIONS

The Average age where patients underwent BDG were late which can be attributed to late diagnosis. Tricuspid atresia is the commonest anomaly palliated with BDG and a higher proportion of patients with TA complete Fontan procedure. Tricuspid atresia has the lowest mortality among all patient groups.

Bidirectional Glenn surgery has overall low mortality rate and good long term survival. It can provide effective long term palliation prior to Fontan completion. Palliation with SV of LV morphology and preserved antegrade pulmonary blood flow are significant predictors of survival.

Bidirectional Glenn surgery with APBF had better Saturations, PA Sizes and the need for surgery in Later stages of life but with same hospital stay and cath pressures.

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# **APPENDIX**

## Telephone Recruitment Script

Hello, my name is Dr Prashant Harsur. I'm calling from Sree Chitra Institute of Medical Sciences and Technology(SCTIMST) about a research study. Am I speaking to \_\_\_\_\_ (name of recruit) or his/ her parent?

*If "no," wait for recruit to pick up, leave a message, or ask for a time to call back.*

*If "yes":*

I got your phone number from the hospital records. Is this a good time to talk?

*Arrange to call at another time, if appropriate.*

I'm calling about a research study of outcomes of an operation that you or your child has underwent called LONG TERM COMPARITIVE ANALYSIS OF SINGLE VENTRICLE PHYSIOLOGY PATIENTS FOLLOWING BIDIRECTIONAL GLENN SHUNT WITH OR WITHOUT ANTEGRADE PULMONARY BLOOD FLOW

The purpose of this research study is to learn more about the long-term results of this operations and your present condition. Joining a research study is completely voluntary. If it's alright with you I'd like to take about 2-3 minutes to explain the basic idea of the study and to see if you would be interested in taking part.If you agree to participate, we will ask you to come into the clinic, where we will discuss the study with you in more detail, and you can decide if you want to participate. There will be no risks for the participants because of participation in the study. No specific intervention will be done. The participants are evaluated in detail for any cardiac cause for functional impairment. A follow up examination and evaluation may be helpful in identification of any risk factors for poor outcomes or functional deterioration. And this is part of routine assessment.

We will do our best to keep your information confidential by not mentioning your identity and keeping the records on a password-protected computer. You don't have to answer these questions, and you can choose to stop at any time without penalty. If you have questions about the study, you can call me at 9591908888. If you have questions about your rights as a research subject or technical clarifications, you can call Dr. Mala Ramanathan, Member Secretary, IEC,

SCTIMST and Additional Professor, AMCHSS, SCTIMST (Email: iec.mem.sec@sctimst.ac.in,  
Phone no. 0471-2524234)

**If accepting: Document eligibility response and make appointment, if appropriate.**

**If the patient has expired and relative replies that “He/ She is no more/ has expired”**

I’m sorry to hear about his/her demise. Can you tell me the time of death and the details about the cause of death? If you are agreeable, can we go through the hospital records of this person?

**If yes:** Thank you. The details might be helpful in preventing similar complications in other

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people. Thank you for your time.

**If no: That’s perfectly understandable. Thank you for your time.**

**NOTE; THERE WILL BE NO TELEPHONIC FOLLOW UP AFTER THIS**

# ASSENT FORM

Participant's name: Date of Birth / Age (in years): I

\_\_\_\_\_,  
FATHER/MOTHER/LEGAL GUARDIAN of \_\_\_\_\_

(Please tick boxes).

Declare that I have read the above information provide to me regarding the study: LONG TERM COMPARITIVE ANALYSIS OF SINGLE VENTRICLE PHYSIOLOGY PATIENTS FOLLOWING

BIDIRECTIONAL GLENN SHUNT WITH OR WITHOUT ANTEGRADE PULMONARY BLOOD FLOW and have clarified any doubts that I had.

I also understand that the participation of my child in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights.

I understand that the study. Staff and institutional ethics committee members may be, not need my permission to look at my health records even if I withdraw consent from the study. I agree to this access. [ ] I understand that my child's identity may be not be revealed in any information released to third parties or published.

I voluntarily agree for my child to take part in this study.

