INTRA-OPERATIVE TRANS-ESOPHAGEAL ECHOCARDIOGRAPHIC (TEE) CHARACTERISTICS OF THE CHITRA HEART VALVE PROSTHESIS (CHVP) IMPLANTED AT MITRAL POSITION

THESIS PROJECT

BY

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DECLARATION

I hereby declare that this thesis entitled, "**INTRA-OPERATIVE TRANS-ESOPHAGEAL ECHOCARDIOGRAPHIC (TEE) CHARACTERISTICS OF THE CHITRA HEART VALVE PROSTHESIS (CHVP) IMPLANTED AT MITRAL POSITION**" has been prepared by me under the capable supervision and guidance of

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CERTIFICATE

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Last, but not the least, I express my heartiest gratitude and sincere regards to my parents and family for their support and encouragement throughout my educational career.

DEDICATION

My humble effort I dedicate to my loving mother & father,

Dear mom and dad,

Many things have changed in my life over time, but your constant love, support and encouragement has never failed me. Thank you for backing my every decision, Thanks for being there always……..

Along with all hard working and respected TEACHERS.

INTRODUCTION

"**Nothing was more painful or more cruel than the denial of a surgical procedure to a patient on the ground that a life saving device was beyond his or her means**," wrote Dr. M.S. Valiathan, who headed the Sree Chitra Tirunal Institute for two decades.

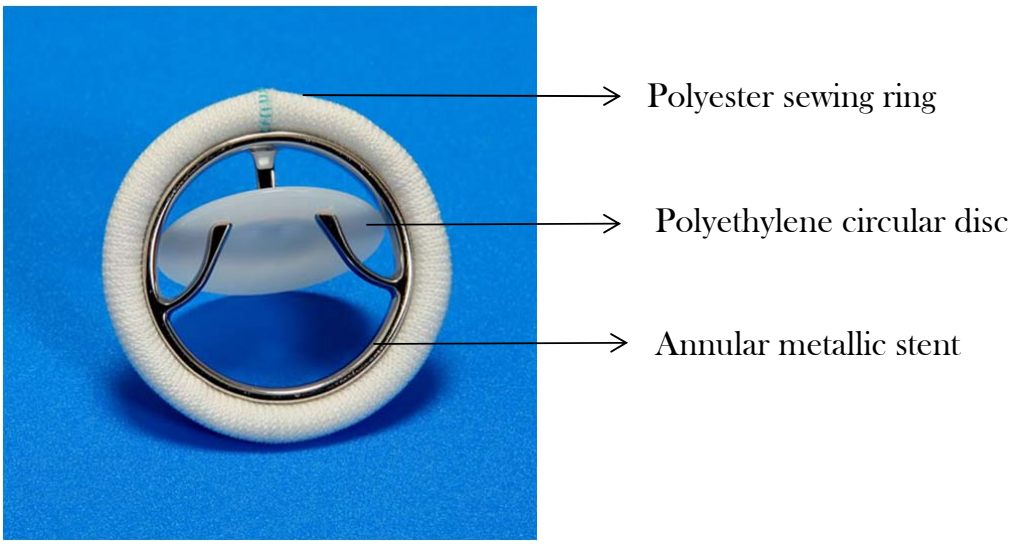
In India, large numbers of people suffer heart valve damage as a result of rheumatic heart disease. This condition is produced when some bacterial throat infections, especially in children, evoke a severe immune response known as rheumatic fever. Without valve replacement patients with rheumatic heart disease are at risk of heart failure and death. The Indian Council of Medical Research has estimated that six out of every 1,000 children between the ages of five and fifteen in the country suffer from rheumatic fever. Over one million children in the country could therefore be at risk of developing valvular disease.

The artificial valve must withstand the stress of opening and closing some 40 million times a year. The materials used for the valve have to be compatible with blood and human tissues. When open, the valve should allow the blood to flow smoothly through. Once closed, the back flow of blood had to be minimal. Characteristics of mechanical valves most commonly implanted in patients with valvular heart disease[1] are depicted in Table 1.

TTK Chitra heart valve prosthesis (CHVP) is a tilting disc artificial heart valve designed and developed by Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) (Figure 1).

It has an ultra-high-molecular-weight polyethylene disc, Haynes-25 alloy (Haynes International Inc., USA) cage, and polyester suture ring. Because of its low cost and proven efficacy, apart from its use in India, the TTK-Chitra valve is also being exported to other countries

Figure 1:- Chitra heart valve prosthesis (CHVP)



Implantation of tilting-disc valves is routinely performed in many centers all over the world. A mechanical tilting-disc valve consists of an annular metallic stent, which is sutured to the native valve annulus with a sewing ring. The occluding mechanism is a circular disc, which is suspended from the annular ring by a single strut. The strut attaches the disc eccentrically so that the back pressure on larger segment of the disc will tend to close the valve. The disc occluder pivots open 60 to 75 degrees. Eccentric disc position produces two orifices of different size and shape; a major orifice and a minor orifice. The complex flow pattern across the valve, wherein 70% of flow passes through major orifice and 30% through the minor orifice, creates impedance to forward flow and a large area of stagnation on the downstream surface of the disc.

Table1:- Characteristics of valve designs[1].

VALVE DESIGN	DESIGN CHARACTERISTICS	DESIGN RELATED DRAWBACKS
Caged ball	• Time tested • Structurally sound built in redundancy in the strut design • Low levels of regurgitation in the closed phase.	• Relatively large valve height • Flow separation downstream of the valve, which might lead to thrombus formation
Tilting disc	• Better hemodynamic characteristics than the caged ball design • Lower valve height and hence suitable for all anatomical locations • Maximum number of valves used till date is of the tilting disc design	• Lower levels of redundancy in the cage strut structure • Lower minor orifice flow can lead to tissue over growth and thrombosis • Strut fracture and related complications have occurred in certain models
Bileaflet	• Uniform flow profiles • Lower levels of structural complications	• Hinge design prone to thrombus formation and valve failure • Leaflet escapement reported in certain models

Transesophageal echocardiography (TEE) is a useful monitoring tool during cardiac surgery. American Society of Anesthesiology and Society of Cardiovascular Anesthesiologists have strongly recommended use of intraoperative TEE in adult patients undergoing valve replacement to confirm and verify the preoperative diagnosis, to detect new or unsuspected pathology, to adjust the anesthetic and surgical plan accordingly, and to assess the results of the surgical intervention[22].

Literature suggests that TEE evaluation of the prosthetic valve performance in post-CPB period has prompted surgeons on many occasions to change the course of surgery[2] . As the use of TEE has become a routine during

valve replacement and as the cardiac surgeons are relying heavily on the post-bypass TEE observations to take surgical decisions, it has become mandatory for an intraoperative echocardiographer to get well acquainted with the normal echo-characteristics of the CHVP. However, there are no intraoperative studies describing characteristic features and flow profile of the CHVP at mitral position.

Prosthetic valve implantation may be associated with complications such as prosthetic valve regurgitation, prosthetic valve stenosis and prosthetic-patient mismatch[3, 4], which must be detected and addressed as early as possible for preventing hemodynamic deterioration. Intraoperative period after weaning the patient from cardiopulmonary bypass (CPB) is the best suited to deal with these complications[2]. However, color Doppler and spectral Doppler features of a prosthetic valve observed during postoperative follow up may not be identical to those noted in the post-CPB period. This is because the intraoperative flow profile is influenced to a large extent by factors like use of inotropes, altered preloading conditions, left ventricular function in the immediate post-CPB period, CPB-induced myocardial edema, and intraoperative myocardial preservation.

Although, various studies substantiating long-term safety and efficacy of CHVP are available[5, 6, 7]; no study had assessed its trans-esophageal echocardiographic characteristics in the immediate post bypass period after implantation. Hence we undertook this study to evaluate intraoperative TEE characteristics of CHVP implanted at mitral position in 45 patients.

REVIEW OF THE LITERATURE

In patients suffering from significant cardiac valvular lesions, an intervention on the valve with repair, valvuloplasty or replacement may be necessary. Although for mitral and tricuspid regurgitant lesions valve repair is frequently performed, valve replacement remains a common choice for many adult patients. The symptoms of prosthetic valve dysfunction may be non-specific. It may be difficult to distinguish on symptomatology alone, the prosthetic valve dysfunction from other conditions such as ventricular dysfunction, pulmonary hypertension and dysfunction of other native valves. Apart from physical examination, other diagnostic modalities are often necessary to evaluate the prosthetic valve function. Echocardiographic Doppler evaluation is the preferred method for non-invasive evaluation of the prosthetic valve function. Most prosthetic valves are associated with trivial or mild trans-prosthetic regurgitation which varies with the design of the particular prosthetic valve.

Transthoracic echocardiographic evaluation of prosthetic valves may be limited by noncardiac tissues shielding the heart, artefact generation, necessity for multiple probe angulations and use of off axis views. Hence incorporation of Transesophageal cardiac ultrasound becomes imperative for assessment of mechanical valves especially in the mitral position.

Transesophageal echocardiography (TEE) is used widely during heart valve replacement surgery. Intraoperative TEE (IOTEE) is of great help to formulate the surgical plan, to assess the cardiac function, and to evaluate surgical outcome. Our study outlines the methodology of IOTEE evaluation of Chitra heart valve prosthesis at mitral position. We noted intraoperative hemodynamic and Doppler characteristics of CHVP and compared them with the Doppler parameters of other commonly used mechanical heart valves. We

also compared the intraoperative Doppler parameters of CHVP with those obtained by TTE in the postoperative period.

Rosenhek et al [8] in their updated review provided an overview of normal Doppler and hemodynamic profiles of prosthetic heart valves in clinical use. In this review they opined that the spectrum of normal values for peak velocities and mean gradients detected across small–sized valves may spread over a wide range which may be attributed to their flow dependence. Hence the normal values for the Doppler data should be defined considering specific flow rates.

Kumar et al [9] studied hemodynamic and Doppler characteristics of Chitra heart valve prosthesis at mitral and aortic position during post-operative follow up. A total of 238 patients were examined for Doppler evaluation of transvalvular gradients and estimation of effective orifice area. In the mitral position, for valve sizes 25, 27 and 29 mm, the mean gradients (in mm Hg) were 5±3, 4±2 and 4±2, and the Effective orifice areas (in cm^2) were 2.8±0.8, 3.1±0.7 and 2.9±0.7 respectively. In the aortic position, for valve sizes 21 and 23 mm, the gradients (in mm Hg) were 10±5 and 9±4, and the Effective orifice areas (in cm^2) were 1.5±0.5 and 1.8±0.3 respectively. They concluded that TTK Chitra valve is hemodynamically comparable to other mechanical valves.

Namboodiri et al [10] studied Doppler echocardiography in 40 patients of CHVP implanted at mitral position. The study objectives were to determine normal values for Doppler parameters of CHVP and to assess whether mitral valve area derived by pressure half time and continuity equation were comparable. All the patients were clinically and hemodynamically stable without any prosthetic valve-related complications such as valve obstruction, infective endocarditis, significant regurgitation, LV dysfunction or any other significant pathology. Valve sizes included in the study were 25, 27 and 29 mm. Mitral valve area was derived by both pressure half time(PHT) and continuity

equation (CE) methods. The peak Doppler gradient ranged from 5 to 21 (mean 11.0) mmHg, and the mean gradient ranged from 1.7 to 9.2 (mean 4.1) mmHg. Mean gradient negatively correlated with an increase in the actual orifice area (AOA) derived from the valve orifice diameter stated by the manufacturer (r= -0.45, P =0.004). Mitral valve area calculated by both PHT and CE increased significantly with an increase in the AOA (r= 0.42, P = 0.007 and r = 0.32, P = 0.046, respectively). Mitral valve area estimated by the CE averaged 1.55 ± 0.36 cm2 and was smaller than that derived by the PHT (mean 2.04 ± 0.41 cm2, range 1.40–3.14 cm2; P = 0.0001; t-test) irrespective of whether the PHT was less than or more than 110 msec. They concluded that CHVP at mitral position is associated with normal hemodynamic and Doppler profile which are comparable with those of other different mechanical valves in common use. Calculated valve areas by PHT and CE methods were similar in selected group of patients. Mitral valve area calculated by both of these methods is smaller than that of the actual orifice area provided by the manufacturers of other valve designs. The data collected should act as reference for the assessment of prosthetic valve dysfunction in clinical practice.

In another study on aortic valve replacement using CHVP, **Namboodiri et al**[11] reported that Doppler parameters were comparable to other commonly used prosthetic valves in the aortic position. Study revealed a wide range of overlap of Doppler derived parameters among valves of different sizes which indicated that these parameters were dependent on flow through the valve. The peak Doppler gradient ranged from 7.7 to 66 mm Hg, and the mean gradient ranged from 3.6 to 37 mm Hg. The Peak velocity as well as peak and mean valve gradients decreased with increasing valve size (r=−0.71, r=−0.69, and r=−0.68 respectively; p value 0.001). DVI was found to be independent of valve size (r=−0.05, p value 0.73). Effective orifice area (EOA) calculated by the

continuity equation ranged from 0.75 to 2.94 cm^2. A significant correlation was observed between EOA and the valve size (r=0.81, p value 0.001).

A common concern raised by perioperative physicians regarding TEE is whether it would be sensitive and accurate enough to provide information on the functioning of prosthetic valves or whether additional TTE and cardiac catheterization studies would be necessary to identify the valve dysfunction.

Khandheria et al [12] surveyed 1494 patients of prosthetic mitral valve with the objective of determining sensitivity and predictive accuracy of TEE, comparing the TEE-data with that obtained on TTE and cardiac catheterization. The TEE findings were abnormal in 48% of patients who were reported to have normal study on transthoracic examination. The overall sensitivity of transesophageal echocardiography was 96%. Authors concluded that TEE is superior to transthoracic echocardiography in evaluation of mitral valve prosthesis and incorporation of TEE is an essential part of comprehensive examination in patients with suspected mitral valve dysfunction. Authors also suggested that cardiac catheterization is not necessary before surgery if TEE satisfactorily demonstrates valve abnormality.

Alton et al[13] analyzed 37 patients implanted with Starr-Edwards prosthetic heart valve. The objectives of the study were to define normal appearance of Starr-Edwards prosthetic heart valve by echocardiography and to compare the utility of transthoracic and Trans esophageal echocardiography in detecting the valve abnormality. They found that TEE is superior to TTE in detection of thrombus, severity of mitral regurgitation and vegetations of infective endocarditis or abscess formation or both. Authors concluded that TEE is an important investigation tool which greatly complements the transthoracic echocardiography in detection of valvular dysfunction and it is also of great

value in detection of mitral regurgitation when surface echocardiography becomes inadequate.

The normal functioning of prosthetic mitral valve is assessed using 2D, M-mode, color Doppler and spectral Doppler methods. Assessment of trans-mitral flow using spectral Doppler remains an invaluable component of comprehensive prosthetic valve examination.

Weinstein et al[14] compared Doppler velocity characteristics of St. Jude medical valves implanted at aortic and mitral position with that of native valves. Their study outcomes suggested that although morphological spectra of echocardiographic Doppler profile were similar higher peak and mean velocities through the prosthetic valves were apparent. Doppler studies of prosthetic valves helped in identifying four cases of paravalvular leaks which were not detected by M mode and two dimensional studies. Hence they concluded that Doppler echocardiography is helpful in providing quantitative information about transprosthetic flow profiles in patients with St. Jude prosthetic valves and is useful for detection of prosthetic dysfunction.

Spectral Doppler evaluation of prosthetic valves provide information on different flow characteristics including peak velocity, mean pressure gradients, effective orifice area of the valve, stroke volume, doppler velocity index (DVI) and pressure half time. Authors of different studies differ in their opinion regarding which Doppler parameters provide accurate information on functioning of prosthetic valves and which among them are relevant in the perioperative period.

Drissa et al [15] evaluated different bileaflet prosthetic valves at mitral position in 90 cases (Saint Jude in 65 cases, Jyros 8 cases, Carbomédics 7 cases, Sorin Bicarbon 7 cases, Edwards Duromédics 2 cases). They observed maximum trans-prosthetic gradient of 15.7 ± 5.06 mm Hg , the mean trans-

prosthetic gradient of 5.6 mm Hg ± 1.07 and the mean prosthetic functional area of 2.37 cm2 ± 0.44 (1.75 cm2 to 3.60 cm2). They concluded that peak gradient, mean gradient and functional mitral valve area may be variable among different sizes and types of prosthetic valves. For prosthetic valves larger than 25 mm, the mean gradient and functional valve area may not depend on size of the valve.

