A RETROSPECTIVE STUDY TO COMPARE EARLY POST-OP GRADIENT AND LV REGRESSION BETWEEN METAL AND BIOPROSTHETIC VALVE OF SIMILAR SIZE IN CASE OF AORTIC STENOSIS

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MCh CARDIOTHORACIC AND VASCULAR SURGERY

THESIS YEAR:2021-2023

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A THESIS SUBMITTED BY

Dr. Pravin Narayan Karande

TO

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AND TECHNOLOGY, TRIVANDRUM.

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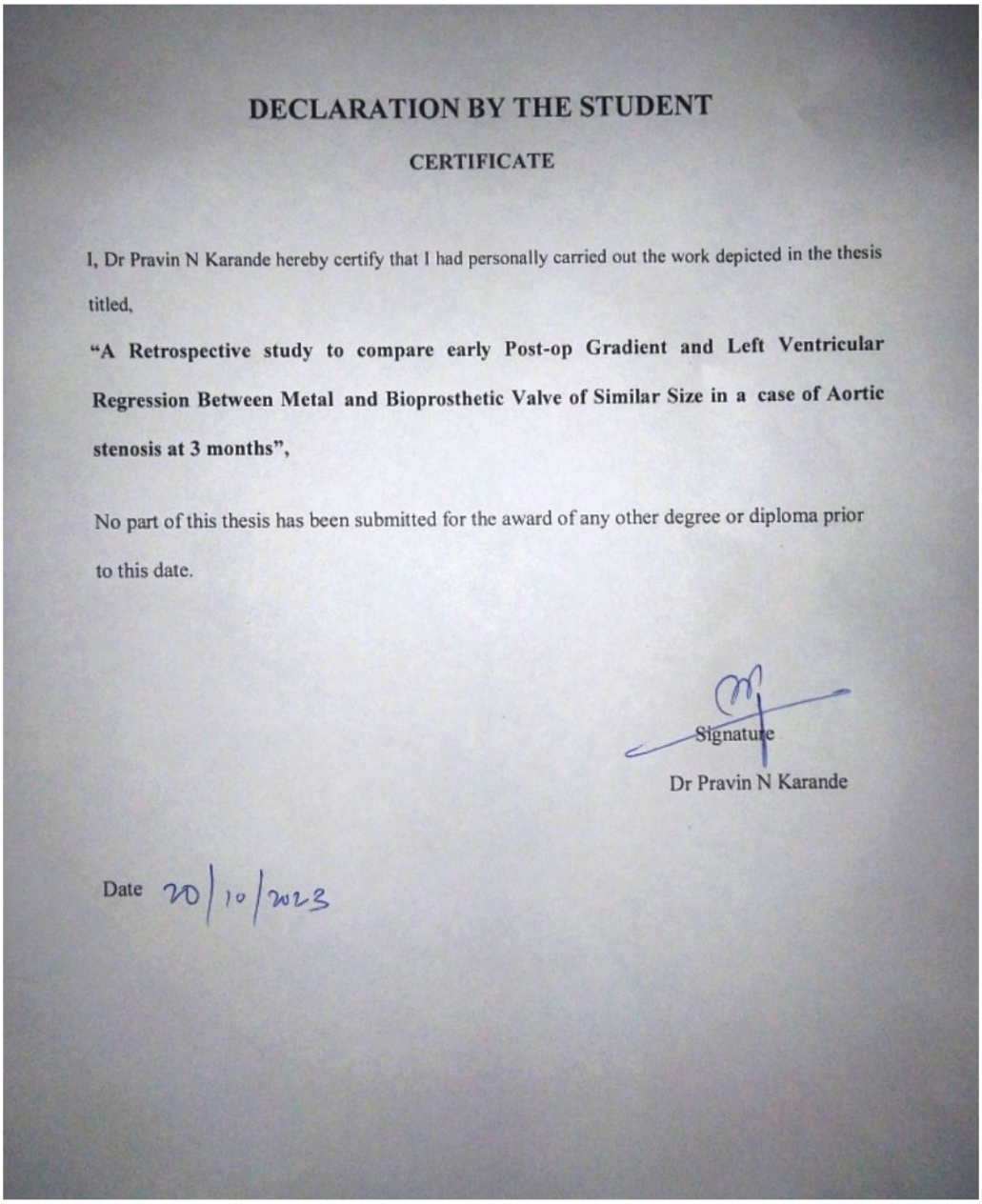
DECLARATION BY STUDENT



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CERTIFICATE

I, Dr Pravin N Karande hereby certify that I had personally carried out the work depicted in the thesis titled,

"A Retrospective study to compare early Post-op Gradient and Left Ventricular Regression Between Metal and Bioprosthetic Valve of Similar Size in a case of Aortic stenosis at 3 months",

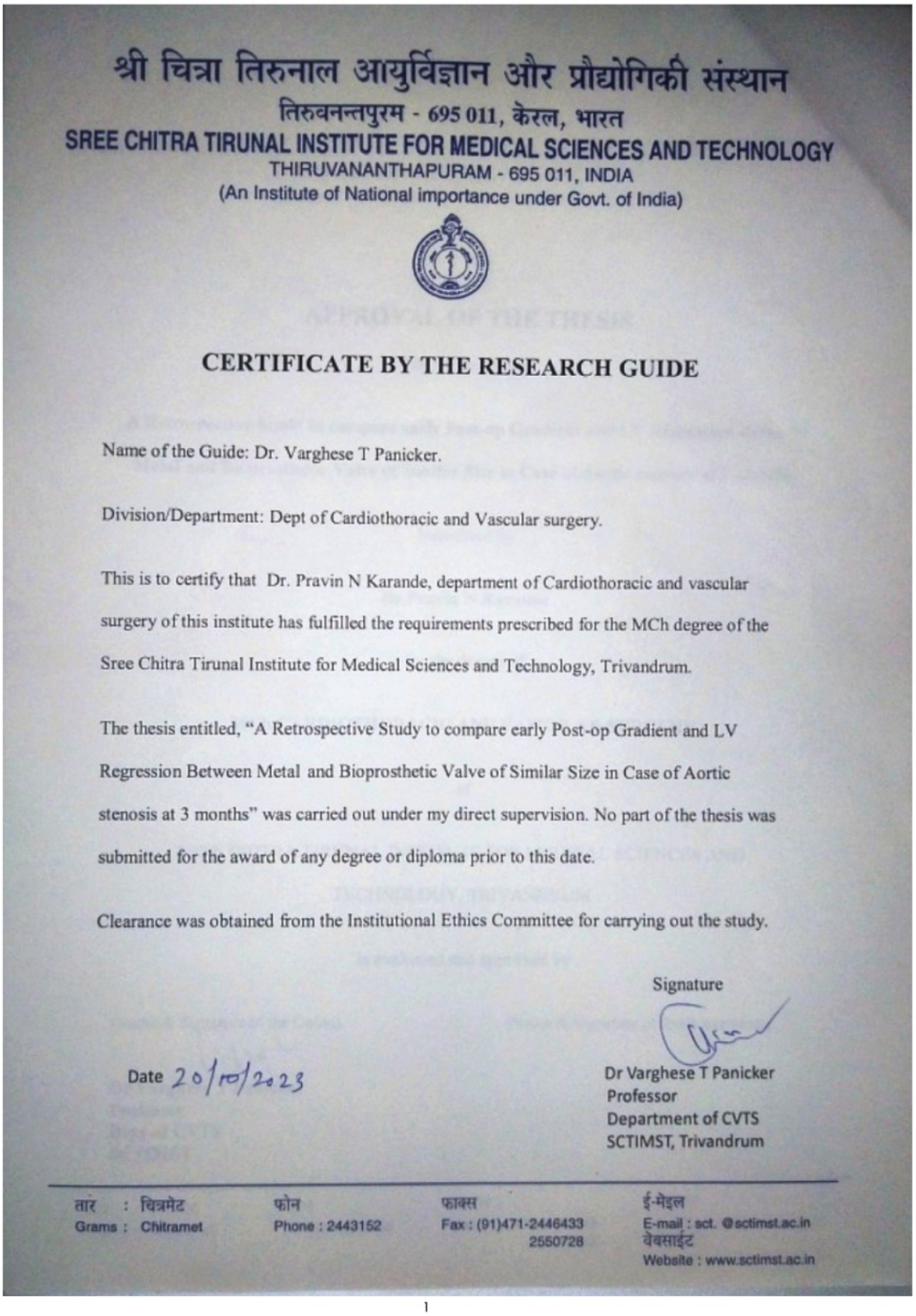
No part of this thesis has been submitted for the award of any other degree or diploma prior to this date.

Signature

Dr Pravin N Karande

Date 20/10/2023

CERTIFICATE BY RESEARCH GUIDE



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Division/Department: Dept of Cardiothoracic and Vascular surgery.

This is to certify that Dr. Pravin N Karande, department of Cardiothoracic and vascular surgery of this institute has fulfilled the requirements prescribed for the MCh degree of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, "A Retrospective Study to compare early Post-op Gradient and LV Regression Between Metal and Bioprosthetic Valve of Similar Size in Case of Aortic stenosis at 3 months" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

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APPROVAL OF THE THESIS

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The thesis entitled

A Retrospective Study to compare early Post-op Gradient and LV Regression Between Metal and Bioprosthetic Valve of Similar Size in Case of Aortic stenosis at 3 months.

Submitted by

Dr.Pravin N Karande

for the degree of

MCh CARDIOTHORACIC AND VASCULAR SURGERY

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LIST OF ABBREVIATIONS

SR NO	ABBREVIATION	FULL FORM
1.	ACC	American College of Cardiology
2.	ACE	Angiotensin-converting enzyme
3.	AHA	American Heart Association
4.	AS	Aortic Stenosis
5.	AVA	Aortic Valve Area
6.	AVR	Aortic Valve Replacement
7.	BAV	Bicuspid Aortic Valve
8.	bAVR	Bicuspid Aortic Valve Replacement
9.	CHVP	TTK Chitra heart valve prosthesis
10.	CMR	Cardiovascular magnetic resonance
11.	CT	Computed Tomography
12.	Dr	Doctor
13.	ESC	European Society of Cardiology
14.	ECM	extracellular matrix

15.	EOA	Effective Orifice Area
16.	EROA	Effective Regurgitant Orifice Area
17.	Hg	mercury
18.	HF	Heart Failure
19.	ICAM	Intercellular adhesion molecule
20.	INR	International normalized Ratio
21.	LV	Left Ventricle
22.	LVEF	Left Ventricle Ejection Fraction
23.	LVIDd	Left Ventricular Internal Dimension in Diastole
24.	LVESD	Left Ventricular-end Systolic Dimension
25.	LVMI	Left Ventricular Mass Index
26.	LVOT	Left Ventricular Outflow Tract
27.	mAVR	Mechanical Aortic Valve Substitutes
28.	MMP	Matrix Metalloproteinases
29.	MRI	Magnetic Resonance Imaging
30.	NYHA	New York Heart Association

31.	PROACT	Providing Rapid Out of Hospital Acute Cardiovascular Treatment
32.	PWDd	Posterior Wall Diameter in diastole
33.	SAVR	Surgical Aortic Valve Replacement
34.	SVD	Supravalvular Aortic Stenosis
35	TAVR	Transcatheter Aortic Valve Replacement
36.	TTE	Transthoracic Echocardiography
37.	TEE	Transoesophageal Echocardiography
38.	VCAM	Vascular Cell Adhesion Molecule
39.	VKA	Vitamin K Antagonists
40.	V_{max}	Maximum Velocity

SYNOPSIS

Aortic stenosis (AS) is a common valvular heart disease affecting the aortic valve, impeding blood flow from the left ventricle to the aorta. The prevalence of AS increases with age, affecting 2-7% of individuals over 65 years old. The most common cause of AS in older individuals is degenerative calcific aortic stenosis, which occurs due to age-related degeneration and calcification of the aortic valve leaflets. Bicuspid aortic valve disease (BAV) is another significant etiology of AS, accounting for a substantial proportion of cases in younger individuals. Other less common causes include rheumatic heart disease, congenital abnormalities, and radiation-induced valvular disease.

Treatment options for aortic stenosis include surgical and transcatheter interventions. Aortic valve replacement is the standard surgical approach, involving the use of mechanical or bioprosthetic valves. Medical management focuses on regular monitoring and controlling associated risk factors such as hypertension and hyperlipidaemia. Aortic valve replacement (AVR) includes surgical AVR (SAVR), transcatheter AVR (TAVR), and balloon valvuloplasty.

The study aims to compare the early post-operative gradient & left ventricular mass regression between metal and bioprosthetic valves of similar size after aortic valve replacement in a case of aortic stenosis. It is important to consider individual patient characteristics, including age, comorbidities, and valve morphology, when deciding on the most appropriate treatment strategy. Regular follow-up and monitoring of patients

with aortic stenosis or aortic regurgitation are essential to detect disease progression and determine the optimal timing for intervention.

After relevant permission taken from the Institute of Ethical Committee (IEC) of a of a Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivendrum (SCTIMST) prior to the study conduction. A retrospective, observational study design is performed by utilizing a secondary recorded data from the Department of Cardiovascular and Thoracic Surgery. We got total 110 number of patients with aortic valve replacement, which underwent surgical management between the 2017-2021 years. From those 50 numbers of cases only participated in our study according to our eligibility criteria. Written informed or telephonic verbal consent was taken prior to the study setting. Confidentiality is maintained during study settings.

Study included patients, who underwent aortic valve replacement surgery, having aortic stenosis only. And excluded the patients having aortic valve redo surgeries, aortic regurgitation, valve repair, double valve replacement surgery, coarctation, aortic aneurysms and combined with coronary artery bypass graft. Preoperative, immediate post-operative and postoperatively after 3 months follow up data was collected through electronic medical records (EMR). Retrospective analysis of data and clinical examination of the post-operative follow-up was performed by the principal investigator and co-investigators.

Compilation of data was done in a systematic manner. Using a Microsoft excel worksheet (Microsoft, USA, version 8.1) A master table was made, accordingly, the data

was subdivided and distributed which was presented in the form of individual tables and figures. Statistical analysis using International Business Machines, Statistical Package for Social Science (Statistics for Windows, version 25.0, Armonk, NY: IBM Corp.) was done and the comparison of data was carried out by applying statistical tests in order to find the statistical significance of the results.

The patients who underwent aortic valve replacement with bioprosthetic valve had a mean age ranging between 64 to 65 years. On the other hand, those who received the metal valve had a slightly younger mean age, ranging from 49 to 52.5 years for all the valve size numbers. Among all patients who underwent aortic valve replacement surgery with both Metal and bioprosthetic valves, a greater number of patients were in NYHA functional class III compared to NYHA functional class II. The transvalvular gradient in a mean is gradually reduced from pre-operative observations to immediate post-operative observations and further post-operative follow up at 3 months value is reduced 1-3% found in all the sizes of metal and bioprosthetic valve patients. This study examines the left ventricle mass regression index (LVMI) after aortic valve replacement using metal and bioprosthetic valves in various sizes. Both valves showed reduction in left ventricular mass index (LVMI), post-surgery. For size 19 and 21 valves, no significant difference in left ventricle mass regression index is observed between the two types. Long-term follow-up is needed for a comprehensive assessment.

This study included patients aged between 42 to 70 years, with a mean age of 56.70 years and a standard deviation of ±8.627. Compared with other studies, Minghao Lin et al. (2020) reported a similar mean age of 53.50±10, while Bo Fu et al. (2021) and Cagayan H A et al. (2021) had higher mean ages of 72.6±5.1 and 83±5, respectively, possibly due to racial similarities and the prevalence of severe aortic stenosis at older ages. The lower mean age in our study may be attributed to India's lower life expectancy of 61 years. The New York Heart Association (NYHA) classifications were similar in both metal and bioprosthetic valve-replaced patients undergoing aortic valve replacement surgery. For Metal valve, 37.9% showed class II, and 62.1% showed class III. Similarly, for bioprosthetic valve, 38.1% showed class II, and 61.9% showed class III. A study by Thomas et al. (2009) on Perimount Magna valve showed 64.95% in NYHA class III, and 14.29% in NYHA class II, which aligns slightly with our class III results. Minghao Lin et al (2020) findings were not specifically mentioned in this context. In patients undergoing valve replacement with metal valve, the mean peak transvalvular gradient decreased from 83.38 mm Hg (pre-operative) to 16.14 mm Hg (immediate post-operative) and 12.41 mm Hg (post-operative). Similar findings were observed in another group with mean peak gradient reducing from 79.52 mm Hg to 16.19 mm Hg (immediate post-operative) and 12.81 mm Hg (post-operative). In a study by T. Ida et al. (2001), aortic valve gradients also decreased significantly following aortic valve replacement, reaching normal levels during early and late follow-up. The left ventricle mass index (LVMI) and relative regression of LVMI in the patients of this study were higher compared to western data but comparable to literature from India. Preoperative LVMI was 192.26±371.14, reducing to

142.42±298.15 post-operatively. In a 3-month follow-up study by Singh et al. (2016), preoperative LVMI was 199g±79.5 g/m2, decreasing to 130g±49.0 g/m2 after aortic valve replacement. There was no significant correlation between left ventricular mass regression and early or late postoperative gradients, possibly due to normal gradients achieved in all patients after surgery.

The study examines early postoperative outcomes of aortic valve replacement in patients with aortic stenosis using metal and bioprosthetic valves. Both types of replacements improve left ventricular function and structure, but some parameters, like left ventricular ejection fraction, differ between the two valve types. These insights aid clinicians in selecting the appropriate valve replacement for individual patients. Retrospective study, hence there may be information bias, The sample size is relatively small, which may limit the generalizability of the findings, Study is conducted in only one institute the outcome rate will be different in different populations and races.

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1. INTRODUCTION

1.1 General Introduction

Aortic stenosis (AS) is a common valvular heart disease that affects the aortic valve. Aortic stenosis refers to the narrowing or obstruction of the aortic valve, impeding the flow of blood from the left ventricle to the aorta (Maganti et al., 2010).

The epidemiology of aortic stenosis (AS) provides insights into the prevalence, incidence, and risk factors associated with these conditions. Here isan overview of the epidemiology of aortic stenosis (AS):

Aortic Stenosis (AS): AS is the most common valvular heart disease in developed countries, primarily affecting the elderly population. The prevalence of AS increases with age, and it is estimated to affect 2-7% of individuals over 65 years old (Nkomo et al., 2006; Osnabrugge et al., 2013). AS is more common in men than in women, with a male-to-female ratio of approximately 1.5:1 (Lindman et al., 2016).

The most common cause of AS in older individuals is degenerative calcific aortic stenosis, which occurs due to age-related degeneration and calcification of the aortic valve leaflets (Roberts and Ko, 2005). Bicuspid aortic valve disease (BAV) is another significant etiology of AS, accounting for a substantial proportion of cases in younger individuals (Zilla et al., 2008). Other lesscommon causes include rheumatic heart disease, congenital abnormalities, and radiation- induced valvular disease (Roberts and Ko, 2005).

Aortic stenosis can have various etiologies, but the most prevalent cause in younger patients is congenital abnormalities of the aortic valve, such as unicuspid or bicuspid aortic valve disease (Osnabrugge et al., 2013). Bicuspid aortic valve disease (BAV) is particularly common and is characterized by the presence of only two cusps instead of the normal three. Over time, the bicuspid valve may undergo structural deterioration, leading to the developmentof aortic stenosis (Akahori et al., 2011; Briand et al., 2005; Egbe et al., 2017). Rheumatic fever, although less common in developed nations, remains a significant cause of aortic stenosis in developing countries (Lindman et al., 2016).

The severity of aortic stenosis scan varies from mild to severe, and treatment decisions are typically based on the more severe dominant lesion. Diagnosis and grading of these conditions involve a comprehensive assessment of symptoms, physical examination, and imaging techniques such as echocardiography (Baumgartner et al., 2017; Nishimura et al., 2014). Timely intervention is crucial to prevent complications and improve patient outcomes.

Treatment options for aortic stenos are include both surgical and transcatheter interventions. Aortic valve replacement is the standard surgical approach, and it can involve the use of mechanical or bioprosthetic valves (Nishimura et al., 2014). Mechanical valves are durable but require lifelong anticoagulation therapy, while bioprosthetic valves have a limited lifespan but do not require anticoagulation. Transcatheter aortic valve replacement (TAVR) is a less invasive alternative suitable for select patients (Baumgartner et al., 2017).

The treatment modalities for aortic stenosis (AS) depend onthe severity of the condition, the presence of symptoms, and individual patient factors. Here is an overview of the treatment options for Aortic Stenosis:

Treatment modalities for Aortic Stenosis (AS):

Medical Management: In the absence of symptoms and with mild or moderate AS, medical management focuses on regular monitoring and controlling associated risk factors such as hypertension and hyperlipidaemia. Medications may be prescribed to manage symptoms and reduce the risk of complications.(Nishimura et al., 2014)

Aortic Valve Replacement (AVR):

a. Surgical Aortic Valve Replacement (SAVR): SAVR involves the complete removal of the diseased aortic valve and its replacement with a prosthetic valve. It is the gold standard treatment for severe symptomatic AS andcan also be considered for selected patients with asymptomatic severe AS (Baumgartner et al., 2017)

b. ranscatheter Aortic Valve Replacement (TAVR): TAVR is a less invasive procedure that involves deploying a prosthetic valve via a catheter inserted through an artery, typically in the groin. TAVR is an alternative to SAVR and is generally recommendedfor patients who are at high or prohibitive surgical risk or deemed inoperable.(Baumgartner et al., 2017; Nishimura et al., 2014)

c. Balloon Valvuloplasty: Balloon valvuloplasty is a procedure in which a balloon-tipped catheter is inserted into the narrowed aortic valve and inflated to widen the valve opening. It is primarily used as a temporary treatment for selected patients, such as infants with critical AS or as a bridge to definitive treatment in certain cases.(Baumgartner et al., 2017)

Research Question: Is there any difference in the early post-operative gradient & left ventricular mass regression between the metal & bioprosthetic valves of similar size after aortic valve replacement in a case of aortic stenosis?

Hypothesis: Is there any difference in the early post-operative gradient & left ventricular mass regression between the metal & bioprosthetic valves of similar size after aortic valve replacement in a case of aortic stenosis? (H)

Null Hypothesis: Yes, is there a difference in the early post-operative gradient & left ventricular regression between the metal & bioprosthetic valves of similar size after aortic valve replacement in a case of aortic stenosis. (H_0)

Alternative Hypothesis: No, there is not any difference in the early post-operative gradient & left ventricular mass regression between the metal & bioprosthetic valves of similar size after aortic valve replacement in a case of aortic stenosis (H_a)

1.2 Aim and Objectives-

Aim: To compare the early post-operative gradient & left ventricular mass regression between the metal & bioprosthetic valve of similar size after aortic valve replacement in a case of aortic stenosis.

Objectives:

1) To assess the early post-operative gradient & left ventricular mass regression of the metal valve after aortic valve replacement in a case of aortic stenosis.
2) To assess the early post-operative gradient & left ventricular mass regression of the bioprosthetic valve after aortic valve replacement in a case of aortic stenosis.
3) To compare the early post-operative gradient & left ventricular regression between the metal & bioprosthetic valves of similar size after aortic valve replacement in a case of aortic stenosis.

1.3 Scope of the Study-

It is important to consider the individual patient's characteristics, including age, comorbidities, and valve morphology, when deciding on the most appropriate treatment strategy (Akahori et al., 2011; Apostolakis et al.). Regular follow-up and monitoring of patients with aortic stenosis is an essential to detect disease progression and determine the optimal timing for intervention (Singh et al., 1999). Despite advances in perioperative evaluation, operative technique and post-operative evaluation, very few studies have focused on the comparison of valve gradient & left ventricular mass regression between

metal & bioprosthetic valves of size in aortic valve replacement in the early postoperative period. This retrospective study of our institutional experience is designed to analyze & compare aortic prosthetic valve gradient & left ventricle mass regression in early postoperative period.

1.4 Structure of the thesis-

In this thesis Introduction, General Introduction, aim and objectives of the study, scope of the study are mentioned earlier. In the chapter of "Literature Review" A brief description of aortic stenosis is given. The following points are described with respect to aortic stenosis and those are, the definition of aortic stenosis, classification of aortic stenosis, anatomy of aortic valve with its diagram, treatment for aortic stenosis along with regurgitation, replacement. At last, the left ventricular mass regression is mentioned in a short context.

In the chapter "Materials and Methods," all the details of study designs, location, selection criteria, sample selection method, conduction of the study, data collection procedure and statistical analytical procedures has described in detail.

The "Result" chapter consisted, of all the results obtained in the present study in a descriptive manner along with tabular figures for each. Results were obtained by demographic details (age, sex) of patients. Then their existing co-morbidity prior to the cardiac surgery has been given. All the variables such as NYHA functional class, height, weight, BSA status, LVEF, LVIDd, LVIDs etc., were recorded on pre-operative and post-operative examinations has been mentioned.

In the "Discussion" chapter our observations were compared and discussed along with existing literature findings. The possible reasons for those outcomes with the strengths and limitations are also mentioned.