I received a copy of this signed consent form.

Name:

Signature:

Date:

Name of witness:

Relation to participant:

Date:

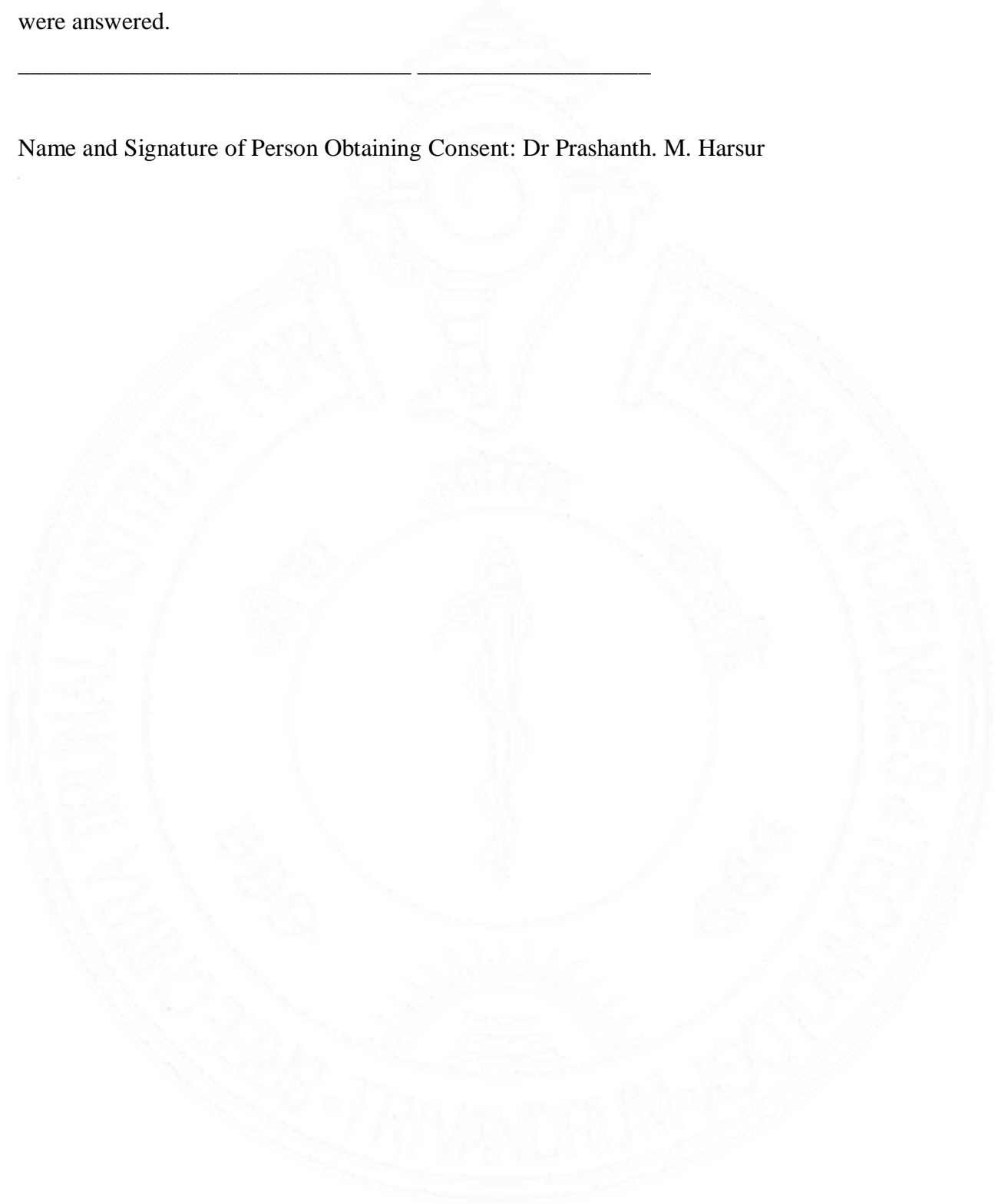
I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed

consent form, including any risks and adverse reactions that may reasonably be expected to occur.