Badano et al [16] prospectively compared Doppler flow characteristics of normally functioning Bicarbon bileaflet prosthetic valves and St. Jude medical valves at mitral and aortic position. Between valve sizes of 27 mm and 31 mm, they did not observe any difference in the transprosthetic gradients, pressure half time or effective orifice area. In aortic valve prosthesis, they noted that there was significant decrease in transprosthetic gradients and increase in effective orifice areas as the size of the valve prosthesis increased. Statistically, the effective orifice area estimated by continuity equation was found to have better correlation with the sizes of the prosthetic valves than the peak and mean gradients alone.

Panidis et al [17] Evaluated 136 normally functioning and 17 malfunctioning valve prosthesis using Doppler echocardiography. Among normally functioning prosthesis, St. Jude, Bjork Shiley, Beall, Starr Edwards and tissue valve were 82, 18, 13, 7 and 7 in number respectively. The malfunctioning valves consisted of St. Jude (4), Bjork-Shiley (2), Beall (4) and tissue valves (7). Study results showed that St. Jude valve had lower peak and mean gradient values and larger orifice area than other prosthetic valves. Mild degree of mitral regurgitation was detected in all the implanted valves which was clinically insignificant. Doppler echocardiography accurately identified malfunctioning prosthetic valve in all patients, except two who received Beall valve. Authors concluded that Doppler echocardiography is a useful method for

the detection of malfunctioning prosthetic valve and St. Jude prosthetic valve provided optimal hemodynamics and valve function compared to other valves.

Over the last five decades various types of prosthetic valves are in clinical use and newer variety of valves being developed by many manufacturers. Although there is no ideal prosthetic valve, the research and development in medical and engineering field aims at improving durability, hemodynamic function and reducing the associated complications. All prosthetic valve types can be roughly classified as either mechanical or biological. Recently, percutaneous valves are being developed mainly at aortic and pulmonary valve diseases. In current clinical practice bileaflet mechanical valves are the most frequently implanted. They vary in design, material used for construction, leaflet opening angle, size and shape of the housing and the design of the sewing ring.

The 2009 **American Society of Echocardiography published guidelines**[18,19] and standards for the evaluation of prosthetic heart valve with Doppler ultrasound states that almost all prosthetic valves are obstructive in nature when compared with normally functioning native valves. The size and type of the valve implanted determines the degree of obstruction. Thus it might be difficult to characterize obstructive nature of prosthetic valves from mild obstruction associated with pathological changes and patient prosthetic mismatch. The pattern of physiological regurgitation associated with the prosthetic valve also varies with the design of the valve. The guideline also recommends use of transesophageal echocardiography for examination of prosthetic valve structure and associated complications including regurgitation particularly in cases of prosthetic valve implanted at mitral position. A complete comprehensive evaluation of a prosthetic valve should include obtaining relevant clinical information, with reference to previous Doppler and

echocardiography studies, especially in case of malfunctioning valve prosthesis (Refer Table 2).

ECHOCARDIOGRAPHIC IMAGING

For visualization of the occluder mechanism and movement of the leaflets, sometimes it is necessary to magnify the real time images using zoom mode. Manipulation of the imaging plane may be needed until the occluder mechanism of a tilting disc valve is visualized. In case of mitral valve prosthesis, preservation of leaflets can cause increased movement of a normally functioning prosthesis; it can be differentiated from valve dehiscence by 2D examination and by the absence of mitral regurgitation in color Doppler study.

Table 2: Essential parameters in the comprehensive evaluation of prosthetic valve function [18]

1) Clinical information	• Date of valve replacement • Type and size of the prosthetic valve • Height, weight, body surface area Symptoms and related clinical findings • Blood pressure and heart rate
2) Imaging of the valve	• Motion of leaflets or occluder • Presence of calcification on the leaflets or abnormal echo densities on the various components of the prosthesis • Valve sewing ring integrity and motion
3) Doppler echocardiography of the valve	• Contour of the jet velocity signal • Peak velocity and gradient, Mean pressure gradient, VTI of the jet, DVI, Pressure half-time in MV and TV, Effective orifice area • Presence, location, and severity of regurgitation
4) Other echocardiographic data	• LV and RV size, function, and hypertrophy • LA and right atrial size

	• Concomitant valvular disease • Estimation of pulmonary artery pressure
5) Previous postoperative studies, when available	• Comparison of above parameters is particularly helpful in suspected prosthetic valvular dysfunction

DOPPLER ECHOCARDIOGRAPHY

Doppler evaluation consists of pulsed wave (PW), continuous wave (CW) and color Doppler in multiple views. Probe manipulation may be required to align the Doppler beam at minimal angulation with the flow. The technique for evaluation and obtaining transprosthetic flow velocities are same as those used for evaluating native valves. The simplified Bernoulli equation is utilized in calculating pressure gradients across valves. In case of smaller valves and high cardiac output states the pressure gradients are overestimated. Effective orifice area is calculated with the help of continuity equation. Many studies[20, 21] have proven that effective orifice area is a better parameter for evaluation of prosthetic valves and it correlates well with the size of the prosthesis.

Bileaflet prosthetic valves exhibit pressure recovery phenomenon at the region of central orifice giving rise to high velocity jet and pressure drop which is limited to the small central orifice. This localized pressure drop is recovered once the flow from the two lateral orifices joins with the central flow. Patient prosthetic mismatch (PPM) occurs when effective orifice area is too small for the patient size, resulting in high transprosthetic velocities and gradients. PPM (patient prosthetic mismatch) has been related to reduced survival, deterioration of functional class, reduced regression of LV and cardiac events. For prosthesis at mitral position indexed orifice area should be more than 1.2 cm^2/m^2 to avoid PPM[18]. Calculation of valve area using PHT formula (220/PHT) is only valid for smaller valve sizes with EOA less than 1.5 cm^2 and in cases of moderate to severe stenosis. For larger valve areas pressure half time reflects LA and LV

compliance, loading conditions and it has no significant relation to the valve area.

Doppler measurements should be obtained in sinus rhythm at a 100 mm/sec sweep speed over 1 to 3 cardiac cycles. However, in atrial fibrillation it should be performed during the periods of sinus rhythm at normal heart rates (65- 85 beats/min) or averaging of 5 to 15 beats has also been suggested but it may not give reliable results because of varying R-R interval. For the calculation of DVI and EOA by continuity equation where different cardiac cycles are used for measurements, matching the R-R interval of the respective cardiac cycles is advised.

PHYSIOLOGIC VERSUS PATHOLOGICAL PROSTHETIC VALVE REGURGITATION [18]

A mild degree of regurgitation jets are common in all mechanical valves termed "physiologic regurgitation jets". Two types have been described,

1) Closing volume - caused by occluder disc mechanism

2) Washing jets – seen where the leaflets meets the housing at hinge points, they are located inside the sewing ring and these washing jets are thought to prevent formation of thrombi at sites of stasis within the housing.

Appearance and number of physiologic regurgitation jets vary with the type of the prosthetic valve. They are located within the sewing ring, usually low in velocity, homogeneous in color, less than 5 cm in length and regurgitant fraction rarely exceeds 15%.

Pathological regurgitation can be central or paravalvular; it can be seen with both the mechanical and biological valve types. Paravalvular regurgitation is seen outside the sewing ring. Mild degree of central regurgitation is commonly seen with biological valves. Prevalence of paravalvular regurgitation

jets is 5 to 20 % immediately following implantation and majority of these leaks have a benign course without causing hemodynamic deterioration and are clinically insignificant. Precise localization of paravalvular regurgitation jets requires multiplane TEE examination and use of off axis views.

EXAMINATION OF THE PROSTHETIC VALVE IN INTRAOPERATIVE PERIOD [18]

In the early 1970s intraoperative echocardiography was added as a diagnostic tool for assessment of valve function in the immediate perioperative period. Since its introduction, TEE has become an indispensable tool for the intraoperative detection of malfunctioning prosthetic valve and suboptimal surgical results. For valve replacement surgery, TEE is strongly recommended by current ACC and AHA practice guidelines. Intraoperative period presents unique challenges for prosthetic valve assessment. Factors like mechanical ventilation, use of inotropic and chronotropic medications, varying loading conditions and electrical pacing of the heart must be taken into consideration during assessment of prosthetic valve function. Intraoperative echocardiography may also help in detecting abnormalities of other heart valves which might need surgical attention. In cases where TEE is contraindicated prosthetic valves can also be assessed using epiaortic or epicardial ultrasound. Table 3 displays Doppler parameters of prosthetic mitral valve function.

Table 3:- Doppler parameters of prosthetic mitral valve function [18]

	Normal	Possible stenosis	Significant stenosis
Peak velocity (m/sec)	< 1.9	1.9 to 2.5	>2.5
Mean gradient (mm Hg)	< 5	6 to 10	>10
VTI_{PrMV}/VTI_{LVOT} (DVI)	< 2.2	2.2 to 2.5	>2.5
EOA by CE (cm^2)	>2	1 to 2	< 1
PHT (m sec)	< 130	130 to 200	>200

AIMS AND OBJECTIVES

Hypothesis

We hypothesize that after weaning the patient from cardiopulmonary bypass; transesophageal echocardiographic examination of a Chitra heart valve prosthesis implanted at mitral position reveals findings of a normally functioning prosthesis.

Aims and objectives

To evaluate the CHVP implanted at mitral position as per the ASE guidelines pertaining to the evaluation of a prosthetic valve.

1. To define the characteristic features and flow profile of CHVP on 2D and color Doppler examination.
2. To study the Doppler parameters of a normally functioning CHVP.
3. To compare Doppler parameters among different sizes of CHVP.
4. To compare the intraoperative transesophageal echocardiographic (IO-TEE) Doppler profile with postoperative transthoracic echocardiographic (TTE) Doppler profile.
5. To compare the Doppler profile of CHVP in our study with the published data of other mechanical valve prosthesis in common use.

MATERIALS AND METHODS

This prospective, observational study was conducted in a tertiary referral center, university-level hospital, which yearly performs 1500 cardiac surgeries. This study was approved by the technical advisory committee (TAC) and Institutional Ethics Committee (IEC).

[IEC registration no - ECR/189/Inst /KL/2013]

Total of 45 consecutive patients fulfilling the inclusion criteria were recruited as study subjects. Patients were consulted on previous day during our preoperative rounds. Patients were educated about the study in the presence of a witness. The witness was allowed to counter question the patient whether he/ she really understood the proposed study, of which he/ she would be a part. An informed consent form was then signed by patient or relative of the patient as per the Institute protocol.

Inclusion criteria:

- Adult patients subjected to elective mitral valve replacement using CHVP without repair or replacement of other valves.

Exclusion criteria:

- Patients below 18 years of age and > 70 years of age.
- Left ventricular ejection fraction < 40%.
- Aortic regurgitation ≥ mild.
- Aortic stenosis ≥ mild.
- Patients requiring re-institution of CPB after successful weaning from CPB, due to inadequate surgical results like severe prosthetic mitral valve regurgitation, inadequate motion of occluder disc etc.
- Concomitant repair or replacement of other valves.

- Re-do mitral valve replacement.
- Emergency surgeries.
- Patient refusing to participate in the project.
- Contraindication to TEE probe placement like esophageal pathologies, gastric ulcer, etc.
- Inability to image the prosthesis satisfactorily to interpret the results.

STUDY PROTOCOL

An adult-size TEE probe was inserted after induction of anesthesia and echocardiographic evaluation of the heart was done using Philips EnVisor HD ultrasound machine or IE 33 Philips medical systems, Bothell, WA, USA. Images of preoperative echocardiography and data on hemodynamic parameters were recorded (Velocity profile, peak and mean pressure gradients, mitral valve area by PHT and CE). Cardiac chambers were evaluated for presence of any thrombi or clots, mitral valve examined for the presence of any calcification of the leaflets, annulus or subvalvular apparatus. Other valves were also examined to rule out any concomitant disease. Cardiopulmonary bypass was established after adequate heparinization and aorta cross-clamped. Antegrade blood cardioplegia delivered into the aortic root to achieve electromechanical quiescence, diseased mitral valve was replaced with appropriately sized Chitra heart valve prosthesis (CHVP). Patient was weaned from CPB after completion of surgery and adequate re-warming. Inotropic infusions were commenced to maintain stable hemodynamics in the post bypass period. TEE examination of the heart and CHVP was done before and after administration of protamine. Echo data was recorded in the hard disc of the Echo machine, which was retrieved on CDs later.

Valve was again examined in the post-operative period using transthoracic echocardiography, 48 hours after surgery, when hemodynamic

condition was stable and inotropes were weaned off. Peak velocity, mean gradient, pressure half time and valve area by PHT as well as continuity equation were noted.

EVALUATION OF CHVP AT MITRAL POSITION.

Two dimensional and color Doppler evaluation.

Two dimensional echocardiographic cardiac examination was performed using TEE for obtaining information related to the function of the prosthetic valve, free leaflet motion, and angle of opening of CHVP. Two-dimensional and Color flow Doppler imaging was performed to assess the degree of regurgitation, and the presence of any paravalvular leaks before as well as after the administration of protamine (Refer to Figure 6 & 7). Doppler echocardiographic studies were performed later and valve hemodynamic parameters were derived.

Doppler evaluation of mitral prostheses

TEE view in which the Doppler beam was aligned parallel to the flow of the prosthetic valve was selected for Doppler evaluation. The following parameters were assessed to evaluate the prosthetic valve in the mitral position; peak velocity, mean gradient, MVA derived by pressure half time, EOA by continuity equation and DVI. Color Doppler was used to identify the major aperture in ME 4C view and Doppler data was recorded using Continuous wave Doppler. From the prosthetic inflow VTI, maximal velocity, peak gradient, and mean gradient were measured. The PHT was measured from diastolic flow envelope using inbuilt software. Mitral valve area was derived using the equation, MVA=220/PHT.

Mitral valve area using the CE was derived as stroke volume through the LVOT divided by the velocity–time integral (VTI) of the mitral inflow. In

patients with atrial fibrillation cardiac cycles should match while deriving either EOA or the DVI (VTI_{PrMV}/VTI_{LVOT} ratio). Similar Doppler parameters were obtained in the post-operative period using the apical views and the values were compared with the intraoperatively obtained parameters. The actual (geometric) orifice area (AOA) was calculated from the valve orifice diameter (VOD) provided by the manufacturer as $\mathbf{AOA=0.785 \times VOD^2}$**.**

The mean gradients were compared between the valves placed in anatomical and anti-anatomical positions using above criteria. In anatomical placement and anti-anatomical placement, the larger aperture was oriented posteriorly and anteriorly respectively. (Refer to Figure 8)

STATISTICAL ANALYSIS

The statistical mean and standard deviation were derived for the continuous variables. The prosthetic valves were grouped into five depending upon their size. Bivariate co-relation analysis using Pearson's co-efficient was used to evaluate co-relation between a parameter and size of the mitral valve prosthesis. Doppler parameters in post-bypass period using IO-TEE were compared with TTE parameters using Paired t- test and a P-value of less than 0.05 considered significant. Comparison CHVP Doppler parameters with other mechanical valves was done using independent t-test with unequal variances. Open Source Epidemiologic Statistics software available online at http://www.openepi.com was used for calculation of P-value with independent t-test where sample size, mean and SD data for each size of the valve studied were entered.

All statistical analysis was performed using **windows SPSS version 16 and Microsoft excel version 2010.**

RESULTS AND OBSERVATIONS

Study included 45 patients who underwent mitral valve replacement, without repair or replacement of other heart valves. Various sizes of replaced valves were 23,25,27,29 and 31 mm in 9, 16, 9, 6 and 5 number of patients respectively.

All prosthetic valves were assessed for normal leaflet motion and color Doppler examination, along with Doppler evaluation for peak velocities, mean gradient and mitral valve area estimation by pressure half time and continuity equation. Examination was carried out in the immediate post-bypass period as well as 48 hours after the surgery.

On preoperative TTE examination, 89% and 11% of the patients were diagnosed with rheumatic heart disease and mitral valve prolapse respectively. About 74 % of them were in sinus rhythm on presentation and remaining had irregular cardiac rhythm. Demographic characteristics and preoperative echo findings listed in table 4 and Table 5 shows distribution of different sizes of valves implanted.

