# SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY. THIRUVANANTHAPURAM.



## PROJECT REPORT



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# CERTIFICATE

I, Dr. Shajeem O. hereby declare that the projects in this book were undertaken by me under the supervision of the faculty, Department of Cardiology, SCTIMST.

Signature

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Trivandrum

Date: 18|10|2006



Forwarded,

The Candidate, Dr. Shajeem O, has carried out the minimum required procedure.

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# Normal Doppler echocardiographic parameters of the TTK Chitra heart valve prosthesis in the mitral and aortic positions

# INTRODUCTION

TTK Chitra Heart Valve is a tilting disc artificial heart valve prosthesis designed and developed by Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), an autonomous institute under the Department of Science and Technology, Government of India[1]. More than 15000 valves have been implanted in various institutions in India since its first implant on December 6, 1990.

Though it has been in use for more than 15 years, there is a dearth of data on the normal echocardiographic parameters of the valve.

Doppler echocardiography is the most widely used tool to assess the normal and abnormal function of heart valve prostheses. It can provide data on pressure gradients, pressure half-time, and effective orifice areas as in native valves. However, the interpretation of such data is difficult when prosthetic valves are to be evaluated. This is because, prosthetic valves, even when they function normally, are to some degree stenotic. Thus, even patients with normally functioning valves present with some gradients across their valves and with reduced orifice areas. This makes it frequently difficult in individual patients to decide from such measurements whether a calculated number represents the performance of a normal valve or whether it indicates prosthetic valve stenosis[2].

The normal values of gradients, pressure half-time, or effective orifice area of the prosthetic valve depends on valve type and valve size. Reliable data on normal values of various prosthetic valve types are necessary so that echocardiographers and cardiologists can easily look up

whether the measurements given in an individual patient are within the normal range. Though data on Doppler echocardiographic parameters are available for most of the valves, the data on many of the newer valve types is insufficient. This assumes special importance in the case of the Chitra heart valve prosthesis, as the role of Fluoroscopy in assessment of prosthetic valve dysfunction is limited.

This study was planned to evaluate the normal Doppler values for the Chitra heart valve prosthesis with a view to provide a reference for its normal Doppler echocardiographic parameters.

# REVIEW OF LITERATURE

The introduction of the cardiopulmonary bypass machine in 1953 by Gibbon made possible the implantation of a prosthetic cardiac valve in its anatomic position[3]. The first successful prosthetic aortic valve replacement with mechanical prosthesis was reported by Harken et al[4] and mitral valve replacement by Starr and Edwards[5] in 1960. Subsequently tissue valves and bioprostheses were introduced. Since then, significant evolution in valve design and types of prosthetic valves has occurred. The current types of mechanical prosthetic valves are caged-ball, tilting-disc, and bileaflet. Heterograft porcine tissue valves from pig aortic valves and bioprostheses from pericardium, usually bovine, have also been constructed. Recent advances include the development of homograft aortic valves and mitral valves taken from cadavers.

TTK Chitra Heart Valve (figure 1) is a tilting disc artificial Heart Valve Prosthesis and has the following three components[6]:

- Frame: made using a Chrome-Cobalt Alloy (Haynes-25 alloy)
- Disc: Fabricated from Ultra High Molecular Weight Poly Ethylene (UHMWPE)
- Sewing Ring: Fabricated from specially knitted Polyester fabric

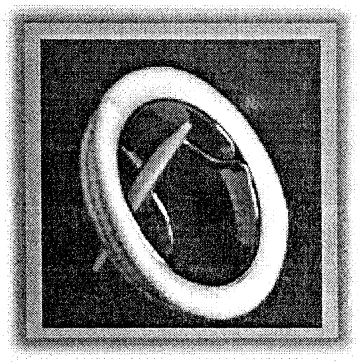
TTK Chitra Heart Valve is unique in design and construction with the UHMWPE disc, which absorbs bulk of the shock generated during closing of the valve. This leads to the following unique features of TTK Chitra Heart Valves.

- Reduced noise generated by the valve, which is usually associated with any artificial heart valve , resulting in a soft closing sound

- Reduced damage to blood and the disc due to the reduction in formation of cavitation bubbles.
- Since the density of the disc material closely matches that of the blood, the valve functions with minimum pressure drop and hence minimum load on the heart.
- Since the disc is lighter, the disc closes faster and reduces the regurgitation (reverse flow of blood) during closure of the valve.

Sankarkumar R et al[6] reported the findings of a multicenter clinical study in 2001. The study found the Chitra valve to be safe and to have a performance comparable with that of other currently used tilting disc valves. A major advantage of the Chitra heart valve prosthesis is its lower cost compared to other prosthetic valves, and this is particularly relevant in India.

Figure 1: Photograph of the TTK Chitra heart valve prosthesis



**Prosthetic valves: Methods of assessment**

Although significant advances have been made, the hemodynamic profile of prosthetic valves is still inferior to that of native valves and patients with prosthetic valves may develop several complications. Patients who are implanted with prosthetic valves need regular followup and evaluation. Changes in symptoms or physical findings are usually the

first signs of prosthetic valve dysfunction. Changes in baseline auscultatory findings and clinical presentation of dyspnea, exercise intolerance, or embolic phenomenon should prompt an evaluation of prosthetic function

Currently available modalities in the evaluation of prosthetic valve function include (1) cinefluoroscopy, (2) cardiac catheterization, and (3) echocardiography. With the advent of Doppler and transesophageal imaging, echocardiography has become the method of choice for the evaluation of prosthetic valve function[7].

**Cinefluoroscopy**

Cinefluoroscopy was the first noninvasive imaging technique in the study of prosthetic valves. It is easily applied to mechanical prosthetic valves because they have a radiopaque base ring and a ball or disc occluder mechanism. It is of limited value for tissue valves, which are either radiolucent or have only a radiopaque base ring. Abnormal tilting or rocking of the base ring is indicative of valve dehiscence. Impaired excursion or incomplete seating of the moving parts of the prosthesis suggests the presence of tissue ingrowth or thrombus. Cinefluoroscopy currently plays a complementary diagnostic role in evaluating disc mobility of mechanical valves in the aortic position, in cases with borderline function of the prosthesis.

The role of cinefluoroscopy is limited in the case of the Chitra heart valve prosthesis. Though the metallic frame is radioopaque, the disc or occluder is radiolucent. Hence, it is not possible to assess the movements of the disc by fluoroscopy.

**Cardiac catheterization**

Cardiac catheterization was the only technique that provided hemodynamic information on prosthetic valves before the introduction of Doppler echocardiography. Cardiac catheterization combines cinefluoroscopic evaluation of prosthetic valves with measurement of flow and pressure gradients and contrast injection for estimation of valve regurgitation. Flow and pressure gradients are used for calculation of effective orifice area of the prosthetic valve using the Gorlin formula. Flow characteristics and normal values of valve gradients and effective areas have been reported for several commonly used prosthetic heart valves[8].

For accurate results, a dual catheter approach is needed to measure pressure upstream and downstream from the valve and determine pressure gradient across the prosthesis. In clinical practice, however, this is infrequently performed due to various reasons. Because Doppler echocardiography currently offers reliable hemodynamic information of prosthetic valves, dual catheter technique for measurement of gradients is performed only in selected rare cases of prosthetic valve dysfunction. Although contrast angiography was the standard for evaluation of prosthetic valve regurgitation, it is currently less used for this purpose with the advent of Doppler and transoesophageal echocardiography (TEE).

**Echocardiography**

With improvements in image quality, resolution, and newer modalities, echocardiography is currently the method of choice for evaluation of prosthetic valves. Because the technique is noninvasive, it also allows for serial follow-up of prosthetic valve function.

Imaging with two-dimensional and M-mode echocardiography evaluates the structure of the prosthesis, the motion of the occluder, and the stability of the valve ring and allows identification of the possible cause or mechanism of valve malfunction. Transthoracic echocardiography may identify calcifications on bioprosthetic valves or allografts but is usually limited in evaluating the structure of mechanical valves. TEE provides a high-resolution imaging of valvular and paravalvular structures and complements the transthoracic approach in this evaluation.

With the application of Doppler echocardiography, hemodynamic information on valve gradients, effective areas, and valve regurgitation are provided. In addition to valve function, echocardiography offers unique information about the anatomy of the cardiac structures adjacent to the prosthesis as well as cardiac size and function and an estimate of pulmonary artery pressure.

**Principles of Doppler evaluation:**

Evaluation of prosthetic valves by Doppler echocardiography utilizes the same principles and formulas that are used for native valve stenosis. Prosthetic valves have inherently some degree of stenosis compared with normal native valves. Hence, velocities and gradients across prosthetic valves are higher than those of normal valves. Factors which determine the velocities and gradients across normal prosthetic valves include valve type, valve size, and flow through the valve. These determinants, in part, account for the wide range of normal parameters of prosthetic valve function in the literature[2,7]. Normal Doppler data of valve function in patients with various types of prosthetic valves in the aortic position are shown in Table 1.

Accurate Doppler assessment of the flow across the prosthetic valve is obtained when the angle between the ultrasonic beam and flow is less than 20 degrees; otherwise, velocities and gradients are underestimated. Thus, interrogation of blood flow velocity is required from multiple windows, particularly for aortic prostheses, to avoid these errors. For mitral or tricuspid prostheses, alignment of the ultrasound beam can be easily obtained with the guidance of color Doppler.

Doppler assessment of prosthetic valves includes the measurement of peak velocities, peak and mean gradients, pressure half-time (PHT) and indices of valve area and resistance derived from these parameters. Normal values for these different parameters differ markedly depending on the given type and size of valves. Interpretation of Doppler measurements with regard to normal or abnormal valve function requires access to data on normal values for the particular valve and size.

Studies have shown a wide range of normal values for the velocities and gradients of different valve types. This is mainly caused by the flow dependence of such variables[9]. In general, maximal and mean gradients across prosthetic valves estimated with Doppler by the modified Bernoulli equation correlate well with simultaneous measurements at cardiac catheterization[10]. Overestimation of gradients may occur when the proximal velocity in the ventricular outflow is greater than 1.5 m/s, leading to errors in the application of the modified Bernoulli equation[11]. Another cause of overestimation of gradients with Doppler is valve design. Bileaflet valves and ball and cage valves have a very inhomogeneous velocity profile. In bileaflet St. Jude Medical prosthesis, a local increase of velocities and gradients is created at the level of the valve through the smaller orifice, between the two leaflets[12]. Continuous-

wave Doppler has a wide beam and records these high velocities. However, overestimation of gradients has not been found to be a significant problem in tilting disc valves like Medtronic-Hall prosthesis.

**Derived Doppler echocardiographic parameters for aortic valve**

These can be divided into parameters that are dependent on valve size and those which are independent of valve size. Size dependent parameters include effective orifice area by continuity equation and valve resistance. A size independent parameter that has been standardized is the Doppler velocity index. Performance index is another parameter of prosthetic valve function that can be derived.

**Effective orifice area**

Effective orifice area (EOA) is calculated with the continuity equation as the stroke volume through the valve divided by the velocity-time integral of the aortic jet recorded by continuous-wave Doppler. Pulsed Doppler is used to calculate the stroke volume at the left ventricular outflow, from the product of cross-sectional area and velocity-time integral of flow.