I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

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Name and Signature of Person Obtaining Consent: Dr Prashanth. M. Harsur



ആന്റിഗ്രേഡ് പൾമനറി രക്തപ്രവാഹം ഉള്ളതോ ഇല്ലാത്തതോ ആയ, ദിദിശാ ഗ്ലീൻ ഷണ്ട് ശസ്ത്രക്രിയയ്ക്ക് വിധേയരായ സിങ്കിൾ വെൻട്രിക്കിൾ ശാരീരികാവസ്ഥയുള്ള രോഗികളിലെ ദീർഘകാല നേട്ടങ്ങളുടെ താരതമ്യ വിശകലനം

**ടെലിഫോൺ വഴി പങ്കാളികളെ ഉൾപ്പെടുത്താനും അഭിമുഖത്തിനുമുള്ള കുറിപ്പ്**

ഹലോ, എന്റെ പേര് ഡോ. പ്രശാന്ത് ഹർസൂർ എന്നാണ്. ശ്രീചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജിയിൽ നിന്നും ഒരു ഗവേഷണപഠനത്തിനായി വിളിക്കുകയാണ്. എനിക്ക് ..... (പഠനത്തിലുൾപ്പെടുത്താനുദ്ദേശിക്കുന്നയാളുടെ പേര്) ആയോ അല്ലെങ്കിൽ അവരുടെ രക്ഷിതാക്കളുമായോ സംസാരിക്കാനാകുമോ?

**ഇല്ലെങ്കിൽ പങ്കെടുപ്പിക്കാനുദ്ദേശിക്കുന്നയാൾ ഫോണെടുക്കുന്നതുവരെ കാക്കുക, അല്ലെങ്കിൽ വീണ്ടും വിളിക്കാൻ പറ്റിയ സമയം ചോദിക്കുക**

**ആണെങ്കിൽ:**

ആശുപത്രി രേഖകളിൽനിന്നാണ് എനിക്ക് താങ്കളുടെ ഫോൺ നമ്പർ കിട്ടിയത്. ഇത് സംസാരിക്കാൻ പറ്റിയ സമയമാണോ.

**അനുയോജ്യമെങ്കിൽ, മറ്റൊരു സമയത്ത് വിളിക്കാൻ ഏർപ്പാടുചെയ്യുക.**

ആന്റിഗ്രേഡ് പൾമനറി രക്തപ്രവാഹം ഉള്ളതോ ഇല്ലാത്തതോ ആയ, ദിദിശാ ഗ്ലീൻ ഷണ്ട് ശസ്ത്രക്രിയയ്ക്ക് വിധേയരായ സിങ്കിൾ വെൻട്രിക്കിൾ ശാരീരികാവസ്ഥയുള്ള രോഗികളിലെ ദീർഘകാല നേട്ടങ്ങളുടെ താരതമ്യ വിശകലനം എന്ന ഒരു ഗവേഷണ പഠനത്തിനായാണ് ഞാൻ വിളിക്കുന്നത്. താങ്കളുടെ/താങ്കളുടെ കുട്ടിയുടെ ദീർഘകാല നേട്ടങ്ങളെപ്പറ്റിയും ഇപ്പോഴത്തെ അവസ്ഥയെപ്പറ്റിയും അറിയുക എന്നതാണ് ഈ ഗവേഷണ പഠനത്തിന്റെ ഉദ്ദേശം. ഗവേഷണ പഠനത്തിൽ പങ്കെടുക്കുന്നത് പൂർണ്ണമായും സ്വമേധയായാണ്. താങ്കളോ /താങ്കളുടെ കുട്ടിയോ പഠനത്തിൽ പങ്കെടുക്കാൻ താല്പര്യപ്പെടുന്നുണ്ടോ എന്നറിയാൻ, പഠനത്തിന്റെ അടിസ്ഥാന ആശയം വിശദീകരിക്കാൻ ഞാൻ 2-3 മിനിറ്റ് എടുക്കുന്നതിൽ കുഴപ്പമില്ലല്ലോ.