Table 4:- Demography and pre-CPB TEE observations

Total number of patients		*(n = 45)*
Sex	Male	21 (46.6 %)
	Female	24 (53.33 %)
NYHA class	Class II	36 (80 %)
	Class III	9 (20 %)
Etiology /diagnosis		
Rheumatic heart disease		
	Predominant MS	24 (53.33 %)
	Predominant MR	16 (35.55 %)
Mitral valve prolapse		5 (11.11 %)

Rhythm	**Sinus rhythm**	33 (73.33 %)
	Atrial fibrillation	12 (26.66 %)
Age (years)		45.47 ± 10.78
Height (Cms)		157.26 ± 8.58
Weight (Kgs)		54.65 ± 9.99
Body surface area (BSA)		1.54 ± 0.17
Echocardiographic parameters (intraoperative TEE)	LVID systolic (mm)	51.53 ± 5.19
	LVID diastolic (mm)	32.49 ± 6.67
	Ejection fraction (%)	61.93 ± 6.51
	Left atrial size	56.80 ± 9.99
	INFERIOR WALL systolic (mm)	11.13 ± 1.24
	SEPTAL WALL systolic (mm)	11.09 ± 1.28

Table 4:- shows that the study subjects were distributed equally between genders. Majority of them belonged to NYHA class II (80%) and remaining (20 %) to NYHA class III. About 40 patients (88.88%) had rheumatic heart disease, 24 (53.33 %) and 16 (35.55 %) of them diagnosed with predominant mitral stenosis and mitral regurgitation respectively. Almost a quarter of them were in atrial fibrillation. Intra-operative TEE demonstrated good LV function as seen in the table, left atrium was enlarged in majority of the patients with mean diameter of 56.80 ± 9.99 mm.

Abbreviations:- NYHA- New York Heart Association, MS- mitral stenosis, MR- mitral regurgitation, LVID- left ventricular internal diameter.

Table 5:- Distribution of valve sizes.

Valve size	Number of patients	Percentage
23	9	20 %
25	16	35.55 %
27	9	20 %
29	6	13.33 %
31	5	11.11 %
Total number	45	

Table 5:- shows distribution of various sizes of CHVP implanted at mitral position. Out of 45 patients, 16 (35.55%) received 25 mm valves and only 5 patients (11.11%) received size 31 mm. Other valves included 23 mm (20%), 27 mm (20%) and 29 mm (13.33%). Abbreviations: - CHVP- Chitra heart valve prosthesis.

Although, Peak transmittal velocity showed significant negative correlation with size of the prosthesis (R= -0.974), mean velocity did not correlate well with the prosthesis size (R= - 0.013). Mean gradient across the prosthesis showed good correlation with the valve size (R = -0.879), whereas peak gradient had a poor correlation (R = -0.351). Mitral valve area calculated by both pressure half time and continuity equation increased significantly with an increase in the size of the prosthesis (R = 0.597, R= 0.986 respectively). (Refer to Table 6 & Figure 2)

Figure 2:- Doppler parameters of various sizes of CHVP studied.

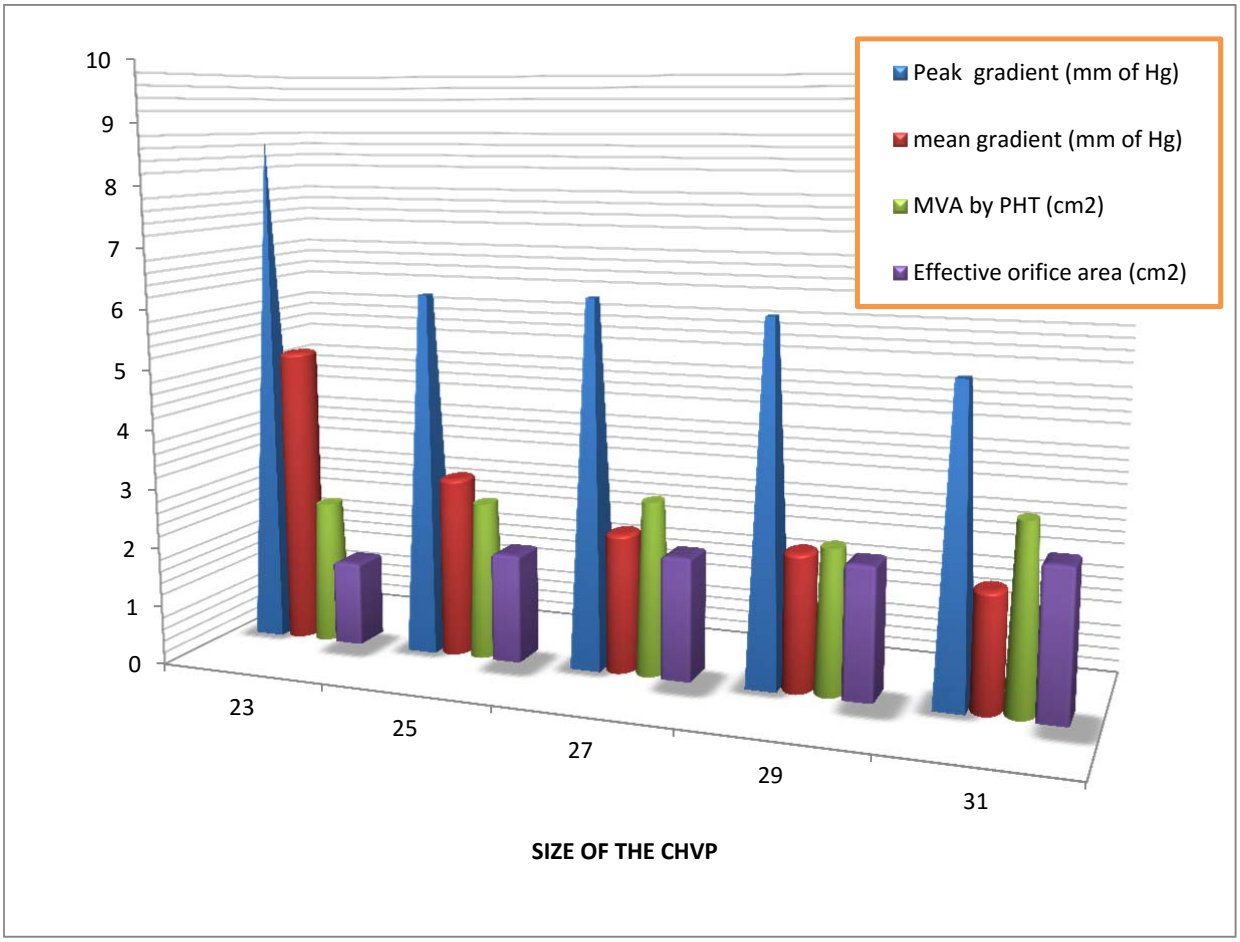


Figure 2:– displays Doppler parameter values (Y-axis) obtained for various sizes of valves studied (X-axis). Effective orifice area by continuity equation and pressure half time increased significantly with increase in valve size. Peak gradient and mean gradient were in higher normal range for smaller sized valves (23 mm).

Table 6:- Doppler parameters for various sizes of Chitra heart valve at mitral position in the post-CPB period.

	23 mm	25 mm	27 mm	29 mm	31 mm	#Correlation (R)
Peak diastolic velocity (m/sec)	1.67 ± 0.22	1.45 ± 0.16	1.26 ± 0.12	1.22 ± 0.14	1.07 ± 0.14	-0.974
Peak gradient (mm of Hg)	8.74 ± 1.56	6.14 ± 2.23	6.21 ± 1.57	6.02 ± 2.08	5.21 ± 2.05	-0.351
Mean diastolic velocity (m/sec)	0.87 ± 0.18	0.76 ± 0.14	0.76 ± 0.09	0.85 ± 0.22	0.82 ± 0.20	-0.013
Mean gradient (mm of Hg)	5.06 ± 1.67	3.06 ± 0.81	2.36 ± 0.25	2.30 ± 0.25	1.99 ± 0.44	-0.879
Heart rate	80.66 ±4.90	81.81 ± 11.29	84.67 ± 12.4	77.67 ± 3.67	80.40 ± 5.90	
PHT (m sec)	92.55 ± 11.41	85.04 ± 13.16	76.44 ± 8.92	92.67 ± 12.42	71.86 ± 9.85	-0.568
MVA by PHT (cm^2)	2.41 ± 0.28	2.65 ± 0.42	2.91 ± 0.32	2.41 ± 0.33	3.11 ± 0.46	0.597
DVI	1.90 ± 0.34	1.31 ± 0.21	1.20 ± 0.27	1.32 ± 0.15	1.18 ± 0.07	-0.270
Effective orifice area by CE (cm^2)	1.44 ± 0.11	1.86 ± 0.17	2.09 ± 0.20	2.24 ± 0.12	2.52 ± 0.30	0.986

Table 6:- peak velocity displayed significant negative correlation with the size of the valve prosthesis implanted; peak gradient did not have any significant correlation. MVA derived by PHT and CE had significant positive correlation with size of the prosthesis. DVI did not seem to correlate with the size of the valve prosthesis. Mean gradient decreased with the increase in size of the valve prosthesis. Heart rate between the groups did not vary significantly. PHT did not exceed 130 msec in any of the patients. [Abbreviations:- DVI- Doppler velocity index, MVA- mitral valve area, PHT –pressure half time, CE- continuity equation]

 # Pearson correlation co-efficient [R]:- positive value denotes direct correlation whereas negative value signifies inverse correlation. (0 to 0.35- poor/weak correlation, 0.36 to 0.55 good correlation, > 0.55 significant correlation).

Correlation of these Doppler parameters with the size of the valve prosthesis is shown in figure 3, figure 4 and figure 5. Mitral valve area by pressure half time

showed linear correlation with mitral valve area by continuity equation (R =0.658). MVA calculated by PHT was higher than that by continuity equation and the difference was statistically significant (P =0.0002, t- test).

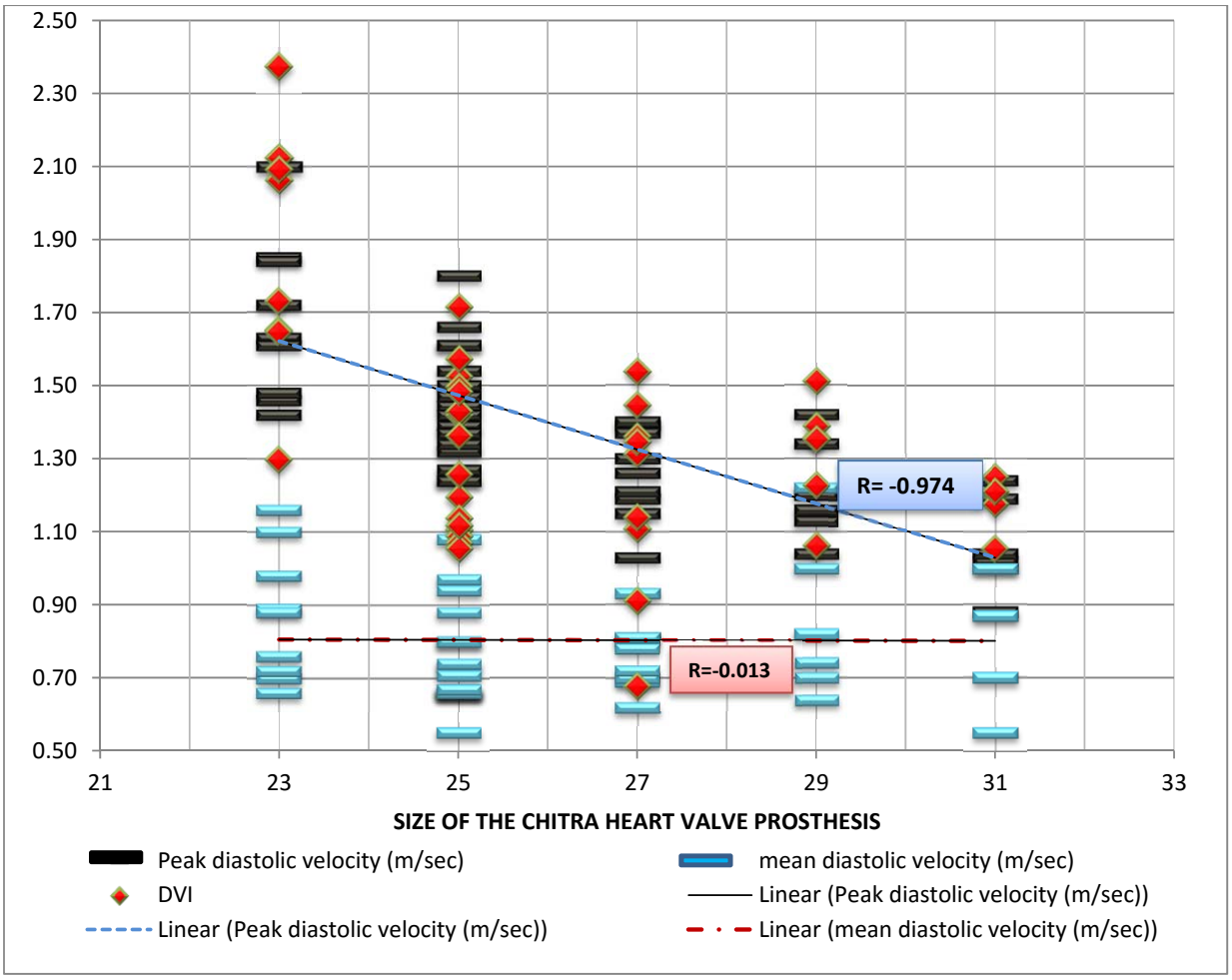
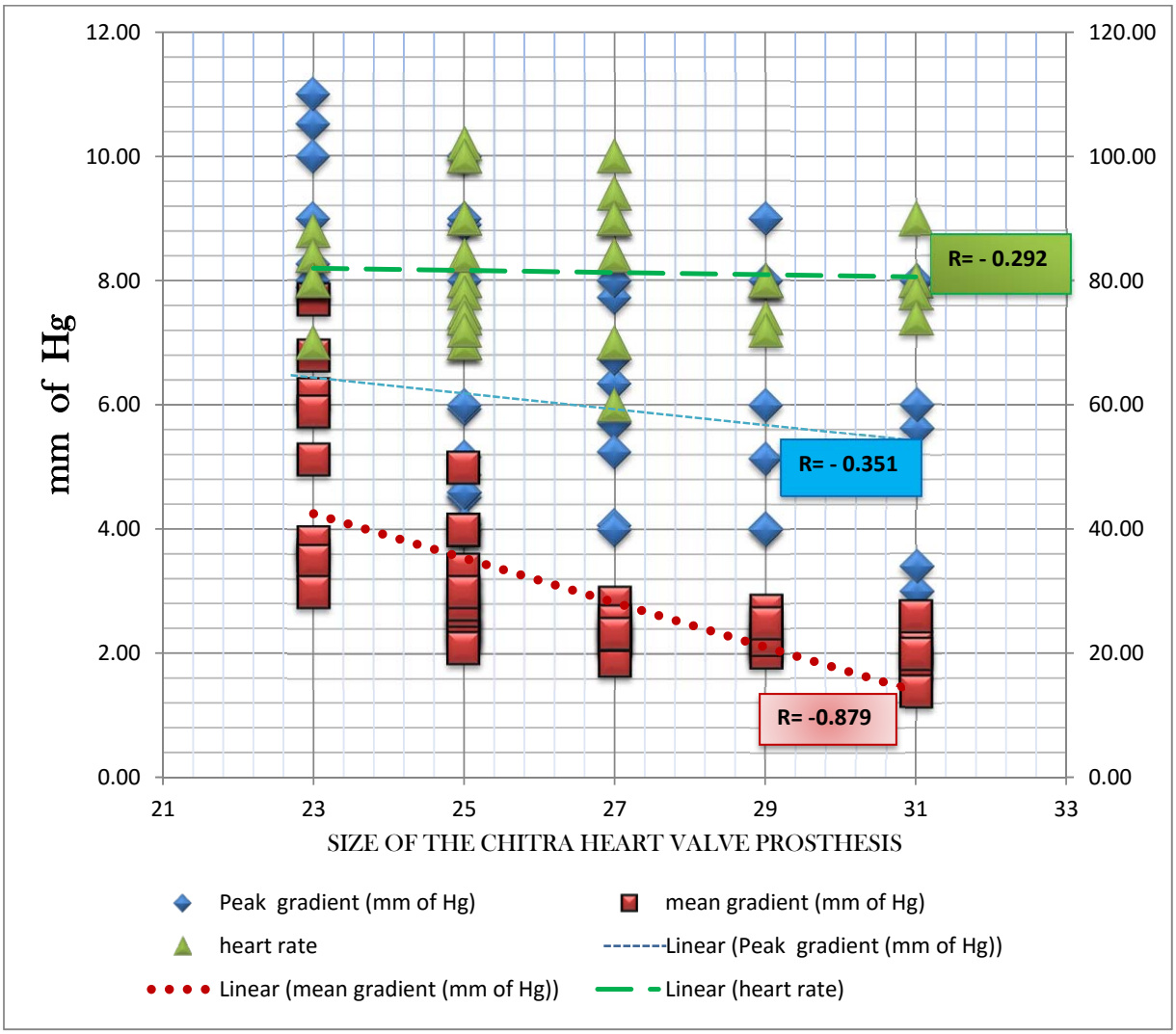


Figure 3:- Relation between size of the CHVP and Doppler velocities. Peak velocity shows inverse relation (R= -0.974) and mean velocity, DVI (R= -0.013) had poor correlation with the size of the prosthesis.