Chapter “Summary and Conclusion” represents, a short description of our discussion with the limitations of this thesis and the conclusion was made by our findings on obtained results and discussion. In the last chapter of “References”, the source of all the referencing literature utilized in this thesis was mentioned. The citations and references followed the guideline of ‘Sage Harvard Referencing 2010’

2. LITERATURE REVIEW

As more and more people opt for minimally invasive procedures when it comes to fixing or replacing their heart's valves, there has been a renewed focus on the anatomy of the normal aortic valve complex. Prostheses must be made to fit a specific anatomical shape, so an understanding of anatomy is crucial to this process (Tilea et al., 2013). Aortic root refers to the aortic valve from its left ventricular outlet to its junction with the ascending portion of the aorta. It is the direct continuation of the left ventricular outflow tract (Anderson, 2007). The anatomic junction, or semilunar lines of attachment of arterial valvular leaflets, represents the hemodynamic ventriculo-arterial junction. The annulus is the virtual ring formed by joining the basal attachment points of leaflets within the left ventricle (Ho, 2009). The nodule of Arantius is a small fibrous mound formed at the center of each leaflet when the closing edge meets the free edge. Between the free and closing edges, there are two crescent-shaped areas called lunulae, representing the sites of cusp apposition during valve closure (Tilea et al., 2013). A study on 91 human semilunar valves from second and third trimester fetus, neonates, children, and normal adults found interesting results (Aikawa et al., 2006). Valves must accommodate to substantial hemodynamic changes throughout their lifetime, with large populations of valve activating myofibroblasts (VICs) undergo phenotypic modulation to become activated myofibroblasts and return to quiescent fibroblasts during adaptive remodeling (Rabkin-Aikawa et al., 2004). VICs and VECs functions likely influence ECM synthesis and remodeling. Fetal valves have a dynamic and adaptive structure, with activated cells gradually becoming quiescent and collagen maturing through increased fiber thickness and alignment. The

structure differs from adult valves, which have a tri layered architecture with a highly specialized and functionally adapted ECM (Aikawa et al., 2006). Fetal valves have higher cellular densities than adult valves, associated with an increased cell proliferation-to-apoptosis ratio (Rabkin-Aikawa et al., 2004). Valvular cell turnover is high during fetal development and continues at a low rate postnatally. Endothelial cells express high levels of SMemb, MMP-1, MMP-13, ICAM-1, and VCAM-1 in fetal and children's valves compared to adult valves. This suggests a progressive adaptation to the prevailing hemodynamic environment, aiding in the assessment of therapeutic strategies for valve disease (Tilea et al., 2013).

Aortic root anatomy

The aortic valve connects the left ventricle and ascending aorta. The sinuses of Valsalva, fibrous interleaflet triangles, and valvular leaflets comprise it (Piazza et al., 2008).

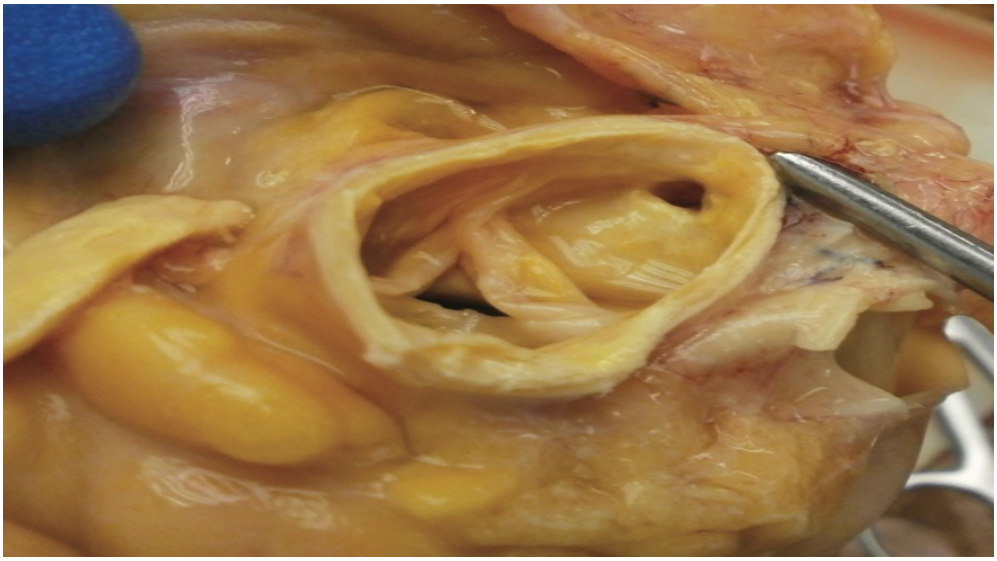

Diagram 1View of a dissected heart (the atrial chambers and the arterial trunks are removed). The heart is photographed from above.

a. Annulus controversy

"Annulus" means a small ring. The aortic root has 3 circular rings and 1 crown-like ring. Root-long valvular leaflets. Thus, in three dimensions, the leaflets form a crown-like ring with hinges from the supporting ventricular structures (Diagram 1). The crown's "annulus" is a virtual ring. The echocardiographer measures the annulus diameter by measuring the inlet from the left ventricular outflow tract into the aortic root.

The term "annulus" appears to describe a circle, a fibrous ring on which the leaflets are inserted, but the aortic valve does not have such a structure. Still no agreement.

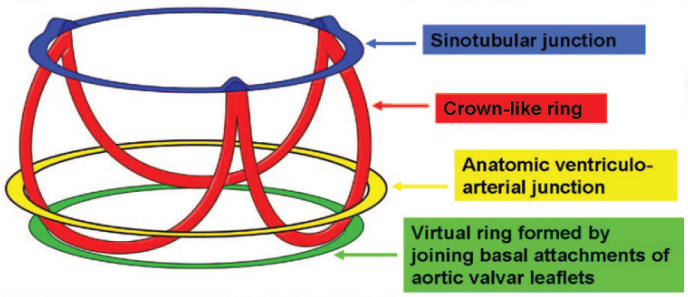

Diagram 2 The “rings” of the aortic root

b. Hemodynamic versus anatomic ventriculo-arterial junction

Above shows that the circular anatomic junction differs from the semilunar hemodynamic junction (Davies, 1980). The hemodynamic junction divides the root into aortic-pressured and left-ventricular-pressured compartments. The semilunar leaflet attachments expose the fibrous aortic root's superior interleaflet triangles to ventricular pressures and the left ventricle's most basal sinus of Valsalva to aortic pressures (Piazza et al., 2008).

c. Sino tubular junction, coronary arteries, and aortic sinuses

Aortic sinuses of Valsalva are the spaces between the luminal surfaces of the three aortic root bulges and their valvular leaflets. Right, left, and noncoronary sinuses are named after their arteries. Right sinus structures are largest, followed by non-coronary sinuses and left coronary sinuses (Tilea et al., 2013). Coronary artery orifices usually arise in the 2 anterior sinuses of Valsalva, just below the sinotubular junction, but rarely centrally. However, the arteries are often above the sinotubular junction.Various studies emphasis large coronary ostia origin variations. In vivo and ex vivo right coronary ostium measurements differ significantly. (Tilea et al., 2013) The sinuses' supra-aortic ridge is the Sino-tubular junction. The Sino-tubular junction joins the sinusal and tubular aortas on the outside. A thickened aortic wall forms a ridge inside. The sino -ubular junction is not circular. It resembles a scalloped trefoil due to the three sinuses. The sino-tubular junction circumference is 95% of the aortic root base circumference(Piazza et al., 2008).

d. aortic leaflets

Normal aortic valves have three leaflets. The three leaflets have free margins and semilunar margins attached to the aortic root. Due to its scoop-shaped free margin, each leaflet is shorter than its sinus. The leaflets fall back into their sinuses when the valve opens, preventing coronary occlusion. At the sino-tubular junction, adjacent leaflets' semilunar hinge lines form commissures. Young leaflets are pliable and thin, but their thickness varies. Age thickens and stiffens leaflets (Ho, 2009).

Each leaflet has a slightly crimped aorta surface and a smoother ventricle surface. The leaflet's free edge is thicker. The lunulae, or zone of apposition, covers the free margin and one-third of the leaflet's depth on its ventricular surface. During valvular closure, the leaflets meet here. The nodule of Arantius covers 60% of the inferior margin of the lunulae and thickens the ventricular surface. When the valve is closed, the inferior margin of the lunulaes meet, separating blood from the aorta and left ventricular cavity. Because lunulae fenestrations are above the closure line, the valve remains competent. (Tilea et al., 2013) (Ho, 2009) Leaflets have endothelial linings on their arterial and ventricular sides and a fibrous core. The anatomic ventriculo-arterial junction is where the left ventricular structures give rise to the fibroelastic walls of the aortic valvular sinuses. The basal attachments of leaflets that originate from the ventricular myocardium are below the anatomic ventriculo-arterial junction. (Tilea et al., 2013) The root's dimensions vary between individuals, but the leaflets' height, width, surface area, and volume of each supporting sinus of Valsalva can vary greatly within an individual. The average width between the peripheral zones of attachment along the sinus ridge for the right, noncoronary, and left coronary leaflets was 25.9, 25.5, and 25.0 mm, respectively, in 200 normal hearts (Tilea et al., 2013; Vollebergh and Becker, 1977).

e. Interleaflet fibrous triangles

The semilunar attachment of the aortic valvular leaflets creates three triangular left ventricular outflow tract extensions that reach the sino-tubular junction. (Tilea et al., 2013) However, the thinned fibrous walls of the aorta between the expanded sinuses of Valsalva

form these triangles. In the triangle between the right and left coronary aortic leaflets, their most apical regions may communicate with the pericardial space or the plane of tissue between the aorta and anteriorly located sleeve-like sub pulmonary infundibulum (Tilea et al., 2013).

The diagnosis and management of valvular heart disease have shown significant advancements in recent years. However, there remains a scarcity of data to informclinical decision-making for patients with multiple valve disease. The extent and pattern of cardiac hypertrophy are contingent upon various factors. The implementation of Aortic Valve Replacement results in the alleviation of mechanical obstruction, which in turn leads to improvements in hemodynamics (Maganti et al., 2010). Consequently, there is a significant reversal of left ventricular hypertrophy. The observed phenomenon can be measured as reduction in the mass of the left ventricle. The regression of left ventricular mass is observed in the early stages following aortic valve replacement and persists for a duration of up to 10 years post-surgery. Extensive research has been conducted on the early and late follow-up periods, yet there is a scarcity of studies that have examined the intermediate time course of regression (Villa et al., 2006).

Pathophysiology of Aortic stenosis: The pathophysiology of aortic stenosis involves the narrowing or obstruction of the aortic valve, leading to restricted blood flow from the left ventricle to the aorta. This narrowing can occur due to different mechanisms (Pujari and Agasthi, 2023)

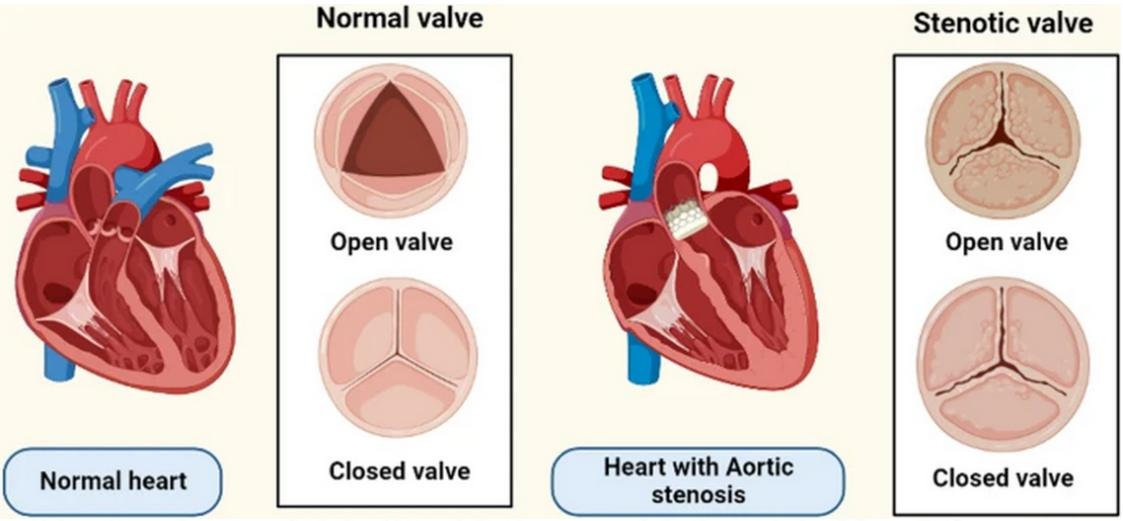

Diagram 3 Pathophysiology of Aortic stenosis

Calcific Aortic Stenosis: This is the most common type of AS and is characterized by the gradual accumulation of calcium deposits on the aortic valve leaflets. Over time, these calcium deposits cause thickening, stiffening, and narrowing of the valve orifice, resulting in decreased valve opening and increased resistance to blood flow.

Congenital Aortic Stenosis: It occurs when an individual is born with a malformed or abnormally narrow aortic valve. The valve leaflets may be fused, reducing the valve's opening and obstructing blood flow. (Singh, 2019)

Rheumatic Aortic Stenosis: Rheumatic fever, caused by an immune response to Group A Streptococcus infection, can lead to scarring and inflammation of the aortic valve. This scarring causes thickening and fusion of the valve leaflets, resulting in stenosis. (Sika-Paotonu et al., 2016) As Aortic Stenosis progresses, the left ventricle compensates for the increased afterload by hypertrophying (thickening) to maintain adequate cardiac output.

However, over time,the hypertrophied ventricle may become less effective, leading to symptoms such as angina (chest pain), syncope (fainting), and heart failure.(Bornstein et al., 2023)

Hemodynamic Impact of Aortic Stenosis:

Aortic stenosis (AS) imposes a significant hemodynamic burden on the heart. As the aortic valve becomes narrowed, the following hemodynamic changes occur (Mantha et al., 2021; Pujari and Agasthi, 2023) Increased Left Ventricular Afterload: The narrowed aortic valve obstructs blood flow from the left ventricle into the aorta, resulting in increased resistance or afterload that the left ventricle must overcome to eject blood. This increased afterload leads to increased myocardial workload (Pibarot and Dumesnil, 2007).

Left Ventricular Hypertrophy: To compensate for the increased afterload, the left ventricle undergoes hypertrophy, which is the thickening of the ventricular walls. This hypertrophy helps to maintain contractility and normalize wall stress in the face of increased pressure (Bornstein et al., 2023). Impaired Diastolic Filling: In severe cases of aortic stenosis, the impaired opening of the aortic valve during systole leads to decreased diastolic filling of the left ventricle. This results in reduced ventricular compliance and impaired relaxation, leading to diastolic dysfunction (Pibarot and Dumesnil, 2007).

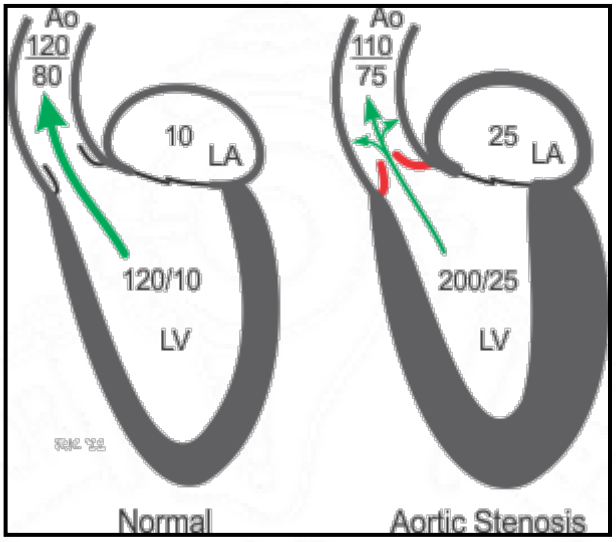

Diagram 4 Hemodynamic Flow of Aortic Stenosis

Increased Left Ventricular Pressure: The increased afterload causes the left ventricle to generate higher pressures to overcome the resistance and eject blood through the narrowed valve. This can result in increased left ventricular end-diastolic and end-systolicpressures (Isaza et al., 2020; LaCombe et al., 2023). The combination of increased afterload, left ventricular hypertrophy, impaired diastolic filling, and increased left ventricular pressure can lead to severe complications.

Diagram 4 Hemodynamic Impact of Aortic Stenosis

Diagnosis and quantification Aortic Stenosis:

The diagnosis and quantification of aortic stenosis (AS) involve a combination of clinical assessment, imaging techniques, and hemodynamic measurements. The followingare commonly used methods for diagnosing and quantifying AS **(Rana, 2022)**

Clinical Assessment: History and Physical Examination: The physician evaluates the patient's symptoms, such as chest pain, dyspnea, and exercise intolerance. Physical examination findings may include the presence of a heart murmur, specifically a systolic ejection murmur, and signs of heart failure (Malik et al., 2023; Thomas et al., 2023).

Echocardiography: Transthoracic Echocardiography (TTE): TTE is the primaryimaging modality used to diagnose and assess the severity of AS. It provides detailed information about the structure and function of the aortic valve, the degree of stenosis, and associated findings such as left ventricular hypertrophy and impaired valve leaflet motion (Grant et al., 2021).

Cardiac Catheterization: Invasive hemodynamic assessment may be performed in cases where there is discordance between clinical and echocardiographic findings or when additional information is needed for decision-making. Pressure measurements obtained through cardiac catheterization can help quantify the severity of AS and assess the overall hemodynamic status.(Hemodynamics in the Cardiac Catheterization Laboratory of the 21st Century | Circulation, n.d.).

It is important to note that the management of AS requires a multidisciplinary approach involving cardiologists, cardiothoracic surgeons, and other healthcare professionals. The specific recommendations for intervention and timing may vary depending on individual patient characteristics, comorbidities, and the presence of additional factors that influence clinical decision-making. Therefore, it is essential to consider each patient's case individually and follow the recommendations provided in current guidelines, such as those

from the American College of Cardiology/American

Treatment Strategy: The first instance of a caged ball valve being implanted to address aortic stenosis occurred in 1960, as documented by Dr Harken (Gott et al., 2004; Harken et al., 1962). Subsequently, mechanical valve prostheses have garnered recognition for their exceptional durability characteristics. Despite the extensive historical availability and evolutionary development of mechanical aortic valve substitutes (mAVR), they remain an imperfect solution, particularly for the demographic of adolescent and young adults. Mechanical valves continue to pose a lifelong risk of complications related to anticoagulation, which significantly affect the long-term survival of nonelderly patients(Bouhout et al., 2014). In a previous publication, Bouhout et al. conducted an observational study that examined the outcomes of nonelderly patients who underwent isolated mechanical aortic valve replacement (mAVR). The study found that nonelderly patients who underwent mAVR had a significantly higher long-term mortality risk compared to the general population. Specifically, the mortality rate at 10 years was 13% for the nonelderly patients undergoing mAVR, whereas it was only 6% for the general population (Bouhout et al., 2014). Moreover, it is important to note that the overall risk of experiencing severe complications associated with prostheses, such as mortality, dysfunction of the prosthesis, thromboembolic events, endocarditis, mechanical prosthesis thrombosis, and significant bleeding necessitating hospitalization and transfusion, reached a cumulative rate of 27% within a span of 10 years (Bouhout et al., 2014). Furthermore, the published report (Bouhout et al., 2014) indicates that the re-operation-free survival rate after mAVR was 82% at the 10-year mark. The efficacy of newer generation bileaflet

mechanical valve prostheses, such as the On-X valve, in reducing the risk of major bleeding and thromboembolic events is not significantly different from that of previous mechanical valve substitutes, even when low-dose warfarin therapy is employed with a target international normalized ratio (INR) of 1.5-2.0. The PROACT trial reported a linearized rate of prosthesis-associated adverse events of 4.4% per patient-year in the low-dose warfarin group, while the standard warfarin group had a rate of 5.2% (Puskas et al., 2014). Hence, the utilization of mechanical valve substitutes for aortic replacement is considered a less than ideal valvular intervention in individuals under the age of 60. 2.2. The procedure of replacing the aortic valve with a bioprosthetic valve, also known as bioprosthetic aortic valve replacement (bAVR).The first glutaraldehyde-treated, stent-mounted pericardial tri-cusp valve was designed and implanted in the aortic position by Marian Ionescu in 1971(Ionescu et al., 1972). Nevertheless, the occurrence of structural valve deterioration (SVD) was observed in these initial studies within a 5-year follow-up period (Ott et al., 1980). To date, the primary limitation of bioprosthetic valve substitutes, particularly in individuals who are not elderly, is still represented by SVD. The continuous use of SVD (supravalvular aortic stenosis) results in a higher demand for reinterventions, which have been linked to a decrease in life expectancy when compared to the overall population (Etnel et al., 2019).

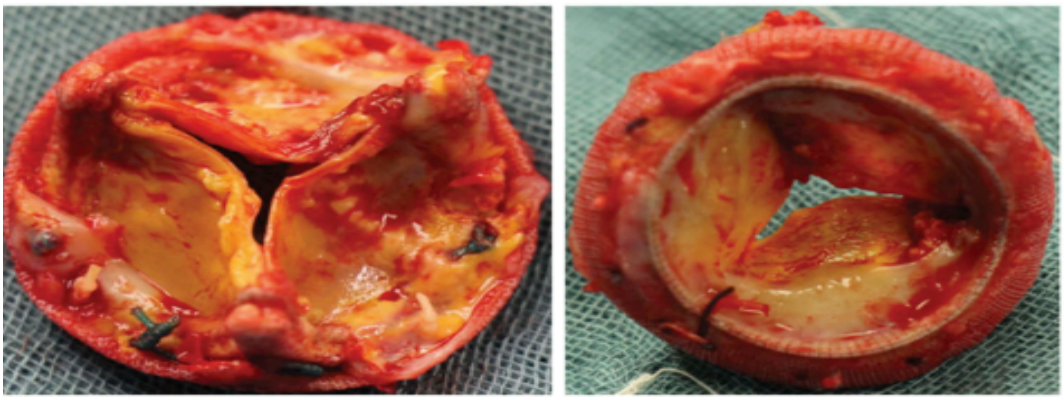

Diagram 5 Image of a degenerated bioprosthetic aortic valve.

One notable benefit of bioprosthetic valves is their ability to circumvent the need for oral anticoagulation. However, prior research has identified the presence of subclinical leaflet thrombosis and observed a decrease in leaflet motion in aortic bioprosthetic valves. This is a potential medical condition that may necessitate therapeutic anticoagulation (Chakravarty et al., 2017; Makkar et al., 2015; Sondergaard et al., 2017).

In a recent publication, H. Takkenberg et al. conducted a meta-analysis utilising a microsimulation model to investigate the topic of bioprosthetic aortic valve replacement in the context of nonelderly adults, specifically those below the age of 55. The meta-analysis incorporated a total of 19 studies, with a sample size of 2686 participants and a mean age of 51 years. The combined mean follow-up duration across the studies was 8 years (Etnel et al., 2019). According to the findings of their research, the actuarial median survival rate over a 20-year period was determined to be 58.7%.

2020 ACC/AHA GUIDELINE FOR THE MANAGEMENT OF PATIENTS WITH VALVULAR HEART DISEASE: A REPORT OF THE AMERICAN COLLEGE OF CARDIOLOGY/AMERICAN HEART ASSOCIATION JOINT COMMITTEE ON CLINICAL PRACTICE GUIDELINES

3.1. Stages of Valvular AS

Medical and interventional approaches to the management of patients with valvular AS depend on accurate diagnosis of the cause and stage of the disease process ACC/AHA Guideline Table 1 shows the stages of AS, ranging from patients at risk of AS (Stage A) or with progressive hemodynamic obstruction (Stage B) to severe asymptomatic (Stage C) and symptomatic AS (Stage D). Each stage is defined by patient symptoms, valve anatomy, valve hemodynamics, and changes in the LV and vasculature. Hemodynamic severity is best characterized by the transaortic maximum velocity (or mean pressure gradient) when the transaortic volume flow rate is normal. Some patients with AS have a low transaortic volume flow rate that is either because of LV systolic dysfunction with a low LVEF or because of a small, hypertrophied LV with a low stroke volume. Severe AS with low flow is designated D2 (with a low LVEF) or D3 (with a normal LVEF). Meticulous attention to detail is required during assessment of aortic valve hemodynamics, either with Doppler echocardiography or cardiac catheterization, and the inherent variability of the measurements and calculations should always be considered in clinical decision-making.

ACC/AHA Guideline Table 1 Stages of Aortic Stenosis

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
A	At risk of AS	BAV (or other congenital valve anomaly) Aortic valve sclerosis	Aortic V_{max} <2 m/s with normal leaflet motion	None	None
B	Progressive AS	Mild to moderate leaflet calcification/fibrosis of a bicuspid or trileaflet valve with some reduction in systolic motion or Rheumatic valve changes with commissural fusion	Mild AS: aortic V_{max} 2.0–2.9 m/s or mean ΔP <20 mm Hg Moderate AS: aortic V_{max}3.0–3.9 m/s or mean ΔP 20–39 mm Hg	Early LV diastolic dysfunction may be present Normal LVEF	None
C: Asymptomatic severe AS					
C1	Asymptomatic severe AS	Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening	Aortic V_{max} ≥4 m/s or mean ΔP ≥40 mm Hg AVA typically is ≤1.0 cm^2(or AVAi 0.6 cm^2/m^2) but not required to define severe AS Very severe AS is an aortic V_{max} ≥5 m/s or mean P ≥60 mm Hg	LV diastolic dysfunction Mild LV hypertrophy Normal LVEF	None Exercise testing is reasonable to confirm symptom status
C2	Asymptomatic severe AS with LV systolic dysfunction	Severe leaflet calcification/fibrosis or congenital stenosis with severely reduced leaflet opening	Aortic V_{max} ≥4 m/s or mean ΔP ≥40 mm Hg AVA typically ≤1.0 cm^2 (or AVAi 0.6 cm^2/m^2) but not required to define severe AS	LVEF <50%	None
D: Symptomatic severe AS					
D1	Symptomatic severe	Severe leaflet calcification/fibrosi	Aortic V_{max} ≥4 m/s or mean ΔP	LV diastolic dysfunction	Exertional

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
	high-gradient AS	s or congenital stenosis with severely reduced leaflet opening	≥40 mm Hg AVA typically ≤1.0 cm^2 (or AVAi ≤0.6 cm^2/m^2) but may be larger with mixed AS/AR	LV hypertrophy Pulmonary hypertension may be present	dyspnea, decreased exercise tolerance, or HF Exertional angina Exertional syncope or pre-syn-cope
D2	Symptomatic severe low-flow, low-gradient AS with reduced LVEF	Severe leaflet calcification/fibrosis with severely reduced leaflet motion	AVA ≤1.0 cm^2 with resting aortic V_{max} <4 m/s or mean ΔP <40 mm Hg Dobutamine stress echocardiography shows AVA <1.0 cm^2 with V_{max}≥4 m/s at any flow rate	LV diastolic dysfunction LV hypertrophy LVEF <50%	HF Angina Syncope or presyn-cope
D3	Symptomatic severe low-gradient AS with normal LVEF or paradoxical low-flow severe AS	Severe leaflet calcification/fibrosis with severely reduced leaflet motion	AVA ≤1.0 cm^2 (indexed AVA ≤0.6 cm^2/m^2) with an aortic V_{max} <4 m/s or mean ΔP <40 mm Hg AND Stroke volume index <35 mL/m^2 Measured when patient is normotensive (systolic blood pressure <140 mm Hg)	Increased LV relative wall thickness Small LV chamber with low stroke volume Restrictive diastolic filling LVEF ≥50%	HF Angina Syncope or presyn-cope

AR indicates aortic regurgitation; AS, aortic stenosis; AVA, aortic valve area circulation; AV Ai, AVA indexed to body surface area; BAV, bicuspid aortic valve;

ΔP, the pressure gradient between the LV and aorta HF, heart failure; LV, left ventricular; LVEF, left ventricular ejection fraction; and V_{max}, maximum velocity.