EOA is dependent on the size of the inserted valve. Knowledge of the size and type of the aortic prosthesis is essential in interpreting the measured EOA as normal or abnormal. For valves of any size, stenosis is suspected when valve area is below 0.8 $cm^2$. For the smallest size valve, however, this may still be normal. In such cases, the availability of a baseline Doppler echocardiogram early after surgery is helpful for comparison. EOA should be referenced to the valve size of a particular valve

**Valve Resistance**

Valve resistance, initially defined from variables obtained at cardiac catheterization, was proposed as an index of native aortic valve stenosis that is less dependent on flow[13]. It can also be measured by Doppler echocardiography. Valve resistance is determined from the mean valve gradient, ejection time and stroke volume[14]. Valve resistance in normal St. Jude Medical aortic valves averages 85±38 dynes.s.cm$^{-5}$.

In a series of symptomatic patients with surgically documented severe St. Jude aortic valve stenosis, all patients had a valve resistance 280 dynes.s.cm$^{-5}$ or greater and it was found to help elucidate whether high gradients are secondary to obstruction or increased flow through the valve. Valve resistance was highest in stenotic prosthetic valves and differentiated best the stenotic valves from regurgitant and normal valves[14]. However, data regarding echocardiographic determination and evaluation of valve resistance in other prosthetic valves, however, are limited.

**Doppler Velocity Index**

Doppler velocity index (DVI) is an index of valve function, which is much less dependent on valve size. It is calculated as the ratio of the velocity in the left ventricular outflow to that across the prosthesis. DVI has no dimensions and incorporates the effect of flow on prosthetic valve velocity. One reason why DVI is less dependent on valve size is the inherent relation of valve size to the cross sectional area of left ventricular outflow tract. With a larger left ventricular outflow area, a larger sized valve can be fitted at surgery.

DVI is always less than unity because velocity always accelerates through the prosthesis. A DVI less than 0.27 is suspicious for significant valve obstruction. DVI does not rely on the left ventricular outflow tract measurements and has the advantage of being less dependent on the valve size. Thus, lack of knowledge of valve size at the time of evaluation does not significantly hinder its functional assessment[15].

**Performance Index**

The performance index (PI) is a measure of how well a prosthetic valve uses the actual orifice area of the prosthesis. This is calculated by dividing the effective orifice area by the actual orifice area provided by the manufacturer. Studies using PI is limited.

In a study[16] on normal echocardiographic characteristics of the sorin bicarbon bileaflet prosthetic heart valve in the aortic position, PI varied from a mean of 55% in 19 mm valve to 71% in the 27 mm valve.

**Table 1: Normal Doppler data in patients with various types prosthetic valves in the aortic postion (mean ± SD)[7]**

| | | Peak Velocity (m/s) | Mean Gradient (mm Hg) | Doppler Velocity Index |
|---|---|---|---|---|
| **Caged-ball** | Starr Edwards | 3.1 ± 0.5 | 24 ± 4 | 0.32 ± 0.09 |
| **Tilting-disc** | Medtronic-Hall | 2.6 ± 0.4 | 14 ± 5 | 0.40 ± 0.10 |
| | Omniscience | 2.4 ± 0.2 | 14 ± 3 | 0.39 ± 0.09 |
| | Bjork-Shiley | 2.8 ± 0.4 | 14 ± 3 | |
| **Bileaflet** | St. Jude Medical | 2.5 ± 0.6 | 12 ± 7 | 0.41 ± 0.12 |
| **Heterograft** | Hancock | 2.4 ± 0.3 | 11 ± 2 | 0.44 ± 0.21 |
| | Carpentier-Edwards | 2.4 ± 0.5 | 14 ± 6 | |
| | Ionescu-Shiley | 2.5 ± 1.7 | 14 ± 4 | |
| **Homograft** | | 1.9 ± 0.4 | 7.7 ± 2.7 | 0.56 ± 0.10 |

**Doppler echocardiographic parameters for mitral valve**

Doppler echocardiographic parameters assessed for the mitral valve include peak velocity, peak and mean gradients, pressure half-time (PHT), Mitral valve area by PHT and effective orifice area derived with the continuity equation. Normal Doppler data of valve function in patients with various types of prosthetic valves in the aortic position are shown in Table 2.

Doppler-derived gradients are currently the standard by which gradients are assessed through the prosthetic valves. Similar to prosthetic aortic valves, valves in the mitral position are influenced by type and size of prosthesis as well as flow. In addition, however, heart rate has a major influence on mitral gradients. Therefore heart rate should always be reported during the evaluation of prosthetic mitral valve function and gradients interpreted accordingly.

**Pressure half-time (PHT) and Valve area by PHT**

The concept of PHT concept was initially used for native mitral valve. It is also used as an index of function for prosthetic valves, where valve area by PHT is derived as 220/PHT. When there is obstruction at the valve, velocity and gradient across the valve increase. Rate of fall of the pressure gradient is reduced. This leads to increase in measured PHT and the calculated valve area is reduced.

PHT provides a good index of valve function in the majority of cases. Area by PHT in normal prosthetic valves, however, does not relate to area by the hydraulic formula or to anatomic orifice area of the valve and is therefore an index of valve function[17]. A limitation is that several

factors affect PHT. These include atrial and ventricular compliance, ventricular relaxation, loading conditions, and the presence of aortic insufficiency. Area by PHT is also unreliable in tachycardia or first-degree atrioventricular block, when merging of early and late mitral velocities occurs or diastolic filling period is short[7].

**Effective Orifice Area by continuity equation**

Effective orifice area using the continuity equation is derived as stroke volume through the prosthesis divided by the time-velocity integral of the mitral jet velocity. In studies on bioprosthetic and St. Jude Medical valves, this index relates well to area by the hydraulic equation and anatomic valve area[17,18]. In a study by Bitar et al[18], derivation of effective orifice area of St. Jude Medical valves in the mitral position allowed better differentiation among valve sizes than mean gradients and PHT and provided a reliable index of prosthetic valve function

**Table 2: Normal Doppler data in patients with various types prosthetic valves in the mitral postion (mean ± SD)[7]**

| | | Peak Velocity (m/s) | Mean Gradient (mm Hg) | Pressure Half-Time (ms) |
|---|---|---|---|---|
| **Caged-ball** | Starr Edwards | 1.9 ± 0.4 | 5 ± 2 | 109 ± 27 |
| **Tilting-disc** | Medtronic-Hall | 1.6 ± 0.3 | 3 ± 2 | 90 ± 22 |
| | Omniscience | 1.7 ± 0.3 | 3 ± 0.9 | 89 ± 19 |
| | Bjork-Shiley | 1.8 ± 0.3 | 3 ± 0.9 | 125 ± 29 |
| **Bileaflet** | St. Jude Medical | 1.6 ± 0.3 | 3 ± 1 | 76 ± 17 |
| **Heterograft** | Hancock | 1.5 ± 0.3 | 4 ± 2 | 129 ± 31 |
| | Carpentier-Edwards | 1.8 ± 0.2 | 6 ± 2 | 90 ± 25 |
| | Ionescu-Shiley | 1.5 ± 0.3 | 3 ± 1 | 93 ± 25 |

Valve areas by the continuity equation are normally smaller than those derived by PHT and relate to valve size. Knowledge of the size of the valve is essential, particularly when dealing with small prostheses. The use of effective areas is particularly helpful in situations in which PHT is unreliable and in cases of discrepancy between information obtained from gradients and area by PHT.

**Doppler echocardiographic parameters of the Chitra heart valve prosthesis**

Data on normal Doppler parameters of the Chitra valve in the literature is limited. Kumar P et al[19] reported the data on transvalvular gradients, peak velocity and effective orifice area of the Chitra valve in mitral and aortic positions in 230 patients. However, the data reported is limited by less number of parameters studied. Data from this study is summarized in table 3.

**Table 3: Transvalvular gradients, Peak velocity and effective orifice area of Chitra valve in Mitral and aortic positions[19]**

| | Valve size (in mm) | Mean Gradient (in mm Hg) | Peak Velocity (in m/ sec) | Effective orifice area (in $cm^2$)* |
|---|---|---|---|---|
| **Mitral** | 25 | 5±3 | 1.8±0.3 | 2.8±0.8 |
| | 27 | 4±2 | 1.7±0.2 | 3.1±0.7 |
| | 29 | 4±2 | 1.7±0.2 | 2.9±0.7 |
| **Aortic** | 21 | 10±5 | 2.9±0.6 | 1.5±0.5 |
| | 23 | 9±4 | 2.6±0.7 | 1.8±0.3 |

* PHT was used for EOA in mitral prostheses.

# AIM OF THE STUDY

To establish the normal Doppler echocardiographic parameters for the Chitra heart valve prosthesis in aortic and mitral positions with the use of transthoracic echocardiography, in a large series of patients with normally functioning valves.

# MATERIAL AND METHODS

The Study population consisted of 120 consecutive patients with a normal functioning Chitra heart valve prosthesis who came for a routine follow-up echocardiographic study.

Exclusion criteria:

- Patients with a short follow-up (< 3 months after surgery)
- Patients with evidence of prosthetic valve dysfunction like significant obstruction, regurgitation or complications like endocarditis
- Significant left ventricular dysfunction (Ejection fraction < 40%)
- Unsatisfactory echocardiographic windows

**Echocardiographic evaluation:**

Two-dimensional and Doppler echocardiographic studies were performed with a System 5 or Vivid 7 echocardiographic system (GE Vingmed Ultrasound A/S, GE Healthcare, Horten, Norway). A complete transthoracic echocardiographic examination was initially obtained to assess the left ventricular function and to visualize the prosthesis and the native valves. Color Doppler flow imaging was then used to characterize the prosthetic forward flow pattern and the regurgitation flow pattern.

**Doppler Evaluation of Aortic Prostheses:**

The following parameters were assessed to evaluate the prosthetic valve in the aortic position

1. Peak velocity
2. Peak gradient
3. Mean gradient

4. Doppler velocity index
5. Effective orifice area
6. Valve resistance
7. Performance index

The highest peak aortic flow velocity across the prosthetic valve was measured with continuous-wave Doppler technique. In each patient, recording of the jet velocity was attempted from multiple windows, including the apical, right parasternal, and suprasternal windows. Cardiac cycles with the highest peak velocities were selected for calculations.

From the Doppler spectral display the following measures were obtained:

1. Peak jet velocity (m.sec-1)
2. Maximal gradient (mm Hg) derived from the simplified Bernoulli equation
3. Mean gradient (mm Hg)
4. Velocity-time integral (VTI)
5. Ejection time

Doppler velocity index (DVI) is calculated as the ratio of the peak velocity in the left ventricular outflow ($V_{LVO}$ in cm/s) to that of the aortic jet ($V_{jet}$ in cm/s)

$$\mathbf{DVI = V_{LVO} / V_{jet}}$$

Effective orifice area (EOA) was calculated with the continuity equation as the stroke volume through the valve divided by the velocity-time integral of the aortic jet recorded by continuous-wave Doppler. Stroke volume was derived at the left ventricular outflow, from the

product of cross-sectional area and velocity-time integral of flow by pulsed Doppler.

$$\mathbf{EOA_{AV} = SV/\ VTI_{jet} = CSA_{LVO} \times VTI_{LVO}\ /VTI_{jet}}$$

where $EOA_{AV}$ is the effective orifice area in $cm^2$, SV is stroke volume in mL, $VTI_{jet}$ and $VTI_{LVO}$ are time velocity integral of the aortic jet and in the left ventricular outflow in cm respectively, and $CSA_{LVO}$ is the cross-sectional area in the left ventricular outflow in $cm^2$.