[R – Pearson correlation co-efficient, positive value closer to 1 indicates significant correlation, whereas negative value signifies inverse correlation.]



In Figure 4:- relation between the size of the CHVP and Doppler gradients is shown. Mean gradient decreased as the size of the CHVP increased displaying inverse relation. Peak gradient did not show any significant correlation with the size of the prosthesis. Heart rate was kept within the range of 65 to 85 per minute during the measurement of Doppler parameters. Smaller sized valves (23 mm) in some patients displayed higher mean gradients without affecting hemodynamic condition.

[R – Pearson correlation co-efficient, positive value closer to 1 indicates significant correlation, whereas negative value signifies inverse correlation.]

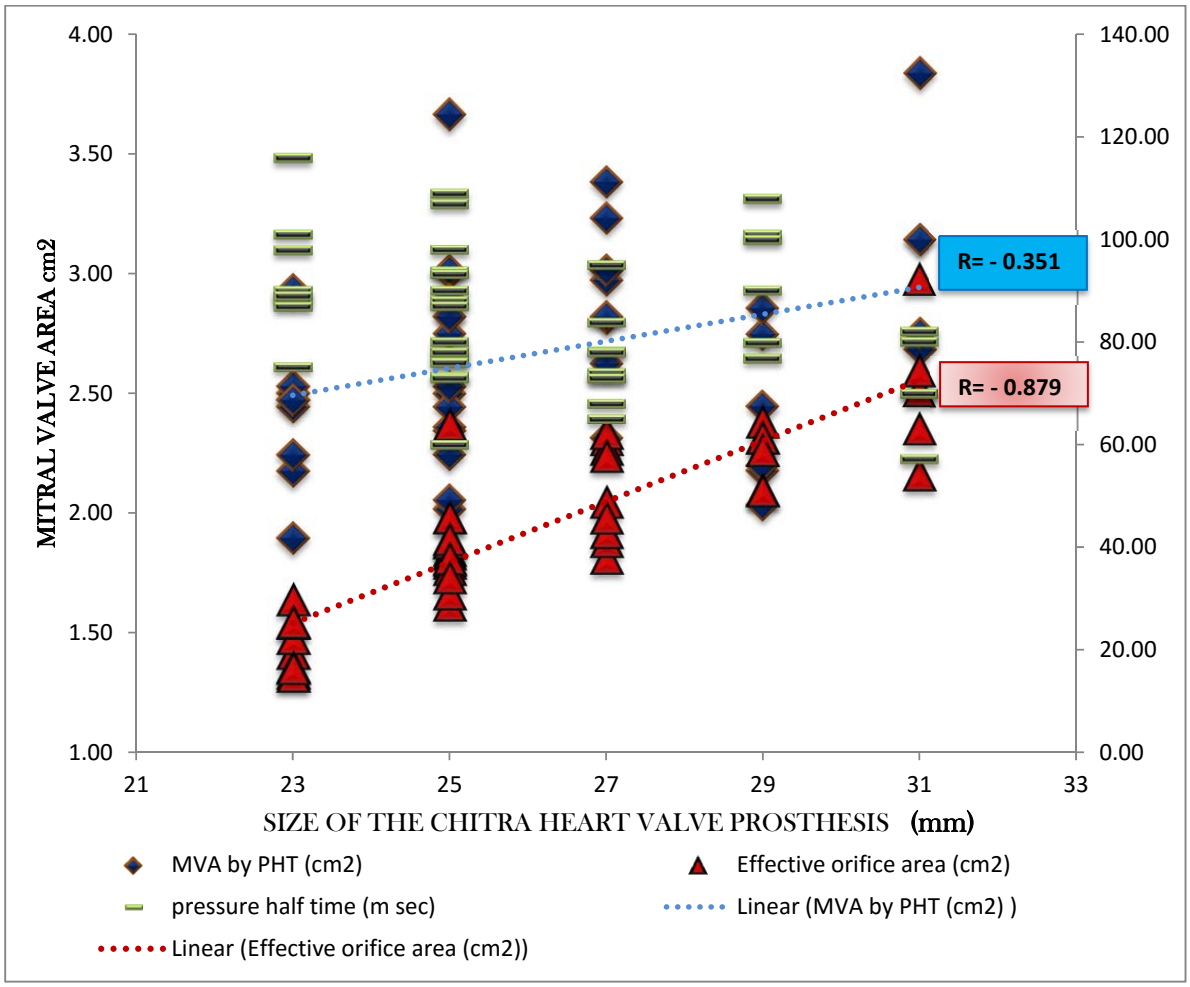


Figure 5:- depicts relation between size of CHVP and mitral valve area calculation by PHT as well as continuity equation. Both areas increased significantly with the increase in size of the prosthesis. MVA by pressure half time was more than that by continuity equation.

[R – Pearson correlation co-efficient, positive value closer to 1 indicates significant correlation, whereas negative value signifies inverse correlation.]

On color Doppler examination majority of the patients (n=39, 86.66%) had minimal to mild physiologic transprosthetic regurgitation with characteristic signature color jets (2 to 3 washing jets at hinge point and 1 to 2 closing jets at the contacting area of the occluder with metallic stent) [Refer to figure 7]. Six patients had moderate transprosthetic regurgitation which was clinically and hemodynamically insignificant.

Similar Doppler parameters for CHVP at mitral position were obtained using transthoracic echocardiography in the post-operative period 48 hours after the surgery. Both TEE and TTE values of Doppler findings were compared using paired t- test (Refer to Table 7).There was a statistically significant difference in peak velocity for 31 size valve (p value= 0.0154) and mitral valve area by PHT for 23(p value=0.044), 25(p value=0.007), 27(p value=0.008) and 29(p value=0.026) valve sizes. Although the difference was statistically significant it does not have any clinical importance as peak velocity and MVA by PHT in both TEE and TTE measurements were within normal limits of Doppler parameters defined by ASE for mitral valve prosthesis.

Table 7:- Comparison of Doppler data between intraoperative TEE and post-operative TTE using the paired t-test. (Green- intraoperative TEE Doppler parameters, orange- postoperative TTE Doppler parameters)

SIZE OF CHVP #	23		25		27		29		31		
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	MODALITY
Peak diastolic velocity (m/sec)	1.68	0.21	1.45	0.16	1.26	0.12	1.22	0.13	1.07	0.13	T E E
Peak diastolic velocity (m/sec)	1.56	0.27	1.43	0.20	1.32	0.13	1.36	0.15	1.42	0.17	T T E
P value (paired t-test)	0.299		0.708		0.212		0.116		0.015		
Peak gradient (mm of Hg)	8.74	1.47	6.14	2.16	6.21	1.48	6.03	1.90	5.21	1.83	T E E
Peak gradient (mm of Hg)	11.56	2.99	9.06	1.78	9.72	1.58	8.20	1.03	6.54	2.09	T T E
P value (paired t-test)	0.039		0.000		0.001		0.122		0.223		
mean diastolic velocity (m/sec)	0.87	0.17	0.76	0.14	0.76	0.09	0.85	0.20	0.82	0.18	T E E
mean diastolic velocity (m/sec)	1.05	0.20	0.85	0.15	0.75	0.17	0.78	0.08	0.60	0.12	T T E
P value (paired t-test)	0.097		0.108		0.909		0.464		0.041		
mean gradient (mm of Hg)	5.07	1.58	3.06	0.78	2.36	0.24	2.31	0.23	1.99	0.39	T E E
mean gradient (mm of Hg)	6.08	0.77	3.18	0.67	2.54	0.51	2.73	0.57	2.58	0.53	T T E
P value (paired t-test)	0.102		0.555		0.262		0.154		0.089		
heart rate	80.67	4.62	81.81	10.93	84.67	11.70	77.67	3.35	80.40	5.28	T E E
heart rate	84.78	12.59	72.75	8.76	69.78	3.12	77.17	4.84	68.00	2.83	T T E
P value (paired t-test)	0.264		0.043		0.015		0.818		0.033		
pressure half time (m sec)	92.56	10.76	85.04	12.74	76.44	8.41	92.67	11.34	71.86	8.81	T E E
pressure half time (m sec)	107.67	13.41	94.56	4.32	90.00	7.73	74.17	3.58	63.80	2.04	T T E
P value (paired t-test)	0.040		0.009		0.010		0.028		0.121		
MVA by PHT (cm2)	2.41	0.27	2.65	0.41	2.91	0.30	2.41	0.30	3.11	0.41	T E E
MVA by PHT (cm2)	2.08	0.27	2.33	0.11	2.46	0.21	2.97	0.15	3.45	0.11	T T E
P value (paired t-test)	0.044		0.007		0.008		0.026		0.158		
DVI	1.90	0.32	1.31	0.20	1.20	0.26	1.32	0.14	1.18	0.07	T E E
DVI	1.69	0.27	1.24	0.23	1.15	0.22	1.05	0.21	0.82	0.07	T T E
P value (paired t-test)	0.081		0.101		0.246		0.017		0.053		
Effective orifice area (cm2)	1.44	0.11	1.86	0.16	2.09	0.19	2.24	0.11	2.52	0.27	T E E
Effective orifice area (cm2)	1.49	0.10	1.95	0.16	2.20	0.09	2.64	0.12	3.10	0.21	T T E
P value (paired t-test)	0.429		0.087		0.119		0.053		0.069		

In table 7:- Comparison of Doppler parameters obtained with two modalities (intraoperative TEE and post-operative TTE) is shown. Values of each Doppler parameter obtained with two modalities are compared using paired t-test and p value less than 0.05 ($\alpha < 0.05$) is considered significant. There was no significant difference between peak velocity (except for 31 mm), mean

gradients, heart rates, DVI and effective orifice area measured by continuity equation among the two groups. The mean gradient remained below 6mm Hg in all patients except three patients who received size 23 mm prosthesis. It was slightly higher on TTE examination in the post-operative period compared to intraoperative TEE; however, the difference was not statistically significant. Heart rate remained in the range of 65 – 85 per minute in most of the patients, which was within acceptable limits. It was slightly higher during intraoperative period than in the post-operative, although, the difference was not insignificant. The PHT obtained by TTE was statistically significantly higher than that of TEE, although, it did not exceed 130 msec in any of the patients. For 31 mm valve size, even though the difference in peak velocities between IOTEE and post-operative TTE was statistically significant, it does not have any clinical relevance as both the values were within normal limits according to ASE guidelines. [Abbreviations: - MVA- mitral valve area, PHT- pressure half time, ASE- American Society of Echocardiography]

We compared CHVP with other mechanical valves implanted at mitral position. The Doppler parameters of 25, 27 29 and 31 mm sizes of St. Jude (bileaflet valve), Bjork Shiley (tilting disc) and Omni-carbon (tilting disc) valves were from the published data. The Doppler profile of CHVP was compared with that of other valves using independent t-test with unequal variance. (Refer to Table 8)

Table 8:- Comparison of Doppler parameters of CHVP with other mechanical valves.

VALVE	SIZE (mm)	Peak velocity (m/sec)	Peak gradient (mm of Hg)	Mean gradient (mm of Hg)	Pressure half time (m sec)	Effective orifice area (cm^2)
Chitra heart valve prosthesis (CHVP)	23	1.67 ± 0.22	8.74 ± 1.56	5.06 ± 1.67	92.55 ± 11.41	1.44 ± 0.11
	25	1.45 ± 0.16	6.14 ± 2.23	3.06 ± 0.81	85.04 ± 13.16	1.86 ± 0.17
	27	1.26 ± 0.12	6.21 ± 1.57	2.36 ± 0.25	76.44 ± 8.92	2.09 ± 0.20
	29	1.22 ± 0.14	6.02 ± 2.08	2.30 ± 0.25	92.67 ± 12.42	2.24 ± 0.12
	31	1.07 ± 0.14	5.21 ± 2.05	1.99 ± 0.44	71.86 ± 9.85	2.52 ± 0.30
Bjork–Shiley (tilting disc)	25	1.75 ±0.38	12 ± 4	6±2	99 ± 27	1.72 ± 0.6
	27	1.6 ± 0.49	10 ±4	5± 2	89 ± 28	1.81 ±0.54
	29	1.37 ± 0.25	7.83 ±2.93	2.83 ± 1.27	79 ± 17	2.1 ± 0.43
	31	1.41 ± 0.26	6 ±3	2±1.9	70± 14	2.2 ± 0.3
St Jude Medical (bileaflet)	23	1.5			160	1
	25	1.34 ± 1.12		2.5± 1	75 ± 4	1.35 ± 0.17
	27	1.61 ± 0.29	11 ± 4	5± 1.82	75 ± 10	1.67± 0.17
	29	1.57 ± 0.29	10 ± 3	4.15 ± 1.8	85 ± 10	1.75 ± 0.24
	31	1.59 ± 0.33	12 ± 6	4.46 ± 2.22	74 ± 13	2.03 ± 0.32
Omni-carbon (tilting disc)	25	1.77 ± 0.24		6.05 ± 1.81	102 ± 16	
	27	1.69 ±0.36		4.89 ± 2.05	105± 33	
	29	1.56 ± 0.27		4.93 ± 2.16	120 ± 40	
	31	1.3 ± 0.23		4.18 ± 1.4	134 ± 31	

Table 8:- We compared CHVP with other mechanical valves implanted at mitral position. We could obtain the Doppler profile of 25, 27 29 and 31 mm sizes of St. Jude (bileaflet valve), Bjork Shiley (tilting disc) and Omni-carbon (tilting disc) valves from the published data. The available Doppler data of 23 mm St. Jude valve consisted of peak velocity, pressure half time and EOA, we could not obtain the values for mean pressure gradient from the published data. When

CHVP (TEE) was compared with St. Jude bileaflet prosthesis (TTE) for valve sizes of 25, 27 29 and 31mm, we did not find significant difference in the peak velocity, mean gradient and PHT. The EOA was significantly higher with CHVP valves. For 23 mm valve, PHT was higher and EOA was lower with St. Jude valve as compared to CHVP. Doppler parameters for Bjork- Shiley 25, 27, 29 and 31 mm were similar to CHVP except the EOA, which was higher for 27, 29 and 31 mm of preceding valve. Omni-carbon (tilting disc) 25, 27, 29 and 31 mm was compared with similar sizes of CHVP. The Peak velocity and mean gradients were similar except for higher values of mean gradients obtained with 25 mm Omni-carbon valve.

Table 9:- Comparison of mean gradients between valves placed in anatomical and anti-anatomical positions.