Recommendations for Timing of Intervention of AS Referenced studies that support the recommendations are summarized in Online Data Supplements 4 and 6 to 10.		
COR	**LOE**	**Recommendations**
1	A	1. In adults with severe high-gradient AS (Stage D1) and symptoms of exertional dyspnea, HF, angina, syncope, or presyncope by history or on exercise testing, AVR is indicated.[1–7]
1	B-NR	2. In asymptomatic patients with severe AS and an LVEF <50% (Stage C2), AVR is indicated.[8–11]
1	B-NR	3. In asymptomatic patients with severe AS (Stage C1) who are undergoing cardiac surgery for other indications, AVR is indicated.[12–16]
1	B-NR	4. In symptomatic patients with low-flow, low-gradient severe AS with reduced LVEF (Stage D2), AVR is recommended.[17–24]
1	B-NR	5. In symptomatic patients with low-flow, low-gradient severe AS with normal LVEF (Stage D3), AVR is recommended if AS is the most likely cause of symptoms.[25–27]
2a	B-NR	6. In apparently asymptomatic patients with severe AS (Stage C1) and low surgical risk, AVR is reasonable when an exercise test demonstrates decreased exercise tolerance (normalized for age and sex) or a fall in systolic blood pressure of ≥10 mm Hg from baseline to peak exercise.[13,28–30]
2a	B-R	7. In asymptomatic patients with very severe AS (defined as an aortic velocity of ≥5 m/s) and low surgical risk, AVR is reasonable.[15,31–35]
2a	B-NR	8. In apparently asymptomatic patients with severe AS (Stage C1) and low surgical risk, AVR is reasonable when the serum B-type natriuretic peptide (BNP) level is >3 times normal.[32,36–38]
2a	B-NR	9. In asymptomatic patients with high-gradient severe AS (Stage C1) and low surgical risk, AVR is reasonable when serial testing shows an increase in aortic velocity ≥0.3 m/s per year.[39,40]
2b	B-NR	10. In asymptomatic patients with severe high-gradient AS (Stage C1) and a progressive decrease in LVEF on at least 3 serial imaging studies to <60%, AVR may be considered.[8–11,33]
2b	C-EO	11. In patients with moderate AS (Stage B) who are undergoing cardiac surgery for other indications, AVR may be considered.

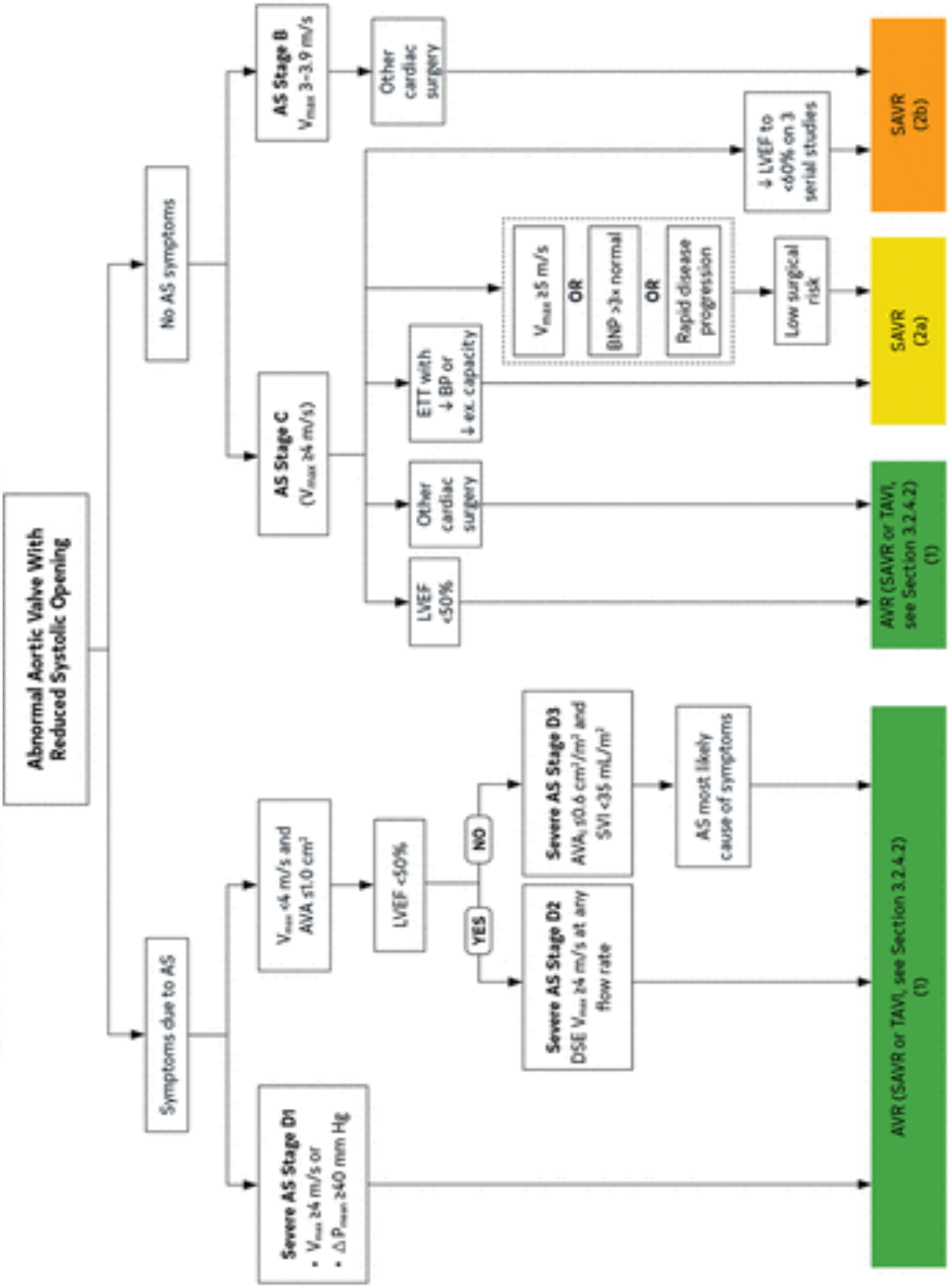

Chart 1 Abnormal Aortic Valve with Reduced Systolic Opening.

ACC/AHA Guideline Table 2 Choice of Mechanical Versus Bioprosthetic AVR

Recommendations for Choice of Mechanical Versus Bioprosthetic AVR Referenced studies that support the recommendations are summarized in Online Data Supplements 11 and 12.		
COR	**LOE**	**Recommendations**
1	C-EO	1. In patients with an indication for AVR, the choice of prosthetic valve should be based on a shared decision-making process that accounts for the patient's values and preferences and includes discussion of the indications for and risks of anticoagulant therapy and the potential need for and risks associated with valve reintervention.
1	C-EO	2. For patients of any age requiring AVR for whom VKA anticoagulant therapy is contraindicated, cannot be managed appropriately, or is not desired, a bioprosthetic AVR is recommended.
2a	B-R	3. For patients <50 years of age who do not have a contraindication to anticoagulation and require AVR, it is reasonable to choose a mechanical aortic prosthesis over a bioprosthetic valve.[1]
2a	B-NR	4. For patients 50 to 65 years of age who require AVR and who do not have a contraindication to anticoagulation, it is reasonable to individualize the choice of either a mechanical or bioprosthetic AVR with consideration of individual patient factors and after informed shared decision-making.[1–10]
2a	B-R	5. In patients >65 years of age who require AVR, it is reasonable to choose a bioprosthesis over a mechanical valve.[1]
2b	B-NR	6. In patients <50 years of age who prefer a bioprosthetic AVR and have appropriate anatomy, replacement of the aortic valve by a pulmonic autograft (the Ross procedure) may be considered at a Comprehensive Valve Center.[11–13]

LV MASS REGRESSION AFTER AORTIC VALVE REPLACEMNET SURGERY

Left ventricular mass regression after aortic valve replacement surgery is a crucial topic in cardiovascular medicine. This process involves a decrease in left ventricle mass, especially in cases of aortic stenosis(Veerapudran et al., 2023). Echocardiography assesses LV mass regression, which is observed within months and can continue for several years. This study helps predict patient outcomes and guide post-operative care. Further research can optimize surgical techniques and post-operative care to maximize the benefits of aortic valve replacement surgery(Veerapudran et al., 2023).

TYPES OF PROSTHETIC HEART VALVE DESIGN

The optimal valve substitute should replicate the attributes of a typical indigenous valve. Specifically, the ideal device should exhibit superior hemodynamic properties, prolonged durability, exceptional resistance to thrombosis, and outstanding suitability for implantation. Regrettably, the existence of an ideal valve substitute remains elusive, as each of the presently accessible prosthetic valves possesses inherent limitations.

Mechanical valves are devices used in the field of medicine for the purpose of replacing damaged or diseased heart valves.

There are three primary categories of mechanical valve design that can be identified as follows: **bileaflet, monoleaflet, and caged ball valves** (as depicted in Diagram 6A, 6B, and 6C, respectively).

Caged ball valves are a type of valve commonly used in industrial applications. These valves consist of a spherical ball with a hole in the center The utilization of caged ball valves, comprising a silastic ball accompanied by a circular sewing ring and a cage

constructed from three metal arches, has become obsolete in contemporary implantation practices. Nevertheless, a significant number of patients continue to possess caged ball valves, necessitating the need for ongoing monitoring and care.

Monoleaflet valves, also known as single-leaflet valves, are a type of heart valve characterized by Monoleaflet valves consist of a solitary disc that is affixed by metal struts positioned either laterally or centrally. The range of the opening angle of the disc in relation to the valve annulus is between 60° and 80°, which leads to the formation of two distinct orifices with varying sizes.

Bileaflet valves, also known as double-disc valves, are a type of mechanical heart valve commonly used Bileaflet valves consist of two semilunar discs that are affixed to a rigid valve ring through the use of small hinges. The leaflets' opening angle in relation to the annulus plane spans from 75° to 90°. The open valve comprises three orifices: a small, slit-like central orifice positioned between the two open leaflets, and two larger semicircular orifices located on the sides.

Bioprosthetic Valves

The topic of interest pertains to stented bio-prostheses. The objective of bio-prostheses is to replicate the anatomical structure of the native aortic valve (see Diagram 6D and 6E). **Porcine bioprosthetic valves** are comprised of three aortic valve leaflets from pigs that have been chemically cross-linked with glutaraldehyde. These leaflets are then affixed to a supporting stent made of either metal or polymer. The construction of pericardial valves involves the utilisation of bovine pericardium sheets that are positioned either internally or externally within a stent for support.

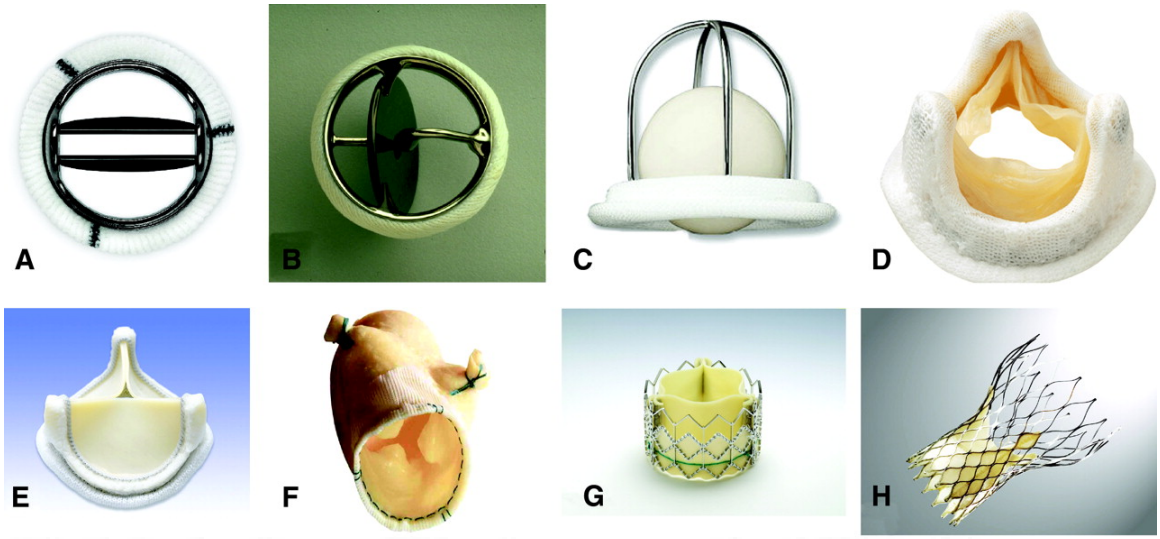

Diagram 6 Different types of prosthetic valves. A, Bileaflet mechanical valve (St Jude); B, monoleaflet mechanical valve (Medtronic Hall); C, caged ball valve (Starr-Edwards); D, stented porcine bioprosthesis (Medtronic Mosaic); E, stented pericardial bioprosthesis (Carpentier-Edwards Magna); F, stentless porcine bioprosthesis (Medtronic Freestyle); G, percutaneous bioprosthesis expanded over a balloon (Edwards Sapien); H, self-expandable percutaneous bioprosthesis (CoreValve)

Stentless bioprostheses refer to a type of medical device used in cardiac surgery, specifically in Various stentless bioprosthetic valves have been developed with the aim of enhancing valve hemodynamics and durability (see Diagram 6F). Stentless bioprostheses are produced using intact porcine aortic valves or constructed using bovine pericardium.

The topic of discussion pertains to percutaneous bioprostheses. The utilisation of percutaneous aortic valve implantation is increasingly being recognised as a viable alternative to the conventional approach of aortic valve replacement (AVR) for patients diagnosed with symptomatic aortic stenosis who are deemed to have a high or prohibitive risk for surgical intervention (Diagram 6G and 6H). The valves are typically inserted

utilising a percutaneous transfemoral technique (Lichtenstein et al., 2006; Walther et al., 2007). To reduce the problems of vascular access and associated complications, a transapical approach through a small thoracotomy may also be used. At present, the procedure appears promising, but it remains experimental and is currently undergoing further investigation.

After the prosthesis type, ie, mechanical versus biological, is selected, one should logically contemplate the prosthesis models that have a well-established track record with regard to long-term durability (bioprostheses) and low thrombogenicity (mechanical prostheses). Thromboembolic rates are a poor indicator of the valve thrombogenicity because they can be highly influenced by patient risk factors and antithrombotic management.9 Thrombogenicity of the individual prosthesis should thus be determined on the basis of reported valve thrombosis rates for that prosthesis in relation to anticoagulation intensity and valve position. In this regard, it should be noted that prostheses cannot be conveniently categorized according to basic design (eg, bileaflet, monoleaflet, etc) or date of introduction to determine the level thrombogenicity (see the Antithrombotic Therapy section).

The next step is to choose a prosthesis model that provides superior hemodynamic performance to prevent prosthesis-patient mismatch (PPM) and thereby minimize postoperative transprosthetic gradients. Hence, among bioprostheses with similar durability or mechanical valves with similar thrombogenicity, one should preferably select the model that provides the largest valve effective orifice area (EOA) in relation to the patient's annulus size (Pibarot and Dumesnil, 2009). The hemodynamic performance or "EOAbility" of the prosthesis is essentially determined by the size of prosthesis that can fit into the

patient's annulus and by the proportion of the total cross-sectional area of that prosthesis that is actually available for blood flow. To this effect, it should be underlined that the hemodynamic performance is not equivalent for all models of prostheses. Indeed, it is generally superior in newer compared with older generations of prostheses, in mechanical compared with stented bioprosthetic valves,(Moon et al., 2006) in stentless compared with stented bioprosthetic valves,(Pibarot and Dumesnil, 2009) and in supraannular compared with intra-annular stented bioprostheses(Pibarot and Dumesnil, 2009). A recent meta-analysis18 shows that, compared with stented bioprostheses, stentless valves provide larger EOAs, reduced transprosthetic gradients, and greater left ventricular (LV) mass regression, but at the expense of prolonged cardiopulmonary bypass time.

Selecting the Optimal Prosthesis in the Individual Patient Bioprosthetic Versus Mechanical Valve

Choosing the right valve for the right patient is a difficult but essential process to optimize the outcome for patients undergoing valve replacement. The first step in this decision-making process is to choose between a mechanical and a bioprosthetic valve (Diagram 6). The most important factors that should be considered in this first step are the patient's age, life expectancy, preference, indication/contraindication for warfarin therapy, and comorbidities. In the recent American College of Cardiology/American Heart Association and European guidelines, the weight given to patient age has been reduced, whereas much greater importance is now given to the patient's preference. The criteria in favor of using a mechanical valve include the following:(Mozaffarian et al., 2015; Nathaniel et al., 2010; Reddy et al., 2018) the informed patient wants a mechanical valve and has no

contraindication for long-term anticoagulation; (Thubrikar et al., 1986)(2) the patient is already on anticoagulation (mechanical prosthesis in another position or at high risk for thromboembolism); (Andell et al., 2017) the patient is at risk of accelerated bioprosthetic structural deterioration (young age, hyperparathyroidism, renal insufficiency); and (Andell et al., 2017) the patients is 65 years of age and has a long-life expectancy. On the other hand, a bioprosthetic may be preferred in the following situations: (1) the informed patient wants a bioprosthetic; (2) good-quality anticoagulation is unavailable (contraindication or high risk, compliance problems, lifestyle); (3) the patient is 65 years of age and/or has limited life expectancy; and (4) the patient is a woman of childbearing age. Bio prostheses degenerate more rapidly in young patients and during pregnancy. Hence, a woman in her late 30s or early 40s who has completed her family should probably be advised to have a mechanical valve.

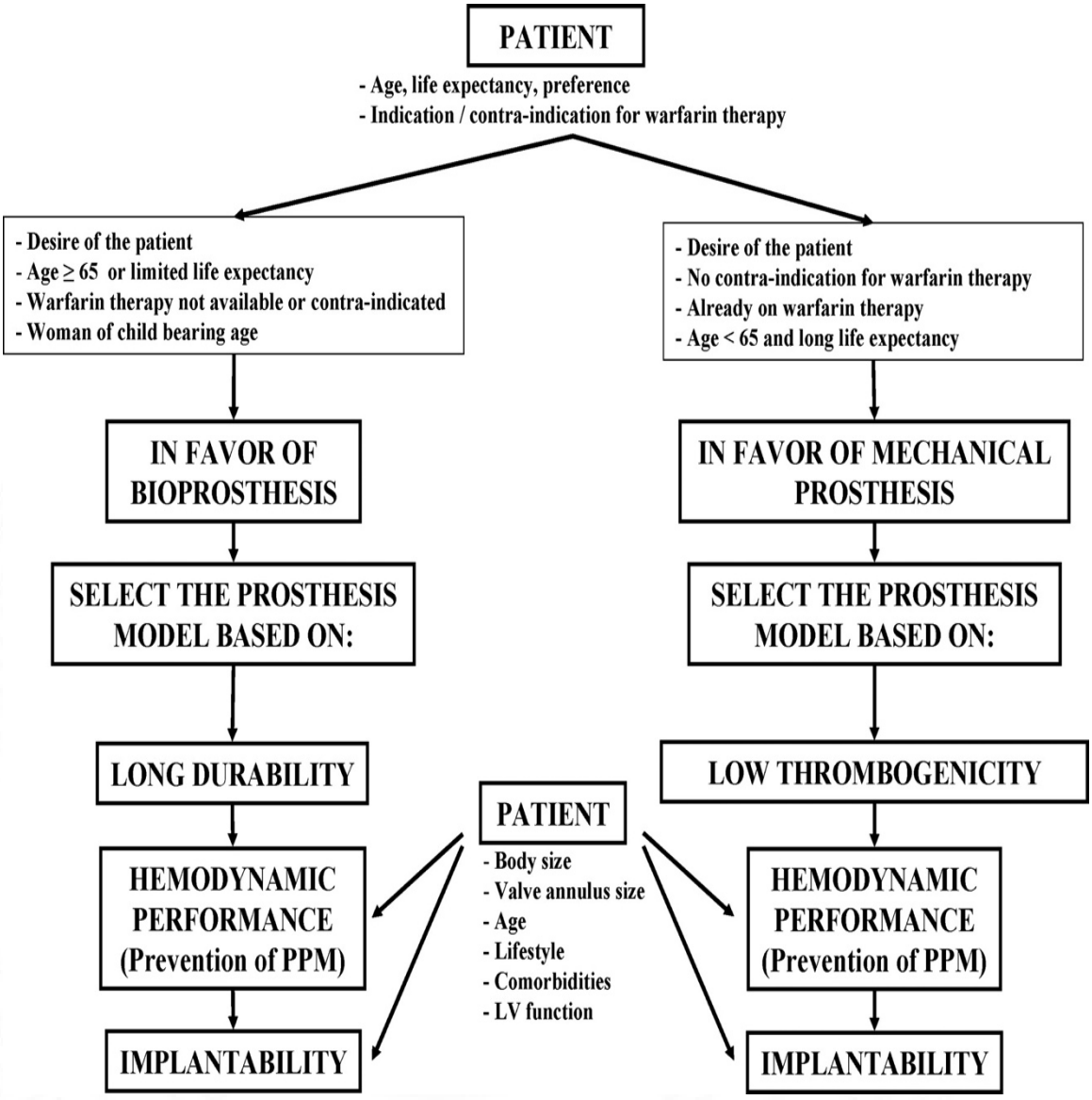

Diagram 7. Algorithm for the selection of the optimal prosthesis in the individual patient.

3. MATERIAL AND METHODOLOGY

STUDY DESIGN: A retrospective, observational study was conducted to compare the early post-operative gradient & left ventricular regression between the metal & bio prosthetic valve of similar size after aortic valve replacement in a case of aortic stenosis.

STUDY AREA: Study was conducted in Department of Cardiovascular and Thoracic Surgery.

ORGANISING THE STUDY:

i. Ethical consideration:

Relevant permission was taken from the Institutional Ethics Committee (IEC) of a Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivendrum (SCTIMST) prior to the study's conduction.

ii. Approval from authorities:

Permission was obtained for the conduction of a study in cardiovascular and thoracic surgery department and from the principal of that particular medical college and the samewere informed to the authority of cardiovascular and thoracic surgery department in SCTIMST.

iii. Designing of Patient, consent form and data collection sheet:

The following forms were designed for the purpose of study:

1) Consent form- Consent form to be signed by participants was prepared.

The patients were explained the purpose of the study, the advantages and the disadvantages associated with the study in Malayalam (local language) and in English (Annexure-Other).

2) **Data collection sheet-** Secondary data were obtained from the department of cardiovascular and thoracic from the medical college. Collection of data was done in structured questionnaire, details of the patient information such as Age, Gender, Preoperative parameters, Co-morbidities, Intra-operative parameters and postoperative parameters along with follow up was compiled. (Annexure-Other).

SAMPLE SIZE DETERMINATION:

Present study is retrospective study hence no need to determination of sample size. We got total 110 number of patients who underwent Aortic valve replacement for aortic stenosis from the year 2017 to 2021. From those number of cases only participated in our study according to our eligibility criteria. hence data were analyzed with those numbers.

SAMPLE SIZE: Total number of patients operated in cardio thoracic department of medical college who underwent aortic valve replacement surgery in the year between 2017 to 2021 were 110, among those 50 patients fulfilled our selection criteria and gave written consent to participate in the study hence sample size is 50.

SAMPLING TECHNIQUE: Convenience sampling.

ELIGIBILITY CRITERIA: Gender, class, caste, ethnicity, race, will NOT be used as Inclusion and/or Exclusion criteria**.**

Inclusion criteria:

-Patients those are ready to give consent for the participation of study.

-Patients with aortic stenosis undergoing Aortic Valve Replacement in the year between 2017 to 2021.

Exclusion criteria:1) Patients who underwent Redo-surgeries, Valve repair, doublevalve replacement surgery, coarctation, aortic aneurysms and combined with coronary artery bypass graft (CABG).

2) Patient who refused to give written informed consent.

ARMAMENTARIUM USED FOR DATA COLLECTION:

Secondary Data from the computer records were obtained and compiled on data collection form. Patients were appointed on call for further examination.