താങ്കൾ പങ്കെടുക്കുവാൻ സമ്മതിക്കുകയാണെങ്കിൽ ക്ലിനിക്കിലേയ്ക്ക് വരുവാൻ ആവശ്യപ്പെടുകയും താങ്കളോട് പഠനത്തിന്റെ കൂടുതൽ വിശദാംശങ്ങൾ ചർച്ചചെയ്യുകയും, പങ്കെടുക്കണോ വേണ്ടയോ എന്ന് താങ്കൾക്ക് തീരുമാനിക്കാനാവുകയും ചെയ്യും. പഠനത്തിൽ പങ്കെടുക്കുന്നതുകൊണ്ട് അപായമൊന്നുമുണ്ടാകില്ല. പ്രത്യേകിച്ച് ഇടപെടലുകളൊന്നും നടത്തില്ല. പങ്കാളികളുടെ പ്രവർത്തന തകരാറുകളുടെ ഹൃദയസമ്പന്ധമായ കാരണങ്ങൾ വിശദമായി വിലയിരുത്തും. മോശം നേട്ടങ്ങളുടെയും പ്രവർത്തനപരമായ തകരാറുകളുടെയും അപായ ഘടകങ്ങൾ കണ്ടെത്താൻ തുടർ പരിശോധനയും വിലയിരുത്തലും നടത്തുന്നത് സഹായകരമാകും. ഇത് പതിവ് വിലയിരുത്തലിന്റെ ഭാഗവുമാണ്.

താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ രേഖപ്പെടുത്താതെ രേഖകൾ പാസ്വേർഡിനാൽ സംരക്ഷിക്കപ്പെട്ട കമ്പ്യൂട്ടറിൽ സൂക്ഷിച്ച് താങ്കളെപ്പറ്റിയുള്ള വിവരങ്ങൾ രഹസ്യമാക്കിവയ്ക്കാൻ ഞങ്ങൾ പരമാവധി പരിശ്രമിക്കും. പിഴയൊന്നും കൂടാതെ താങ്കൾക്ക് ഏതുസമയത്തും പങ്കാളിത്തം അവസാനിപ്പിക്കാം. പഠനത്തെപ്പറ്റി ചോദ്യങ്ങളുണ്ടെങ്കിൽ താങ്കൾക്ക് എന്നെ 959190888 എന്ന നമ്പറിൽ ബന്ധപ്പെടാം. ഗവേഷണപങ്കാളിയെന്നനിലയിലുള്ള താങ്കളുടെ അവകാശങ്ങളെപ്പറ്റിയുള്ള ചോദ്യങ്ങൾക്കോ, സാങ്കേതിക വിശദീകരണങ്ങൾക്കോ താങ്കൾക്ക് ബന്ധപ്പെടാം ഡോ. ശ്രീനിവാസ് ജി മെമ്പർ സെക്രട്ടറി, IEC, SCTIMST., ഫോൺ നമ്പർ 0471-2524234, ഇമെയിൽ [iec.mem.sec@sctimst.ac.in](mailto:iec.mem.sec@sctimst.ac.in)

**സമ്മതിക്കുന്നെങ്കിൽ, അനയോജ്യമാണെങ്കിൽ യോഗ്യത രേഖപ്പെടുത്തുക, രോഗി മരിക്കുകയും ബന്ധു “അഭഹം മരിച്ചു” എന്നു മറുപടി നൽകിയാൽ അദ്ദേഹത്തിന്റെ മരണത്തിൽ ഞാൻ അനുശോചിക്കുന്നു. താങ്കൾക്ക് മരണമടഞ്ഞ സമയം പറയാനാകുമോ, മരണകാരണത്തിന്റെ വിശദാംശങ്ങൾ നൽകാനാകുമോ?**

താങ്കൾ സമ്മതിക്കുമെങ്കിൽ ഈ വ്യക്തിയുടെ ആശുപത്രി രേഖകൾ പരിശോധിക്കാമോ.സമ്മതമെങ്കിൽ. നന്ദി. മറ്റുള്ളവരിൽ സമാനമായ സങ്കീർണ്ണതകൾ തടയാൻ വിശദാംശങ്ങൾ സഹായിച്ചേക്കാം. താങ്കളുടെ സമയത്തിന് നന്ദി.  
വേണ്ടായെങ്കിൽ. അത് മനസ്സിലാക്കാനാകും. താങ്കളുടെ സമയത്തിന് നന്ദി.