Left ventricular outflow tract (LVOT) diameter was measured in the parasternal long-axis view, just below the prosthetic valve. It was used to derive the $CSA_{LVO}$ by echocardiography as $\pi D^2/4$, where D is the LVOT diameter. Systolic velocity and velocity-time integral in the LVOT was obtained with the pulsed Doppler method from the apical five-chamber view, with a sample volume positioned at the level corresponding to the diameter measurement.

Valve resistance (in $dynes.s.cm^{-5}$) is determined from the mean valve gradient (MG in mm Hg), ejection time (ET in msec), and stroke volume (SV in mL) as:

$$\mathbf{Valve\ resistance = (MG \times ET/SV) \times 1.33}$$

The performance index was calculated by dividing the effective orifice area by the actual orifice area provided by the manufacturer:

$$\mathbf{Performance\ index\ (\%) = EOA_{AV}\ /\ AOA}$$

Where AOA is the actual orifice area which is calculated from the Valve orifice diameter (VOD) provided by manufacturer as $\pi.VOD^2/4$.

**Doppler Evaluation of Mitral Prostheses:**

The following parameters were assessed to evaluate the prosthetic valve in the mitral position

1. Peak velocity
2. Peak gradient
3. Mean gradient
4. Pressure half-time (PHT)
5. Mitral valve area by PHT
6. Effective orifice area derived with the continuity equation

Flow velocity across the mitral prosthesis was recorded with continuous-wave Doppler guided by color flow Doppler. Measurements were made from the view with the least angulation with flow, most commonly from the apical window. Color flow Doppler was used in evaluating the direction of flow into the left ventricle and optimizing Doppler recordings of jet velocity.

From the tracing of prosthetic inflow velocity, maximal velocity, peak gradient and mean gradient were measured. Pressure half-time (PHT) was measured from the tracing of prosthetic inflow velocity as the time required for the peak gradient to be reduced by one-half. Mitral valve area by pressure half-time is derived as 220/PHT.

Effective orifice area using the continuity equation ($EOA_{MV}$) is derived as stroke volume (SV) through the prosthesis divided by the velocity-time integral ($VTI_{MV}$) of the mitral jet velocity:

$$\mathbf{EOA_{MV} = SV / VTI_{MV}}$$

Stroke volume through the mitral valve is substituted for that through the left ventricular outflow when there is no significant mitral or aortic regurgitation. Valve areas by the continuity equation are normally smaller than those derived by PHT and relate to valve size.

**Statistical analysis**

Analysis was performed using SPSS version 14.0 for Windows. All continuous data were reported as mean ± standard deviation. For the purpose of analysis, all patients were classified into 2 groups: those who have undergone AVR and MVR. They were again divided into subgroups based on the size of the valve implanted.

Continuous variables between multiple groups were compared using the one-way analysis of variance (ANOVA). Correlations between each variable and valve size were tested using bivariate correlation analysis. Discrete variables were compared using the Chi square test.

A p value of less than 0.05 was considered significant.

# RESULTS

There were a total of 760 patients who had undergone implantation of the TTK Chitra heart valve prosthesis at the Institute from 1990 to 2005. 120 randomly selected patients were included in the study. These patients had received a total of 137 implants, 40 in the mitral position and 97 in the aortic position. 53 patients had undergone aortic valve replacement (AVR) alone, 23 patients mitral valve replacement (MVR) alone, and 44 patients double valve replacement (mitral and aortic).

Of the 44 patients who had undergone DVR, all 44 had Chitra valve at the aortic position. At the mitral position, 17 had Chitra valve and 27 had Starr Edwards prosthesis.

Baseline characteristics are shown in table 4. Mean age of the patients was 39.2 years. 76 patients (63.7%) were males and 44 patients (36.7%) were females. Rheumatic heart disease was the most common etiology for which valve replacement was done.

**Table 4: Baseline Characteristics.**

| | | |
|---|---|---|
| Age | | 39.2 ± 11.1 years |
| Sex | Male | 75 (63.3%) |
| | Female | 43 (36.7%) |
| Diagnosis | Rheumatic | 86 (71.7%) |
| | Degenerative | 13 (10.8%) |
| | Bicuspid AV | 8 (6.7%) |
| | Other | 13 (10.8%) |
| NYHA class | 1 | 87 (70%) |
| | 2 | 36 (30%) |
| Rhythm | Sinus rhythm | 93 (77.5%) |
| | Atrial fibrillation | 26 (21.8%) |
| | Other | 1 (0.8%) |

The follow-up echocardiographic examination was done at a median duration of 33.8 months (Range: 3 months to 15 years) after the valve implantation.

At the time of evaluation, 84 patients were in NYHA functional class I, and 36 were in NYHA functional class II. 93 patients were in sinus rhythm and 26 were in atrial fibrillation. One patient had undergone permanent pacemaker implantation for complete heart block, which developed following AVR.

Mean Left ventricular ejection fraction was 66.6% (Range 40 – 85%). Other baseline echocardiographic parameters are shown in table 5

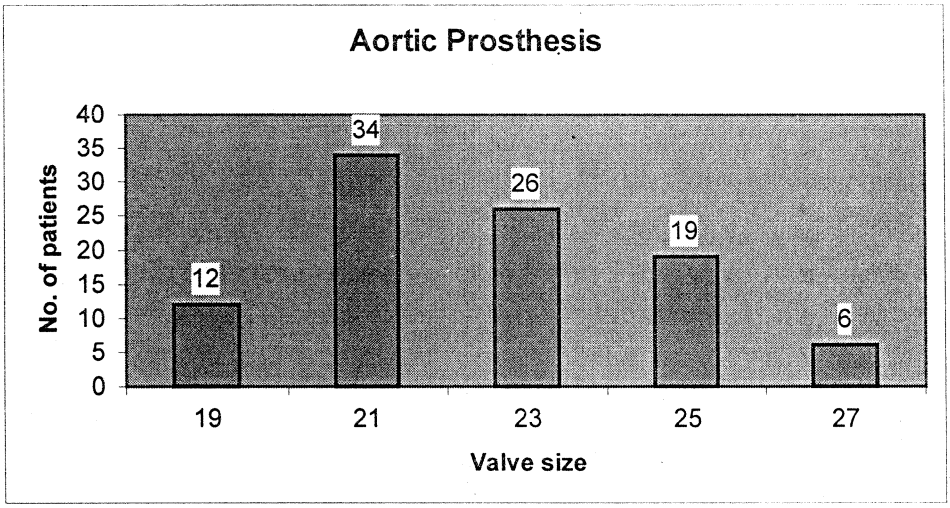
**Table 5: Baseline Echocardiographic parameters**

| Parameter | Mean ± SD |
|---|---|
| LVIDD, mm | 48.1 ± 6.6 |
| LVIDS, mm | 33.1 ± 6.2 |
| EF, % | 66.6 ± 8.0 |
| LA, mm | 41.2 ± 8.8 |
| Aorta, mm | 30.9 ± 3.8 |

**Doppler echocardiographic parameters of the prosthesis at the Aortic position:**

In the 95 patients with Chitra heart valve prosthesis at the aortic position, the size of the prosthesis ranged from 19 to 27 mm and included all the intermediate sizes. The number of patients with each valve size included in the study is shown in figure 2. 21 mm size valve was the most commonly implanted and 27 mm size, the least common. The 27 mm size Chitra valve for aortic position is not available. The mitral prosthesis of 27 mm was used at aortic position in a reversed manner.

**Figure 2: No. of patients with each size of Aortic prosthetic valve**




Mean age of patients who had AVR was 39.2 ± 11.4 years. 63 patients (64.9%) were males and 34 (35.1%) were females. Most common diagnosis was rheumatic heart disease (67%), followed by degenerative aortic valve disease (13.4%).

Echocardiographic evaluation was carried out at a median period of 30.9 months (Range: 3 months to 15 years) after the surgery.

An adequate recording of the aortic jet velocity through the prosthetic valve was obtained in all patients. The normal values (Mean ± Standard Deviation with range in parentheses) for the peak velocity, peak and mean gradients, Doppler velocity index, effective valve orifice area and the valve resistance according to valve size are shown in Tables 6 and 7.

The peak Doppler gradient ranged from 7.7 to 66 mm Hg, and the mean gradient ranged from 3.6 to 37 mm Hg. Peak velocity, peak and mean valve gradients decreased with increasing valve size ($r = -0.71$, $r = -0.69$, and $r = -0.68$ respectively; $p < 0.001$). However, there was a wide

range of gradients, and there was significant overlap between gradients from valves of different sizes. But when small-size groups were compared with large-size groups, significant differences in peak and mean gradients were found (One-way ANOVA; $p < 0.001$)

**Table 6: Baseline Doppler echocardiographic parameters of Chitra valve in aortic position**

| Valve size, mm | No. of patients | Peak Velocity, $m.sec^{-1}$ | Peak Gradient, mm Hg | Mean Gradient, mm Hg |
|---|---|---|---|---|
| **19** | 12 | 3.21 ± 0.46 (2.60 – 4.06) | 42.0 ± 12.2 (27.0 – 66.0) | 21.3 ± 6.2 (15.6 – 37.0) |
| **21** | 34 | 2.75 ± 0.39 (2.10 – 3.63) | 30.8 ± 8.7 (17.7 – 52.9) | 15.8 ± 5.0 (8.1 – 28.7) |
| **23** | 26 | 2.44 ± 0.31 (1.94 – 3.25) | 24.1 ± 6.3 (15.0 – 42.2) | 12.0 ± 3.8 (7.0 – 24.5) |
| **25** | 19 | 2.14 ± 0.37 (1.55 – 3.09) | 19.0 ± 6.9 (9.6 – 38.3) | 9.2 ± 3.6 (5.3 – 19.1) |
| **27** | 6 | 1.78 ± 0.33 (1.40 – 2.29) | 13.0 ± 4.9 (7.7 – 21.0) | 5.8 ± 1.3 (3.6 – 7.0) |
| **Total** | 97 | 2.54 ± .53 (1.40 – 4.06) | 27.0 ± 11.1 (7.7 – 66.0) | 13.6 ± 6.1 (3.6 – 37.0) |

Doppler Velocity Index (DVI) ranged from 0.28 to 0.61. Though it is considered to be independent of valve size, there was a significant correlation between DVI and the valve size ($r = 0.31$, $p = 0.003$). However, when smaller sizes of 19 and 21 were excluded from the analysis, DVI was found to be independent of valve size ($r = -0.05$, $p = 0.73$).

**Table 7: Doppler echocardiographic parameters of Chitra valve in aortic position – Derived indices**

| Valve size, mm | N | Doppler Velocity Index (DVI) | Effective Orifice Area, $cm^2$ | Valve Resistance, $dynes.s.cm^{-5}$ |
|---|---|---|---|---|
| **19** | 12 | 0.36 ± 0.06 (0.28 – 0.49) | 0.91 ± 0.19 (0.75 – 1.46) | 154.5 ± 33.7 (68.4 – 204.6) |
| **21** | 34 | 0.39 ± 0.08 (0.28 – 0.61) | 1.13 ± 0.25 (0.76 – 1.87) | 109.3 ± 33.9 (50.5 – 206.4) |
| **23** | 26 | 0.43 ± 0.06 (0.31 – 0.55) | 1.49 ± 0.27 (1.05 – 1.85) | 72.2 ± 19.2 (45.0 – 124.1) |
| **25** | 19 | 0.43 ± 0.07 (0.32 – 0.60) | 1.93 ± 0.39 (1.21 – 2.94) | 49.7 ± 19.5 (25.2 – 108.5) |
| **27** | 6 | 0.43 ± 0.04 (0.37 – 0.47) | 2.15 ± 0.18 (1.83 – 2.30) | 34.9 ± 5.2 (30.1 – 44.1) |
| **Total** | 97 | 0.41 ± 0.08 (0.28 – 0.61) | 1.42 ± .48 (0.75 – 2.94) | 88.6 ± 44.4 (30.1 – 206.4) |

Effective aortic orifice area (EOA) calculated by the continuity equation ranged from 0.75 to 2.94 cm2. A significant correlation was observed between the effective orifice area and the valve size ($r = 0.81$, $p < 0.001$). Effective orifice areas were always smaller than the actual orifice areas for the same size of prostheses provided by the manufacturer. With analysis of variance, effective aortic valve area by continuity equation, differentiated various valve sizes ($F = 45.5$, $p < 0.001$) better than peak gradients ($F = 23.6$, $p < 0.0001$) or mean gradients ($F = 21.5$, $p = 0.0001$) alone did.