CLINICAL PROCEDURE AND EXAMINATION:

After obtaining permission from IEC, Data was collected with a semi structured questionnaire proforma, from hospital records and analyzed, details of patients who were lost to follow up was only be collected over phone and requested to come on follow up. Permission of the patient was taken before asking questions. Preoperative, intraoperative and post-operative data were collected, and retrospective analysis of data were performed by principal investigator and co

investigators after the procedure. All the patients follow up after the procedure were assessed clinically as well as with ECHO as per departmental protocol. These data were collected through electronic medical records (EMR). The data was kept by the principal investigator. Patient details was kept confidential. Total number 50 underwent Aortic Valve Replacement from the year 2017- 2021, who meet the inclusion criteria and exclusion criteria will be included in the study. All the patients operated during that time which is more than the required sample size, data will be collected from the hospital records in a structured questionnaire, details of the patient who have lost follow up will be collected on phone, permission of the patient was taken for the same mentioning that this is a follow up study after Aortic Valve Replacement and it will take only few minutes, data will be analyzed in terms of absolute values, average, percentage and will be compared with literature.

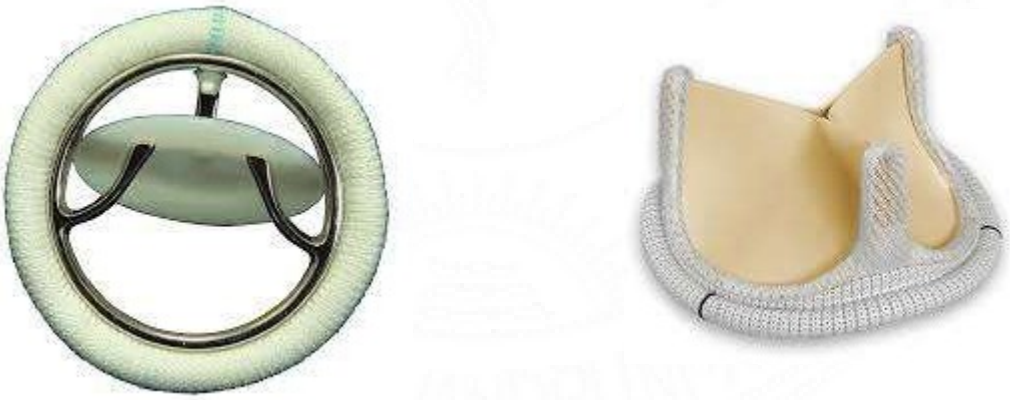

Diagram 8 TTK CHVP and Perimount Magna valve these two valves arecomparing in the present study.

STATISTICAL PROCEDURE:

The statistical procedures were carried out in two steps:

1. Compilation and presentation of data:

Compilation of data was done in systematic manner. Using Microsoft excel worksheet (Microsoft, USA, version 8.1) A master table was made, accordingly the data was subdivided and distributed which was presented in the form of individual tables and the graphs.

2. Statistical Analysis:

Statistical analysis using IBM Statistical Package for Social Science (Statistics for windows, version 21.0, Armonk, NY: IBM corp.) was done and the comparison of data was carried out by applying statistical tests in order to find statistical significance of the results.

Statistical tests employed for the obtained data:

Qualitative data will be expressed in terms of percentages and proportions.

- Quantitative data was expressed in terms of mean and standard deviation.
- Descriptive statistics of each variable was presented in terms of Mean, standarddeviation, standard error of mean.
- Chi square test was applied to analyze the statistical significance of the data.
- P value of <0.05 was considered as statistically significant whereas a p value of <0.001 was considered as highly significant.

4. RESULTS

A retrospective study is conducted with the aim to compare the early post-operative gradient & left ventricular mass regression between the metal & bioprosthetic valve of similar size after aortic valve replacement in a case of aortic stenosis after 3 months postoperatively. Total 50 patients male and female are enrolled in the study. 21 patients underwent aortic valve replacement surgery had the bioprosthetic valve (Perimount magna) and 29 patients underwent aortic valve replacement surgery had the metal valve (CHVP)

Table 1: Cumulative distribution of study patients according to their age.

Sr. No.	Age Group (Years)	No. of Patients n (%)	Mean Age	Standard Deviation
1.	41-50	16 (32)		
2.	51-60	12 (24)		
3.	61-70	22 (44)	**56.70**	**±8.627**
Total		**50 (100)**		

Cumulative distribution of study patients according to their age: Total out of 50 (100) study patients, a maximum that is 44% (n=22) patients were between the age of 61 to 70 years old. Followed by 32% and 24% were from the age group of 41-50, and 51-60 years old respectively. **(Table no.1) (Figure no.1).**

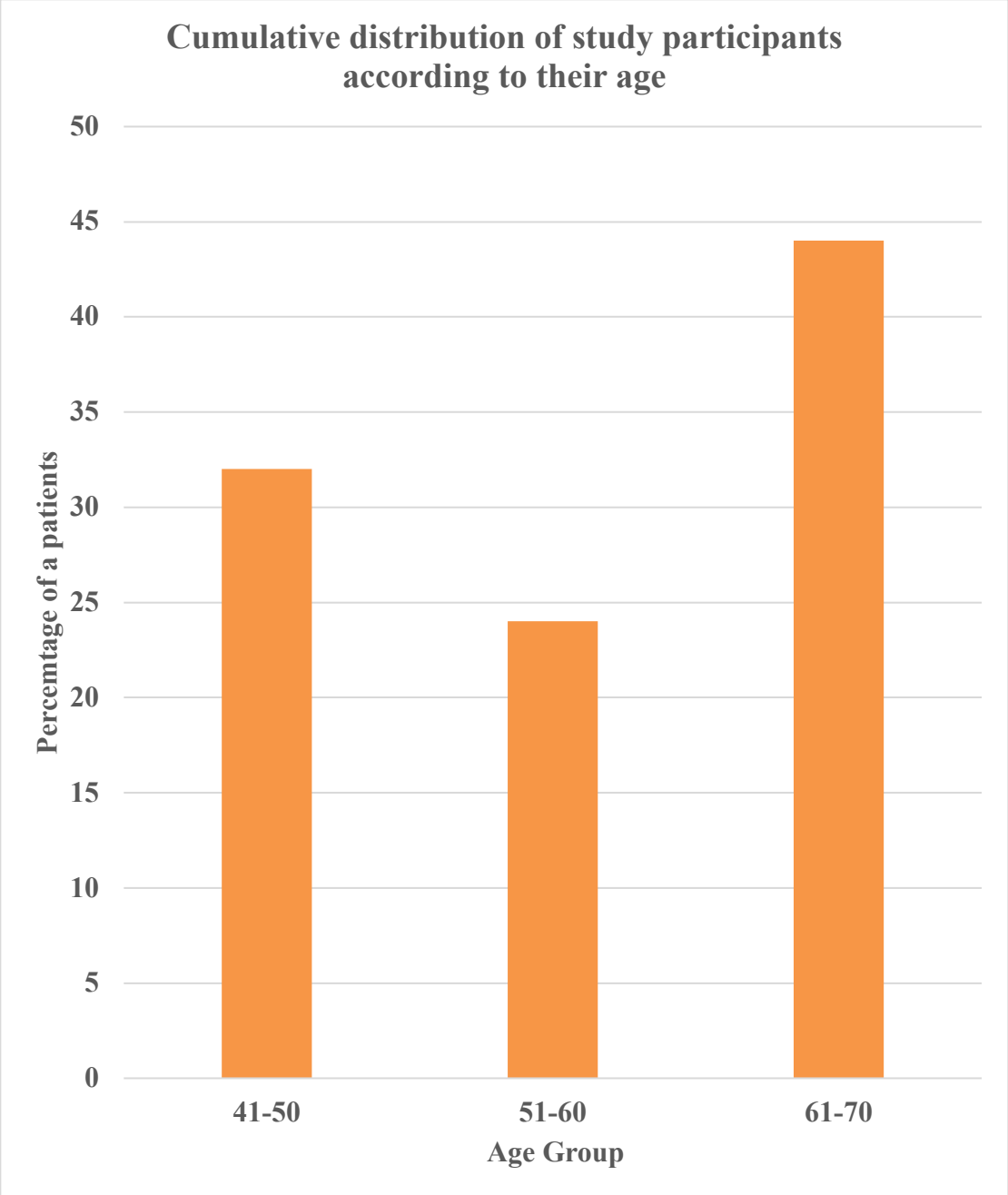

Figure 1. Cumulative distribution of study patients according to their age

Table 2: Comparative distribution of study patients according to their prosthetic valve type Metal and Bioprosthetic valve.

Sr. No.	Type of Mitral Valve	No. of Patients n (%)
1	**Metal Valve (CHVP)**	29 (58)
2	**Bioprosthetic Valve (Peri Mount Magna)**	21 (42)
Total		**50 (100)**

Comparative distribution of study patients according to their prosthetic valve type Metal and Bioprosthetic valve: Among, all 100% (n=50) 58% patients underwent Aortic valve replacement surgery using CHVP valve and nearly similar amount that was 42% (n=21) patients underwent aortic valve replacement surgery using bioprosthetic valve, that is perimount magna **(Table 2) (Figure 2).**

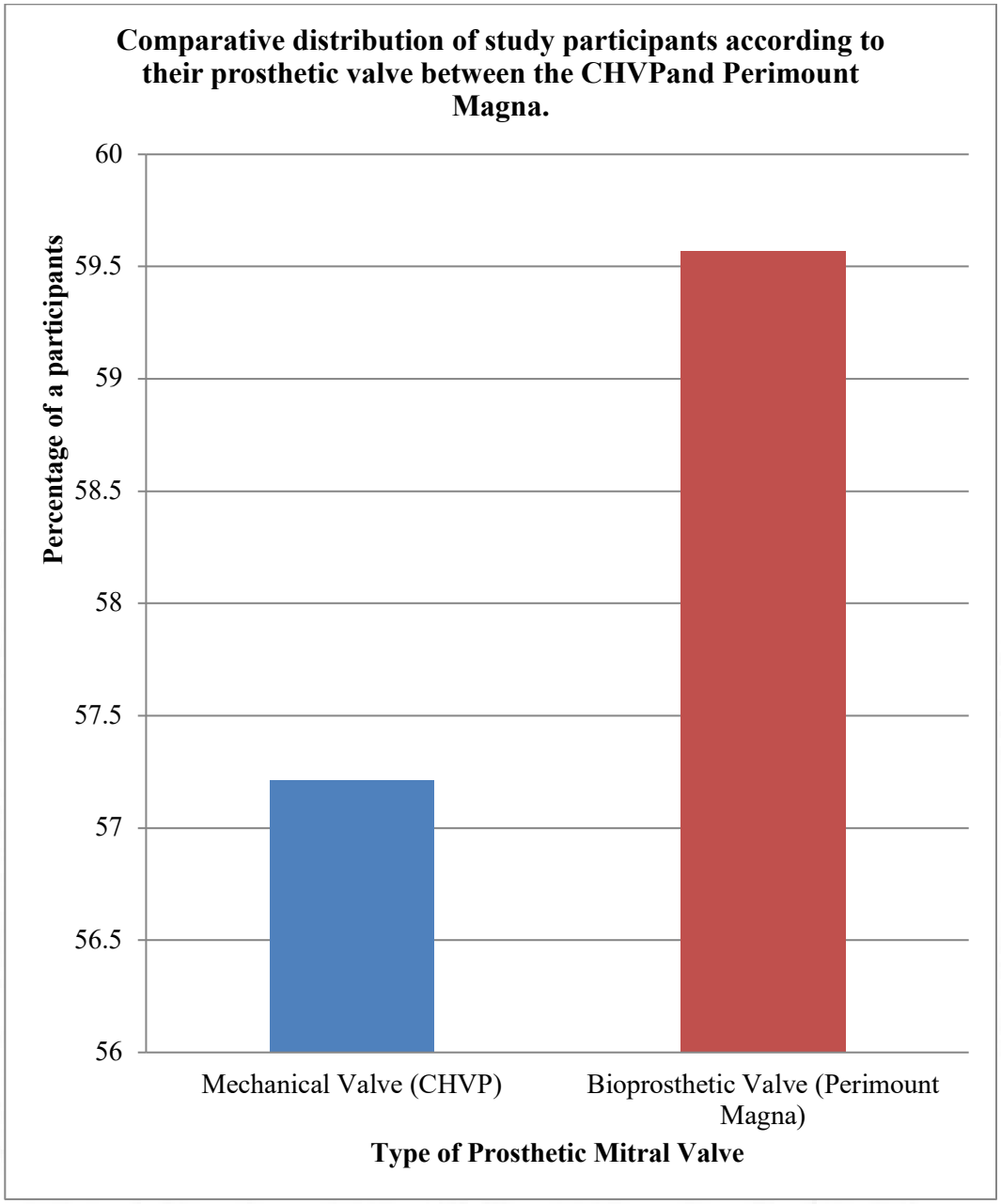

Figure 2. Comparative distribution of study patients according to their prosthetic valve between the Metal and Bioprosthetic valve.

Table 3: Comparative distribution of study patients according to their mean age between the Metal and Bioprosthetic valve.

Sr. No.	Age	Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)
1	Mean Value	50.62	65.09
2	Standard Deviation	±5.240	± 4.036

Comparative distribution of study patients according to their mean age between the Metal and Bioprosthetic valve: The mean value of patient's age from those underwent AVR using Peri Mount Magna Prosthetic valve was 50.62 years with standard deviation ± 9.537 seems nearly similar in the group of patients those using CHVP for AVR., and their mean age was 59.57+- 8.207. **(Table no.3)(Figure no.3).**

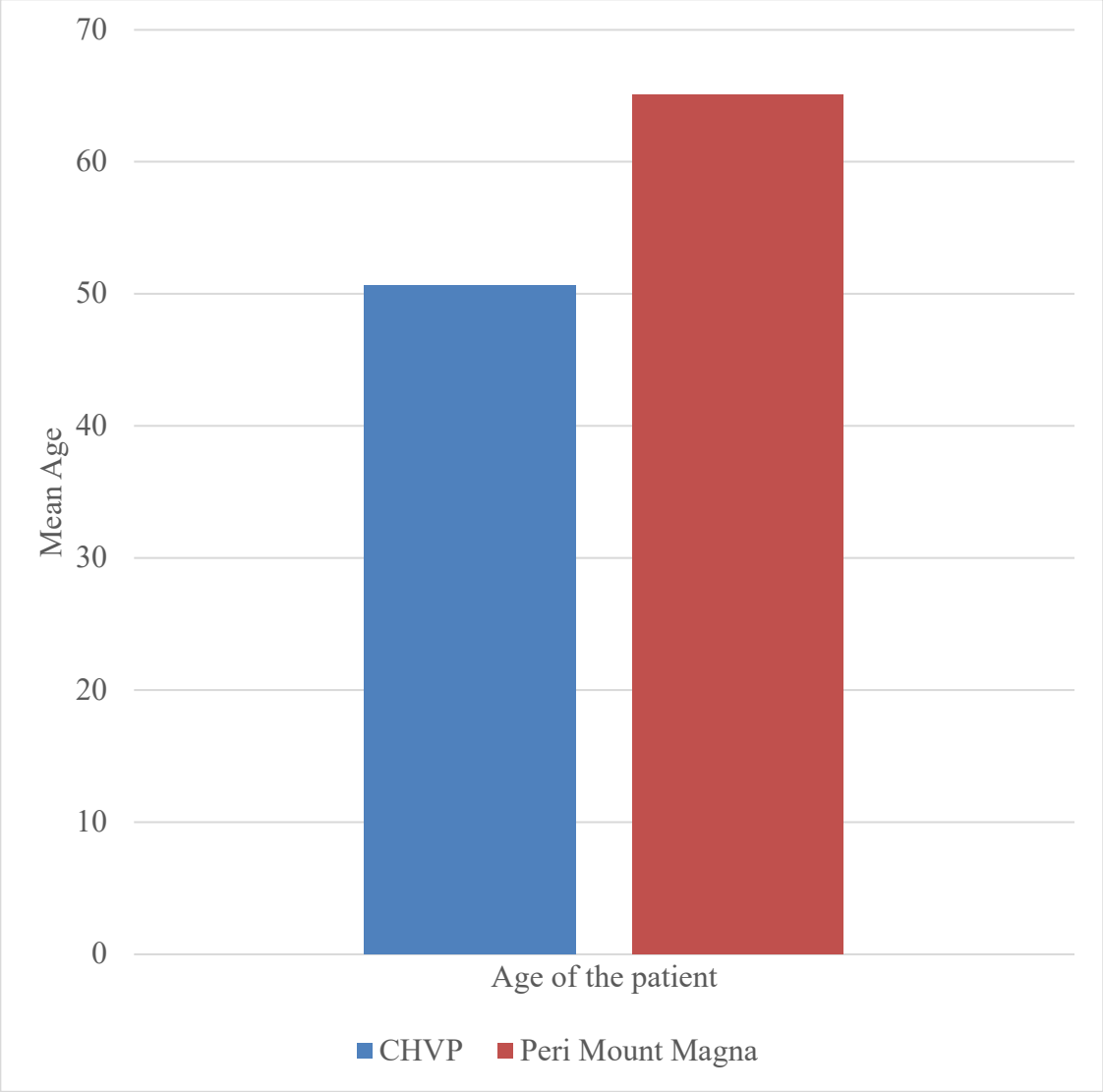

Figure 3. Comparative distribution of study patients according to their mean age between the Metal and Bioprosthetic valve.

Table 4: Comparative distribution of study patients according to their sex between the Metal and Bioprosthetic valve.

Sr. No.	Sex	Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)
1	**Male**	11 (37.9)	10 (47.6)
2	**Female**	18 (62.1)	11 (52.4)
Total		29 (100)	21(100)

Comparative distribution of study patients according to their sex between the Metal and Bioprosthetic valve: The total 100% (n=29) patients, those using CHVP prosthesis for aortic valve replacement surgery. Among them females were slightly more, that was 62.1% (n=18) in number than the male and they are 37.9% (n=11). Same trend was observed in 100% (n=21) patients, those underwent AVR using PM magna valve. Among them females were slightly more that is 52.4% (n=11) in number than the male and they were 47.6% (n=10). **(Table 4) (Figure 4).**

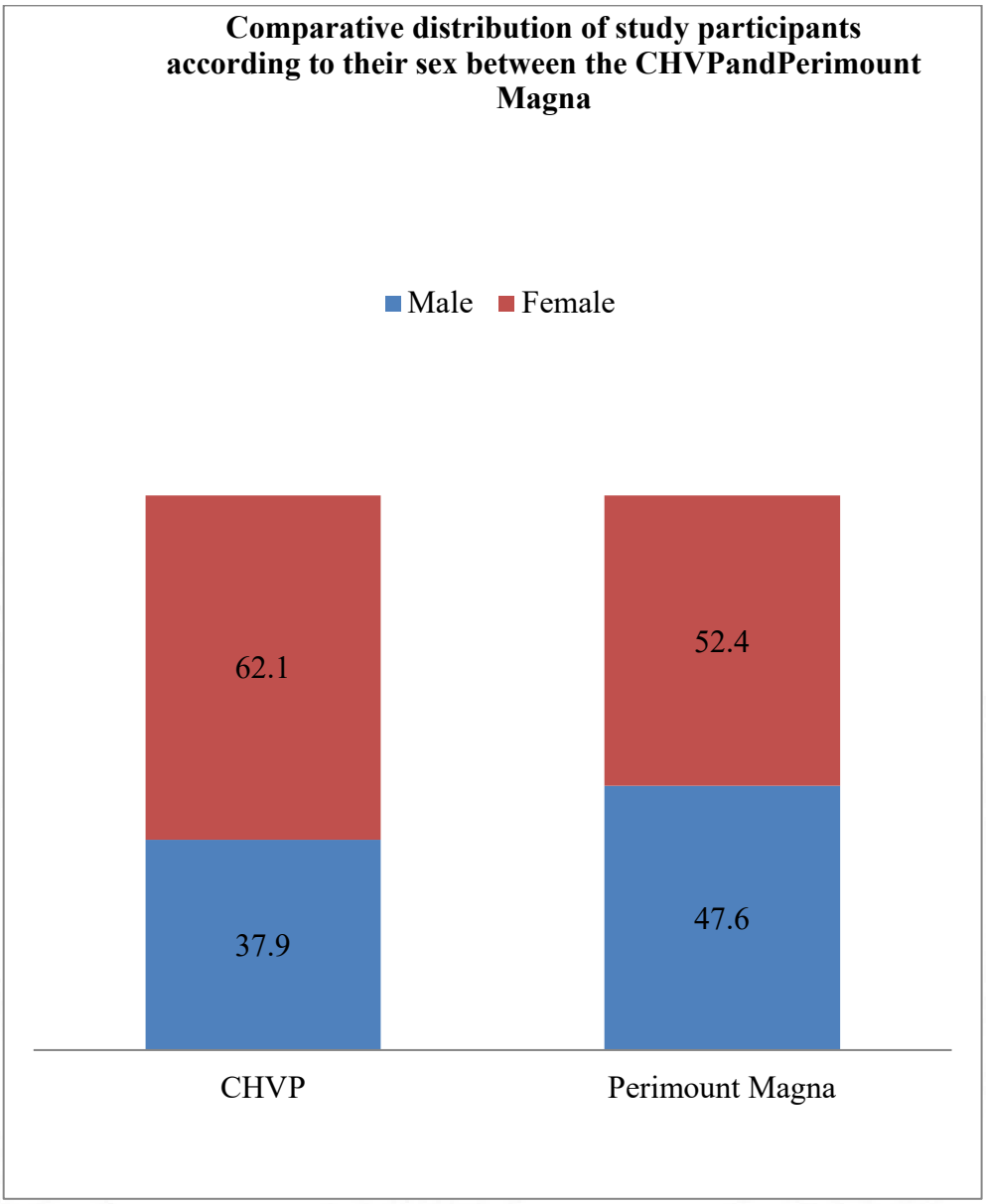

Figure 4: Comparative distribution of study patients according to their sex between the Metal and Bioprosthetic valve.

Table 5: Comparative distribution of study patients according to their weight between the Metal and Bioprosthetic valve.

Sr. No.	Weight (Kilogram)	Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)
1	Mean Value	69.55	70.71
02	Standard deviation	±9.537	± 8.207

Comparative distribution of study patients according to their weight between the CHVP and Peri Mount Magna: In the CHVP group, the mean weight value was 69.55 kg, with a standard deviation of ±9.537 kg. In contrast, the Peri Mount Magna group had a slightly higher mean weight value of 70.71 kg, with a standard deviation of ±8.207 kg. There is not much difference in the weight of the patient in both groups prior the surgery**. (Table 5) (Figure 5)**

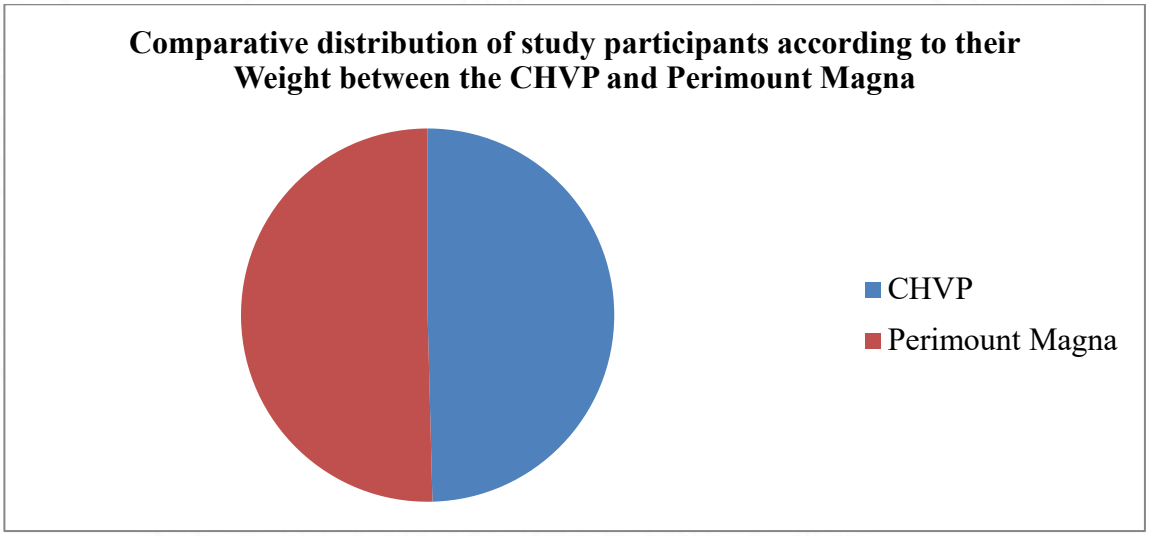

Figure 5: Comparative distribution of study patients according to their weight between the Metal and Bioprosthetic valve.

Table 6: Comparative distribution of study patients according to their New York Heart Association functional class between the Metal and Bioprosthetic valve.

Sr. No.	NYHA	Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)
1	**Class II**	11 (37.9)	8 (38.1)
2	**Class III**	18 (62.1)	13 (61.9)
Total		**29 (100)**	**21 (100)**

Comparative distribution of study patients according to their New York Heart Association functional class between the Metal and Bioprosthetic valve

The total 100% (n=29) patients, those underwent AVR using CHVP, among them, 62.1% (n=18) patients observed with NYHA functional class III were slightly higher in number with NYHA functional class II and they are 37.9% (n=11). Same trend was observed in 100% (n=21) patients, those underwent AVR using Peri Mount magna aortic valve, among them, 61.9% (n=13) patients observed with NYHA functional classIII were slightly higher that is in number with NYHA functional class II and they were 38.1% (n=8).