VALVE SIZE (mm)	ANATOMICAL (33) Mean ± SD	ANTI-ANTOMICAL (12) Mean ± SD	P value
23	4.9 ± 1.08	5.27 ± 2.01	0.7327
25	3.14 ± 0.84	3.32 ± 0.27	0.4172
27	2.45 ± 0.21	2.51 ± 0.22	0.1882
29	2.23 ± 0.15	2.7	0.0752
31	1.98 ± 0.39		

Table 9:- shows the comparison of mean gradients between valves placed in anatomical and anti-anatomical positions. Even though smaller sized valves (23 mm) had comparably higher gradients in anti-anatomical position, the difference was not statistically significant. (Independent t-test P value of < 0.05 is significant)

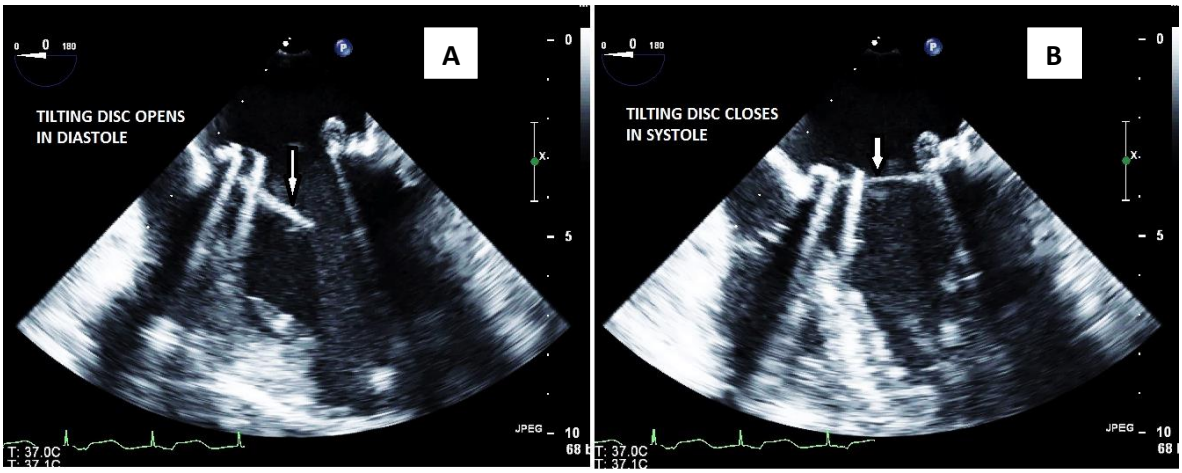


Figure 6:- 2D image of CHVP in open position--diastole (A), and closed position—systole (B). Arrows shows the tilting disc movement in diastole and systole.

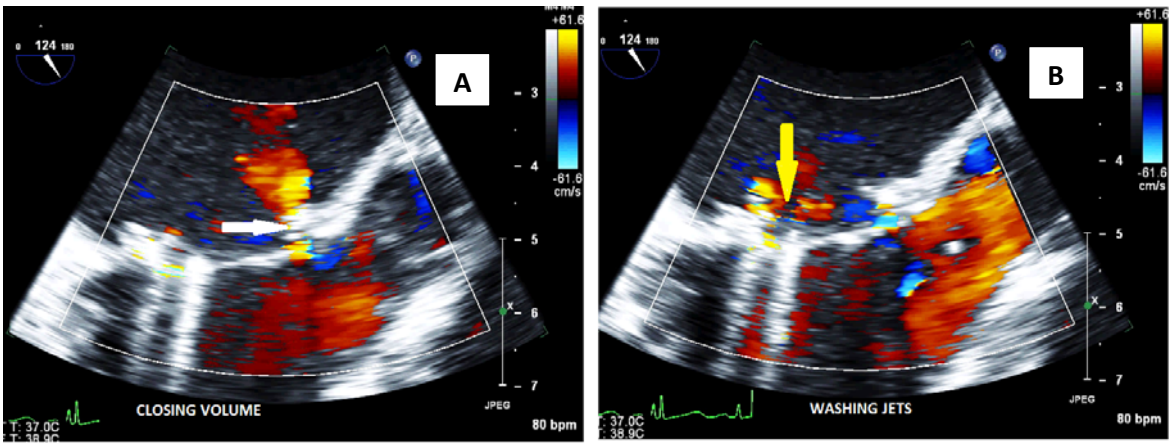


Figure 7:- Color Doppler images of CHVP depiction closing volume (A-white arrow) at the contact of tilting disc with annular ring during systole and washing jets (B-yellow arrow) seen at the hinge point. Both the jets are seen inside the valve annulus (intravalvular) and mitral regurgitation is of mild degree.

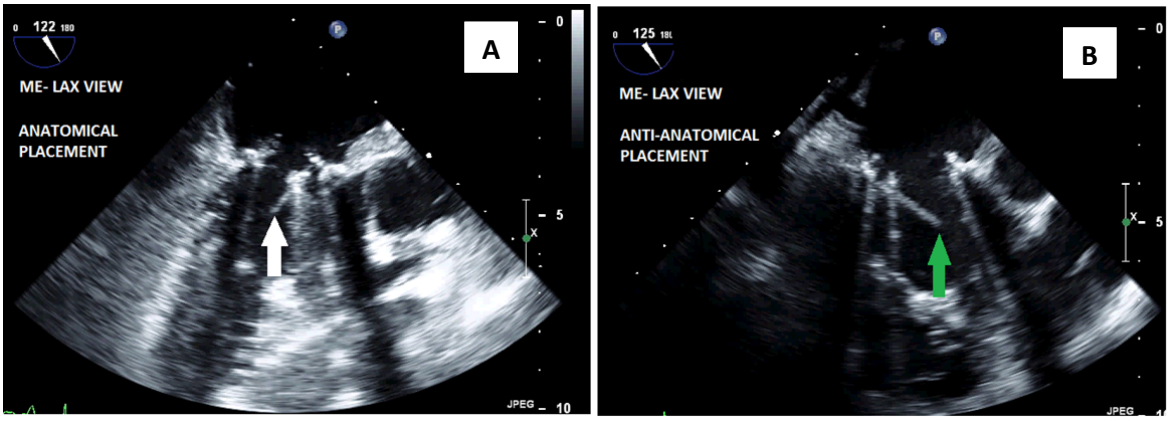


Figure 8:- shows anatomical (A) and anti-anatomical (B) placement of CHVP. In anatomically placed tilting disc valve major orifice opens posteriorly (white arrow), whereas in anti-anatomical position major orifice opens anteriorly (green arrow). Surgeon chooses anti-anatomical placement of tilting disc valve in some cases of mitral valve replacement, where posterior mitral leaflet preservation is done. It prevents flow restriction due to the presence of subvalvular tissue in cases where chordae are preserved.

DISCUSSION

Chitra heart valve prosthesis (CHVP), a tilting-disc valve developed by SCTIMST, Kerala, has gained an immense popularity in the developing countries because of its low cost, high quality and durability. CHVP is a tilting disc mechanical valve consisting of circular disc, which is suspended from the annular ring by a single strut. Eccentric position of the disc produces two orifices major (70%) and minor (30%). Circular disc opens at an angle of 60 to 75 degrees. The freely floating disc of CHVP is able to rotate on its central axis, thus it is capable of distributing wear on its surface which improves its durability and prevents the formation of thrombus at the hinge points[1]. Thousands of patients with valvular heart diseases have been benefited after implantation of Chitra valves. Previous studies [9, 10, 11] have demonstrated a proven clinical efficacy of the CHVP using TTE in the postoperative follow up studies. The Doppler parameters obtained with a CHVP in the mitral and aortic position are comparable with those obtained with the different tilting-disc prosthetic valves in common use. Recent ASE/SCA guidelines strongly recommend[22] the use of TEE for evaluation of prosthetic valves and establishment of baseline parameters and function after replacement[23, 24].

As the use of TEE has become a routine during valve replacement, cardiac surgeons are relying heavily on the post-bypass TEE observations to take surgical decisions. Thus, it is essential to define Doppler parameters for normally functioning valve prosthesis in the perioperative period. Till date none of the studies have come up with intraoperative TEE Doppler parameters of a normally functioning CHVP at mitral position to the best of our knowledge. In our study we intended to define intraoperative Doppler parameters of CHVP at mitral position in the post-CPB period using TEE and compare this data with the post operatively obtained Doppler parameters using TTE. The normal

Doppler parameters obtained in this study were also compared with the published Doppler parameters[8] of other prosthetic valves.

Differences in the hemodynamic condition in post-CPB period and postoperative period

Gradients and velocities across the prosthetic valve are affected by various confounding factors especially in the immediate post bypass period[4]. The intravascular volume status may not remain constant in the immediate post-CPB period due to surgical bleeding, infusion of blood and intra-venous fluids and return of oxygenator blood. This may result in frequent preload changes, which in turn influences the measurement of Doppler parameters. Hence, it is necessary to maintain unfaltering loading conditions prior to the Doppler evaluation of prosthetic valves. Use of inotropes in the post-CPB period induces tachycardia and increased contractile state. Tachycardia alters the transmitral flow by shortening diastolic period and may falsely increase the transmitral gradients. Lusitropic drugs like Dobutamine and Milrinone may alter diastolic LV filling. Ventricular pacing prevents atrial kick mechanism which remains a major source of LV filling in the post-CPB period. In atrial fibrillation there is absence of A- wave and irregularly spaced R-R intervals that changes beat-to-beat filling of LV. It generates VTI of varying morphology and directly affects the Doppler derived parameters. Hemodilution and use of inotropes also is associated with increase in the cardiac output. It has a direct impact on the measurements of peak velocity and mean gradient. In our study, we maintained constant preloading conditions at least for some time before performing the Doppler measurements. Hematocrit was maintained at about 30 % as per our institutional protocol. This also reduced the consequences of hemodilution. As we included only those patients having good LV systolic function in our study, inotropes were required infrequently in the post-CPB period.

Post-operative TTE examination was performed 48 to 72 hours after the surgery, when the inotropes had been weaned off and the loading conditions maintained constant. The hemodynamic conditions were more stable during postoperative TTE than the intraoperative TEE. Despite this fact, we did not observe gross disparity in the Doppler profile between the modalities of echocardiography.

Echocardiographic characteristics of CHVP

The 2D and color Doppler characteristics of CHVP were compliant with the guidelines issued by the ASE for evaluation of prosthetic valve[4]. On 2D examination, the annular stent was seen in stable condition without any dehiscence. The occluder disc was opening in an unrestricted manner at 60 to 70 degrees. Color Doppler examination revealed two orifices, major and minor, encompassing 70 % and 30 % of the orifice area respectively. Characteristic signature jets were observed in all the patients. Intravalvular regurgitation was of less than mild degree in majority of the patients. Six patients had moderate degree of MR on initial evaluation, which reduced to mild degree after protamine administration. None of the patients were noted to have any pathological transprosthetic regurgitation. Trivial paravalvular regurgitation at the suture sites was observed in 4 patients, which disappeared after heparin reversal with protamine.

Anatomical versus anti-anatomical placement of the CHVP

The flow characteristics across the mitral prosthetic valve depend to some extent whether the prosthesis is placed in anatomical or anti-anatomical fashion[25, 24]. In a native mitral valve the height of AML is usually more than that of PML. Hence, the blood enters LV cavity through posterior aspect of the mitral valve aperture. In anatomically placed tilting disc prosthesis, the major aperture opens posteriorly which preserves the normal LV diastolic vortices.

Preservation of the posterior subvalvular apparatus may sometimes hinder free movements of the occluder. In those circumstances, the surgeon prefers to direct the major aperture anteriorly (anti-anatomical orientation). As this disturbs current of the physiological flow, the flow velocities and pressure gradients may be elevated. In our series, we observed that the CHVP of different sizes placed in anti-anatomical fashion (in 12 patients) had slightly increased peak velocities and mean gradients. It was more pronounced in size 23 valves. However, the effective orifice area estimated by continuity equation did not differ in patients irrespective of anatomical or anti-anatomical placement.

Doppler evaluation of CHVP

The systematic evaluation of mitral valve prosthesis has been described in ASE guidelines [18]. The common parameters measured peak velocity, mean gradient, heart rate at the time of Doppler, PHT, DVI, EOA and presence, location and severity of mitral regurgitation (MR) were also noted. If the peak velocity exceeds 2 m/sec and the mean gradient exceeds 5mm hg then the prosthetic valve need further evaluation. The possible causes may include valve stenosis or dysfunction, patient prosthetic mismatch (PPM), increased flow across the valve and MR. Presence of tachycardia exceeding 100 per min may also falsely elevate the mean gradient. In an obstructed or stenosed valve, the PHT exceeds 130 msec. When the EOA exceeds 1.5 $cm^2/m^{2,}$ the PHT is an unreliable parameter to estimate the EOA as it reflects the compliance of the LV and LA pressures more than the transvalvular obstruction.

Doppler-derived gradients

Doppler velocities and gradients differ widely depending on the size and type of the valve prosthesis as shown by various studies [8, 9, 10] . In our study we found that peak velocity and mean gradients decreased as the size of the valve prosthesis increased [Refer to Figure 2 & 4]. Our study also revealed that DVI

and mean velocities have poor correlation with the size of the prosthesis. [Refer to Figure 3 & table 6]. Our observations are consistent with results of previous studies by Namboodiri et al [10] for prosthetic mitral valve.

Mitral valve area by continuity equation.

Actual orifice area takes in to account the valve orifice diameter (VOD) which depends on the size of the valve prosthesis. However, in a prosthetic valve, the effective orifice area represents the true size of the orifice. After valve replacement the surgical sutures placed around the annular metallic stent occupy some portion of the valve orifice. A mechanical valve creates some degree of flow obstruction which may be considered equivalent to mild to moderate stenosis of a native valve[25, 26]. Hence, the effective orifice area is invariably smaller than the actual orifice area as stated by the manufacturer.

In our study MVA measured by continuity equation and PHT had significant positive correlation with the size of the valve prosthesis, and mitral valve area calculated by both these methods was smaller than the actual orifice area for the valve size as noted in the user manual by the manufacturer.

None of the methods for measurement of valve area using Doppler are without any drawbacks; mitral valve area derived by continuity equation may correlate with the EOA. However, it may underestimate the actual orifice area[26, 27]. Many studies have shown that valve area calculated in experimental models using flow equations also underestimate the actual orifice area[28, 27]. In studies on Bio prosthetic valves and St. Jude valve prosthesis [14, 15, 27] have shown that valve area measurement by continuity equation had significant correlation with the size of the prosthetic valve or actual orifice area, and was smaller compared to valve area calculation by PHT. Our study also displayed similar results as the other studies on mechanical valves

Mitral valve area by PHT

MVA calculation by PHT was basically derived from the studies on stenotic native valves[28,29], and its application in calculation of valve area in case of normally functioning mitral prosthesis is controversial. Pressure half time measurement is affected by factors such as compliance of left atrium(LA) and left ventricle (LV), pressure difference between LA and LV in early diastole, tachycardia, loading conditions, stroke volume and transmitral pressure gradients. However higher values of PHT should arouse suspicion of prosthetic valve stenosis as PHT in a normally functioning valve rarely exceeds >130 msec. In the presence of MR in a prosthetic valve, the velocities and gradients may be elevated; however, the PHT does not exceed 130 msec. In our study pressure half time values were within normal range across all valve sizes studied. The prosthetic mitral valve evaluation may be affected by other cardiac pathologies and hemodynamic parameters. Our inclusion criteria consisted of normally functioning other native valves, which eliminated the possibility of confounding results by the other valvular diseases. Also, Doppler parameters obtained intraoperatively using TEE were compared with the post-operative TTE values performed 48 hours after the surgery to remove any confounding factors. We found no significant difference between the Doppler parameters obtained by these two modalities (TEE and TTE) and are comparable to one another (Refer to Table 7).

St. Jude medical prosthesis (SJM) was introduced in clinical practice in the late 1970s. Its construction consists of a special hinge mechanism where two semicircular leaflets function in synchrony inside the valve annulus. It was the first bileaflet mechanical valve prosthesis with very good hemodynamic profile; its efficacy in mitral position has been proven both in vitro and in vivo by many clinical studies[29, 30, 31 ,32].

We compared the Doppler parameters obtained for different sizes of CHVP at mitral position with published data for other mechanical tilting disc valves like St. Jude medical, Medtronic hall, Omni-carbon and Bjork–Shiley (Refer Table 8). Statistical analysis with independent t- test showed significantly higher effective orifice area of CHVP compared to other valves. However, smaller sized CHVP (23 mm) had gradients and velocities in the higher normal range. Similar findings were noted by Namboodiri et al [11], Pawan et al [9].

CONCLUSION

The CHVP can be satisfactorily evaluated on intraoperative TEE. On 2D evaluation, CHVP was normally functioning in all patients. All patients had less than mild MR on color Doppler evaluation. As per ASE recommendations for Doppler evaluation of prosthetic valve, we studied peak velocity, mean gradient, effective orifice area by continuity equation and pressure half time and DVI in all patients. The Doppler profile obtained was compliant with the ASE guidelines.