Valve resistance calculated by echocardiography ranged from 25.2 to 206.4 $dynes.s.cm^{-5}$. A significant negative correlation was observed between valve resistance and the valve size ($r = -0.78$, $p < 0.001$).

The performance index was calculated by dividing the effective orifice area by the actual orifice area provided by the manufacturer (Table 8). There was no correlation between valve size and the performance index ($r = 0.14$, p= not significant).

Minimal to mild intravalvular aortic regurgitation (AR) was a common finding by colour Doppler flow imaging. In 81 of the 97 normally functioning valves (83.5%), aortic regurgitation was present. AR was grade 1 in 60 patients (61.9%) and grade 2 in 21 patients (21.7%). The 81 prosthetic valves with minimal AR were equally distributed among the various valve sizes.

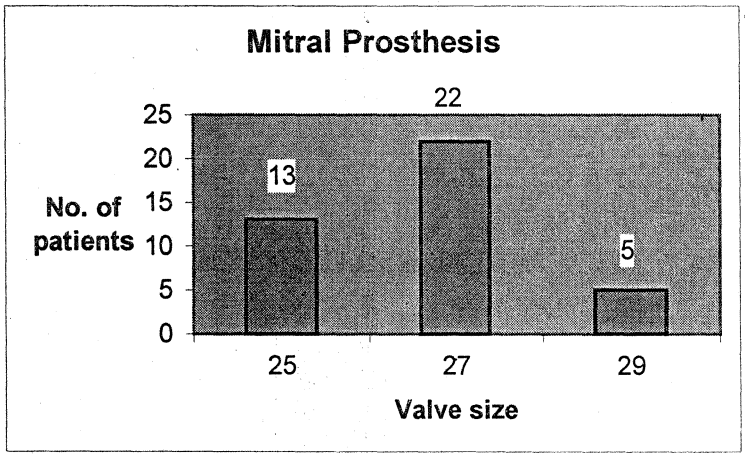
Table 8: Performance index of various sizes of the Chitra valve at the aortic position

| **Valve size, mm** | **Valve Orifice Diameter (VOD, mm)** | **Actual Orifice Area, $cm^2$** | **Effective Orifice Area, $cm^2$** | **Performance Index (%)** |
|---|---|---|---|---|
| **19** | 14.4 | 1.63 | 0.91 ± 0.19 (0.75 – 1.46) | 55.7 ± 11.7 (46.0 – 89.3) |
| **21** | 16.0 | 2.01 | 1.13 ± 0.25 (0.76 – 1.87) | 56.1 ± 12.3 (37.7 – 93.2) |
| **23** | 18.0 | 2.54 | 1.49 ± 0.27 (1.05 – 1.85) | 58.6 ± 10.4 (41.2 – 72.9) |
| **25** | 20.0 | 3.14 | 1.93 ± 0.39 (1.21 – 2.94) | 61.6 ± 12.5 (38.4 – 93.6) |
| **27** | 22.0 | 3.78 | 2.15 ± 0.18 (1.83 – 2.30) | 57.0 ± 4.7 (48.4 – 60.8) |
| **Total** | | | 1.42 ± .48 (0.75 – 2.94) | 57.8 ± 11.4 (37.7 – 93.6) |

**Doppler echocardiographic parameters of the prosthesis at the mitral position**

In the 40 patients studied, the sizes of the Chitra valve prosthesis were 25, 27 and 29 mm. The number of patients with each valve size included in the study is shown in figure 3. 27 size valve was the most commonly implanted and 29 size, the least common. None of the patients had 23 and 31 mm size valves implanted.

Figure 3: **No. of patients with each size of mitral prosthetic valve**




Mean age of patients who had mitral valve replacement (MVR) was 38.8 years. 23 patients (57.5%) were males and 17 patients (42.5%) were females. 95% of the patients who underwent MVR had rheumatic heart disease as the etiological diagnosis.

Echocardiographic evaluation was carried out at a median period of 50.1 months (Range: 3 months to 15 years) after the surgery. An adequate recording of the mitral jet velocity through the prosthetic valve was obtained in all patients. The normal values (mean ± standard deviation with range in parentheses) for the peak velocity, peak and mean gradients, pressure half-time, pressure half-time mitral valve area and the

effective orifice area by continuity equation according to valve size are shown in tables 9 and 10.

**Table 9: Baseline Doppler echocardiographic parameters of Chitra valve in mitral position**

| Valve size, mm | No. of patients | Peak Velocity, $m.sec^{-1}$ | Peak Gradient, mm Hg | Mean Gradient, mm Hg |
|---|---|---|---|---|
| **25** | 13 | 1.74 ± 0.33 (1.17 – 2.30) | 12.6 ± 4.5 (5.5 – 21.0) | 5.09 ± 1.93 (2.1 – 9.2) |
| **27** | 22 | 1.60 ± 0.21 (1.14 – 1.97) | 10.3 ± 2.7 (5.2 – 15.5) | 3.72 ± 1.01 (1.7 – 5.9) |
| **29** | 5 | 1.54 ± 0.38 (1.12 – 2.06) | 10.0 ± 4.9 (5.0 – 17.0) | 3.26 ± 0.62 (2.5 – 4.0) |
| **Total** | 40 | 1.64 ± 0.28 (1.12 – 2.30) | 11.0 ± 3.7 (5.0 – 21.0) | 4.11 ± 1.50 (1.7 – 9.2) |

**Table 10: Doppler echocardiographic parameters of Chitra valve in mitral position – Derived indices**

| Valve size, mm | No. of patients | Pressure half time, msec | Mitral valve area by PHT, $cm^2$ | Effective orifice area, $cm^2$ |
|---|---|---|---|---|
| **25** | 13 | 123 ± 16 (95 – 157) | 1.80 ± 0.25 (1.40 – 2.32) | 1.42 ± .35 (0.85 – 1.91) |
| **27** | 22 | 107 ± 17 (71 – 147) | 2.12 ± 0.36 (1.50 – 3.10) | 1.56 ± .29 (1.04 – 2.26) |
| **29** | 5 | 103 ± 29 (70 – 129) | 2.30 ± 0.71 (1.70 – 3.14) | 1.81 ± .59 (1.15 – 2.41) |
| **Total** | 40 | 112 ± 20 (70 – 157) | 2.04 ± 0.41 (1.40 – 3.14) | 1.55 ± .36 (0.85 – 2.41) |

The peak Doppler gradient ranged from 5 to 21 mm Hg (mean 11.0 mm Hg), and the mean gradient ranged from 1.7 to 9.2 mm Hg (mean 4.1

mm Hg). Pressure half-time ranged from 70 to 157 ms (mean 112 ms) and pressure half-time mitral valve area ranged from 1.40 to 3.14 $cm^2$ (mean 2.04 $cm^2$). Effective orifice area of mitral valve by continuity equation ranged from 0.85 to 2.41 $cm^2$ (mean 1.55 $cm^2$).

Peak velocity and peak gradient did not correlate well with the valve size ($r = -0.26$, $r = -0.27$, respectively; p = Not significant). Mean gradient and Pressure half-time, however, decreased significantly with increase in valve size ($r = -0.45$, $p=0.004$ and $r = -0.39$, $p=0.014$ respectively). Correspondingly, calculated mitral valve area by both pressure half-time and by continuity equation increased significantly with increase in valve size ($r = 0.42$, $p=0.006$ and $r = 0.32$, $p=0.046$ respectively).

There was a substantial overlap in all the values among the various valve sizes. With analysis of variance, only the mean gradient, pressure half-time and mitral valve area by pressure half-time showed significant differences between the three sizes. Effective orifice area by continuity equation did not show a significant difference between 3 groups ($p = 0.124$, One way ANOVA). Mitral valve area calculated by continuity equation tended to be lower than that calculated by pressure half time and this difference was statistically significant ($p < 0.001$, t test).

On Colour Doppler imaging, 36 patients (90%) showed minimal to mild intravalvular mitral regurgitation (MR). MR was grade 1 in 26 patients (65%) and grade 2 in 10 patients (25%). They were equally distributed among the various valve sizes.

# DISCUSSION

This study provides a comprehensive overview of the data on the normal values for Doppler echocardiographic parameters for normally functioning Chitra heart valve prostheses in the aortic and mitral positions obtained in a large series of patients. This study is unique being the first comprehensive study to evaluate all clinically relevant Doppler echocardiographic parameters.

Rosenhek et al[2] had recently published a review of the normal Doppler echocardiographic values of the various prosthetic heart valves based on the available literature. The Doppler parameters obtained with the Chitra heart valve prosthesis in the current study are comparable to those obtained with the different prosthetic valves in common use. Normal Doppler parameters of the commonly used prosthetic valves at the aortic position are shown for comparison in table 11.

The Doppler values of peak velocity, peak gradient and mean gradient obtained with the Chitra valve at the aortic position are similar to those obtained the other tilting disk valves. The values are maximum for the smallest size valve of 19 mm and minimum with the largest size valve of 27 mm. This indicates that the prosthetic valves have inherently some degree of stenosis compared with native valves. The degree of stenosis depends on the valve size, being more for valves of smaller size. Transprosthetic gradients, however, are highly dependent on flow and, to be correctly interpreted, need flow information[2,7].

Calculation of effective orifice area (EOA) by continuity equation represents a measure of valve performance that is independent of flow.