There is not much difference of having NYHA functional class II and III observations of the patient in both groups prior to the surgery. **(Table 6) (Figure 6)**

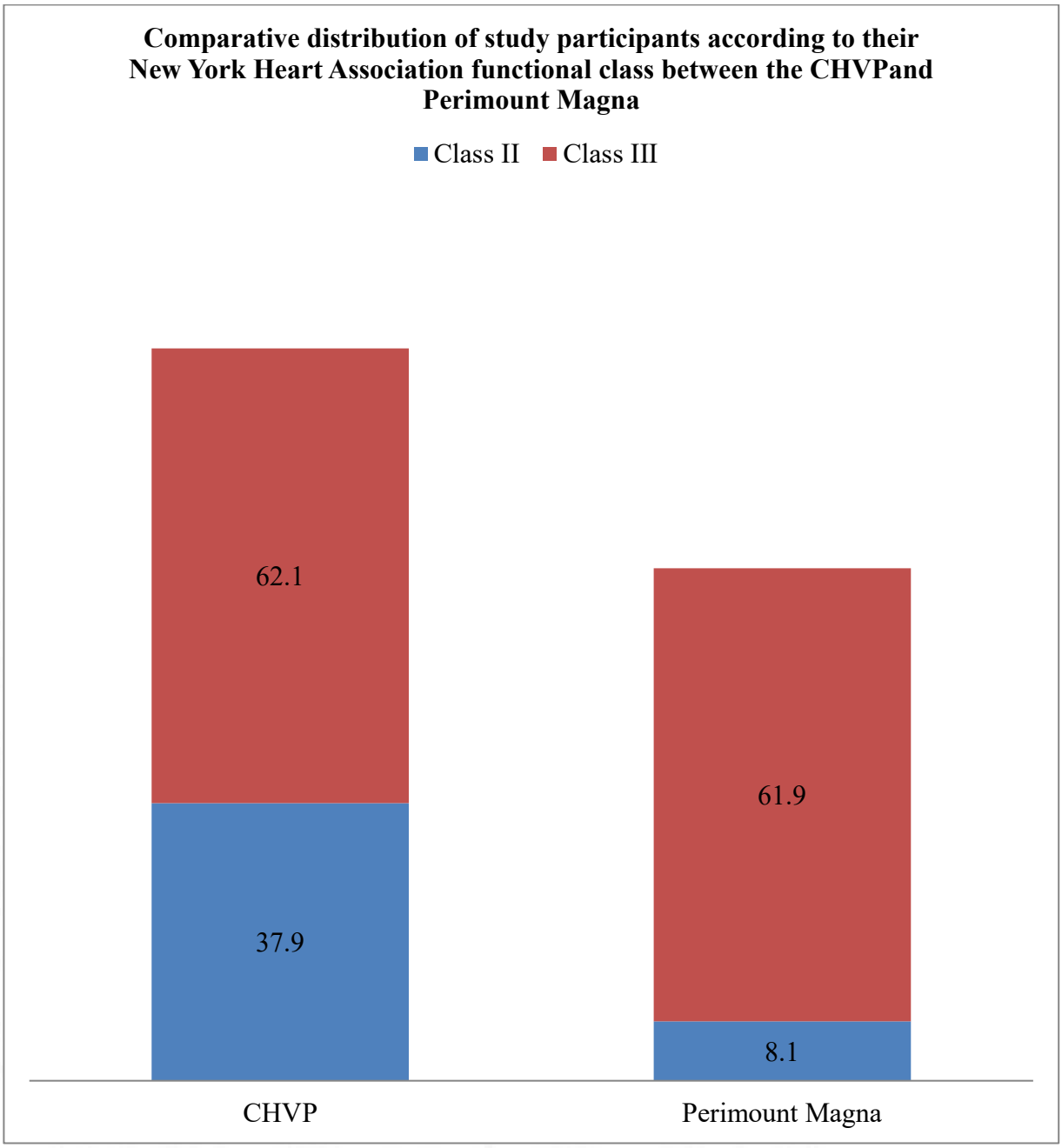

Figure 6: Comparative distribution of study patients according to their New York Heart Association functional class between the Metal and Bioprosthetic valve.

Table 7: Comparative distribution of study patients according to their Left Ventricular Diameter in diastole (LVIDd) on pre-operative and post-operative at 3 months examinationbetween Metal and Bioprosthetic valve.

Sr. No.	LVIDd	Pre-Operative		Post-operative after 3 months	
		Metal Valve (CHVP)	Biopros-thetic Valve (Perimount Magna)	Metal Valve (CHVP)	Biopro-sthetic Valve (Perimount Magna)
1	Mean Value	45.00	51.24	42.00	45.10
2	Standard Deviation	± 4.206	± 4.847	± 4.206	4.110

Comparative distribution of study patients according to their Left Ventricular Diameter in diastole (LVIDd) on pre-operative and post-operatively at 3 months examination between Metal and Bioprosthetic valve. Total patients those underwent aortic valve replacement surgery with CHVP valve had a mean value for LVIDd value 45.00 mm, with a standard deviation of ± 4.206 mm. There is a decrease in the mean value of LVIDd slightly,where the mean value of LVIDd was 42.00 with a standard deviation were observed on pre-operative examination.

Total patients who underwent aortic valve replacement surgery with Peri Mount magna type of valve had a mean value for LVIDd value was 51.24 mm, with a standard deviation of ± 4.847 mm.there is a decrease in LVIDd, where the mean value of LVIDd was 45.10 with a standard deviation were observed pre-operatively at 3 months examination. **(Table 7) (Figure 7)**

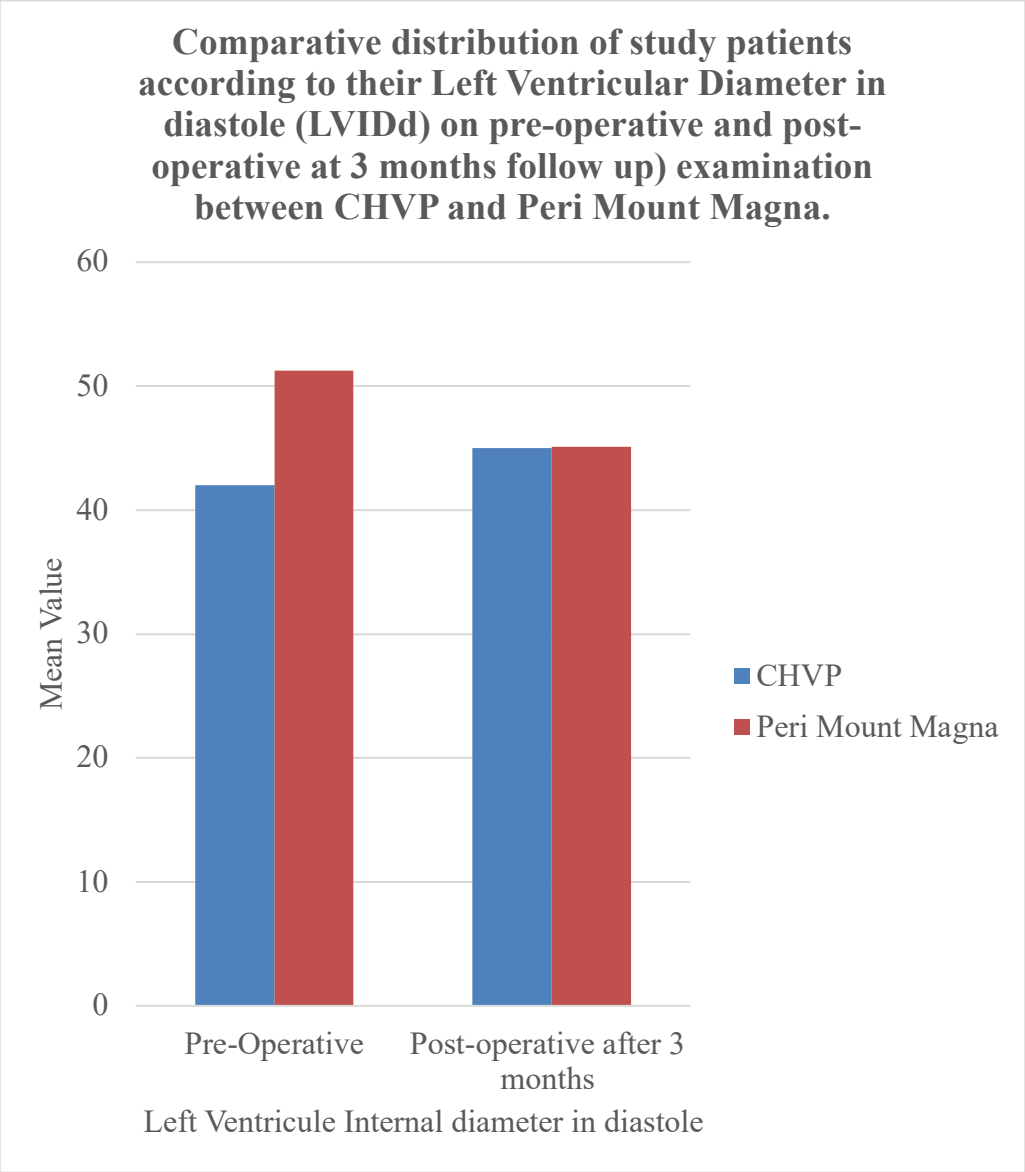

Figure 7: Comparative distribution of study patients according to their Left Ventricular Diameter in diastole (LVIDd) on pre-operative and post-operatively at 3 months follow up examination between Metal and Bioprosthetic valve.

Table 8: Comparative distribution of study patients according to their posterior walldiameter in diastole (mm), pre-operative and post-operatively at 3 months examination between Metal and Bioprosthetic valve.

Sr. No.	Posterior wall diameterin diastole (mm)	Mean value of Posterior wall diameter in diastole			
		Pre-Operative		Post-operative at 3 months	
		Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)	Metal Valve (CHVP)	Bioprosth-etic Valve (Perimount Magna)
1	Mean Value	14.79	15.57	12.90	14.10
2	Standard deviation	±1.953	±1.938	±1.611	±1.895

Comparative distribution of study patients according to their posterior wall diameter in diastole (mm) on pre-operative and post-operative examination after 3 months between Metal and Bioprosthetic valve. Total patients those underwent aortic valve replacement surgery with CHVP valve had the mean value for PWDd was 14.79 mm, with a standard deviation of ± 1.953 mm. there is decrease in the mean value of PWDd and it was 12.90 with a standard deviation ±1.953 were observed on pre-operative examination.

Total patients those underwent aortic valve replacement surgery with Peri Mount magna type of valve had the mean value for PWDd was 14.10 mm, with a standard deviation of ± 1.895 mm. there is decrease in the mean value of PWDd and it was 15.57 mm with a standard deviation ±1.938 were observed on pre-operative examination

(Table 8) (Figure 8)

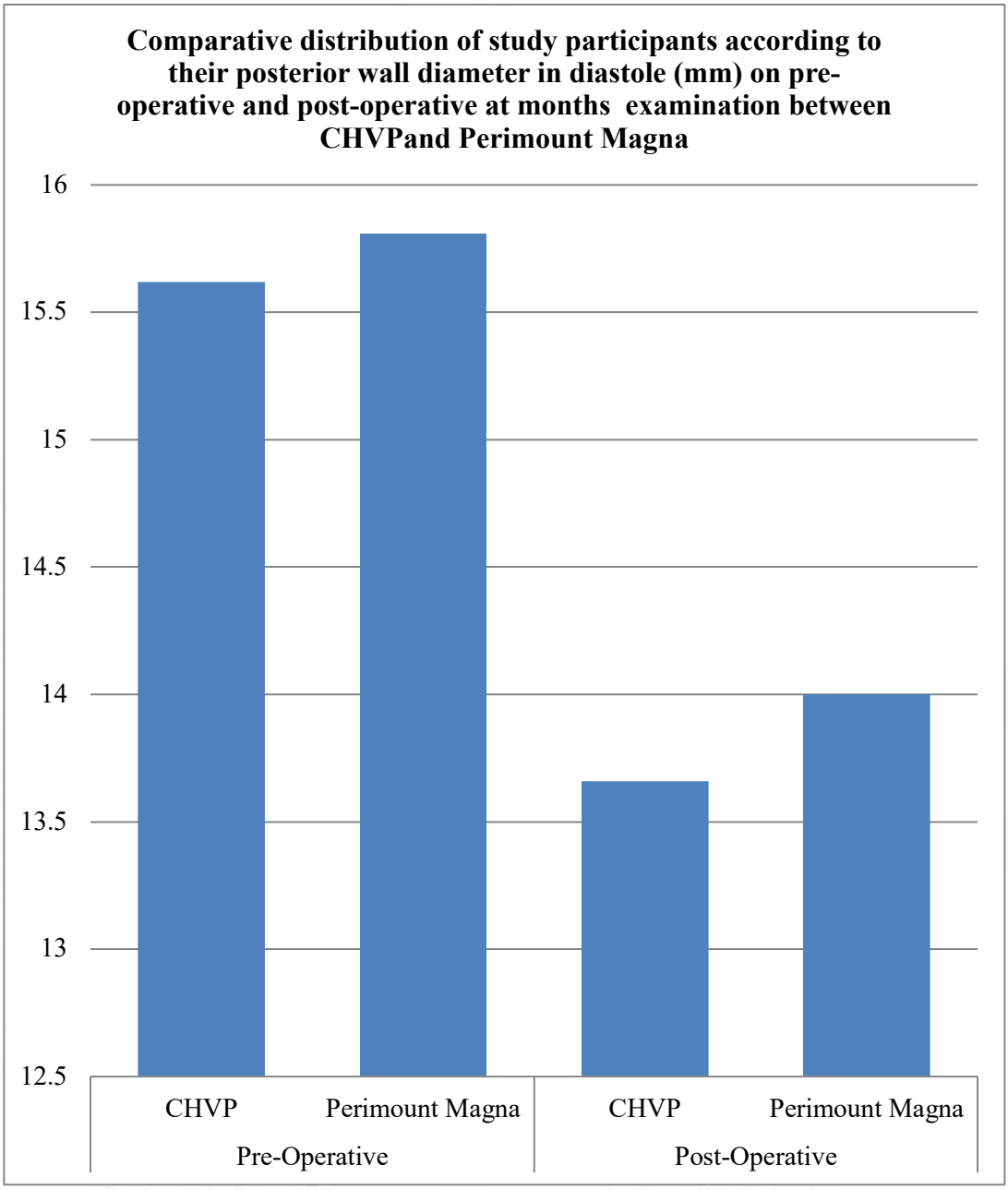

Figure 8: Comparative distribution of study patients according to their posterior wall diameter in diastole (mm) on pre-operative and post-operatively at 3 months examination between Metal and Bioprosthetic valve.

Table 9: Comparative distribution of study patients according to their septal thickness in diastole (mm) on pre-operative and post-operative after 3 months examination between Metal and Bioprosthetic valve.

Sr. No.	Septal thicknessin diastole (mm)	Pre-Operative		Post-operative after 3 months	
		Metal Valve (CHVP)	Peri Mount Magna	Metal Valve (CHVP)	Peri Mount Magna
1	Mean Value	15.62	15.81	13.66	14.00
2	Standar Deviation	±1.720	± 1.601	±1.610	± 1.449

Comparative distribution of study patients according to their septal thickness in diastole (mm) on pre-operative and post-operative after 3 months examination between Metal and Bioprosthetic valve:

Total patients those underwent aortic valve replacement surgery with CHVP type of valve showed, the mean value for septal thickness in diastole was 13.66 mm, with a standard deviation of ± 1.610 mm after 3 months at post-operative examination. There is decrease in the mean value of septal thickness in diastole and it was 15.62 with a standard deviation ±1.720 were observed on pre- operative examination. Total patients those underwent aortic valve replacement surgery with Peri Mount magna valve had the mean value for septal thickness in diastole 14.00 mm, with a standard deviation of ± 1.449 mm after 3 months at post-operative examination. There is decrease in the mean value of septal thickness in diastole and it was 13.66 mm with a standard deviation ±1.601 were observed

on pre-operative examination **(Table 9) (Figure 9).**

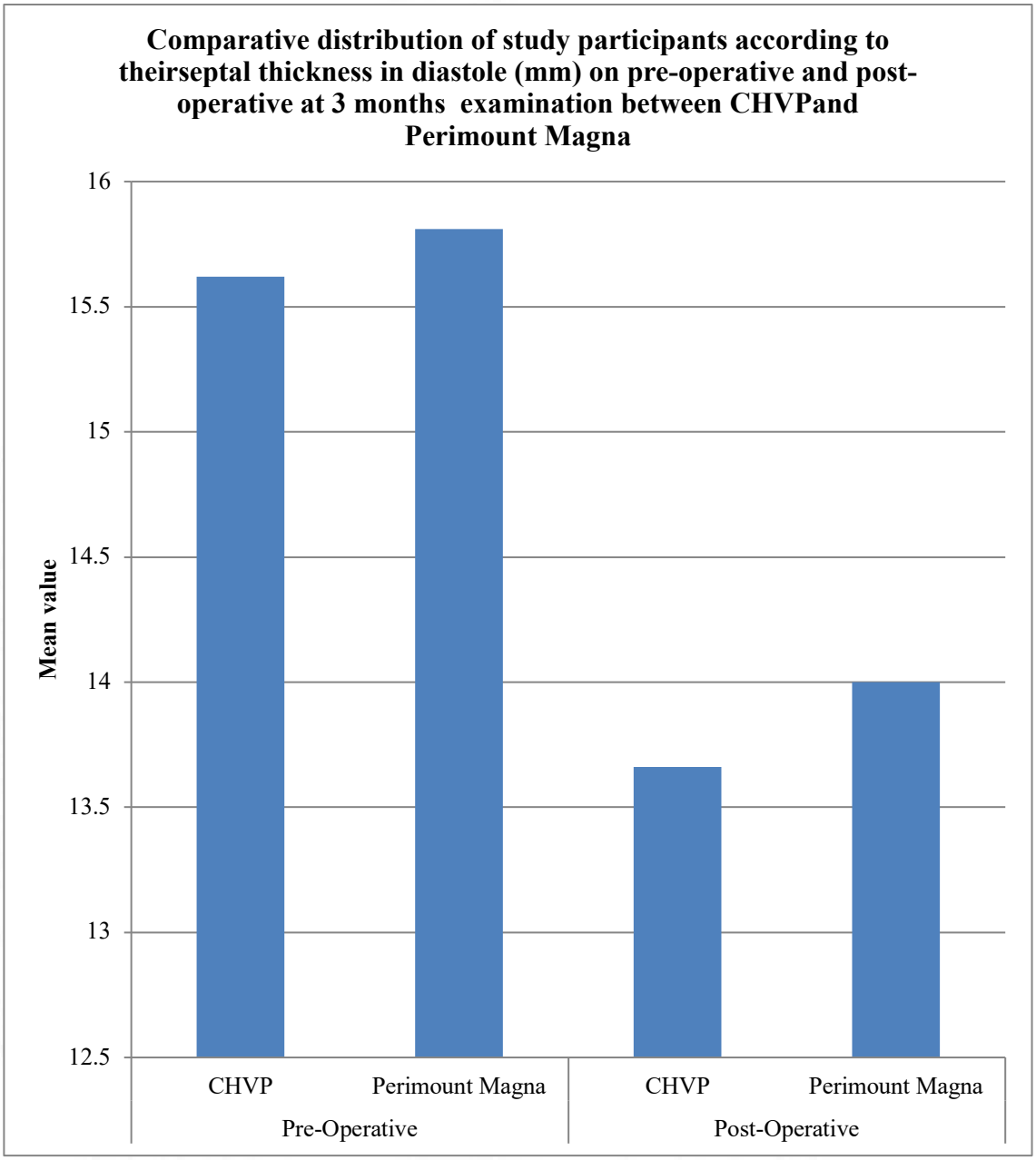

Figure 9: Comparative distribution of study patients according to their septal thickness in diastole (mm) on pre-operative and post-operative at 3 months examination between Metal and Bioprosthetic valve.

Table 10: Cumulative distribution of study patients according to left ventricular ejection fraction (LVEF) on pre-operative and post-operatively at 3 months examination between Metal and Bioprosthetic valve.

Sr. No.	Left Ventricular ejection Fraction	Pre-Operative		Post-operative at 3 months	
		Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)	Metal Valve (CHVP)	Biopro-sthetic Valve (Perimount Magna)
1	Mean Value	61.34	51.24	63.69	55.5
2	Standard deviation	± 7.047	± 4.847	± 5.819	± 4.110

Cumulative distribution of study patients according to left ventricular ejection fraction (LVEF)on pre-operative and post-operatively after 3 months examination between Metal and Bioprosthetic valve: The mean value of left ventricular ejection fraction was 61.34 with the standard deviation of 7.047 those are improved up to 63.69 with the standard deviation of ± 5.819. Improving status of LVEF observed following aortic valve replacement surgery using CHVP valve. A similar trend is present among patients with Peri Mount magna valve. The observation was the mean value of the left ventricular ejection fraction was 51.24 with a standard deviation of 4.847 those are improved up to 55.50 with a standard deviation of ± 4.110.**(Table 10) (Figure 10).**

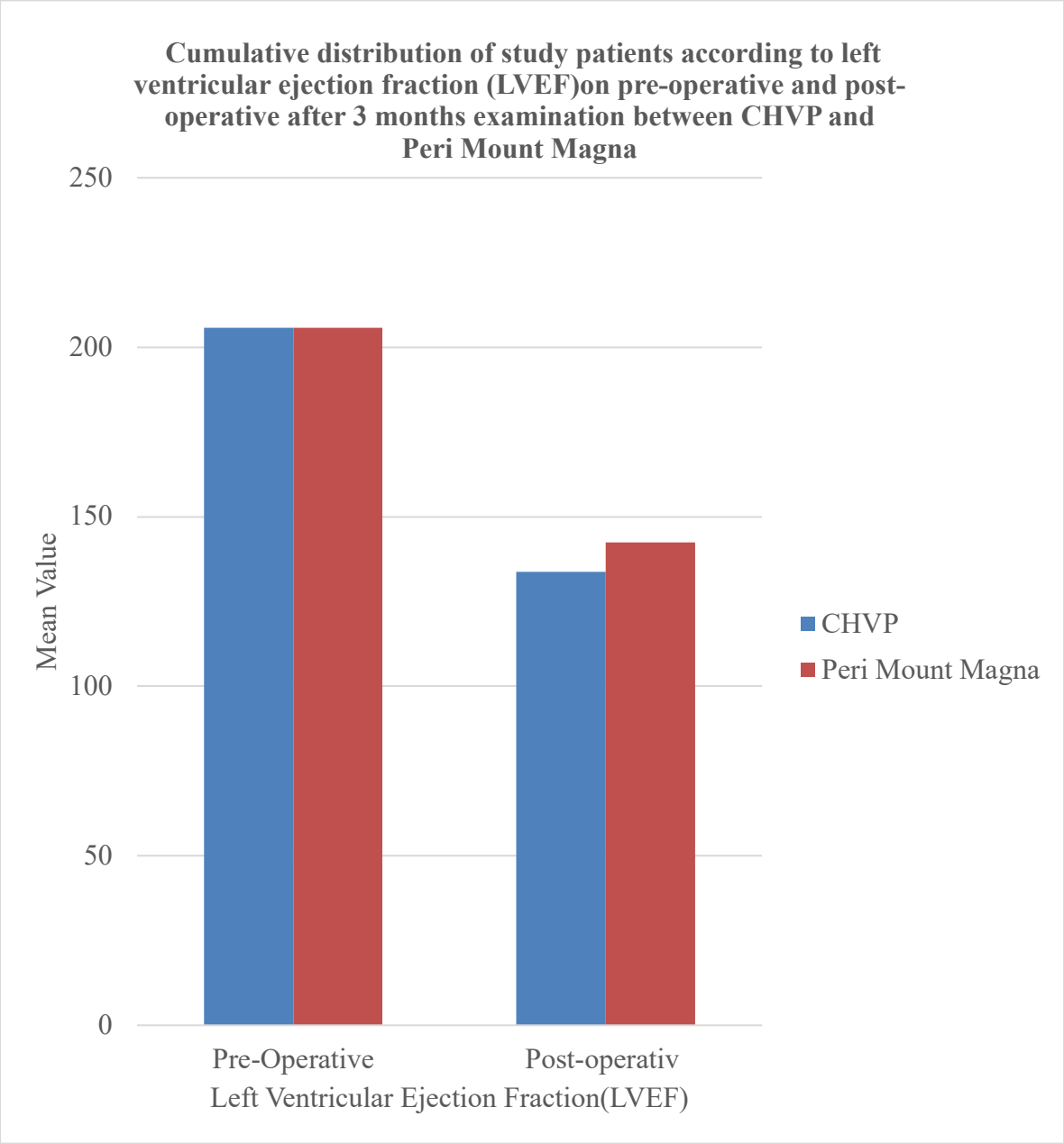

Figure 10: Cumulative distribution of study patients according to left ventricular ejection fraction (LVEF)on pre-operative and post-operatively after 3 months examination between Metal and Bioprosthetic valve.

Table 11: Comparative distribution of study patients according to their trans valvular gradient in peak on pre-operative, immediate-post-operative and post-operatively at 3 months follow up.