അനുവാദപത്രം

പഠനശീർഷകം. ആന്റിഗ്രേഡ് പൾമനറി രക്തപ്രവാഹം ഉള്ളതോ ഇല്ലാത്തതോ ആയ, ദിദിശാ ഗ്ലീൻ ഷണ്ട് ശസ്ത്രക്രിയയ്ക്ക് വിധേയരായ സിങ്കിൾ വെൻട്രിക്കിൾ ശാരീരികാവസ്ഥയുള്ള രോഗികളിലെ ദീർഘകാല നേട്ടങ്ങളുടെ താരതമ്യ വിശകലനം

പങ്കെടുക്കുന്നയാളുടെ പേര് ..... ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ).....

..... അച്ഛൻ/അമ്മ/നിയമപരമായ രക്ഷകർത്താവ്

(ദയവായി കോളങ്ങൾ അടയാളപ്പെടുത്തുക)

പഠനശീർഷകം. ആന്റിഗ്രേഡ് പൾമനറി രക്തപ്രവാഹം ഉള്ളതോ ഇല്ലാത്തതോ ആയ, ദിദിശാ ഗ്ലീൻ ഷണ്ട് ശസ്ത്രക്രിയയ്ക്ക് വിധേയരായ സിങ്കിൾ വെൻട്രിക്കിൾ ശാരീരികാവസ്ഥയുള്ള രോഗികളിലെ ദീർഘകാല നേട്ടങ്ങളുടെ താരതമ്യ വിശകലനം എന്ന പഠനസംബന്ധിയായി എനിക്ക് നൽകിയ വിവരങ്ങൾ വായിച്ചു എന്നു പ്രസ്താവിക്കുന്നു. എനിക്കുണ്ടായിരുന്ന സംശയങ്ങൾ പരിഹരിച്ചു [ ]

.....

എന്റെ കുട്ടിയുടെ ഈ പഠനത്തിലുള്ള പങ്കാളിത്തം പൂർണ്ണമായും സ്വമേധയായാണെന്നും അനുവാദം എനിക്ക് ഏതുസമയത്തും എന്റെ ചികിത്സയെ യും നിയമപരമായ അവകാശങ്ങളെയും ബാധിക്കാതെ പിൻവലിക്കാൻ അവകാശമുണ്ടെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]

ഞാൻ ഈ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും പഠനം നടത്തുന്നവർക്കും സ്ഥാപനത്തിലെ നൈതിക കമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ ആരോഗ്യരേഖകൾ പരിശോധിക്കുന്നതിന് എന്റെ അനുവാദം ആവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിനോട് ഞാൻ യോജിക്കുന്നു.[ ]  
എന്റെ കുട്ടിയെ തിരിച്ചറിയാനുകുന്ന വിവരങ്ങൾ ഒന്നും മറ്റുള്ളവർക്കു നൽകുകയോ പ്രസിദ്ധീകരിക്കുകയോ ചെയ്തില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. [ ]

ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു [ ]

സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു കോപ്പി എനിക്കു കിട്ടി [ ]

പേര് ..... ഒപ്പ് ..... തീയതി.....

സാക്ഷിയുടെ പേര് ..... ഒപ്പ്.....തീയതി.....

രോഗിയുമായുള്ള ബന്ധം.....

(സമ്മതം വാങ്ങുന്നയാൾ)

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി

**PATIENT INFORMATION PROFOMA (Format)**

DIAGNOSIS

ANTEGRADE PULMONARY BLOOD FLOW

PA SIZE (PRE OP)

PRE OP SATURATION

POST OP SATURATION

FOLLOW UP

LAST SEEN SATURATION PRIOR TO FONTAIN

CURRENT SATURATION

CURRENT PA SIZES ( ECHO)

CURRENT PA SIZES (CT)

CATH PRESSURES PRIOR TO FONTAN

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