**Table 11: Normal Doppler echocardiographic values for aortic valve prosthesis[2]**

| Valve | Size | Peak gradient (mm Hg) | Mean gradient (mm Hg) | Peak Velocity (m/s) | Effective orifice area ($cm^2$) |
|---|---|---|---|---|---|
| **Bjork-Shiley monostrut (Tilting disc)** | 19 | 46.0 | 26.67 ± 7.87 | 3.3 ± 0.6 | 0.94 ± 0.19 |
| | 21 | 32.41 ± 9.73 | 18.64 ± 6.09 | 2.9 ± 0.4 | |
| | 23 | 26.52 ± 9.67 | 14.5 ± 6.2 | 2.7 ± 0.5 | |
| | 25 | 22.33 ± 7 | 13.3 ± 4.96 | 2.5 ± 0.4 | |
| | 27 | 18.31 ± 8 | 10.41 ± 4.38 | 2.1 ± 0.4 | |
| | 29 | 12 ± 8 | 7.67 ± 4.36 | 1.9 ± 0.2 | |
| **Medtronic-Hall (Tilting disc)** | 20 | 34.37 ± 13.06 | 17.08 ± 5.28 | 2.9 ± 0.4 | 1.21 ± 0.45 |
| | 21 | 26.86 ± 10.54 | 14.1 ± 5.93 | 2.42 ± 0.36 | 1.08 ± 0.17 |
| | 23 | 26.85 ± 8.85 | 13.5 ± 4.79 | 2.43 ± 0.59 | 1.36 ± 0.39 |
| | 25 | 17.13 ± 7.04 | 9.53 ± 4.26 | 2.29 ± 0.5 | 1.9 ± 0.47 |
| | 27 | 18.66 ± 9.71 | 8.66 ± 5.56 | 2.07 ± 0.53 | 1.9 ± 0.16 |
| **St Jude Medical (Bileaflet)** | 19 | 35.17 ± 11.16 | 18.96 ± 6.27 | 2.86 ± 0.48 | 1.01 ± 0.24 |
| | 21 | 28.34 ± 9.94 | 15.82 ± 5.67 | 2.63 ± 0.48 | 1.33 ± 0.32 |
| | 23 | 25.28 ± 7.89 | 13.77 ± 5.33 | 2.57 ± 0.44 | 1.6 ± 0.43 |
| | 25 | 22.57 ± 7.68 | 12.65 ± 5.14 | 2.4 ± 0.45 | 1.93 ± 0.45 |
| | 27 | 19.85 ± 7.55 | 11.18 ± 4.82 | 2.24 ± 0.42 | 2.35 ± 0.59 |
| | 29 | 17.72 ± 6.42 | 9.86 ± 2.9 | 2 ± 0.1 | 2.81 ± 0.57 |
| **Starr-Edwards (Ball-and-cage)** | 21 | 29.0 | | | 1.0 |
| | 22 | 32.6 ± 12.79 | | 4 ± 0 | |
| | 23 | 34.13 ± 10.33 | 21.98 ± 8.8 | 3.5 ± 0.5 | 1.1 |
| | 24 | 31.83 ± 9.01 | 22.09 ± 7.54 | 3.35 ± 0.48 | |
| | 26 | 30.82 ± 6.3 | 19.69 ± 6.05 | 3.18 ± 0.35 | |
| | 27 | 29 ± 9.3 | 18.5 ± 3.7 | | 1.8 |
| | 29 | 29.0 | 16.3 ± 5.5 | | |
| **TTK Chitra valve (Tilting disc)** | 19 | 42.0 ± 12.2 | 21.3 ± 6.2 | 3.21 ± 0.46 | 0.91 ± 0.19 |
| | 21 | 30.8 ± 8.7 | 15.8 ± 5.0 | 2.75 ± 0.39 | 1.13 ± 0.25 |
| | 23 | 24.1 ± 6.3 | 12.0 ± 3.8 | 2.44 ± 0.31 | 1.49 ± 0.27 |
| | 25 | 19.0 ± 6.9 | 9.2 ± 3.6 | 2.14 ± 0.37 | 1.93 ± 0.39 |
| | 27 | 13.0 ± 4.9 | 5.8 ± 1.3 | 1.78 ± 0.33 | 2.15 ± 0.18 |

The available data on EOA shows a high correlation with the valve size. Our data also shows a very good correlation of EOA of the aortic prosthetic valve with the valve size. The mean value for the lowest size valve of 19 mm was just 0.91 $cm^2$ and the lowest measured was 0.75 $cm^2$. In general, prosthetic valve stenosis is suspected when valve area is below 0.8 $cm^2$. However, this value may still be normal for valves of the

smallest size. Thus the data on EOA should be interpreted taking into account the size and type of the valve implanted[7].

Our data shows that Doppler velocity index (DVI) is lower with valves of size 19 and 21 mm. Though it is less dependent on the valve size, our data suggest that DVI may be lower for smallest size valves. When the 19 and 21 mm sizes were excluded, there was no significant correlation between valve size and DVI. A study on the bileaflet St. Jude prosthesis in the aortic position had also shown lower values for smaller size valves (See table 12).

**Table 12: Doppler velocity index of Chitra valve vis a vis St. Jude Medical valves in aortic position** [15]

| Valve size, mm | DVI of St Jude valves | DVI of Chitra valves |
|---|---|---|
| **19** | 0.37 ± 0.07 | 0.36 ± 0.06 |
| **21** | 0.40 ± 0.06 | 0.39 ± 0.08 |
| **23** | 0.37 ± 0.06 | 0.43 ± 0.06 |
| **25** | 0.42 ± 0.08 | 0.43 ± 0.07 |
| **27** | 0.46 ± 0.10 | 0.43 ± 0.04 |
| **29** | 0.49 ± 0.04 | |
| **31** | 0.49 ± 0.19 | |

A DVI less than 0.27 is suspicious for significant valve obstruction[14]. This is consistent with our Doppler derived value as the lowest value recorded in our series of normally functioning prostheses was 0.28. Thus, DVI is useful for diagnosing significant valve stenosis regardless of the size of the valve.

Data on valve resistance determined by Doppler echocardiography as an index of valve function is limited. Our data shows the valve resistance for the whole group to be 88.6 ± 44.4 dynes.s.cm$^{-5}$. There was a significant negative correlation between the valve size and the valve

resistance, the smaller size valves having a higher valve resistance than larger ones. The maximum recorded value of valve resistance was 206.4 dynes.s.cm$^{-5}$ in a 19 mm valve. A previous study on St. Jude valve had suggested a value greater than 280 dynes.s.cm$^{-5}$ as suggestive of significant stenosis[14]. Our data suggest that the upper limit of valve resistance may be lower in Chitra valves compared to the standard values derived for Bileaflet valves.

The performance index of the Chitra valve in aortic position ranged from 55.7% for 19 mm valves to 61.6% for 25 mm valves. This suggests that the hemodynamic potential of the valve is used well. There was no significant correlation between valve size and performance index suggesting that the performance index is similar with different sizes of the Chitra valve.

## Assessment of Chitra valve at the mitral position

In this study, we have obtained data on three sizes of the Chitra heart valve prosthesis at mitral position – 25,27 and 29 mm. Though 23 and 31 mm valves are available, they are infrequently implanted. Published data on normal Doppler parameters of the commonly used prosthetic valves at the mitral position are compared that of the Chitra valve in Table 13.

Data on peak velocity, peak and mean gradients of various prosthetic valves at the mitral position show a poor correlation with the valve size. Our data also shows that peak velocity and peak gradient did not correlate with the valve size. However, there was a significant relationship between the mean gradient and the valve size, though it was not as strong in the case of aortic prosthesis. The possibility of a correlation may have been reduced by the narrow range of valve sizes and

the flow rate, which, in the mitral position, is lower than that in the aortic position and minimizes the increase in gradient that would be caused by reducing orifice area.

**Table 13: Normal Doppler echocardiographic values for mitral valve prosthesis[2]**

| Valve | Size | Peak gradient (mm Hg) | Mean gradient (mm Hg) | Peak Velocity (m/s) | Pressure half-time (ms) | Effective orifice area ($cm^2$) |
|---|---|---|---|---|---|---|
| **Bjork-Shiley (Tilting disc)** | 25 | 12 ± 4 | 6 ± 2 | 1.75 ± 0.38 | 99 ± 27 | 1.72 ± 0.6 |
| | 27 | 10 ± 4 | 5 ± 2 | 1.6 ± 0.49 | 89 ± 28 | 1.81 ± 0.54 |
| | 29 | 7.83 ± 2.93 | 2.83 ± 1.27 | 1.37 ± 0.25 | 79 ± 17 | 2.1 ± 0.43 |
| | 31 | 6 ± 3 | 2 ± 1.9 | 1.41 ± 0.26 | 70 ± 14 | 2.2 ± 0.3 |
| **Omnicarbon (Tilting disc)** | 25 | | 6.05 ± 1.81 | 1.77 ± 0.24 | 102 ± 16 | |
| | 27 | | 4.89 ± 2.05 | 1.69 ± 0.36 | 105 ± 33 | |
| | 29 | | 4.93 ± 2.16 | 1.56 ± 0.27 | 120 ± 40 | |
| | 31 | | 4.18 ± 1.4 | 1.3 ± 0.23 | 134 ± 31 | |
| **St Jude Medical (Bileaflet)** | 25 | | 2.5 ± 1 | 1.34 ± 1.12 | 75 ± 4 | 1.35 ± 0.17 |
| | 27 | 11 ± 4 | 5 ± 1.82 | 1.61 ± 0.29 | 75 ± 10 | 1.67 ± 0.17 |
| | 29 | 10 ± 3 | 4.15 ± 1.8 | 1.57 ± 0.29 | 85 ± 10 | 1.75 ± 0.24 |
| | 31 | 12 ± 6 | 4.46 ± 2.22 | 1.59 ± 0.33 | 74 ± 13 | 2.03 ± 0.32 |
| **Starr-Edwards (Ball-and-cage)** | 26 | | 10.0 | | | 1.4 |
| | 28 | | 7 ± 2.75 | | | 1.9 ± 0.57 |
| | 30 | 12.2 ± 4.6 | 6.99 ± 2.5 | 1.7 ± 0.3 | 125 ± 25 | 1.65 ± 0.4 |
| | 32 | 11.5 ± 4.2 | 5.08 ± 2.5 | 1.7 ± 0.3 | 110 ± 25 | 1.98 ± 0.4 |
| | 34 | | 5.0 | | | 2.6 |
| **TTK Chitra (Tilting disc)** | 25 | 12.6 ± 4.5 | 5.09 ± 1.93 | 1.74 ± 0.33 | 123 ± 16 | 1.42 ± .35 |
| | 27 | 10.3 ± 2.7 | 3.72 ± 1.01 | 1.60 ± 0.21 | 107 ± 17 | 1.56 ± .29 |
| | 29 | 10.0 ± 4.9 | 3.26 ± 0.62 | 1.54 ± 0.38 | 103 ± 29 | 1.81 ± .59) |

There was a significant correlation in our data between the valve size and pressure half-time. Pressure half-time is known to show poor correlation with valve size in many of the published studies. This may be because several factors affect PHT as previously discussed[7]. These confounding variables were minimized in our study by excluding immediate postoperative cases, patients with suspected prosthetic valve dysfunction and absence of significant AR in any patient. This might

have accounted for the better correlation of PHT with valve size in our study. Similarly, mitral valve area calculated by pressure half-time also showed a significant correlation with valve size.

We also calculated the mitral valve area by continuity equation. This showed significant correlation with the valve size, similar to published studies of other valves[7]. The valve area calculated by continuity equation tended to be smaller than that calculated by PHT. Though a study on St. Jude Medical bileaflet valves had shown that derivation of effective orifice area in the mitral position allowed better differentiation among valve sizes than mean gradients and PHT, our study did not support this contention for Chitra valve.

This study assessed the normal parameters assessed for all commonly used sizes of the Chitra heart valve prosthesis. Reference values were prepared in a comprehensive format. Doppler derived echocardiographic parameters that are apparently independent of valve sizes were validated for the first time. The data collected acts as a guide for assessment of prosthetic valve dysfunction in clinical practice especially in a setting where the fluoroscopic assessment is limited as in the case of the Chitra valve. However, the wide range of these normal values suggests that optimal sensitivity and specificity in detecting prosthesis malfunction can be achieved only if a postoperative baseline study is available for comparison.

# CONCLUSIONS

Our Doppler echocardiographic study provides the normal values for the velocities, pressure gradients, effective orifice areas and other Doppler parameters of the Chitra heart valve prosthesis. The Doppler parameters obtained with the Chitra heart valve prosthesis in the current study are comparable to those obtained with the different prosthetic valves in common use. Reference to normal values for gradients and effective orifice areas for different valve sizes may be helpful in identifying patients with prosthetic valve dysfunction by Doppler echocardiography.