On comparing Doppler parameters among different sizes of CHVP, the Peak velocity and mean gradients were inversely related to the size of the prosthesis. Effective orifice area calculated by PHT and CE were in direct correlation with the valve size. However, both of these values were smaller than the actual (geometric) orifice area defined by the manufacturer. DVI and mean velocities did not seem to have any significant correlation with the size of the valve implanted. Heart rate between the groups did not vary significantly and PHT was within 130 msec in all patients. Mean gradients did not differ significantly between anatomical and anti-anatomical placement of CHVP at mitral position. The Doppler parameters obtained on IO-TEE did not differ significantly from those obtained on postoperative TTE. When the intraoperative data of CHVP was compared with the published data of other mechanical valves, like St. Jude, Medtronic Hall, Bjork-Shiley and Omni-carbon the EOA of CHVP obtained by CE was higher than that of the other valves. Other Doppler parameters were similar among these valves.

ABBREVIATIONS

- CHVP- Chitra heart valve prosthesis
- SCTIMST- Sree Chitra Tirunal institute for medical sciences and technology
- USA- United States of America
- TTK- T. T. Krishnamachari (founder of TTK Conglomerate)
- TEE- Trans-esophageal echocardiography
- CPB- Cardio-pulmonary bypass
- IOTEE- Intraoperative trans-esophageal echocardiography
- PHT- Pressure half time
- CE- Continuity equation
- AOA- Actual orifice area
- PPM- Patient prosthesis mismatch
- LA- Left atrium
- LV- Left ventricle
- DVI- Doppler velocity index
- EOA- Effective orifice area
- ACC- American College of Cardiology
- AHA- American Heart Association
- ME 4C –Mid-esophageal four chamber view
- ME LAX – Mid-esophageal long axis view
- VTI – velocity time integral
- VOD – Valve orifice diameter
- LVID –Left ventricular internal diameter
- BSA – Body surface area
- NYHA – New York Heart Association
- MVA – Mitral valve area

- TTE – Trans thoracic echocardiography
- SD – Standard deviation
- ASE – American Society of Echocardiography
- SCA – Society of Cardiovascular Anesthesiologists
- AML – Anterior mitral leaflet
- PML – Posterior mitral leaflet
- MR – Mitral regurgitation

Consent form

Title of study: study of Intraoperative hemodynamic performance and echocardiographic characteristics evaluation of Chitra heart valve prosthesis in the mitral position using Trans-esophageal echocardiography.

Study numbers: We request you to participate in the study wherein we are planning to evaluate Intraoperative hemodynamic performance and echocardiographic characteristics evaluation of Chitra heart valve prosthesis in the mitral position using Trans-esophageal echocardiography.

What is mitral valve?

Heart valves lie at the exit of each of your four heart chambers and maintain one-way blood flow through your heart. The four heart valves make sure that blood always flows freely in a forward direction and that there is no backward leakage. Mitral valve is one of the heart valves lying between left atrium and left ventricle. Heart valve disease occurs when the heart valves do not work the way they should. Heart valve disease can develop before birth (congenital) or can be acquired sometime during one's lifetime. Sometimes the cause of valve disease is unknown.

Mitral valve replacement is open heart surgery to replace the mitral valve. The mitral valve normally opens and closes to let blood pass through the heart. If your mitral valve does not open or close correctly, blood may not flow as it should through your heart. Valve replacement means replacing the diseased heart valve.

What is Trans-esophageal echocardiography?

Trans-esophageal echocardiography or TEE is a test that uses sound waves to create high-quality moving pictures of the heart and its blood vessels. This can pin point the problematic areas of the heart and helpful in assessing function of heart valves before and after valve replacement surgery. TEE involves a flexible tube (probe) with a transducer at its tip. Your doctor will guide the probe down your throat and into your esophagus (the passage leading from your mouth to your stomach). This will be done when you are under anesthesia and will not cause any discomfort. This approach allows your doctor to get more detailed pictures of your heart because the esophagus is directly behind the heart.

What is the role of Trans-esophageal echocardiography in valve replacement surgery?

Trans-esophageal echocardiography (TEE) is a useful monitoring tool during cardiac surgery. American society of Anesthesiology and society of cardiovascular Anesthesiologists have strongly recommended use of intraoperative TEE in adult patients undergoing valve replacement to confirm and refine the preoperative diagnosis, to detect new or unsuspected pathology, to adjust the anesthetic and surgical plan accordingly, and to assess the results of the surgical intervention. This can pin point the problematic areas of the heart and helpful in assessing function of heart valves before and after valve replacement surgery. This is of great help in assessing the heart function during the operation.

How is Trans-esophageal echocardiography performed?

This will be done when you are under anesthesia and will not cause any discomfort. Your doctor will insert the lubricated probe into your mouth. He or she will then gently guide it down your throat into your esophagus. Your esophagus lies directly behind your heart. During this process, your doctor will take care to protect your teeth and mouth from injury.

What are the risks and side-effects?

You will be under the effect of anesthesia while the test is being performed thus you are unlikely to experience any discomfort.

Why are we doing this study?

The purpose of our research is to find out the hemodynamic characteristics of Chitra heart valve placed in mitral position with the help of Trans-esophageal echocardiography. This research will involve collection of the data obtained during intraoperative period for the purpose of research and publication regarding the study of hemodynamic profile of the Chitra heart valve prosthesis.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

Will you have to pay for the study?

No.

Will your personal details be kept confidential?

Your personal details will be kept confidential. The result of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results.

If you have any further questions, please ask:

Dr. Jagadeesh.N., Senior Resident, Department of Anaesthesia (Tel: 90481868883 or mail me: jagadeesh@sctimst.ac.in)

Dr.Rupa Sreedhar, Professor, Department of Anaesthesia (Tel: 9446314043)

Dr. Shrinivas Gadhinglajkar, Professor, Department of Anaesthesia (Tel: 0944630404)

Study independent contact person:- Dr.Anoop Kumar .T, Member Secretary, IEC.

Scientist 'F', Molecular Medicine SCITMST, BMT Wing, Poojappura Thiruvananthapuram-695012 (Tel:

DECLARATION

I, _____ (Please tick boxes)
Declare that I have read the above information provided to me regarding the study: **INTRAOPERATIVE HEMODYNAMIC PERFORMANCE AND ECHOCARDIOGRAPHIC CHARACTERISTICS EVALUATION OF CHITRA HEART VALVE PROSTHESIS IN THE MITRAL POSITION USING TRANS-ESOPHAGEAL ECHOCARDIOGRAPHY.**

- And have clarified any doubts that I had. [ ]
- I also understand that my participation 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 will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]
- I understand that my identity will not be revealed in any information released to third parties or published [ ]
- I voluntarily agree 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:

(Person Obtaining Consent)

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.

_____ _____

Name and Signature of Person Obtaining Consent

പ്രതിജ്ഞ

ഞാൻ . . . . . (പങ്കെടുക്കുന്ന ആളിന്റെ പേര്) ജനനതീയതി/ വയസ് . . . . (വർഷത്തിൽ) ഞാൻ ഈ പഠനത്തെ സംബന്ധിച്ച് മേൽപ്പറഞ്ഞ വിവരങ്ങൽ മനസ്സിലാക്കി.

''ബൈപ്പാസ് ശസ്ത്രക്രിയക്ക് വിധേയരാകുന്ന രോഗികളിൽ ഇടതു മമ്മറി രക്തക്കുഴലിലൂടെയുള്ളരക്ത പ്രവാഹത്തിൽ സ്റ്റിലേറ്റ് നാഡീകേന്ദ്രത്തിൽ ബ്ലോക്ക് കൊടുത്താലുള്ള ഫലവും ശസ്ത്രക്രിയ കഴിഞ്ഞതിനുശേഷമുള്ള രക്തസമ്മർദ്ദത്തിന്റെ വ്യതിയാനവും.

ദയവായി അടയാളപ്പെടുത്തുക (√).

- ഇതു വായിച്ചതിനുശേഷം എന്റെ എല്ലാ സംശയങ്ങളും മാറി ( )
- പഠനത്തിൽ പങ്കെടുക്കുന്നത് എന്റെ സ്വന്തം താല്പര്യപ്രകാരമാണെന്നും എപ്പോൾ വേണമെങ്കിലും ഇതിൽ നിന്നും പിൻമാറാവുന്നതാണെന്നും അത് എന്റെ ചികിത്സയെ ഒരു തരത്തിലും ബാധിക്കുകയില്ലെന്നും ഞാൻ മനസ്സിലാക്കുന്നു ( )
- ഈ പഠനത്തിൽ നിന്ന് ഞാൻ പിൻമാറുകയാണെങ്കിൽ ഈ പഠനം ചെയ്യുന്ന ആളിനോ ആശുപത്രി മേധാവിക്കോ എന്റെ അനുവാദമില്ലാതെ തന്നെ എന്റെ ആരോഗ്യ വിവരങ്ങൾ പരിശോധിക്കാവുന്നതാണ്. ഇത് ഞാൻ സമ്മതിക്കുന്നു ( )
- എന്റെ വ്യക്തി വിവരങ്ങൾ മൂന്നാമതൊരാൾ വായിക്കുകയോ പ്രസിദ്ധീകരണങ്ങളിലോ മറ്റോ ഉണ്ടാകില്ലെന്നും ഞാൻ മനസ്സിലാക്കുന്നു ( )
- ഞാൻ സ്വന്തം ഇഷ്ട പ്രകാരം ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നു ( )
- ഒപ്പു വച്ച സമ്മതപത്രത്തിന്റെ ഒരു കോപ്പി ഇതോടൊപ്പം ഞാൻ സ്വീകരിക്കുന്നു ( )

പേര് :

ഒപ്പ് :

തീയതി :

സാക്ഷിയുടെ പേര് :

പങ്കെടുക്കുന്ന ആളുമായുള്ള ബന്ധം :

തീയതി :

പങ്കെടുക്കുന്ന ആളിനെ ഉൾപ്പെടുത്തിക്കൊണ്ടുള്ള സമ്മതപത്രം

ഈ ഗവേഷണ പഠനത്തിന് ആവശ്യമായിട്ടുള്ള മുകളിൽ പറഞ്ഞ എല്ലാ കാര്യങ്ങളും ഒപ്പുവച്ച സമ്മതപത്രവും എനിക്കു ലഭിച്ചതായി ഞാൻ സമ്മതിക്കുന്നു. ഈ സമ്മതപത്രത്തിന്റെ ഒരു പകർപ്പ് പങ്കെടുക്കുന്ന ആൾക്ക് നൽകുകയും എല്ലാ കാര്യങ്ങളും പറഞ്ഞു മനസ്സിലാക്കുകയും ചെയ്തിട്ടുണ്ട്. കൂടാതെ പങ്കെടുക്കുമ്പോൾ ഉണ്ടായേക്കാവുന്ന പാർശ്വഫലങ്ങളും പറഞ്ഞു മനസിലാക്കിയിട്ടുണ്ട്. പങ്കെടുക്കുന്ന ആളിനെക്കൊണ്ട് സംശയങ്ങൾ ചോദിപ്പിക്കുവാനും ചോദിച്ച സംശയങ്ങൾക്ക് മറുപടി നൽകുവാനും എനിക്ക് സാധിച്ചതായി ഞാൻ സമ്മതിച്ചുകൊള്ളുന്നു.

ഡോക്ടറുടെ പേര് ഒപ്പ്

OBSERVATION CHART

Intraoperative transesophageal echocardiographic characteristics of the Chitra heart valve prosthesis implanted at mitral position

Name of the patient:
Age:
Sex:
Hospital number:
Weight (kg):
Height (cm):
Body surface area (kg/ cm^2):

Diagnosis and surgery:
Date of surgery:
Preoperative features:
NYHA:
Heart rate and rhythm:
Transthoracic echo report:

Preoperative medication:
Intraoperative echocardiographic observations:

TEE findings before CPB:

Parameter	Echo finding
LVEF (%)	
LVEDD (mm)	
LVESD (mm)	
LV posterior wall thickness systolic/ diastolic (mm)	
Septal wall thickness systolic/ diastolic (mm)	
Mitral valve examination:	
MVA by pressure half time (cm^2)	
MV pressure gradient (peak systolic & mean) mmHg	
LA size	
RVSP	
Calcification of annulus	
Grade of MR	
Associated Aortic stenosis or regurgitation (grade)	
Associated TR	
Any other	

CPB details:

CPB duration (minutes)	
Aortic cross-clamp time (minutes)	
Inotropes (mcg/ kg/ min)	
1.	
2.	
Other drug infusions	
1.	
2.	
Number of weaning attempts	

Surgical details:

Size of mitral valve prosthesis	
Chordal preservation	
Orientation anatomical/ antianatomical	

Hemodynamic and TEE findings after weaning from CPB:

Hemodynamic	
Heart rate (beats/ minute)	
BP systolic /diastolic/mean during assessment mmHg	
1.	
2.	
Rhythm	
Cardiac Pacing, type	
Filling pressures (mmHg)	
Other	
LVEF (%)	
LVEDD (mm)	
LVESD (mm)	
RVSP (mmHg)	
Grade of AR or AS	

TEE Observations on CHVP examination

2D examination of CHVP	
Motion of occluder disc (free/ restricted)	
Angle of opening (degree)	
Motion of CHVP sewing ring (absent/ present)	
Any characteristic appearance	
Color Doppler examination of CHVP	
Central leakage regurgitant jet (grade and number)	
Regurgitant jet at contact between disc and stent (grade, number)	
Paravalvular regurgitant jet grade (before protamine administration)	
Paravalvular regurgitant jet grade (After protamine administration	
Spectral Doppler examination of CHVP	
Peak diastolic velocity (m/ sec)	

Peak diastolic gradient (mmHg)	
Mean diastolic velocity (m/ sec)	
Mean diastolic gradient (mmHg)	
Pressure half time (msec)	
CHVP EOA by pressure half time (cm^2)	
CHVP EOAi by pressure half time (cm^2/ m^2)	
Actual orifice area (cm^2)	
Actual orifice area index (cm^2/ m^2)	
Valve area by continuity equation	
Diameter of LVOT (cm)	
LVOT area (cm^2)	
VTI of LVOT (cm)	
Stroke volume (ml/ min)	
Heart rate (beats/ minute)	
Blood pressure(S/D mm hg)	
Cardiac output (lit/ min)	
Cardiac Index (lit/ min/ m^2)	
VTI of CHVP (cm)	
EOA of CHVP (cm^2)	
EOAi of CHVP (cm^2/ m^2)	
VTI prosthesis/ VTI LVOT (DVI)	
BSA	
Any other observations	

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान
तिरुवनन्तपुरम - 695 011, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY
THIRUVANANTHAPURAM - 695 011, INDIA
(An Institute of National importance under Govt. of India)

Institutional Ethics Committee (IEC)
(IEC Regn No. ECR/189/Inst/KL/2013)

SCT / IEC- 307/ APRIL-2014 22-04-2014

Dr. Jagadeesh
Senior Resident
Department of Cardiothoracic & Vascular Anesthesia
SCTIMST.

Dear Dr. Jagadeesh,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "INTRAOPERATIVE HEMODYNAMIC PERFORMANCE AND ECHOCARDIOGRAPHIC CHARACTERISTICS EVALUATION OF CHITRA HEART VALVE PROSTHESIS IN THE MITRAL POSITION USING TRANSESOPHAGEAL ECHOCARDIOGRAPHY" (IEC/307) on 12th April, 2014.

The following documents were reviewed:

1. *Covering letter addressed to the Chairman, IEC, SCTIMST for IEC approval.*
2. *Status report of the previous study.*
3. *Letter of IEC recommendations dated 28.11.2013.*
4. *IEC Application form.*
5. *Proposal for study.*
6. *Short CVs of PI and Co-PI.*
7. *Observation chart.*
8. *Declaration form.*
9. *Consent form in English and Malayalam.*
10. *Annual Report.*

तार : चित्रमेट फोन फाक्स ई-मेइल
Grams : Chitramet Phone : 2443150

The following members of the Ethics Committee were present at the meeting held on 12th April, 2014 at G.Parthasarathi Board Room, AMCHSS, SCTIMST.