Sr. No.	Trans valvular gradientin peak	Pre-Operative		Immediate Post-operative		Post-operative at 3 months follow up	
		Metal Valve (CHVP)	Biopro-sthetic Valve (Perimount Magna)	Metal Valve (CHVP)	Peri Mount Magna	Metal Valve (CHVP)	Biopro-sthetic Valve (Perimount Magna)
1	Mean Value	83.38	79.52	16.14	16.19	12.41	12.81
2	Standard deviation	± 9.194	± 19.369	± 3.472	± 2.822	± 2.860	± 1.914

Comparative distribution of study patients according to their trans valvular gradient in peak on pre-operative, immediate- post-operative and post-operatively at 3 months follow up: the mean value of transvalvular gradient in peak were observed at the pre-operative, Immediate post-operative and post-operatively after 3 months follow up period were observed 83.38 ± 9.194, 16.14 ± 3.472, and 12.81 ± 1.914 respectively. Amongst the patients underwent aortic valve replacement surgery with using CHVP valve. While the patients who underwent aortic valve replacement surgery with Peri Mount magna valve had similar pattern of their observation with the CHVP type valve and they are 79.52 ± 19.369, 16.19 ± 2.822 and 12.81± 1.914 respectively **(Table 11) (Figure 11).**

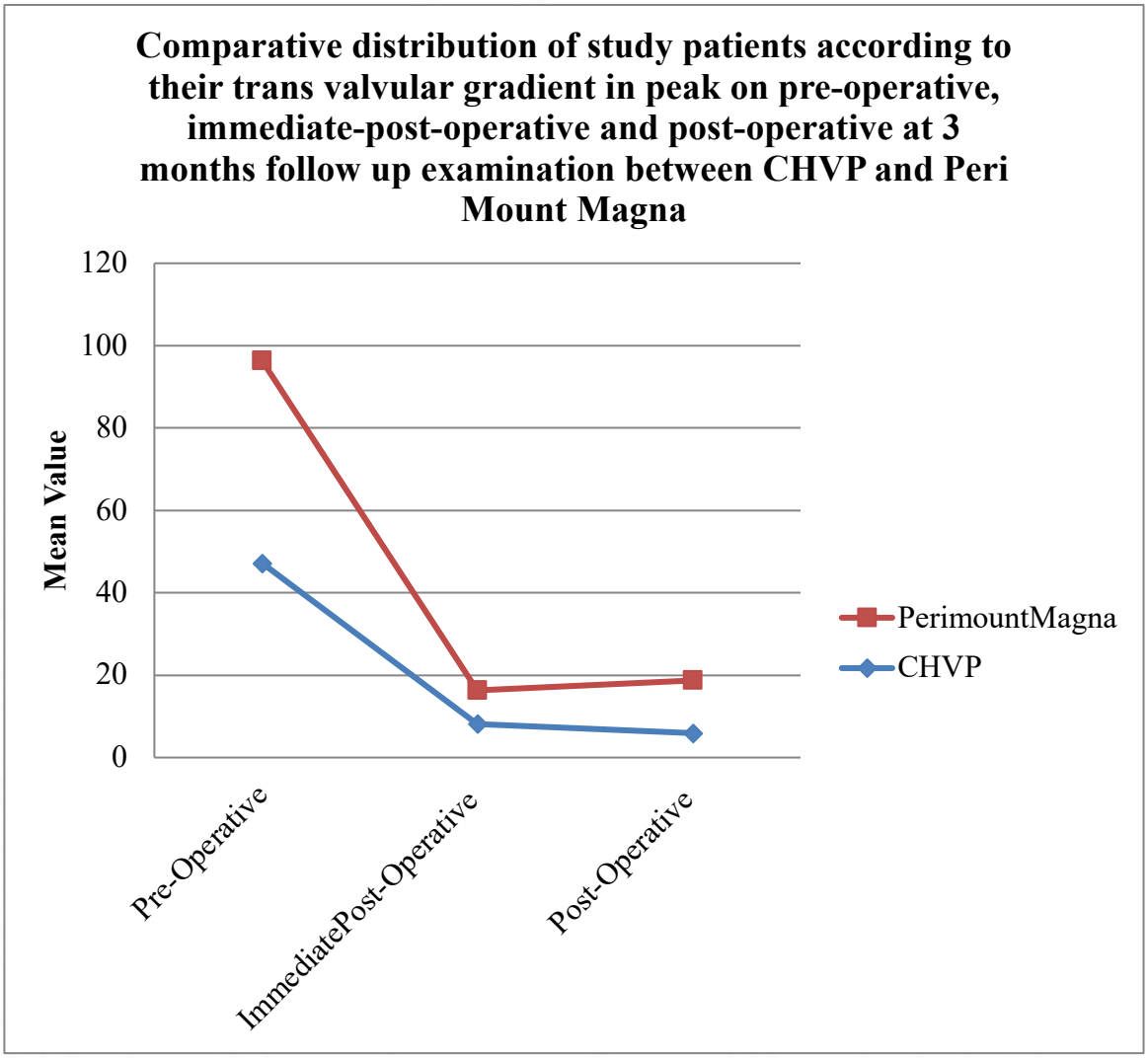

Figure 11: Comparative distribution of study patients according to their trans valvular gradient in peak on pre-operative, immediate-post-operative and post-operative at 3 months follow up examination between Metal and Bioprosthetic valve.

Table 12: Comparative distribution of study patients according to their trans valvular gradient in mean on pre-operative, immediate post-operative and post-operatively at 3 monthsfollow up examination between Metal and Bioprosthetic valve.

Sr. No.	Trans valvular gradientin mean	Pre-Operative		Immediately Post-operative		Post-operative at 3 months follows up	
		Metal Valve (CHVP)	Biopro-sthetic Valve (Perimount Magna)	Metal Valve (CHVP)	Peri Mount Magna	Metal Valve (CHVP)	Biopros-thetic Valve (Perimount Magna)
1	Mean Value	47.21	49.14	8.17	8.14	5.93	6.48
2	Standard deviation	± 4.475	± 12.459	±2.331	± 1.590	± 1.510	± 1.250

Comparative distribution of study patients according to their mean trans valvular gradient on pre-operative, immediate-post-operative and post-operatively at 3 months follow up examination between Metal and Bioprosthetic valve.: the mean value of transvalvular gradient in mean were observed at the pre-operative, Immediate post-operative and post-operatively after 3 months follow up period were observed 47.21 ± 9.194, 8.17 ± 3.472, and 5.93± 1.510 respectively, amongst patients underwent aortic valve replacement surgery using CHVP type of aortic valve. While the patients underwent aortic valve replacement surgery with the Peri Mount magna valve had similar pattern of their observation with the CHVP type valve and they were 49.14± 12.459, 8.14±331 and 5.93± 1.510 respectively **(Table 12) (Figure 12).**

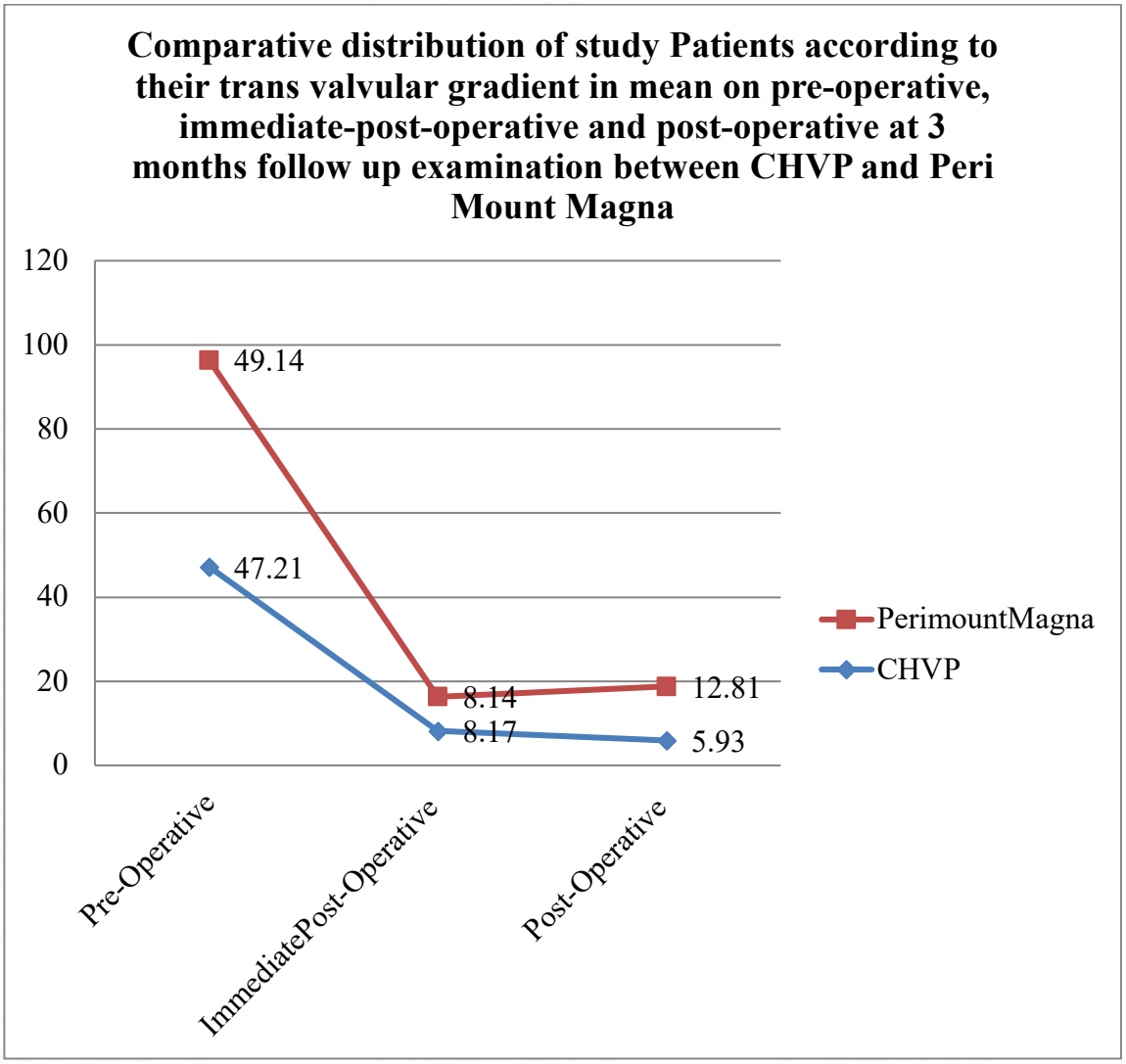

Figure 12: Comparative distribution of study patients according to their trans valvular gradient in mean on pre-operative, immediate-post-operative and post-operative at 3 months follow up examination between Metal and Bioprosthetic valve.

Table 13: Comparative distribution of study patients according to their pre-operative and post-operative LV mass after 3 months between Metal and Bioprosthetic valve.

Sr. No.	Left Ventricular Mass Regression	Pre-Operative		Post-operative at 3 months follows up		ActualValue (Before-After)	
		Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)	Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)	Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)
1	Mean Value	341.51	362.17	235.12	251.19	106.38	110.97
2	Standard deviation	±59.088	±66.782	±44.847	±41.885	±36.343	±42.22

Comparative distribution of study patients according to their pre-operative LV mass and post-operative LV mass regression after 3 months between Metal and Bioprosthetic valve.

The preoperative left ventricular mass (mean value) was observed 341.51±59.088 and 362.17 ±66.782 for patients those underwent aortic valve replacement surgery using Metal and Bioprosthetic valve respectively.

LV Mass decreases following aortic valve replacement and patient with havingCHVP valves showed mean value 235.12±44.847 while patients having Perimount Magna valve 251.19 ±44. 847.The actual LV Mass regression was observed 106.19 ±36.343 and 110.97±42.22 for patients who has underwent AVR using Metal and Bioprosthetic valve respectively. These results showed that there is not much difference in both the valves groups on LV Mass Regression. **(Table13) (Figure 13).**

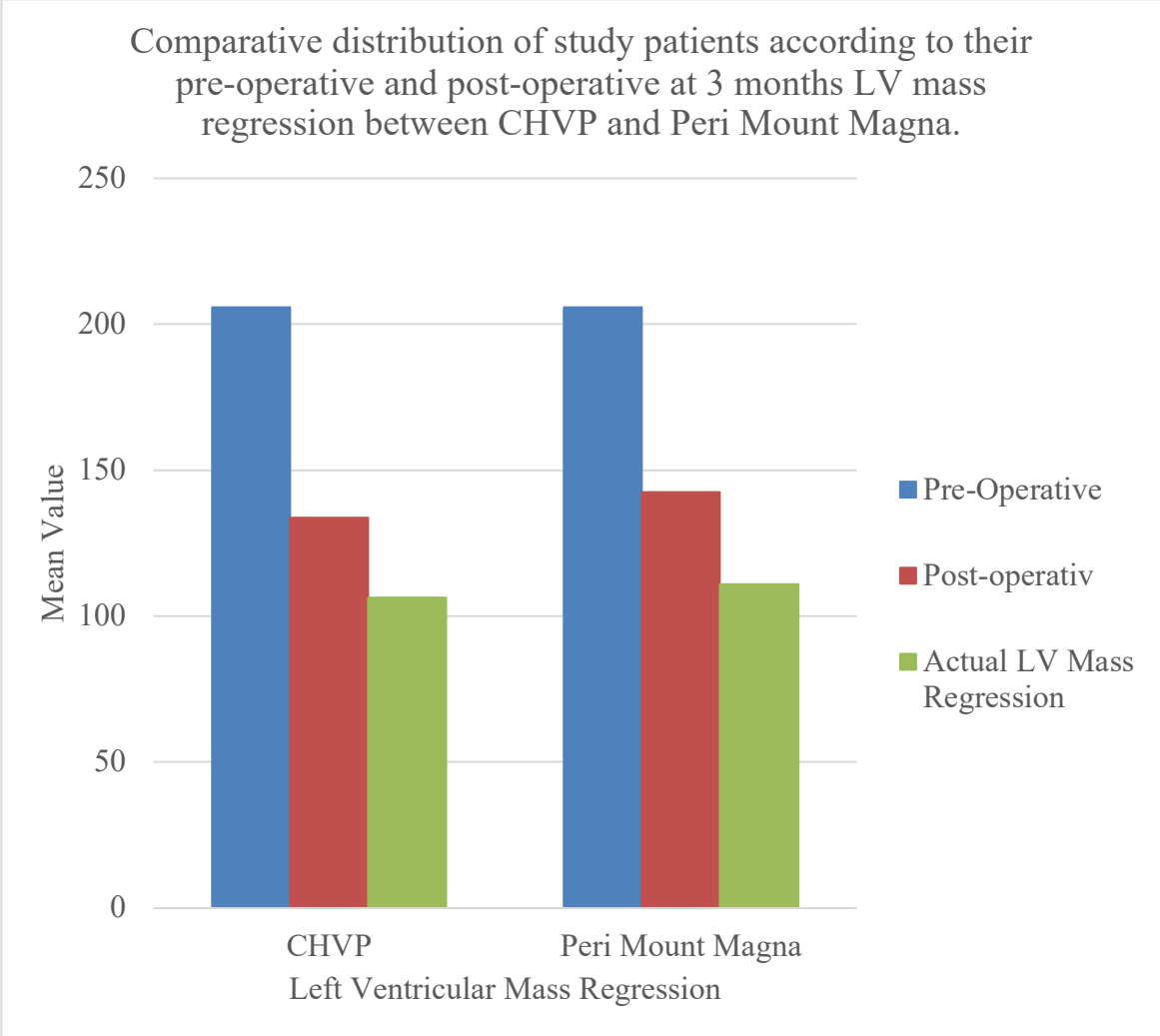

Figure 13: Comparative distribution of study patients according to their pre-operative and post-operative at 3 months LV mass regression between Metal and Bioprosthetic valve.

Table 14: Comparative distribution of study patients according to their pre-operative and post-operative Left Ventricular Mass Index (LVMI) after 3 months between Metal and Bioprosthetic valve

Sr. No.	Left Ventricular Mass Index	Pre-Operative		Post-operative at 3 months follows up	
		Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)	Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)
1	Mean Value	194.30	200.51	134.18	144.40
2	Standard Deviation	±37.81	±42.93	±29.69	±27.49

Comparative distribution of study patients according to their pre-operative and post-operative Left Ventricular Mass Index (LVMI) after 3 months between Metal and Bioprosthetic valve: The left ventricular mass index was reduced and following the similar trend for both groups of patients. The pre-operative LVMI was 294.30 ±37.81 and 200.51 ±42.93 respectively for Metal and Bioprosthetic valve group. The post-operative follows up at 3 months showed the positive impact and the observations were 134.18±29.69 and 144.40 ±27.49 respectively for Metal and Bioprosthetic valve group. **(Table 14.) (Graph 14).**

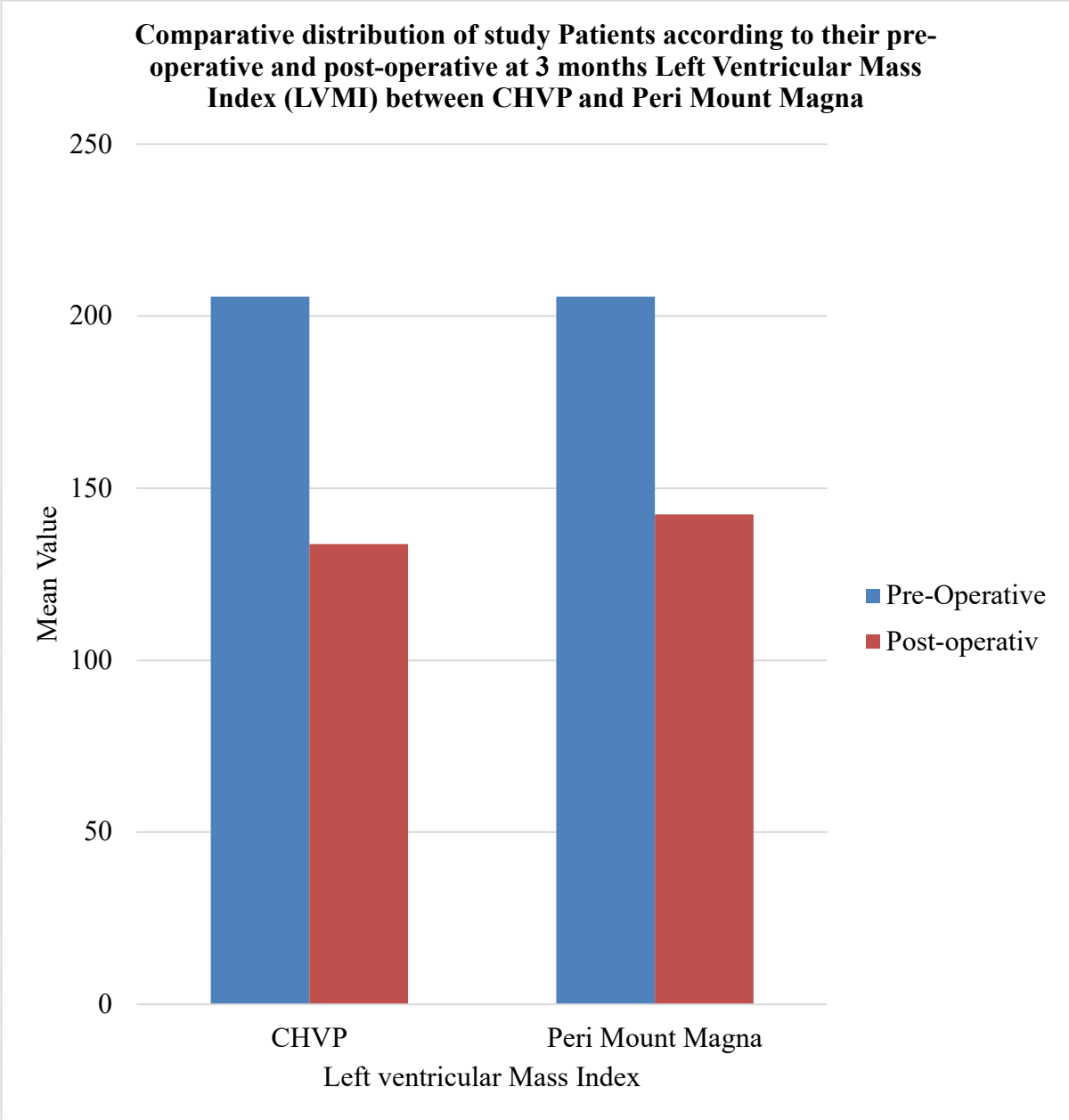

Figure 14: Size wise comparative distribution of study patients according to their pre-operative and post-operative at 3 months Left Ventricular Mass Index (LVMI) between Metal and Bioprosthetic valve.

Table 15: Size wise comparative distribution of study patients according to their age the sizes of Metal and Bioprosthetic valve.

Sr. No.	Size	Mean Value with standard deviation of Age in years	
		Bioprosthetic Valve (Perimount Magna)	Metal Valve (CHVP)
1	**19**	65.33 ±6.802	49 ± 4.583
2	**21**	65.25 ±1.669	52.33 ± 5.454
3	**23**	64.71 ±8.960	49.46 ± 5.292
4	**25**	0	49.60 ± 6.465

Size wise comparative distribution of study patients according to their age between the sizes of Metal and Bioprosthetic valve.

The mean value of age among the patient is between 64 to 65.5 for the patients who underwent aortic valve replacement using bioprosthetic valve Peri mount magna and the range of mean value of age is 49-52.5 for the patients who underwent aortic valve replacement surgery with metal valve CHVP. **(Table no 15) (Figure no 15).**

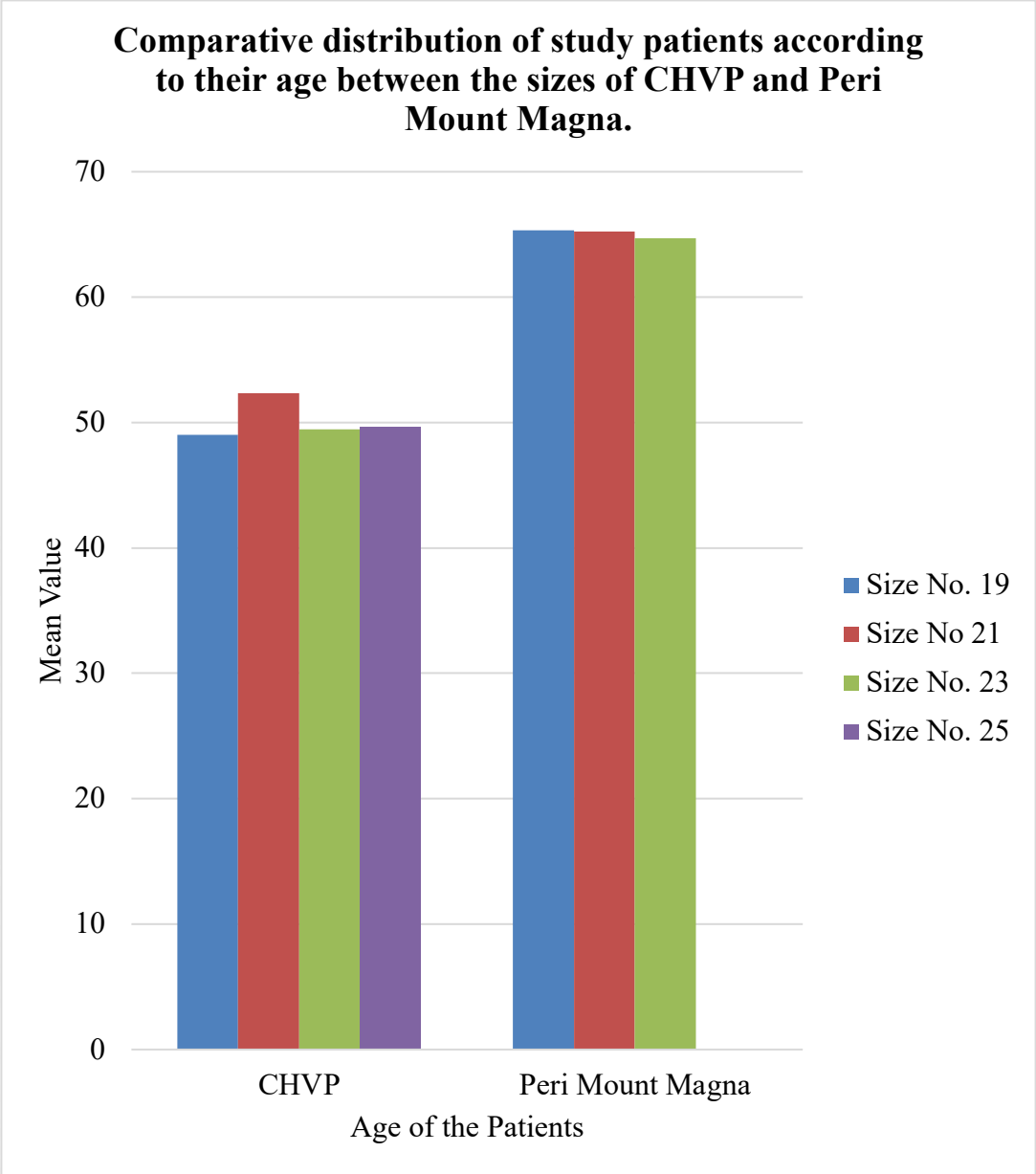

Figure 15. Size wise comparative distribution of study patients according to their age between the sizes of Metal and Bioprosthetic valve.

Table 16: Size wise comparative distribution of study patients according to their sex between the sizes of Metal and Bioprosthetic valve.

Sr. No.	Size	Number of patients n (%)			
		Bioprosthetic Valve (Perimount Magna)		Metal valve (CHVP)	
		Male	Female	Male	Feale
1	Size no. 19	3(50)	3(50)	1(33.3)	2(66.7)
2	Size no. 21	2(25)	6(75)	3(33.3)	6(66.7)
3	Size no. 23	5(71.4)	2(28.6)	5(41.7)	7(58.3)
4	Size no. 25	0	0	2(40)	3(60)

Size wise comparative distribution of study patients according to their sex between the sizes of Metal and Bioprosthetic valve.