# ABBREVIATIONS

| | |
|---|---|
| AR | : Aortic regurgitation |
| AV | : Aortic valve |
| AVR | : Aortic Valve Replacement |
| CSA | : Cross sectional area |
| DVI | : Doppler velocity index |
| EF | : Ejection fraction |
| EOA | : Effective orifice area |
| ET | : Ejection time |
| MR | : Mitral regurgitation |
| MV | : Mitral valve |
| MVR | : Mitral Valve Replacement |
| LA | : Left atrium |
| LVIDD | : Left ventricular internal dimension, diastolic |
| LVIDS | : Left ventricular internal dimension, systolic |
| LVOT | : Left ventricular outflow tract |
| MVA | : Mitral valve area |
| PHT | : Pressure half-time |
| PI | : Performance index |
| SD | : Standard deviation |
| SV | : Stroke volume |
| VTI | : Velocity time integral |

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# PROJECT 2

# Follow-up of patients undergoing bidirectional cavopulmonary anastomosis with special reference to the development of systemic venous collaterals

# INTRODUCTION

Bidirectional Glenn shunt, also called bidirectional superior cavopulmonary anastomosis (BCPA), is used as interim palliation for high-risk Fontan candidates[1]. In some patients, it is also used as definitive palliation or as part of a "one and a half ventricle repair"[2,3]. Many centers now utilize BCPA as a staged palliation in Fontan candidates regardless of the presence or absence of risk factors[4, 5].

BCPA provides a controlled, low pressure source of pulmonary blood flow that has growth potential and relieves the volume load on a functionally univentricular heart[6]. In BCPA physiology, the superior vena caval (SVC) and pulmonary artery systems are in direct continuity and are at equal pressures in the absence of stenoses. The inferior vena cava (IVC) is isobaric with the atria. Pulmonary artery pressure must be higher than that in the pulmonary venous atrium in order to overcome pulmonary vascular resistance. Hence, SVC pressure is elevated over IVC pressure to a degree that is equivalent with the transpulmonary pressure gradient.

Elevation of the SVC pressures above the IVC pressures is postulated to lead to the development of venous collaterals between the superior caval and the inferior caval venous system or right atrium. After a classic unidirectional Glenn anastomosis, the development of venous collaterals can lead to progressive cyanosis by reducing the effective pulmonary blood flow[7]. Systemic venous collaterals that develop after the BCPA may also result in significant cyanosis[8]. Systemic venous collaterals have also been reported to develop after the Fontan procedure[9].

It has also been noted that after BCPA, the pulmonary arteries do not grow as expected with the increase in body surface area.

This study was planned as a follow-up study of patients who underwent BCPA, with particular attention to the development of venous collateral channels between the superior and inferior venacaval systems.

# REVIEW OF LITERATURE

The feasibility of creating a connection between the superior vena cava (SVC) and the pulmonary artery to increase pulmonary blood flow was first explored experimentally by Carlon, Mondini and deMarchi in 1951 and Glenn and Patino in 1954. Glenn WW, a professor of surgery at Yale University, first reported the clinical application of this concept in 1958[10]. In the classic Glenn shunt, an anastomosis is made between the transected distal end of the right pulmonary artery and the side of the SVC, which is ligated distal to the anastomosis. The azygous vein is ligated to prevent decompression of flow from the SVC. Systemic venous return from the head and upper extremities is to the right lung, driven by the pressure gradient from the SVC to the left atrium.

The bidirectional cavopulmonary anastomosis (BCPA) was first performed in 1966 by Haller et al[11]. Here, the transected end of the SVC is anastomosed to the side of the undivided right pulmonary artery, allowing flow to both lung fields. If bilateral vena cavae exist, both can be anastomosed end-to-side to the pulmonary artery. Completion of the Fontan circuit is much easier after a BCPA than the classic Glenn shunt.

The Glenn shunt is palliative and not corrective. Depending on the diagnosis and the surgical era, the Glenn shunt may be the only palliation for the cyanotic patient, one of several palliative surgeries, or a step prior to corrective surgery or the Fontan form of total right heart bypass. Initially, BCPA was the final stage in palliation and was performed in older children. As the Fontan procedure came to be used as a method to separate circulations, BCPA was performed as an intermediate step. Over

time, it was performed as an alternative for patients who were considered high-risk Fontan candidates.

The Glenn shunt does not create volume overload of the ventricle or increased work for the ventricle, unlike systemic-pulmonary artery shunts. It provides venous flow to the lung fields for oxygenation, rather than an arteriovenous mixture. The venous return is under relatively low pressure, unlike systemic-pulmonary artery shunts, and the risk for pulmonary artery distortion and late pulmonary vascular obstructive disease is substantially less.

Long-term efficacy and complications

In a follow-up study from Yale University School of Medicine[12], it was found that the Glenn shunt provides some form of palliation with or without further corrective or palliative procedures in 81% of patients at 10 years and in 50% of patients at 20 years. Only a minority of patients, however, can expect to be free of further operative procedures to augment pulmonary blood flow by 25 years after the Glenn shunt.

Other studies confirm that the palliation achieved by the Glenn shunt alone is adequate for 5-10 years in most patients. Thereafter further intervention is usually necessary.

The causes of worsening oxygenation late after a Glenn shunt include

- Decreased flow to the contralateral lung due to progression of the specific cyanotic pathophysiology
- Intravascular pulmonary thrombosis
- Development of veno-venous collaterals

- Recanalization of the ligated connection between the SVC and the right atrium
- Thrombosis and stricture of the Glenn shunt
- Increased pulmonary vascular resistance, primarily or as a result of increasing blood viscosity due to hypoxemia from the above causes
- Pulmonary arteriovenous malformations
- Pulmonary ventilation-perfusion abnormalities
- Somatic growth with a relative decrease in venous return from the head and upper extremities

**Systemic venous collaterals after BCPA**

Development of venous collaterals between the between the superior caval and the inferior caval venous systems have reported to occur in 12.5% to 43% of patients[13,14,15]. The difference in the incidence may be related to the variation in the criteria used to define them, methods used to identify them and the meticulousness with which they were looked for. One study considered them significant if they were >3 mm diameter[16]. Collateral sizes have also been graded relative to the diameter of brachiocephalic vein or smaller of the 2 SVC when bilateral SVC was present[14].

Development of venous collaterals is attributed to the pressure difference between the high pressure SVC system and the low pressure IVC system after BCPA. The pressure difference may lead to the opening up of the collateral connections SVC system and IVC system to decompress SVC[1,8]. Pre-operative absence of collaterals has been documented in some studies[13,14].

Formation of collateral channels may represent reversal of flow in the azygous or hemiazygous systems, reopening of preexisting channels that disappeared during development of IVC or de novo angiogenesis with opening of a new channel[13,14]. Collaterals have been reported to develop within hours of surgery and this suggests the reopening of preexisting channels[8]. These hypotheses are not mutually exclusive. If the "de novo development" hypothesis is correct, there is a risk that new collaterals may develop once the original collaterals have been occluded. In view of this, any child who becomes significantly more cyanosed at follow up should have repeat angiography to look for new collaterals.

**Factors predicting the development of collaterals**

Magee AG et al[13] reported that development of venous collaterals is associated with the presence of bilateral superior vena cava and postoperative factors including PA distortion, increased SVC pressure, increased PA mean pressure, lower right atrial mean pressure, and increased mean gradient between SVC and RA. With multiple logistic regression analysis, only increased mean gradient between SVC and RA (SVC-IVC gradient) was independently associated with collateral development. This gradient may be increased by the relative reduction in caval or PA cross-sectional area after ligation of one SVC (in the setting of bilateral cavae), the presence of PA hypoplasia or distortion, or obstruction of the anastomosis. An inadequate PA distribution, increased pulmonary resistance, and pulmonary venous obstruction could also contribute to an elevated caval vein pressure. Marked cyanosis may also lead to an increase in transpulmonary gradient by increasing blood viscosity[17]. Another study showed no relationship of collaterals to postoperative hemodynamic data[15].

**Physiological effects of venous collaterals**

Venous collaterals may lead to reduce arterial saturation from either a reduced effective pulmonary blood flow or increased admixture of pulmonary venous return. In many patients, they do not cause significant systemic desaturation, as many of them are small and represented an insignificant right to left shunt at rest. In a patient who is planned for Fontan completion, collaterals draining below diaphragm may be left alone as they are of no physiological consequence after Fontan completion. Large collaterals, however, may result in clinically unacceptable desaturation requiring intervention. Channels draining to the pulmonary veins or common atrium generally require occlusion as they will still cause desaturation even after Fontan completion[13]. Patients who are not candidates for Fontan completion will also require interruption of the collaterals if they cause significant symptoms.

# AIMS OF THE STUDY

1. To study the medium term haemodynamic and angiographic follow-up of patients undergoing bidirectional cavopulmonary anastomosis.

2. To study the frequency, anatomic details and factors associated with the development of systemic venous collateral channels between the superior and inferior venacaval systems after BCPA.

# MATERIAL AND METHODS

## Patients

Patients who underwent a BCPA form the institute and had cardiac catheterization studies prior to and after BCPA were included in the study. Post-BCPA studies were generally scheduled to assess suitability for Fontan completion. The haemodynamic and angiographic data were reviewed from the records and angiographic films were reviewed where available. The time of restudy after BCPA was noted. Patients who did not have a pre-BCPA study, but were studied after BCPC were also included in the study.

## Clinical data

Baseline clinical data of the patients at the time of pre and post BCPA cardiac catheterization were noted from medical records. These included the age, body surface area and the basic cardiac diagnosis. The details of the surgical procedure, including any additional procedures, if any were noted. Followup data from medical records were reviewed and subsequent procedures undergone by patients were noted.

## Haemodynamic study

Arterial and venous access was obtained via femoral route. Jugular vein was also cannulated to access the SVC after BCPA. Arterial saturation was obtained in the basal state. Cardiac index was calculated. Left atrium and pulmonary veins were entered through patent foramen ovale or atrial septal defect where possible.

Mean pressures in right atrium and SVC (after BCPA) were noted. Mean pressure of pulmonary artery (PA) was obtained either directly

(after BCPA) or from pulmonary vein wedge mean pressure (before BCPA). In patients who had bilateral BCPA, the average of mean pressure in left and right PA was considered as the mean PA pressure. Stenosis of BCPA or PA was noted by pullback pressures and from PA to SVC. The difference between post-BCPA pressure in SVC and IVC or RA, the SVC-IVC gradient (SIG) was noted.

**Angiographic study**

Angiographic study included injections into the PA and descending aorta to assess pulmonary anatomy, size and aortopulmonary collaterals. Postoperative studies included injections into SVC to assess the patency of the shunt and to look for systemic venous collaterals.

**Venous collaterals**

Systemic venous collaterals were defined as venous channels from the BCPA circuit to Inferior vena cava (IVC), atrium, or pulmonary veins. Systemic venous collaterals, when present, were characterized according to size, origin from the SVC system, entry into the IVC system and course followed from the SVC to IVC system. The diameters of collateral channels and SVC (both if bilateral) were measured. Magnification was corrected by standardization to the catheter size.

**Anatomy of PA**

Right and left PA diameters were measured proximal to their first branches using catheter diameter for magnification factor. Before BCPA, the largest diameter of PA in either antero-posterior or lateral view was taken and the same projection used after BCPA. Descending aorta (DA) was measured at the level of the diaphragm.