Sl. No	Member Name	Highest Degree	Gender	Scientific / Non-scientific	Affiliation with Institution (s)
1.	Justice M.R. Hariharan Nair.	MA BL	Male	Legal Expert (Chairperson)	No
2.	Dr. J. M. Tharakan	MD	Male	Clinician (Cardiologist)	Yes
3.	Dr. K. A. Kumar	MD	Male	Clinician (Psychiatrist)	No
4.	Dr. O.S. Neelakandan Nair	BE	Male	Engineer	Yes
5.	Smt. Lalithambika IAS	MBA	Female	Lay Person (Administrator)	No
6.	Dr. Rema M. N	MD	Female	Pharmacologist	No
7.	Dr. Meenu Hariharan	DM	Female	Clinician (Gastro Enterologist)	No
8.	Dr.R V G Menon	PhD	Male	Lay Person	No
9.	Dr. Premila P.G.	MD	Female	Clinician (Paediatrician)	No
10.	Dr. S.Sivasankaran	MD	Male	Clinician (Cardiologist)	Yes
11.	Dr. Anoopkumar Thekkuveettil	PhD	Male	Basic Scientist (Molecular Biology) /Ethicist (Member Secretary)	Yes

IEC Decision

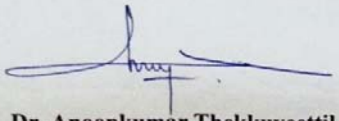
1. The status of report of the original study needs to be submitted for IEC review.
2. Approved the study with the above recommendation.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Yours Sincerely



Dr. Anoopkumar Thekkuveettil
Member Secretary, Ethics Committee.

Thesis_ **JAGADEESH N. VAGGAR**

ORIGINALITY REPORT

19%

SIMILARITY INDEX

SIMILARITY INDEX SATISFACTORY

PRIMARY SOURCES

1	S. K. Dora. "Doppler echocardiographic assessment of TTK Chitra prosthetic heart valve in the mitral position", European Journal of Echocardiography, 05/07/2008 CrossCheck	300 words — 3%
2	beta.thehindu.com Internet	202 words — 2%
3	www.spbcardio.ru Internet	130 words — 1%
4	Namboodiri, N.. "Hemodynamic performance evaluation of TTK Chitra heart valve prosthesis in the aortic position using Doppler echocardiography", International Journal of Cardiology, 20100514 CrossCheck	101 words — 1%
5	Pawan Kumar. "TTK Chitra tilting disc valve: Hemodynamic evaluation", Indian Journal of Thoracic and Cardiovascular Surgery, 07/2004 CrossCheck	96 words — 1%
6	S. K. Dora. "Doppler echocardiographic assessment of TTK Chitra prosthetic heart valve in the mitral position", European Journal of Echocardiography, 03/18/2008 CrossCheck	80 words — 1%
7	lib.bioinfo.pl Internet	67 words — 1%
8	Mehmet Uzun. "A Simple Different Method to Use Proximal Isovelocity Surface Area (PISA) for Measuring Mitral Valve Area", The International Journal of	64 words — 1%

PRE-OPERATIVE TRANSTHORACIC ECHO FINDINGS

SR NO	NAME	HOSPITAL ID	AGE	SEX	WEIGHT	HEIGHT	Body surface area	NYHA	LVID diastolic	LVID systolic	Ejection fractio	RVSP
1	PRAVEEN K	363173	20	Male	48	168	1.49	2	53	37	55	46
2	MARY JOHNY	370734	57	Female	52	144	1.44	2	46	26	69	18
3	MARIYAMMA YOHANAI	286459	53	Female	52.5	150	1.47	3	45	26	68	38
4	SELVI	360114	22	Female	48.5	150	1.42	2	55	32	60	44
5	SUMATHY C.T	8808738	53	Female	43	153	1.35	3	50	29	64	30
6	VALSAMMA. T. K	372026	49	Female	54	155	1.52	2	48	26	60	34
7	DHANYA. K. S	260298	26	Female	36.6	152	1.24	2	44	25	62	60
8	CHELLAMMA	356250	38	Female	43	148	1.32	2	43	23	60	50
9	SARASWATHI AMMA	22184	56	Female	43	140	1.29	2	56	27	65	90
10	SHYLA. R	212918	36	Female	47.5	153	1.42	2	60	30	68	52
11	NITHYA. J	361059	28	Female	42	154	1.33	3	63	38	64	36
12	PECHIYAMAL	362280	48	Female	53	155	1.51	2	55	32	70	35
13	DHANUJA AUGUSTIN	360468	30	Female	65	160	1.69	2	64	34	65	0
14	FATHIMA BEEVI	364014	53	Female	67.5	158	1.71	2	55	27	60	12
15	SHIRLEY	322874	48	Female	54.4	150	1.5	3	53	30	60	57
16	NAFEESA	9408839	48	Female	41.5	146	1.29	2	48	24	65	24
17	SYAMALA	362281	53	Female	62.8	149	1.61	2	46	27	65	28
18	ROSILY DEVASSY	369677	52	Female	43	140	1.29	2	44	23	63	50
19	SIVADASAN E.K	374489	48	Male	65.8	168	1.75	2	49	29	66	0
20	PRAJITHA. K	227264	25	Female	50	153	1.45	3	53	31	70	20
21	RAMESAN. P	332222	32	Male	50	152	1.45	2	55	35	66	19
22	CHANDRA.S	194327	64	Male	51.6	151	1.47	2	49	34	60	38
23	SHOJI. P. O	377176	37	Male	67	160	1.72	2	48	25	65	56
24	PONNAN	377697	47	Male	52.5	158	1.51	2	53	39	63	67
25	VALSADEVI AMMA	366873	65	Female	53	158	1.52	2	46	26	53	80
26	SHANTI KUMARI	9205203	54	Female	50	150	1.44	2	44	20	60	0
27	HARIDASSAN. A	357028	49	Male	54	168	1.58	2	48	33	62	36
28	ASHRAF.K.K	366252	47	Male	89	175	2.07	2	60	48	55	12
29	SHYLAMANI	361202	45	Female	53	154	1.5	2	53	35	60	24
30	LALLY. M.J	8701740	46	Female	47	157	1.43	3	51	39	45	57
31	KUMARAN. P	271081	60	Male	60	164	1.65	2	52	30	75	0
32	SULAIMAN. K	9009798	53	Male	62	168	1.7	2	55	36	63	46
33	HARI. G	8700774	54	Male	54	162	1.54	2	55	35	65	30
34	LYSSAMMA ROCKY	351822	49	Female	57	148	1.53	3	48	30	61	20
35	BINDU. K	331752	35	Female	63	168	1.71	3	54	41	72	20
36	SIDHIQUE. K	371402	42	Male	51	171	1.55	2	49	35	55	53
37	SOMAN. S	338498	52	Male	50	154	1.46	2	59	44	42	40
38	RAMACHANDRAN. K	350448	55	Male	62	162	1.67	2	56	45	55	30
39	SINOY ABRAHAM	348944	35	Male	72	165	1.81	2	56	43	65	15
40	SHAJI.V.J	378227	49	Male	60	164	1.65	3	53	40	66	30
41	RAMAN KUTTY	342112	45	Male	65	172	1.75	2	52	38	52	26
42	SHAJI. K	8606156	45	Male	40	158	1.35	2	47	37	55	57
43	BALAKRISHNAN K	378062	43	Male	68	170	1.79	2	44	34	67	26
44	MANOHARAN P	383866	54	Male	55	160	1.56	2	53	40	58	26
45	SABU V.P	9207657	46	Male	60	162	1.64	2	49	24	68	24

PRE-OPERATIVE TRANSTHORACIC ECHO FINDINGS										
SR NO	NAME	Left atrial size	Left atrial clot	Rhythm	IW (sys)	IW (dia)	SW (sys)	SW (dia)	TRANSTHORACIC ECHO REPORT	CHIEF COMPLAINTS
1	PRAVEEN K	70	N	Regular	12	9	12	9	RHD, SEVMR, MILD MS, SEV PAH	DOE, PALP
2	MARY JOHNY	50	N	Regular	12	9	12	9	RHD, SEV MS, MOD MR, MOD PAH, SR	DOE
3	RIYAMMA YOHAN	49	Y	Regular	11	8	10	8	RHD, SEV MS, MOD MR, LA CLOT,PAH	DOE, EDEMA
4	SELVI	60	N	Regular	11	8	11	8	RHD, SEV MS, MOD MR, MILD TR, GDLV	DOE,PALP
5	SUMATHY C.T	63	Y	Irregular	10	7	10	7	D, SEV CAL MS, MOD MR, MILD PAH, GD	DOE, PALP
6	VALSAMMA. T. K	44	N	Regular	10	8	10	8	RHD, SEV CAL MS, MILD MR, MOD PAH	DOE, PND, PALP
7	DHANYA. K. S	53	N	Regular	11	8	11	8	RHD, SEV MS, SEV PAH, ASD	DOE, PALP
8	CHELLAMMA	60	N	Regular	11	8	11	8	RHD, SEV MS, MOD AR, MOD PAH	DOE, PALP
9	RASWATHI AMM	40	N	Regular	10	8	10	8	RHD, SEV CAL MS, SEV PAH	DOE
10	SHYLA. R	50	N	Regular	11	9	12	9	RHD, SEV MR, MILD MS, SEV PAH, GDLV	DOE, PALP
11	NITHYA. J	70	N	Irregular	10	8	10	8	RHD, SEV MR, GD LV	DOE
12	PECHIYAMAL	64	N	Regular	13	10	14	10	RHD, SEV MR, MOD MS	DOE
13	ANUJA AUGUST	70	N	Irregular	11	8	11	7	RHD, MOD MS, SEV MR	DOE
14	FATHIMA BEEVI	55	N	Regular	10	8	10	8	RHD, MOD MS, MOD MR, GDLV	DOE
15	SHIRLEY	71	N	Irregular	10	8	12	9	RHD, SEV MS, MOD MR, SEV PAH, AF	DOE, PALP
16	NAFEESA	64	N	Regular	10	8	10	9	RHD, MODMS, MOD MR,TR, GDLV	DOE
17	SYAMALA	45	N	Regular	10	8	10	8	RHD, SEV MS, MOD MR, GDLV	DOE, PALP
18	ROSILY DEVASSY	40	N	Regular	10	8	10	8	D , SEV MS, MILD AR, MOD PAH, MR, GD	DOE
19	SIVADASAN E.K	62	N	Regular	12	8	12	8	RHD, SEV MS, MILD MR, GDLV	DOE, PALP
20	PRAJITHA. K	70	N	Regular	11	8	11	8	RHD, SEV MR, MILD MS, GDLV	DOE, PALP
21	RAMESAN. P	43	N	Regular	10	8	10	8	RHD, MOD MR, MILD MS, GDLV	DOE, PALP
22	CHANDRA.S	72	N	Regular	11	8	10	8	RHD, SEV MS, GDLV	DOE
23	SHOJI. P. O	62	Y	Irregular	11	8	11	8	RHD, SEV MS, MOD MR, GDLV	DOE, PALP
24	PONNAN	58	N	Regular	12	8	12	8	MVP, SEV MR, GDLV	DOE, PALP
25	VALSADEVI AMM	56	N	Irregular	8	6	8	6	RHD, SEV MS, MOD TR, GDLV, PAH	DOE, PALP
26	SHANTI KUMARI	44	N	Irregular	11	7	10	7	RHD, MOD MR, MOD MS	DOE, SYNCOPE
27	HARIDASSAN. A	62	N	Irregular	11	8	11	8	RHD, SEV MS, MOD MR	DOE, PALP
28	ASHRAF.K.K	62	N	Irregular	10	9	10	8	RHD,SEV MR, MILD PAH, GDLV, AF	DOE
29	SHYLAMANI	60	Y	Irregular	15	13	15	11	RHD SEV MS, MOD MR, GDLV	DOE, PALP
30	LALLY. M.J	61	N	Irregular	10	8	10	9	RHD, SEVMS, MILD MR, TR, PAH, FAIR LV	DOE,PALP
31	KUMARAN. P	60	N	Irregular	11	8	11	8	RHD, MOD MS, SEV MR, MOD AR, GDLV	DOE
32	SULAIMAN. K	43	N	Regular	12	8	11	8	RHD, SEV CAL MS, MOD MR, MOD PAH	DOE
33	HARI. G	60	N	Regular	11	8	11	8	, MOD MS, MOD MR, MOD TR, MILD PR,	DOE, PALP
34	YSSAMMA ROCK	49	N	Irregular	12	8	12	8	RHD, SEV MS, GDLV, AF	DOE, PALP
35	BINDU. K	75	N	Regular	11	9	11	9	RHD, SEV MR, DIL LV,	DOE
36	SIDHIQUE. K	52	N	Irregular	12	8	12	9	RHD, SEV MS, MOD TR, GDLV	DOE
37	SOMAN. S	52	Y	Irregular	10	8	10	8	RHD, SEV MS, MOD PAH, LA CLOT	DOE, PALP
38	AMACHANDRAN.	35	N	Regular	12	10	12	10	MVP OF AML, SEV MR, GDLV	DOE
39	SINOY ABRAHAM	45	N	Regular	14	11	14	12	MVP AML, PML, SEV MR, DIL LV	DOE, AOE, SYNCOPE
40	SHAJI.V.J	48	N	Regular	13	10	13	10	MVP AML, PML, GD LV, SR,COPD	AOE
41	RAMAN KUTTY	70	Y	Irregular	13	10	11	9	RHD, SEV MS, MOD MR, MOD LVD	DOE
42	SHAJI. K	60	N	Regular	11	8	11	8	RHD, SEV MR, MILD MS, GDLV	DOE
43	ALAKRISHNAN	60	N	Irregular	12	10	12	10	RHD, SEV MS, MOD MR, PAH	DOE, PALP
44	MANOHARAN P	55	N	Regular	11	8	11	8	MVP AML, PML, SEV MR	DOE
45	SABU V.P	62	N	Regular	11	8	11	8	RHD, MOD PAH, SEV MS, MOD AR	DOE, SYNCOPE