The females are comparatively more in number than males were observed in both type of aortic valve replacement surgery except size number 23 peri mount magna replacement took place more 71.4% (n=5) of male patients than the female patients 28.6% (n=2). **(Table 16) (Figure 16).**

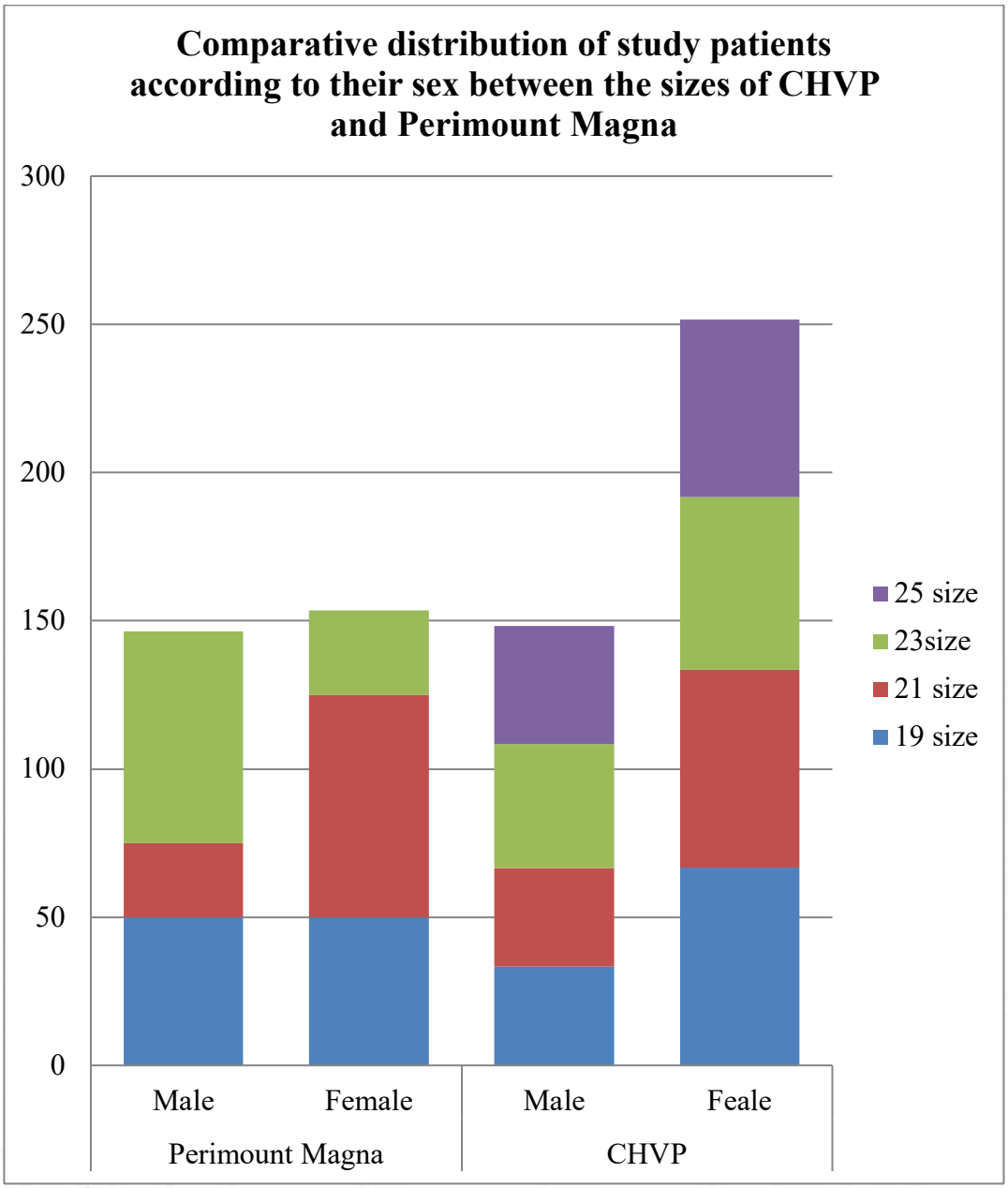

Figure 16: Size wise comparative distribution of study patients according to their sex between the sizes of Metal and Bioprosthetic valve.

Table 17: Size wise comparative distribution of study patients according to their Left Ventricular Diameter in diastole (LVIDd) on pre-operative and post-operative after 3months) examination between the sizes of Metal and Bioprosthetic valve.

Sr. No.	Size	Mean Value with standard deviation LVIDd			
		Peri Mount Magna		Metal Valve (CHVP)	
		Pre-op	Post-op	Pre-op	Post-op
	Size no. 19	53.50 ±1.834	46.00 ±4.336	49.33 ±4.163	44.67 ±4.619
	Size no. 21	52.13 ±4.357	45.25 ±4.34	52.33±3.640	45.20 ±3.962
	Size no. 23	48.29 ±5.251	44.14 ±4.220	50.42 ±3.965	46.08 ±4.481
	Size no. 25	0	0	51.20 ±4.764	51.20 ±4.764

Size wise comparative distribution of study patients according to their Left Ventricular Diameter in diastole (LVIDd) on pre-operative and post-operative after 3 months examination between Metal and Bioprosthetic valve.

The mean value of Left ventricular diameter in diastole (LVIDd) were apparently decreased after the aortic valve replacement surgery using both type of aortic valve that is Metal and Bioprosthetic valve observed for all the sizes. **(Table 17) (Figure 17).**

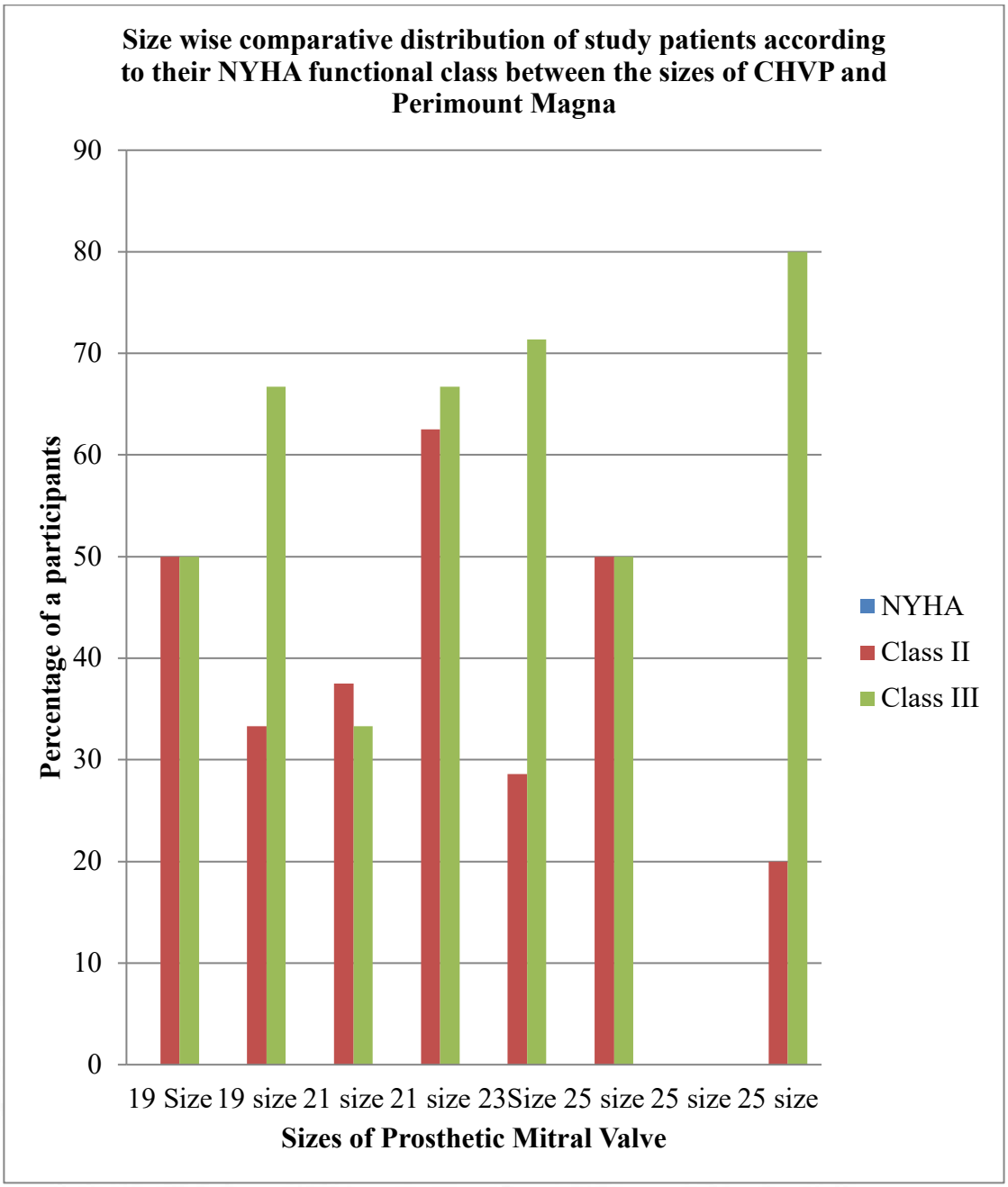

Figure 17: Size wise comparative distribution of study Patients according to their NYHA functional class between the sizes of Metal and Bioprosthetic valve.

Table 18: Size wise comparative distribution of study patients according to their posterior wall diameter in diastole (mm) on pre-operative and post-operatively after 3 months examination between the sizes of Metal and Bioprosthetic valve.

Sr. No.	Size	Mean Value with standard deviation Posterior Wall Diameter in diastole (PWDd) mm			
		Bioprosthetic Valve (Perimount Magna)		Metal Valve (CHVP)	
		Pre-op	Post-op	Pre-op	Post-op
	Size no. 19	15.67 ±2.338	14.17 ±.317	14.33 ±.0 .577	12.33 ±0.577
	Size no. 21	16.13 ±1.642	14.50 ±1.604	15.22 ±.2.224	13.00 ±1.871
	Size no. 23	14.86 ±1.952	13.57 ±1.988	14.17 ±1.267	12.58 ±1.165
	Size no. 25	0	0	15.80 ±3.033	13.80 ±2.387

The mean value of posterior wall diameter in diastole is reducing up to 1-3 mm from the preoperative measurements to post-operative follow up at 3 months measurements in all the sizes of Peri Mount magna and CHVP valve replaced patients. **(Table 18) (Figure 18).**

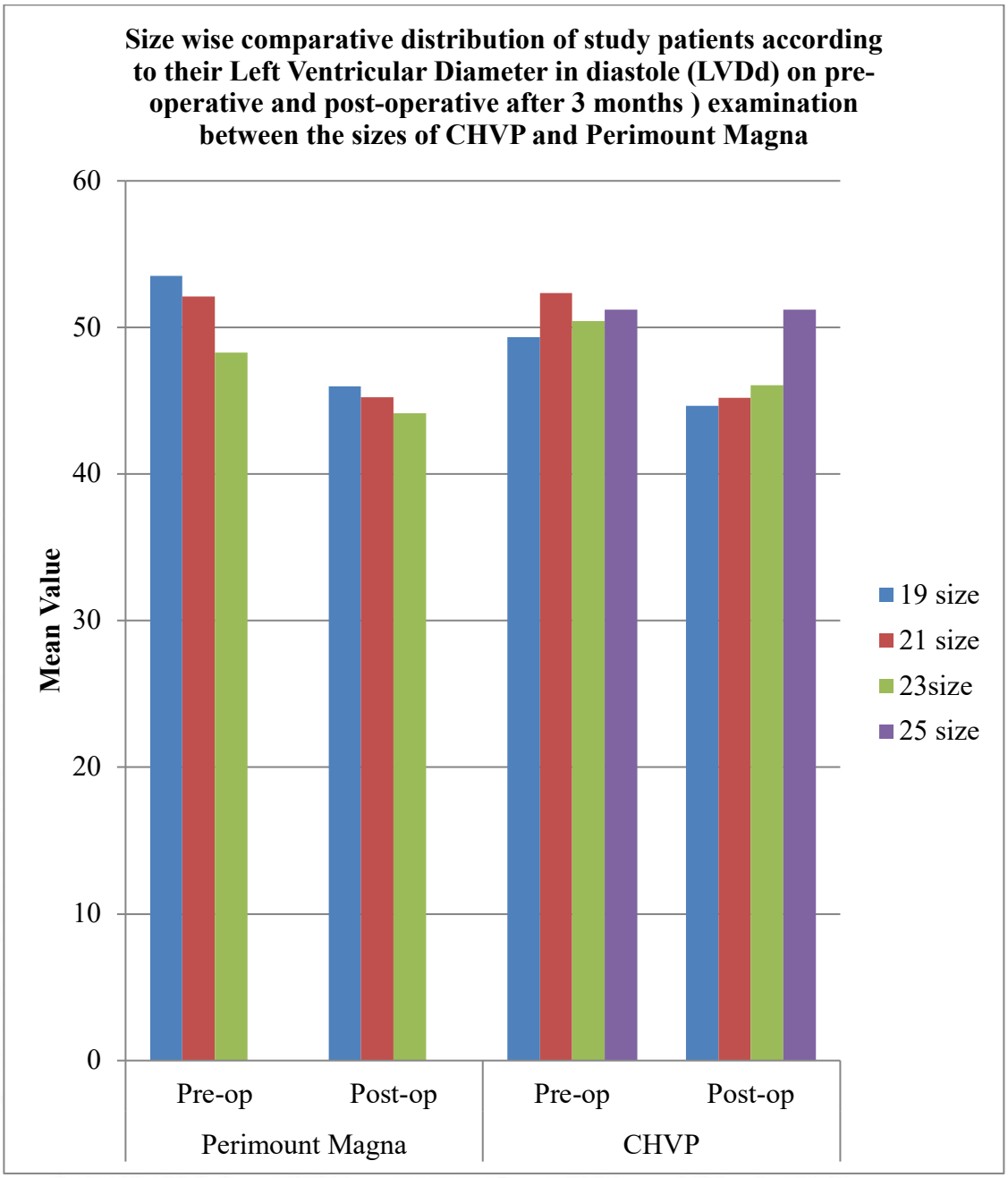

Figure 18: Size wise comparative distribution of study patients according to their Left Ventricular Diameter in diastole (LVIDd) on pre-operative and post-operative after 3 months examination between the sizes of Metal and Bioprosthetic valve.

Table 19: Size wise comparative distribution of study patients according to their septal thickness in diastole (mm) on pre-operative and post-operatively at 3 months examination between the sizes of Metal and Bioprosthetic valve.

Sr. No.	Size	Mean Value of Septal thickness with standard deviation			
		Bioprosthetic Valve (Perimount Magna)		Metal Valve (CHVP)	
		Pre-op	(3 months) post-op	Pre-op	(3 months) post-op
1	Size no. 19	15.83 ±.408	13.83 ±0.408	16.33 ±1.155	13.33 ±1.528
2	Size no. 21	16.13 ±1.1.808	14.50 ±1.512	15.44 ±1.590	13.56 ±1.509
3	Size no. 23	15.43 ±2.070	14.44 ±4.220	15.67 ±2.060	13.43 ±1.946
4	Size no. 25	0	0	15.40 ±1.673	13.60 ±1.342

Size wise comparative distribution of study patients according to their septal thickness in diastole (mm) on pre-operative and post-operatively at 3 months examination between the sizes of Metal and Bioprosthetic valve.

The mean value of septal thickness is reducing up to 1-3 mm from the prior surgery measurements to post-operative follow up at 3 months measurements in all the sizes of Peri Mount magna and CHVP valve replaced patients. **(Table 19) (Figure 19).**

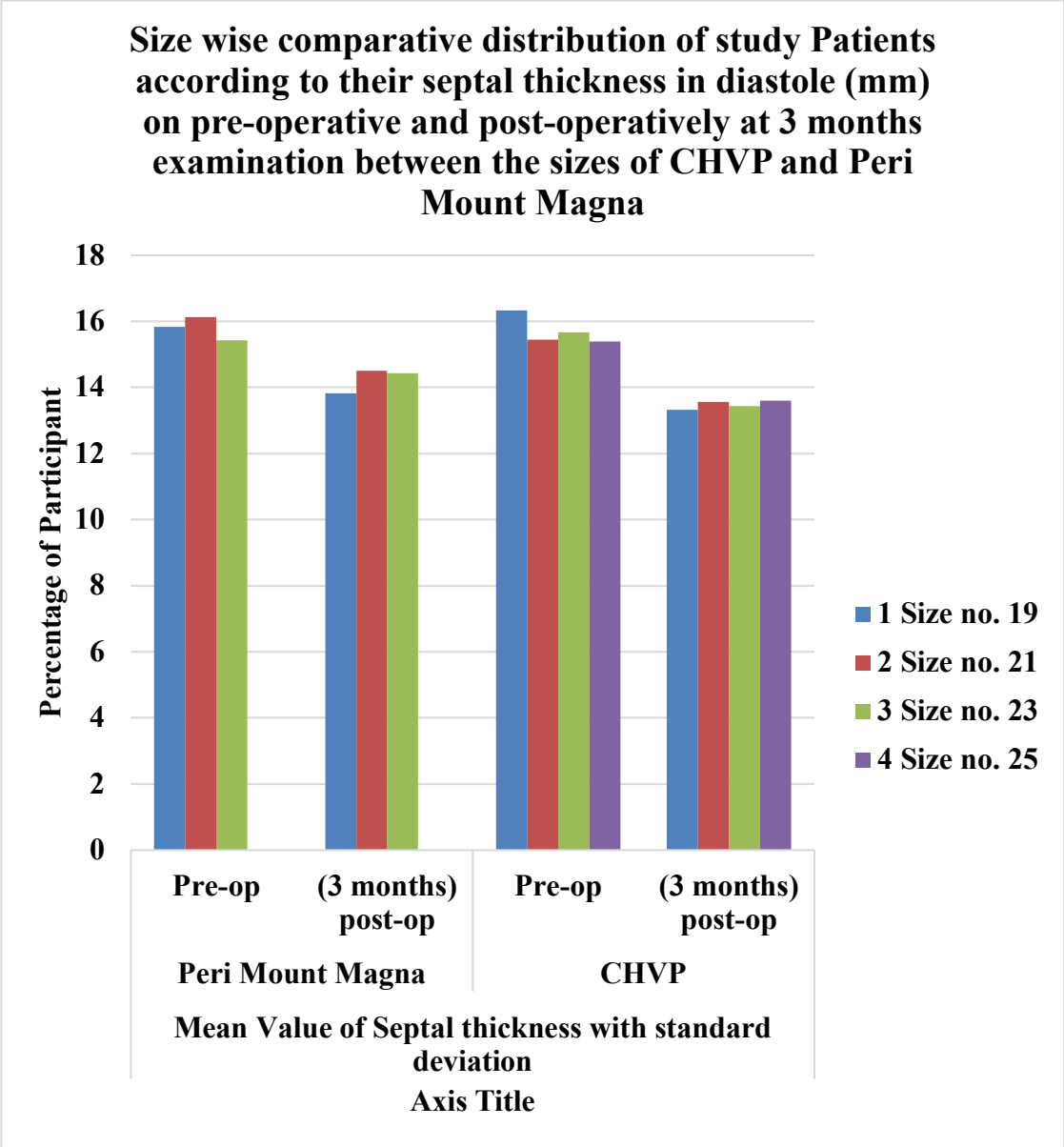

Figure 19: Size wise comparative distribution of study Patients according to their septal thickness in diastole (mm) on pre-operative and post-operatively at 3 months examination between the sizes of Metal and Bioprosthetic valve.

Table 20: Size wise comparative distribution of study patients according to left ventricular ejection fraction (LVEF)on pre-operative and post-operatively at 3 months examination between the sizes of Metal and Bioprosthetic valve.

Sr. No.	Size	Mean Value of LVEF with standard deviation			
		Bioprosthetic Valve (Perimount Magna)		Metal Valve (CHVP)	
		Pre-op	(3 months) Post-op	Pre-op	(3 months) post-op
	Size no. 19	64.33 ±8.454	66.00 ±5.367	53.33 ±4.163	57.00 ±4.359
	Size no. 21	65.25 ±5.651	65.25 ±5.651	65.33 ±6.557	63.33 ±5.362
	Size no. 23	66.14 ±7.48	66.71 ±4.445	66.50 ±7.77	65.33 ±5.74
	Size no. 25	0	0	61.60 ±7.797	64.40 ±6.066

Size wise comparative distribution of study patients according to left ventricular ejection fraction (LVEF)on pre-operative and post-operatively at 3 months examination between the sizes of Metal and Bioprosthetic valve, the mean value of LVEF increases up to 1-3% from the prior surgery measurements to post-operative follow up at 3 months measurements in all the sizes of Peri Mount magna and CHVP valve replaced patients. **(Table20) (Figure 20).**

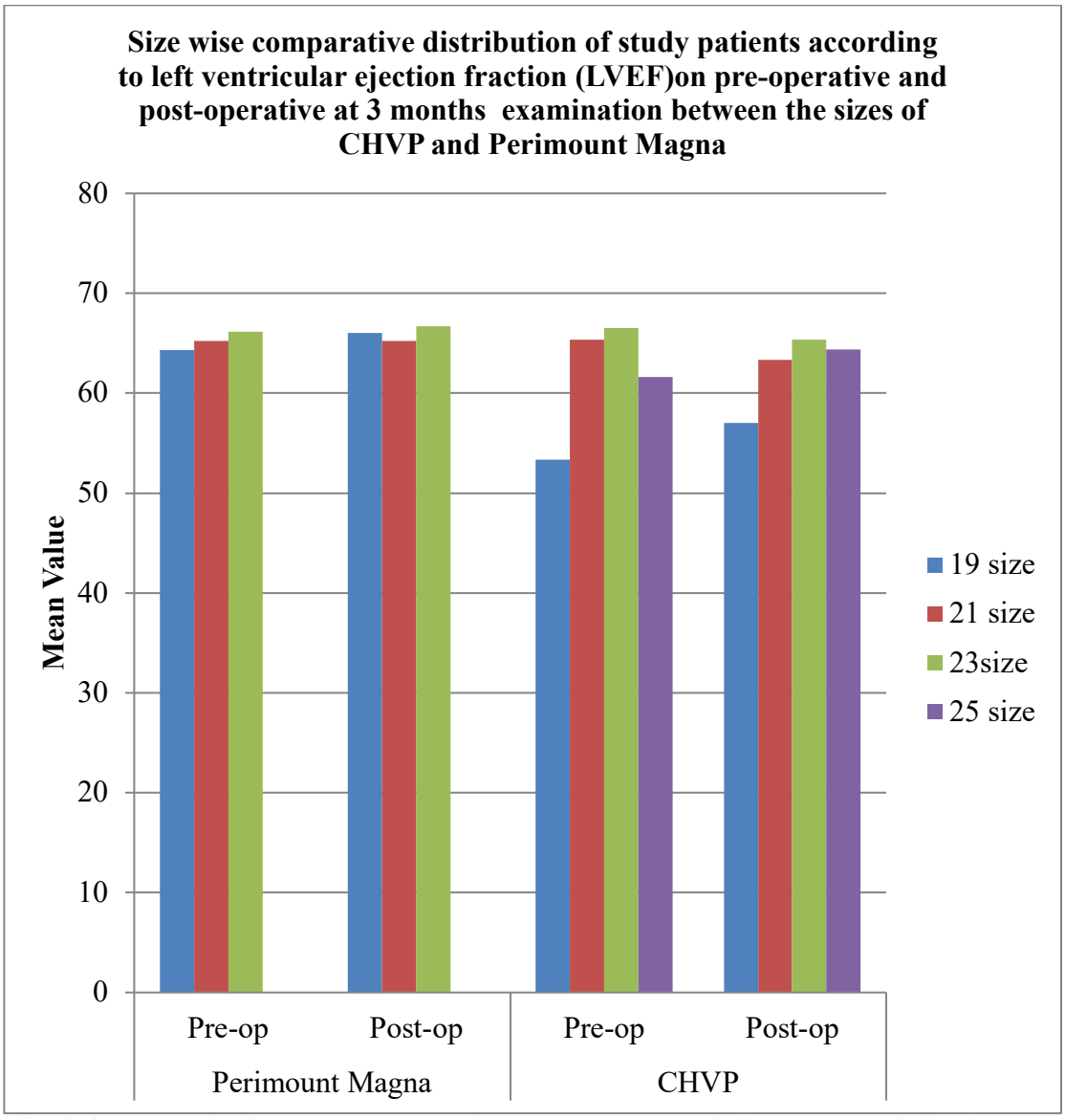

Figure 20. Size wise comparative distribution of study patients according to left ventricular ejection fraction (LVEF)on pre-operative and post-operative at 3 months examination between the sizes of Metal and Bioprosthetic valve

Table 21: Size wise comparative distribution of study patients according to their trans valvular gradient in peak on pre-operative, immediate-post-operative and post-operatively after 3 months follow up examination between the sizes of Metal and Bioprosthetic valve.