The McGoon's ratio (MR) was calculated by the formula[18]:

**MR = (Right PA + left PA) / DA**

Nakata index (pulmonary artery index) was calculated as previously described[19] by dividing the sum of the cross sectional areas of the right and left PA in $mm^2$ by the body surface area in $m^2$. The change in MR and Nakata index was noted after BCPA. Presence of stenosis of BCPA or PA was noted. The degree of distortion of PA was noted in patients with previous arterial shunts.

**Statistical Analysis**

Analysis was done using SPSS for Windows, version 14.0 (SPSS Inc, Chicago, IL). Population characteristics were expressed as frequencies, ranges and mean ± standard deviation. The paired two-tailed t test for continuous variables and the Chi square test for categoric variables were used to test differences before and after BCPA.

2 groups were formulated: group I with venous collaterals and group II without collaterals. The unpaired t test was used to compare continuous variables between groups I and II. Significant predictors associated with collateral formation were tested in multiple logistic regression analysis. The dependent variable was the presence of collaterals. The unit of analysis was the patient, so patients with small and larger channels were given the same weight. Further, as the number of patients was small, such a subgroup analysis was not done.

Correlations were assessed using Spearman's correlation co-efficients between the presence of collaterals and (1) post-BCPA SVC pressure, (2) SIG and (3) changes in (a) right atrial mean pressure, (b) MR and (c) arterial saturation.

Sensitivity and specificity of various cutoff values of SIG were found to predict the presence of collaterals. Presence of collateral was considered "positive" for this analysis. Sensitivity and specificity were defined as:

Sensitivity (%) = TP x 100 / (TP + FN)

Specificity (%) = TN x 100 / (TN + FP)

Where TP= number of true positives, TN= number of true negatives, FP= number of false positives and FN= number of false negatives.

A p value of $\leq 0.05$ was taken as significant.

# RESULTS

A total of 169 patients underwent BCPA from the Institute during a period of 1995 to 2004. The study population consisted of 42 patients who had a post BCPA cardiac catheterization study. 35 of them had both pre and post BCPA catheterization studies. 7 patients only had a post BCPA catheterization study. Baseline characteristics of the patients included in the study are given in table 1.

**Table 1: Baseline characteristics**

| | | |
|---|---|---|
| Age at pre BCPA study | | 6.3 ± 5.3 yrs (Range: 0.25 – 26) |
| Age at BCPA | | 6.5 ± 5.3 yrs (Range: 0.6 – 26) |
| Age at pre BCPA study | | 8.8 ± 5.0 yrs (Range: 2-27) |
| Sex | Male | 27 (64.3%) |
| | Female | 15 (35.7%) |
| Time after BCPA (months) | | 25.0 ± 21.3 |
| Basic diagnosis | | |
| Single ventricle | | 12 (28.6%) |
| Tricuspid atresia | | 13 (30.9%) |
| Mitral atresia | | 2 (4.8%) |
| Double outlet right vetricle | | 8 (19.0%) |
| Transposition | | 4 (9.5%) |
| Others | | 3 (7.1%) |

Mean age at the time of the post BCPA study was 8.4 ± 5.0 years. Post BCPA study was done after a mean period of 25.0 ± 21.3 months after the surgery. The basic diagnoses of the patients (apart from pulmonary stenosis and with or without ventricular septal defect) were tricuspid atresia in 9 patients, single ventricle in 12 patients, double outlet right ventricle in 8 patients, mitral atresia in 2 patients and transposition of great arteries in 4 patients. One each had the following: ventricular septal defect with pulmonary atresia, tetralogy of Fallot with straddling

tricuspid valve and right ventricular endomyocardial fibrosis in a 26 year old man.

**Surgery**

BCPA was performed under cardiopulmonary bypass. Ten patients (23.8%) with bilateral SVC underwent bilateral BCPA. Two patients with bilateral SVC had a bilateral unidirectional Glenn anastomosis. Four patients had reconstruction of left PA stenosis at origin. The azygous vein was ligated, except in 3 patients, 2 with azygous continuation of IVC and one in whom azygous vein was not identified peroperativley. Atrial septectomy was done in 2 patients to widen the interatrial communication. Two patients had PA banding in neonatal period. 9 patients had a previous Blalock-Taussig shunt that was taken down at the time of BCPA.

**Haemodynamic Data**

Haemodynamic parameters assessed are shown in table 2. Right atrial (RA) and PA mean pressure were normal before BCPA and did not change at the time of post BCPA study. Arterial oxygen saturation significantly improved after BCPA. Data on SVC pressure was not available in the pre-BCPA study. SVC pressure after BCPA was high. There was no significant pressure gradient between SVC and PA. Mean SVC-IVC gradient (SIG) was 4.96 ± 4.92 mm Hg at post BCPA study. Data on cardiac output and pulmonary blood flow was not available for most patients.

**Table 2: Haemodynamic parameters**

| | Pre BCPA | Post BCPA | Difference (Post – Pre) | Significance (t Test) |
|---|---|---|---|---|
| **SVC mean pressure (mm Hg)** | | 11.06 ± 3.98 | | |
| **RA mean pressure (mm Hg)** | 5.18 ± 2.65 | 5.71 ± 2.76 | -0.13 ± 2.96 | p=NS |
| **PA mean pressure (mm Hg)** | 10.47 ± 3.99 | 11.07 ± 3.21 | 1.03 ± 4.01 | p=NS |
| **SVC-IVC gradient (SIG, mm Hg)** | | 4.96 ± 4.92 | | |
| **Arterial oxygen saturation (%)** | 73.4 ± 11.9 | 85.1 ± 7.9 | 13.3 ± 13.5 | p< 0.001 |

**Change in PA size after BCPA**

PA size, McGoon ratio (MR) and Nakata index before and after BCPA are shown in table 3. The difference in these parameters in whom both pre and post BCPA data are available is shown in table 4.

**Table 3: PA size, MR and Nakata index before and after BCPA**

| | Pre BCPA | Post BCPA |
|---|---|---|
| **Right PA size (mm)** | 8.71 ± 2.97 | 10.32 ± 2.84 |
| **Left PA size (mm)** | 7.88 ± 2.22 | 9.07 ± 2.55 |
| **McGoon Ratio** | 1.53 ± 0.27 | 1.69 ± 0.27 |
| **Nakata Index ($mm^2/m^2BSA$)** | 185.7 ± 79.6 | 189.5 ± 69.8 |

**Table 4: Change in PA size, MR and Nakata index before and after BCPA**

| | No. of patients | Change (Post – Pre) | Significance (t test) |
|---|---|---|---|
| **Right PA size (mm)** | 16 | 1.89 ± 1.92 | p=0.001 |
| **Left PA size (mm)** | 16 | 1.83 ± 1.70 | p=0.001 |
| **McGoon Ratio** | 29 | 0.14 ± 0.16 | p<0.001 |
| **Nakata Index ($mm^2/m^2BSA$)** | 15 | 30.7 ± 50.8 | p=0.04 |

There was an increase in Mcgoon ratio from 1.53 ± 0.27 prior to BCPA to 1.69 ± 0.27 after BCPA. The mean increase in Mcgoon ratio was 0.14 ± 0.16. The difference was statistically significant ($p < 0.01$). The increase in McGoon ratio was significantly more in patients who had venous collaterals (0.26 ± 0.18 vs. 0.10 ± 0.13, $p = 0.01$). When patients, who had an increase in McGoon ratio by at least 0.1 were compared to others, they had a significantly higher SIG and were more likely to have venous collaterals. Though, they had a trend towards increase in saturation, this was not statistically significant.

By correlation analysis, increase in Mcgoon ratio had statistically significant correlation with higher SIG and SVC pressure, lower RA pressure and the presence of collaterals. There was a trend towards a higher improvement in arterial saturation, but this was not statistically significant ($p=0.09$). There was also no significant association between increase in MR and presence of antegrade PA flow. On multiple logistic regression analysis, no factor was found to independently predict the increase in McGoon ratio by any degree.

Nakata index also significantly increased after BCPA. However, there was no significant association between any variable and the increase in Nakata index. Increase in SIG showed a trend towards association with increase in Nakata index, but this did not reach statistical significance.

The size of both right and left PA also increased significantly after BCPA. Preferential growth of right PA versus left PA in patients who had undergone right-sided BCPA and bilateral BCPA were analyzed. In patients who had undergone right sided BCPA, RPA size increased by

2.56 ± 2.47 mm, while LPA size increased only by 1.78 ± 2.11 mm. Patients who had undergone bilateral BCPA had increase in RPA size by 2.43 ± 3.57 mm and LPA size 4.03 ± 2.17 mm. However, the differential increase in LPA size did not reach statistical significance.

Major aortopulmonary collaterals (MAPCA) were present in 12 patients (28.6%). 2 patients had MAPCA to both lungs and 10 patients had MAPCA to one lung only. Only one patient had a pulmonary arteriovenous malformation. None of the patients studied had stenosis or obstruction in the BCPA circuit.

**Systemic Venous Collaterals**

Venous collaterals were seen in 16 patients (38%). The size of collaterals was 3.8 ± 3.4 (range 3.1-6.4) mm. Majority of collaterals (n=13, 81.3%) arose from the brachiocephalic vein or between the junction between brachiocephalic vein with the SVC. In the 3 patients in whom the azygous vein was not ligated, it formed the collateral channel. Drainage was mostly to the azygous or hemiazygous veins (n=14). One drained to the internal thoracic vein. One collateral drained via a residual left SVC to the common atrium.

Patients who had collaterals were compared to those who did not have collaterals (Table 5). None of the parameters measured at the pre BCPA study was associated with the development of collaterals. At the post BCPA study, SVC pressure and SVC-IVC gradient (SIG) were higher in the group with collaterals. RA mean pressure was significantly lower in the group with collaterals. PA mean pressure did not show statistical difference between the two groups.

**Table 5: Comparison of patients with collaterals (group I) and without collaterals (group II)**

| Parameter | Group I (n=16) 38% | Group II (n=26) 62% | P value |
|---|---|---|---|
| Male | 9 (56.3%) | 18 (69.2%) | NS |
| Time (months) | 20.9 ± 17.2 | 31.5 ± 25.9 | NS |
| Double SVC | 5 (31.3%) | 5 (19.2%) | NS |
| MAPCA | 4 (26.7%) | 8 (32%) | NS |
| **Pre BCPA parameters** | | | |
| Age (years) | 5.0 ± 4.3 | 7.0 ± 5.8 | NS |
| RA mean (mm Hg) | 4.2 ± 1.9 | 5.7 ± 2.9 | NS |
| PA mean (mm Hg) | 10.8 ± 4.0 | 10.2 ± 4.1 | NS |
| RPA size, mm | 8.6 ± 3.7 | 9.0 ± 3.3 | NS |
| LPA size, mm | 9.0 ± 4.1 | 7.8 ± 2.5 | NS |
| McGoon Ratio | 1.47 ± 0.16 | 1.57 ± 0.32 | NS |
| Nakata index | 156.2 ± 53.8 | 196.2 ± 86.2 | NS |
| Arterial $O_2$ saturation (%) | 75.9 ± 5.6 | 72.4 ± 14.3 | NS |
| **Post BCPA parameters** | | | |
| Age (years) | 8.4 ± 4.1 | 8.6 ± 5.6 | NS |
| SVC mean (mm Hg) | 12.9 ± 4.0 | 9.9 ± 3.6 | 0.03 |
| RA mean (mm Hg) | 4.3 ± 2.3 | 6.7 ± 2.7 | 0.02 |
| PA mean (mm Hg) | 11.4 ± 3.9 | 10.9 ± 2.8 | NS |
| SIG, mm Hg | 9.0 ± 5.2 | 2.6 ± 2.9 | 0.01 |
| RPA size, mm | 10.7 ± 3.3 | 10.9 ± 3.7 | NS |
| LPA size, mm | 9.9 ± 3.4 | 9.3 ± 3.3 | NS |
| McGoon Ratio | 1.73 ± 0.23 | 1.66 ± 0.31 | NS |
| Nakata index | 186.3 ± 50.7 | 191.4 ± 81.1 | NS |
| Arterial $O_2$ saturation (%) | 84.3 ± 10.2 | 85.3 ± 6.3 | NS |
| **Difference between Post and Pre BCPA data** | | | |
| RA mean (mm Hg) | -0.63 ± 2.62 | 0.13 ± 3.18 | NS |
| PA mean (mm Hg) | 0.65 ± 4.20 | 1.39 ± 3.96 | NS |
| RPA size, mm | 1.68 ± 1.04 | 2.82 ± 2.88 | NS |
| LPA size, mm | 2.13 ± 2.66 | 2.22 ± 2.21 | NS |
| McGoon Ratio | 0.26 ± 0.18 | 0.10 ± 0.13 | 0.02 |
| Nakata index | 37.2 ± 66.1 | 28.3 ± 47.6 | NS |
| Arterial $O_2$ saturation (%) | 10.4 ± 8.8 | 15.0 ± 15.5 | NS |