INTRA-OPERATIVE TRANS ESOPHAGEAL ECHO FINDINGS OF CHVP														
SR NO	Chordal preservation	Peak velocity (m/sec)	Peak gradient (mm of Hg)	mean velocity (m/sec)	mean gradient (mm of Hg)	heart rate	PHT (m sec)	MVA by PHT (cm2)	LVOT diamet (CMs)	LVOT VTI	CHVP VTI	DVI	EOA (cm2)	i EOA (cm2/m2)
1	Y	1.85	7.9	0.89	3.6	84	101	2.2	1.9	16	34	2.1	1.3	0.9
2	Y	1.63	8.3	0.66	5.1	88	89	2.5	2.0	16	38	2.4	1.3	0.9
3	Y	1.46	10.5	0.70	6.2	80	116	1.9	1.9	16	32	2.1	1.4	1.0
4	N	1.42	6.0	0.98	3.8	70	90	2.4	1.5	20	26	1.3	1.4	1.0
5	Y	1.48	8.0	0.88	5.9	80	88	2.5	2.0	16	34	2.1	1.5	1.1
6	Y	2.10	10.0	1.10	7.7	84	87	2.5	1.9	17	30	1.7	1.6	1.1
7	Y	1.84	9.0	0.76	3.5	80	75	2.9	1.8	18	30	1.7	1.5	1.2
8	Y	1.72	11.0	1.16	6.8	80	89	2.5	1.9	17	36	2.1	1.4	1.0
9	Y	1.61	8.0	0.72	3.0	80	98	2.2	1.8	17	28	1.6	1.5	1.2
10	Y	1.24	5.2	0.73	2.5	100	94	2.3	1.9	14	21	1.5	1.9	1.3
11	Y	1.66	4.5	0.71	2.3	102	93	2.4	1.8	19	29	1.6	1.6	1.2
12	N	1.44	4.9	0.67	3.0	80	60	3.7	1.7	20	22	1.1	2.0	1.3
13	Y	1.24	4.6	0.74	2.4	90	73	3.0	1.9	17	20	1.2	2.4	1.4
14	Y	1.50	8.9	0.66	2.4	70	76	2.9	1.6	25	28	1.1	1.8	1.1
15	Y	1.80	4.6	0.55	3.4	80	109	2.0	1.9	19	28	1.5	1.9	1.3
16	Y	1.42	5.9	0.80	3.0	84	73	3.0	1.7	21	26	1.3	1.8	1.4
17	Y	1.47	4.1	0.66	2.5	74	76	2.9	2.0	19	32	1.7	1.8	1.1
18	N	1.32	4.0	0.66	2.7	70	107	2.1	1.8	17	25	1.4	1.8	1.4
19	Y	1.61	10.0	1.08	5.0	78	80	2.8	1.6	17	18	1.1	1.9	1.1
20	Y	1.54	9.0	0.97	4.0	70	78	2.8	1.9	22	32	1.4	2.0	1.4
21	Y	1.34	4.0	0.66	2.8	75	88	2.5	1.6	20	23	1.1	1.8	1.2
22	N	1.27	4.6	0.67	2.1	74	98	2.2	1.7	22	30	1.4	1.7	1.1
23	N	1.39	8.0	0.94	4.0	100	90	2.4	1.9	19	28	1.5	1.9	1.1
24	Y	1.37	6.0	0.80	3.0	72	78	2.8	1.6	24	25	1.1	1.8	1.2
25	Y	1.61	10.0	0.88	4.0	90	87	2.5	1.6	22	25	1.1	1.7	1.1
26	Y	1.19	5.7	0.69	2.4	100	73	3.0	1.6	19	21	1.1	1.8	1.3
27	Y	1.15	5.3	0.80	2.3	90	78	2.8	2.0	21	28	1.4	2.3	1.5
28	Y	1.26	6.4	0.78	2.2	90	95	2.3	1.9	18	27	1.5	1.9	0.9
29	Y	1.21	4.1	0.62	1.9	94	74	3.0	1.7	20	23	1.1	1.9	1.3
30	Y	1.39	7.7	0.81	2.3	70	78	2.8	1.9	19	24	1.3	2.0	1.4
31	Y	1.30	6.8	0.93	2.5	84	84	2.6	1.4	28	19	0.7	2.3	1.4
32	N	1.40	8.0	0.81	2.8	60	73	3.0	2.0	19	26	1.3	2.3	1.4
33	Y	1.37	8.0	0.70	2.5	84	65	3.4	1.9	17	25	1.4	2.0	1.3
34	Y	1.03	4.0	0.72	2.3	90	68	3.2	1.6	23	21	0.9	2.2	1.5
35	Y	1.20	4.0	0.74	2.3	80	101	2.2	1.8	16	20	1.2	2.1	1.2
36	Y	1.04	4.0	0.82	2.1	74	80	2.8	2.1	13	20	1.5	2.4	1.5
37	N	1.13	5.1	0.64	2.0	80	108	2.0	1.8	25	26	1.1	2.3	1.6
38	Y	1.16	6.0	0.70	2.2	80	77	2.9	2.0	17	23	1.4	2.3	1.4
39	Y	1.42	9.0	1.00	2.7	80	90	2.4	2.0	18	25	1.4	2.3	1.2
40	Y	1.34	8.0	1.22	2.5	72	100	2.2	1.9	17	23	1.4	2.1	1.3
41	N	1.19	5.6	0.70	1.8	80	57	3.8	1.9	14	17	1.2	2.4	1.3
42	Y	0.88	3.0	0.55	2.1	90	82	2.7	2.0	22	23	1.1	3.0	2.2
43	N	1.02	3.4	0.87	1.4	80	80	2.8	2.0	16	20	1.3	2.5	1.4
44	Y	1.24	8.0	1.00	2.6	78	70	3.1	1.8	17	20	1.2	2.2	1.4
45	Y	1.04	6.0	1.00	2.0	74	70	3.1	2.0	19	23	1.2	2.6	1.6

INTRA-OPERATIVE TRANS ESOPHAGEAL ECHO FINDINGS OF CHVP												
SR NO	IW (sys)	IW (dia)	SW (sys)	SW (dia)	CHVP #	AOA (cm2)	LVEF	LVID dias	LVID sys	CPB duration (min)	CC duration (min)	weaning attempts
1	12	9	12	9	23	2.54	65	60	40	74	48	1
2	12	9	12	9	23	2.54	60	40	23	110	75	1
3	11	8	10	8	23	2.54	63	31	19	85	56	1
4	11	8	11	8	23	2.54	65	42	28	72	46	1
5	10	7	10	7	23	2.54	52	38	28	98	48	1
6	10	8	10	8	23	2.54	62	40	27	80	53	1
7	11	8	11	8	23	2.54	65	38	25	71	50	1
8	11	8	11	8	23	2.54	68	34	26	65	41	1
9	10	8	10	8	23	2.54	65	30	20	232	158	2
10	11	9	12	9	25	3.14	62	52	32	114	65	1
11	10	8	10	8	25	3.14	62	60	34	90	54	1
12	13	10	14	10	25	3.14	65	54	38	76	56	1
13	11	8	11	7	25	3.14	60	62	40	82	58	1
14	10	8	10	8	25	3.14	60	44	28	99	64	1
15	10	8	12	9	25	3.14	41	40	32	60	44	1
16	10	8	10	9	25	3.14	48	47	24	155	106	2
17	10	8	10	8	25	3.14	65	40	27	87	50	1
18	10	8	10	8	25	3.14	60	41	30	52	33	1
19	10	9	10	8	25	3.14	62	46	31	79	58	2
20	15	13	15	11	25	3.14	65	51	30	110	76	1
21	10	8	10	9	25	3.14	65	49	35	74	47	1
22	11	8	11	8	25	3.14	60	52	30	112	89	1
23	12	8	11	8	25	3.14	64	40	26	86	66	1
24	11	8	11	8	25	3.14	70	56	33	74	50	1
25	12	8	12	8	25	3.14	65	39	28	67	51	1
26	11	9	11	9	27	3.79	60	42	30	80	50	1
27	12	8	12	9	27	3.79	60	54	32	106	56	1
28	10	8	10	8	27	3.79	55	51	38	88	69	1
29	15	13	15	11	27	3.79	45	38	28	64	45	1
30	10	8	10	9	27	3.79	40	43	30	142	101	1
31	11	8	11	8	27	3.79	50	53	23	98	48	1
32	12	8	11	8	27	3.79	62	46	33	109	65	2
33	11	8	11	8	27	3.79	68	44	28	116	73	1
34	12	8	12	8	27	3.79	65	45	30	65	34	1
35	11	9	11	9	29	4.52	60	60	33	120	66	1
36	12	8	12	9	29	4.52	60	48	35	98	64	1
37	10	8	10	8	29	4.52	55	45	32	114	76	1
38	12	10	12	10	29	4.52	60	43	37	104	72	1
39	14	11	14	12	29	4.52	60	54	35	97	60	1
40	13	10	13	10	29	4.52	70	50	34	122	75	1
41	13	10	11	9	31	5.30	55	50	36	131	75	1
42	11	8	11	8	31	5.30	60	58	40	107	69	1
43	12	10	12	10	31	5.30	62	50	28	117	63	1
44	11	8	11	8	31	5.30	60	54	33	107	56	1
45	11	8	11	8	31	5.30	65	53	30	112	60	1

POST-OPERATIVE TRANSTHORACIC ECHOCARDIOGRAPHY FINDINGS

SR NO	NAME	LVID dias	LVID sys	IW (sys)	IW (dia)	SW (sys)	SW (dia)	CHVP #	MR	TR	AR	PR
1	PRAVEEN K	50	39	10	8	10	8	23	0	1	0	0
2	MARY JOHNY	38	21	11	8	11	8	23	0	0	0	0
3	MARIYAMMA YOHANAN	38	25	11	8	11	8	23	0	1	0	0
4	SELVI	40	27	9	7	9	7	23	0	1	0	0
5	SUMATHY C.T	43	27	10	8	10	8	23	1	0	0	0
6	VALSAMMA. T. K	38	25	10	8	10	8	23	1	0	0	0
7	DHANYA. K. S	35	25	10	8	10	8	23	0	3	1	0
8	CHELLAMMA	40	28	9	7	9	7	23	0	1	0	0
9	SARASWATHI AMMA	53	35	12	8	12	8	23	1	2	0	0
10	SHYLA. R	48	29	10	8	10	8	25	0	1	0	0
11	NITHYA. J	41	36	10	8	10	8	25	0	1	0	0
12	PECHIYAMAL	41	31	10	8	10	8	25	0	1	0	0
13	DHANUJA AUGUSTIN	51	40	11	7	11	7	25	0	1	0	0
14	FATHIMA BEEVI	40	27	11	8	11	8	25	0	2	0	0
15	SHIRLEY	49	36	10	7	10	7	25	0	1	0	0
16	NAFEESA	44	33	11	8	11	8	25	0	0	0	0
17	SYAMALA	46	34	11	8	11	8	25	0	1	0	0
18	ROSILY DEVASSY	46	30	10	8	10	8	25	0	0	0	0
19	SIVADASAN E.K	45	28	11	8	11	8	25	1	1	0	1
20	PRAJITHA. K	45	32	11	6	11	8	25	0	1	0	0
21	RAMESAN. P	46	30	11	8	11	8	25	0	0	0	0
22	CHANDRA.S	46	26	11	8	11	8	25	0	0	0	0
23	SHOJI. P. O	45	32	12	8	12	8	25	0	0	0	0
24	PONNAN	51	34	12	8	12	8	25	2	2	0	1
25	VALSADEVI AMMA	36	25	12	9	12	9	25	0	2	2	0
26	SHANTI KUMARI	50	37	10	7	10	7	27	0	0	0	0
27	HARIDASSAN. A	43	27	11	8	11	8	27	1	0	1	0
28	ASHRAF.K.K	52	40	11	8	11	8	27	0	1	0	0
29	SHYLAMANI	50	32	13	8	13	8	27	0	0	0	0
30	LALLY. M.J	50	37	10	8	10	8	27	0	0	0	0
31	KUMARAN. P	42	25	11	8	11	8	27	0	0	0	0
32	SULAIMAN. K	44	35	11	8	11	8	27	0	0	0	0
33	HARI. G	46	30	12	8	12	8	27	0	0	0	0
34	LYSSAMMA ROCKY	50	36	11	8	11	8	27	0	1	1	0
35	BINDU. K	54	40	10	8	10	8	29	0	1	2	0
36	SIDHIQUE. K	45	28	12	8	12	8	29	0	0	0	0
37	SOMAN. S	34	46	10	8	10	8	29	1	1	0	0
38	RAMACHANDRAN. K	54	36	14	11	14	11	29	0	1	0	0
39	SINOY ABRAHAM	51	25	12	10	12	10	29	0	0	0	0
40	SHAJI.V.J	48	27	11	9	11	9	29	1	1	0	1
41	RAMAN KUTTY	46	22	14	10	14	10	31	0	1	0	0
42	SHAJI. K	55	30	10	8	10	8	31	0	0	0	0
43	BALAKRISHNAN K	47	24	11	7	11	7	31	1	2	0	0
44	MANOHARAN P	51	38	12	9	11	8	31	0	1	0	0
45	SABU V.P	49	35	10	8	10	7	31	0	0	0	0

POST-OPERATIVE TRANSTHORACIC ECHOCARDIOGRAPHY FINDINGS

SR NO	CHVP #	Peak velocity (m/sec)	Peak gradient (mm of Hg)	mean velocity (m/sec)	mean gradient (mm of Hg)	heart rate	PHT (m sec)	MVA by PHT (cm2)	LVOT diamet (CMs)	LVOT VTI	CHVP VTI	DVI	EOA (cm2)	i EOA (cm2/m2)
1	23	1.9	16	1.2	7.0	87	120	1.8	1.9	17	34	2.0	1.4	1.0
2	23	1.2	11	1.3	6.0	100	88	2.5	1.8	20	32	1.6	1.6	1.1
3	23	1.6	13	0.9	6.3	98	114	1.9	1.9	20	35	1.7	1.7	1.2
4	23	1.3	6	0.8	5.0	66	117	1.9	1.4	25	25	1.0	1.6	1.1
5	23	2.0	15	1.3	7.0	88	105	2.1	1.8	20	36	1.8	1.4	1.0
6	23	1.6	9	1.2	7.0	102	107	2.1	1.9	19	36	1.9	1.5	1.0
7	23	1.7	13	1.1	6.0	72	130	1.7	1.8	18	32	1.8	1.4	1.1
8	23	1.2	9	0.9	5.0	74	88	2.5	1.7	22	36	1.6	1.4	1.1
9	23	1.5	12	0.8	5.4	76	100	2.2	1.8	18	32	1.8	1.4	1.1
10	25	1.2	7	0.8	4.0	68	98	2.2	1.9	18	31	1.7	1.6	1.2
11	25	1.2	10	0.8	5.6	71	98	2.2	1.8	19	28	1.5	1.7	1.3
12	25	1.1	9	0.7	5.0	63	90	2.4	1.7	19	22	1.2	1.8	1.2
13	25	1.4	10	0.8	4.2	66	87	2.5	1.9	25	34	1.3	2.1	1.3
14	25	1.5	8	1.1	4.8	80	98	2.2	1.6	23	24	1.1	1.9	1.1
15	25	1.5	12	0.7	3.2	83	97	2.3	1.9	24	33	1.4	2.1	1.4
16	25	1.8	6	1.1	3.8	81	98	2.2	1.7	22	27	1.2	1.9	1.4
17	25	1.2	10	0.8	4.0	73	96	2.3	1.8	29	36	1.2	2.0	1.3
18	25	1.8	8	1.1	3.5	74	100	2.2	1.8	24	34	1.4	1.8	1.4
19	25	1.3	11	0.7	4.0	65	92	2.4	1.6	35	31	0.9	2.3	1.3
20	25	1.6	8	1.1	4.0	68	102	2.2	1.9	26	39	1.5	1.9	1.3
21	25	1.3	8	1.0	3.0	69	90	2.4	1.6	28	29	1.1	1.9	1.3
22	25	1.7	6	0.8	4.1	98	92	2.4	1.7	29	35	1.2	1.9	1.3
23	25	1.4	11	0.7	3.0	71	93	2.4	1.9	23	30	1.3	2.1	1.2
24	25	1.4	11	0.9	3.0	71	94	2.3	1.6	32	31	0.9	2.0	1.3
25	25	1.4	10	0.8	4.0	63	88	2.5	1.6	33	30	0.9	2.1	1.4
26	27	1.3	9	0.9	3.0	66	104	2.1	1.6	28	27	1.0	2.1	1.4
27	27	1.2	6	0.7	3.0	64	76	2.9	2.0	22	31	1.4	2.3	1.4
28	27	1.5	11	0.6	3.9	69	90	2.4	1.9	23	29	1.3	2.3	1.1
29	27	1.3	9	1.1	5.0	69	98	2.2	1.7	29	31	1.1	2.0	1.4
30	27	1.1	11	0.7	4.1	70	90	2.4	1.9	26	31	1.2	2.2	1.6
31	27	1.5	11	0.8	4.0	70	89	2.5	1.5	31	25	0.8	2.2	1.3
32	27	1.4	11	0.9	4.2	73	94	2.3	2.0	20	29	1.5	2.1	1.3
33	27	1.4	9	0.7	4.0	74	86	2.6	1.9	27	34	1.3	2.2	1.4
34	27	1.2	11	0.6	2.8	73	83	2.7	1.6	26	23	0.9	2.3	1.5
35	29	1.6	10	0.9	3.0	80	76	2.9	1.8	34	32	0.9	2.7	1.6
36	29	1.5	8	0.7	3.2	80	78	2.8	2.1	21	31	1.5	2.4	1.6
37	29	1.2	9	0.9	3.0	84	74	3.0	1.8	31	29	0.9	2.6	1.8
38	29	1.2	7	0.7	4.0	77	78	2.8	2.0	31	36	1.2	2.7	1.6
39	29	1.5	8	0.8	4.0	72	70	3.1	1.8	29	27	0.9	2.8	1.5
40	29	1.3	7	0.8	3.8	70	69	3.2	1.7	26	23	0.9	2.6	1.6
41	31	1.4	9	0.7	3.2	66	64	3.4	1.8	26	23	0.9	2.9	1.7
42	31	1.2	6	0.5	2.0	64	66	3.3	1.9	26	24	0.9	3.1	2.3
43	31	1.7	3	0.5	1.9	68	65	3.4	1.9	35	29	0.8	3.4	1.9
44	31	1.5	7	0.8	2.8	72	64	3.4	1.7	31	25	0.8	2.8	1.8
45	31	1.3	8	0.6	3.0	70	60	3.7	1.7	35	25	0.7	3.2	2.0

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