Patients in group I more often had bilateral SVC, but this difference was not statistically significant. Though there was no statistically significant difference in the McGoon ratios between the 2 groups at baseline and after BCPA, increase in McGoon ratio was significantly more in group I patients. The difference in Nakata index was not statistically significant. The arterial oxygen saturations were not significantly different between the 2 groups. Though the difference in saturation after BCPA was more in patients without collaterals, this did not reach statistical significance.

By correlation analysis, the presence of collaterals significantly correlated with post BCPA RA and SVC pressures, SIG, and increase in McGoon ratio after BCPA (table 6). On multiple logistic regression analysis, no factor, pre or post BCPA, independently predicted the development of venous collaterals.

**Table 6: Correlations of presence of collaterals with other variables**

| Parameter | Correlation co-efficient | P value |
|---|---|---|
| **Time after BCPA** | **0.215** | **NS** |
| **Post BCPA RA pressure** | **-0.45** | **0.02** |
| **Difference in RA pressure** | **-0.19** | **NS** |
| **Post BCPA SVC pressure** | **0.338** | **0.05** |
| **SIG** | **0.622** | **0.002** |
| **Post BCPA McGoon ratio** | **0.196** | **NS** |
| **Difference in McGoon** | **0.471** | **0.01** |
| **Post BCPA saturation** | **0.028** | **NS** |
| **Difference in saturation** | **-0.040** | **NS** |

Sensitivity of SIG >5 mm Hg to predict presence of systemic venous collaterals was 75% with a specificity of 70%. When the cutoff

limit was reduced to 3 mm Hg, the sensitivity increased to 87.5%, but specificity decreased to 50%. On multiple logistic regression analysis, no factor, pre or post BCPA, independently predicted a significant increase in SIG.

**Change in arterial oxygen saturation after BCPA**

Saturation increased after BCPA from a basal level of 73.4% ± 11.9% to 85.1% ± 7.9%. The average improvement in saturation was 13.3% ± 13.5% and the difference was statistically significant ($p < 0.01$). Though patients with venous collaterals had a trend towards lower improvement in saturation, this difference was not statistically significant. No factor including difference in McGoon ratio independently predicted the improvement in saturation.

**Management**

Three patients with venous collaterals underwent surgical ligation of the collaterals. One of these patients subsequently underwent Fontan completion, but died post operatively. One patient was restudied, but was found to have persistent venous collaterals and MAPCA. Another patient is awaiting Fontan completion.

Coil occlusion of collateral to common atrium was done in one patient who was subsequently kept on medical follow-up due to unfavourable anatomy.

8 other patients subsequently underwent Fontan completion successfully. One patient had atrial fibrillation immediately after surgery for Fontan completion and developed hypotension. Fontan was taken

down, but he died during re-surgery. In two patients who were taken up for Fontan completion, surgery was not done due to extensive adhesions in one and inadvertent aortic injury in one. None of the patients with venous collaterals had a successful Fontan completion.

Out of the remaining 27 patients, 11 patients are awaiting Fontan completion. It was not done in the remaining due to high PA pressure (n=5) or unfavourable PA anatomy (left PA stenosis, n=5) or other reasons (n=6).

# DISCUSSION

Bidirectional cavopulmonary anastomosis has become established in the management of patients with complex cyanotic congenital heart disease with univentricular physiology either as a bridge to Fontan surgery or as the definitive palliation in certain patients. We studied the follow-up data of of a group of post-BCPA patients who had undergone post BCPA cardiac catheterization study with particular attention to development of systemic venous collaterals.

Mean age at time of surgery in our patients was 6.5 years, which is much older, compared to Western series[13]. Many of the older patients had undergone previous systemic to pulmonary shunt prior to BCPA. Patients had a significant improvement in arterial oxygen saturation after BCPA.

**Venous collaterals**

Our study showed a prevalence of 38% for significant venous collaterals. This similar to the prevalence of 31% in an earlier study by Magee AG et al[13] and 33% in a study by McElhinney DB et al[14].

Most of the collaterals originated form the brachiocephalic vein or its junction with SVC drained via azygous or hemiazygous system to IVC. In patients with unligated azygous veins, decompression into the azygous vein formed the only collateral. Most series mention azygous as the commonest site of initial and IVC as the eventual site of drainage[13,14]. One patient had a collateral draining as a left SVC to coronary sinus. In this patient, a tiny superior intercostal vein became a large left SVC draining to coronary sinus by virtue of reopening of foetal posterior

cardinal system. This system was involved in 3 of 31 collateral channels in one study[14].

In the analysis of factors predicting the development of collaterals after BCPA; a high SVC pressure, low RA pressure and high gradient between SVC and IVC (SIG) were associated with the presence of collaterals. This supports the hypothesis that high SVC and low RA mean pressure with consequent high SIG leads to opening up of venous channels that were not dilated preoperatively. However, multiple logistic regression analysis failed to show an independent association of SIG with development of venous collaterals. This may be due to the small number of patients studied. Presence of bilateral SVC was associated with venous collaterals in one study[13]. In our study, though collaterals were more common in patients with bilateral SVC, this association was not statistically significant.

There was no significant reduction in arterial oxygen saturation in patients who had collaterals in our study. Though the improvement in saturation after BCPA was less in patients with collaterals, this difference was also not statistically significant. In the study by McElhinney DB et al[14], saturation was significantly lower in patients with collaterals.

**Change in PA size after BCPA**

Our study noted a significant, though small, increase in McGoon ratio after BCPA. The increase in McGoon ratio was significantly higher in patients with venous collaterals. An increase in Nakata index was also noted. This is in contradiction to previous studies which has shown a significant decrease in pulmonary artery size after BCPA. Mendelsohn et al reported a significant decrease in the Nakata index of total cross-

sectional pulmonary artery area more than 15 months after BCPA[20]. They noted a decrease of 32% in Nakata index. Significant reduction in the size of central pulmonary arteries has also been reported after Fontan procedure[21,22].

Reddy et al[23] also noted a non-significant decrease in central pulmonary artery indices after BCPA. However, when they analyzed indexed cross-sectional area of the lower lobe branch of the right and left pulmonary arteries, there was no change pre and post BCPA. Lower lobe pulmonary arteries are less likely to be altered surgically with systemic-pulmonary shunts, pulmonary artery repair, and the BCPA itself. They also noted that patients who underwent PA augmentation at the time of BCPA, had significantly greater changes in the right and left pulmonary artery index after BCPA, compared to those who did not undergo pulmonary artery repair. This may be related to the PA repair itself. In our study, the number of patients who underwent PA augmentation was small.

In our study, there was a correlation between a higher SIG and the presence of venous collaterals with increase in McGoon index. A higher SIG may increase the pulmonary blood flow compared to those with lower SIG and this may result in better PA growth. Presence of venous collaterals is expected to decrease pulmonary blood flow. But venous collaterals may just be manifestation of higher SIG, which by itself results in increase in PA size.

Another factor, which led to the increase in McGoon ratio, could be the presence of antegrade pulmonary flow in many patients. Patients who had antegrade pulmonary blood flow had greater increase in

McGoon ratio in our study, but this was not statistically significant. Yoshida M et al[24] noted that the presence of additional pulmonary blood flow in the from of antegrade PA flow or Blalock-Taussig shunt suppresses the decrease in the size of the pulmonary arteries after BCPA. Uemura H et al[25] also reported that that maintenance of forward flow in pulmonary artery protects against regression of pulmonary arterial size.

**Management of venous collaterals**

In our study, three patients underwent surgical ligation of collaterals and one patient underwent coil embolisation. Coil embolization is the preferred method of occluding the venous collaterals in patients who require intervention. Surgical ligation should be reserved for situations in which coil embolization is technically difficult or unsuccessful. In one study, coil embolization of 10 channels was done in 6 patients, with consequent increase in oxygen saturation of 16%[13]. In another series, 2 patients (arterial saturation, 85%) underwent coil occlusion with increase in arterial saturation to > 90%[15].

Management of collaterals depends on their functional consequences and drainage. Collaterals that drain to the atria, coronary sinus or cavoatrial junction create a permanent right to left shunt and should be occluded. Those that drain to the IVC are of no significance following the Fontan procedure and may safely be left unless they are large enough to reduce pulmonary blood flow and cause desaturation. They may require coil occlusion or ligation at the time of Fontan completion[13].

If collateral channels are suspected in patients in whom BCPA is planned as an intermediate or long-term palliation, treatment should be undertaken on the basis of symptoms. When BCPA is a part of a one-and-

a-half ventricle repair, only collateral channels draining to the pulmonary venous atrium need to be occluded[13].

## Limitations of the study

- Study was retrospective in nature
- All patients who underwent BCPA were not included in the study. Only surviving patients who underwent post-BCPA cardiac catheterization were included.
- Pre operative study was not available in all patients
- Selection bias exists as only standard cases for BCPA were selected for the initial surgery - patients with high PA pressure were not taken up
- All patients did not have data on all the parameters studied, as the data obtained varied depending on the preferences of individual operator and change in practices over a long period of study
- Number of patients in the study was small

# CONCLUSIONS

- BCPA provides good interim palliation in patients who are being planned for a staged Fontan surgery or who are otherwise at high risk for Fontan with significant improvement in systemic arterial oxygen saturation.
- Systemic venous collaterals commonly develop after BCPA, but may not lead to significant desaturation in many patients.
- Collaterals need to be actively sought for in post-BCPA patients undergoing cardiac catheterization, especially if SVC-RA gradient is higher than 3mm Hg.
- Management of collaterals needs to be individualized depending on functional consequences and site of drainage.
- There is a suggestion of increase in PA size after BCPA, but this needs to be confirmed.

# ABBREVIATIONS

| | |
|---|---|
| BCPA | : Bidirectional cavopulmonary anastomosis |
| DA | : Descending aorta |
| IVC | : Inferior vena cava |
| MR | : McGoon ratio |
| LPA | : Left pulmonary artery |
| PA | : Pulmonary artery |
| RA | : Right atrium |
| RPA | : Right pulmonary artery |
| SIG | : SVC-IVC gradient |
| SVC | : Superior vena cava |

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