Sr. No.	Size	Mean Value of LVIDd with standard deviation					
		Bioprosthetic Valve (Perimount Magna)			Metal Valve (CHVP)		
		Pre-op	Intra-op	Post-op	Pre-op	Intra-op	Post-op
	Size no. 19	72.50 ±8.891	14.50 ±3.391	12.23 ±2.338	82.33 024	17.33 ±3.55	13.67 ±1.528
	Size no. 21	79.63 ±13.669	16.88 ±2.642	12.63 ±1.847	86.67 ±6.764	15.56 ±3.678	11.78 ±3.930
	Size no. 23	85.43 ±30.226	16.86 ±2.193	13.43 ±1.718	82.75 ±10.704	47.50 ±5.916	12.67 ±2.741S
	Size no. 25	0	0	0	79.7b ±1.784	79.60 ±10.784	12.20 ±1.483

Size wise comparative distribution of study patients according to their trans valvulargradient in peak on pre-operative, immediate-post-operative and post-operatively at 3 months follow up examination between the sizes of Metal and Bioprosthetic valve.: The transvalvular gradient in a peak is gradually reduced to the optimal level from pre- operative observations to immediate post-operative observations

and further post-operative follow up at 3 months. value was reduced to 1-3%, found in all the sizes of Peri Mount magna and CHVP valve replaced patients. **(Table 21) (Figure 21).**

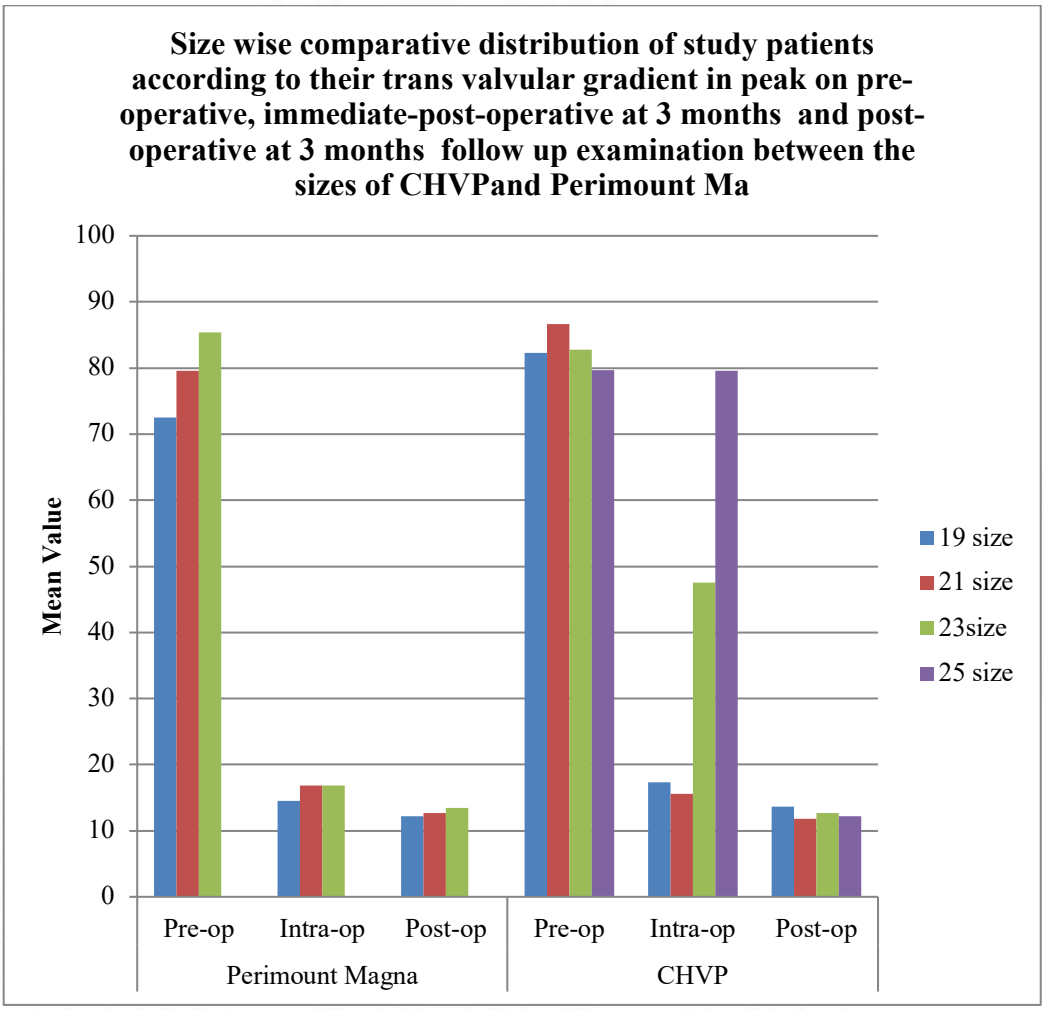

Figure 21: Size wise comparative distribution of study patients according to their trans valvular gradient in peak on pre-operative, immediate-post-operative and post-operative at 3 months follow up examination between the sizes of Metal and Bioprosthetic valve.

Table 22: Size wise comparative distribution of study patients according to their trans valvular gradient in mean on pre-operative, immediate-post-operative and post-operatively at 3 months follow up examination between the sizes of Metal and Bioprosthetic valve.

Sr. No.	Size	Mean Value with standard deviation LVIDd					
		Bioprosthetic Valve (Perimount Magna)			Metal Valve (CHVP)		
		Pre-op	Intra-op	Post-op	Pre-op	Intra-op	Post-op
	Size no. 19	44.00 ±2.449	7.17 ±1.329	10.33 ±1.506	45.33 ±4.163	9.00 ±0.00	6.67 ±1.155
	Size no. 21	49.38 ±8.927	8.50 ±1.690	6.38 ±0.916	48.44 ±2.877	7.89 ±2.749	5.67 ±11.871
	Size no. 23	3.29 ±19.311	8.57 ±1.512	6.71 ±1.496	47.50 ±5.916	7.67 ±2.605	5.92 ±1.564
	Size no. 25	0	0		45.40 ±2.881	9.40 ±.0.894	6.00 ±1.00

Size wise comparative distribution of study patients according to their trans valvular gradient in mean on pre-operative, immediate-post-operative and post-operatively at 3 months follow up examination between the sizes of Metal and Bioprosthetic valve.

The transvalvular gradient in a mean is gradually reduced to the optimal level from pre-operative observations to immediate post-operative observations and further post-operative follow up at 3 months. Value is reduced up to 1-3% in all the sizes of Peri Mount magna and CHVP valve replaced patients. **(Table 22) (Figure 22).**

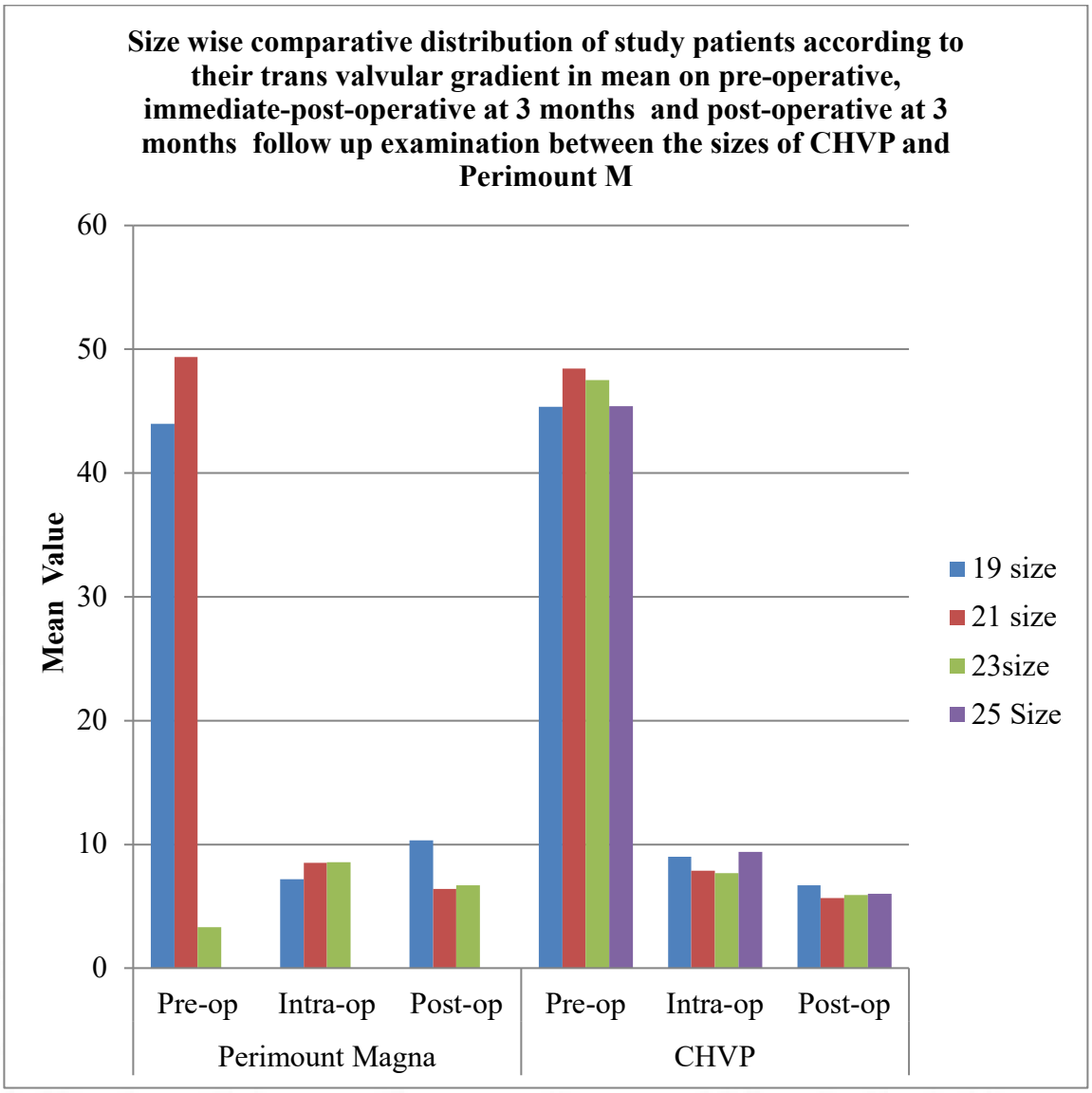

Figure 22: Size wise comparative distribution of study patients according to their trans valvular gradient in mean on pre-operative, immediate-post-operative and post-operative at 3 months follow up examination between the sizes of Metal and Bioprosthetic valve.

Table 23: Size wise comparative distribution of study patients according to their pre-op andpost-op left ventricular mass between Metal and Bioprosthetic valve.

Sr. No.	Size number of Valve	Mean Value with standard deviation of l e f t ventricular Mass Regression (LV MASS)					
		Pre-Operative		Post-operative at 3 months		Actual Value (Before-After)	
		Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)	Metal Valve (CHVP)	Peri Mount Magna	Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)
1	19 number	326.39 ±32.420	386.47 ±69.790	216.82 ±42.071	258.23 ±52.07	109.57 ±27.771	109.57 ±27.771
2	21 Number	360.33 ±70.061	388.32 ±49.591	233.52 ±53.397	264.27 ±34.225	126.81 ±38.274	124.05 ±34.517
3	23 Number	334.22 ±56.796	311.46 ±58.609	239.20 ±42.320	230.22 ±37.822	95.01 ±32.706	812.39 ±28.048
4	25 Number	356.18 ±70.799	0	245.03 ±593.367	0	111.07 ±24.270	0

Size wise comparative distribution of study patients according to their pre-op and post-op left ventricular mass between Metal and Bioprosthetic valve.

The pre operative left ventricular mass (mean value) was observed that 326.39±32.420 and 356.47 ±69.790 for patients who underwent aortic valve replacement surgery with size 19 Metal and Bioprosthetic valve, respectively. The preoperative left ventricular mass (mean value) was 360.33±70.061and 388.32 ±49.591 for patients who underwent aortic valve replacement surgery with size 21 Metal and Bioprosthetic valve, respectively.

The preoperative left ventricular mass (mean value) was 334.22±56.796 and 311.46 ±58.609 for patients who underwent aortic valve replacement surgery with size 19 Metal and Bioprosthetic valve, respectively.

LV MASS decreases following aortic valve replacement surgery with size 19, CHVP valves with value 216.82±42.071 & Peri mount Magna valve with value 258.23 ±52.07.

LV MASS decreases following aortic valve replacement surgery with size 21, CHVP valves with value 233.52±53.397 & Peri mount Magnavalve with value 264.27 ±34.225.

LV MASS decreases following aortic valve replacement surgery with size 23, CHVP valves with value 239.20±42.320 & Peri mount Magnavalve with value 230.22 ±37.822.

The actual LV Mass regression were observed 109.57±27.771 and 109.57±27.771 for patients with size number 19 of Metal and Bioprosthetic valve respectively. These results showed there is not much difference between both valves impact on LV Mass Regression.

The actual LV Mass regression were observed 126.81 ±368.343 and 124.05±34.517 for patients with size number of 21 of Metal and Bioprosthetic valve respectively. These results showed there is not much difference between both the valves impact on LV Mass Regression.

The actual LV Mass regression were observed 95.01±32.706 and 812.39±28.048 for patients replaced with size number 23 Metal and Bioprosthetic valve respectively. These results showed there is not much difference for both the valves impact on LV Mass Regression.

The LV Mass of a size 25 for CHVP valve observed at the time of pre- operative examination were 356.18±70.799 and that was reduced up to 245.03±59.336 after post-operative follow up at 3 months. The actual LV Mass regression value was 111.07±24.270. **(Table 23) (Figure 23).**

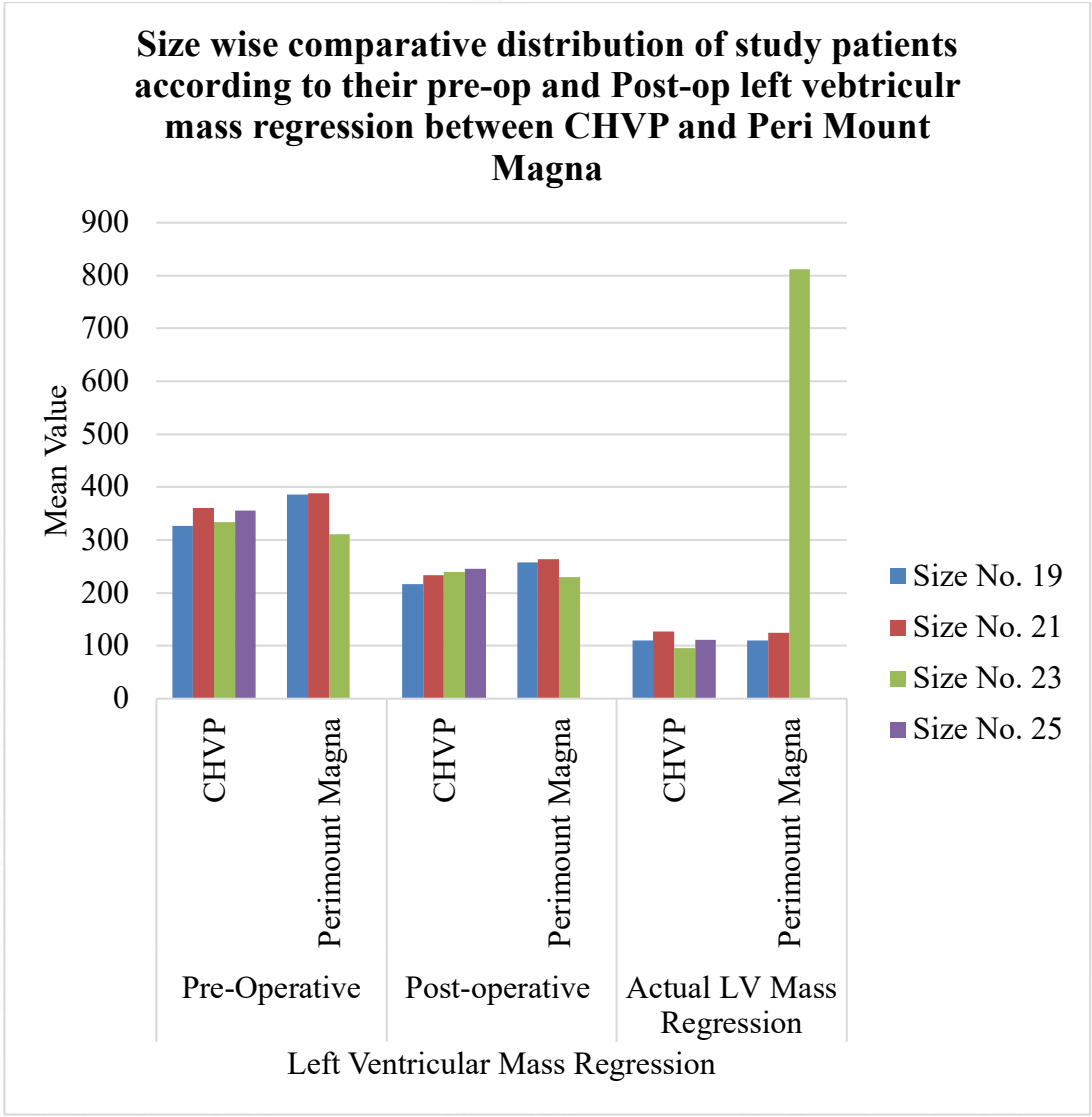

Figure 23: Size wise comparative distribution of study patients according to their pre-op and post-op left ventricular mass regression between Metal and Bioprosthetic valve

Table 24: Size wise comparative distribution of study patients according to their pre-op andpost-op left ventricular mass index (LVMI) between Metal and Bioprosthetic valve.

Sr. No.	Size Number Of Prosthetic Valve	Pre-Operative		Post-operative at 3 months	
		Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)	Metal Valve (CHVP)	Bioprosthetic Valve (Perimount Magna)
1	19 number	184.41 ±13.50	221.88 ±34.42	122.83 ±24.23	149.34 ±38.10
2	21 Number	201.56 ±42.89	221.35 ±34.32	134.66 ±29.23	148.58 ±20.27
3	23 Number	179.79 ±28.51	180.09 ±31.34	129.16 ±17.62	130.75 ±23.12
4	25 Number	204.05 ±44.00	0	140.02 ±34.78	0

Size wise comparative distribution of study patients according to their pre-op and post-op left ventricular mass index (LVMI) between Metal and Bioprosthetic valve.

The size wise left ventricular mass index was reduced to optimal level among patients underwent aortic valve replacement surgery using various sizes of Metal and Bioprosthetic valve. **(Table 24) (Figure 24).**

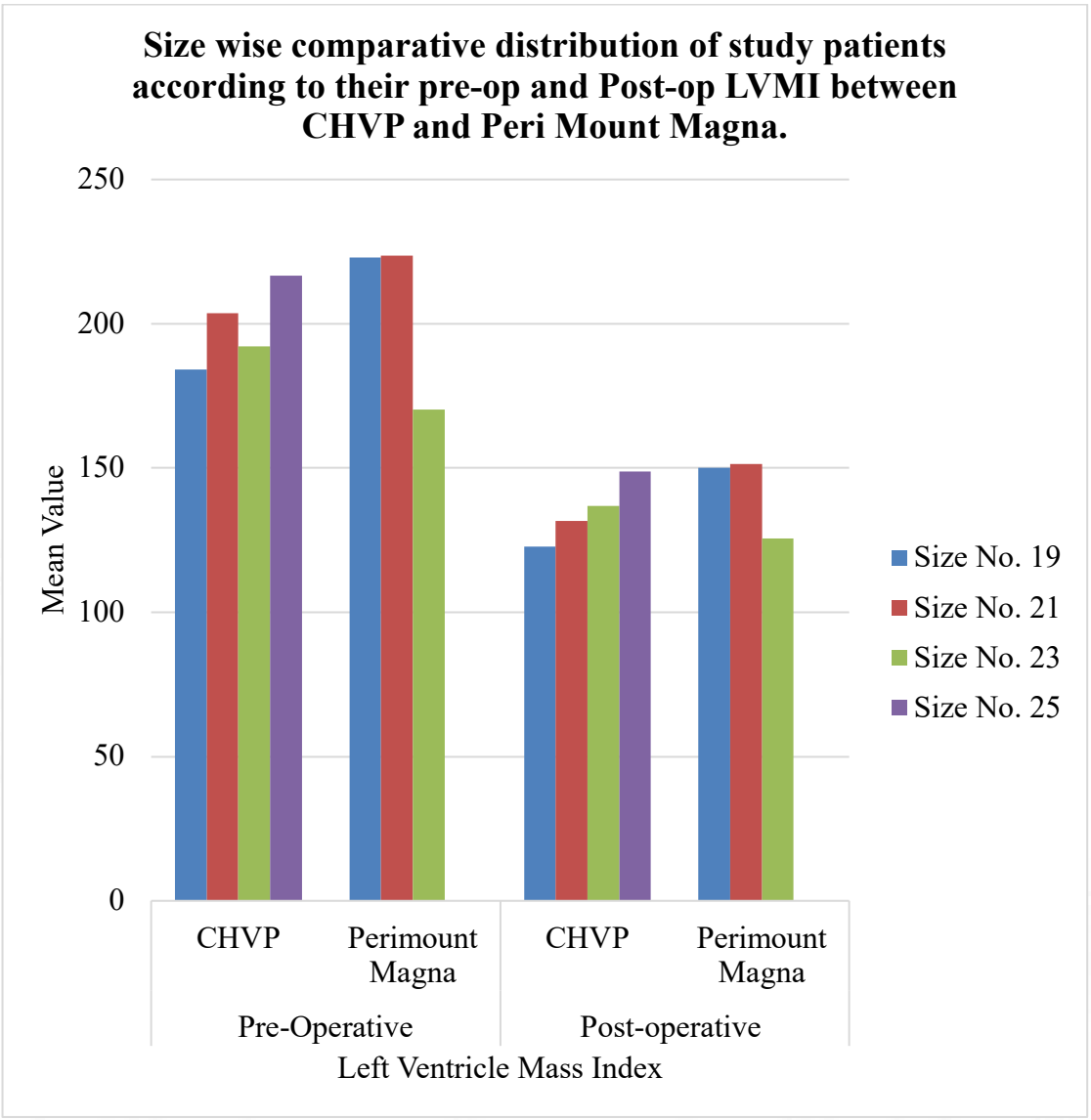

Figure 24: Size wise comparative distribution of study patients according to their pre-op and Post-op LVMI between Metal and Bioprosthetic valve.

5. DISCUSSION AND LIMITATIONS

Present study design was retrospective which was conducted to compare the early post-operative gradient & left ventricular regression between the metal & bioprosthetic valve of similar size after aortic valve replacement in a case of aortic stenosis. Total 50 participants were included in this study that fulfilled our eligibility criteria. All the study participants were taken from the same institute. Ethical clearance was obtained from the respective authority of the same institute. Results were obtained and presented in tabular and graphical form.

This study is conducted in only one institute and data of the patient retrieved from records of the institutes. Patients were appointed for examination and follow up on phone calls. According to our eligibility criteria we got 50 patients for the study. All the patients were from the age between 41 to 70 years old while 56.7 years is the mean age of the participants. And standard deviation is ± 8.627. In the study conducted by ***Minghao Lin et al*** (Lin et al., 2020) approximately similar mean age that is of the patients were included and 53.50±10. and the range of those patients were below 50 years to more than 90 years. There is higher the mean age from our study was found a research of ***Bo Fu et al*** (Fu et al., 2021) and the mean age of that patients was 72.6±5.1. The highest mean age that is 83±5 was found in the study of ***Cagalayan H A et al***(Caglayan et al., 2021) This may be due to the similar racial people. This may be due to severe aortic stenosis mostly appears at the age of 75 years. According to Europian society of cardiology. But our studies have lower mean age because in India life expectancy is low and it is 61 years.

The sex distribution of male and female observed nearly similar but slightly more that is 58% (n=29) females than male that is 42% (n=21) and the similar pattern also observed in the study of ***Brancaccio et al 2021***(Brancaccio et al., 2021) that 48.6%(n=147) were the male and 51.4% (n=155) were female recruited in their study. In the study of the opposite pattern of male female ratio is observed and male were slightly higher than the females were included in their study and they were 56% and 44% for male and female respectively. ***Caglayan H A et al.***(Caglayan et al., 2021)

The mean value for height and weight of the study participants were found that, 167.72±8.538 and 70.04±12.827 respectively. Approximately similar results were found in the study of ***Toh Hiroyuki et al*** (Toh et al., 2021) .

The age difference is nearly similar in both the group of patients that who are managed with Bioprosthetic valve is 57.21±9.537 years, and who are operated with Mechanical valve that is 59.57±8.207 years in our study. The New York Heart Association classification were similar in both group of patients, Class II were observed among 37.9%(n=11) and Class III observed among 62.1% (n=18) patients who underwent aortic valve replacement surgery with the metal valve. And the similarly that is 38.1% (n=8) and 61.9% (n=13) patients showed class II and Class III functional class who underwent aortic valve replacement surgery with the bioprosthetic valve. In the study of ***Thomas et al*** (Wyss et al., 2010) the similar functional classes of the patients were observed for the patients who underwent Perimount magna aortic valve prosthesis. They did not used CHVP prosthesis. There were 64.95% (n=117) of the patients had NYHA class III on the observations and 14.29% of the patients had NYHA class II these results

slightly in accordance with our results for class III functional class. ***Minghao Lin et al*** (Lin et al., 2020) .

The left ventricular ejection fraction was 61.34% and 51.24% on a pre-operative examination for the patients using Metal and Bioprosthetic valve respectively. And those are increased slightly up to 63.69% patients with mechanical valve and 55.5% patients with bioprosthetic valve. This study finding is in accordance with study of se ***Jin Choi et al*** (Jin Choi et al., 2021) and the pre-operative LVEF were 60.3% and 36% respectively in the group.

Septal Thickness were 15.62 mm and 15.81 mm observed on pre-operative examination while this is reduced up to 13.66 mm and 14.00mm for those patients who underwent aortic valve replacement with Mechanical and Bioprosthetic valve. Our findings were nearly similar in a study ***Ferrazzi P et al*** (Ferrazzi et al., 2015) 17 ± 1mm were observed on pre-operative examination, it reduces up to 14 ± 2 mm after the surgery.

The mean Trans-valvular gradient in peak were observed pre-operative, immediate post-operative and post-operatively after 3 months reduced from 83.38mm Hg to 16.14 mm Hg to 12.41mm Hg respectively, for the patients who underwent AVR using Mechanical valve. The mean Trans-valvular gradient in peak were observed pre-operative, immediate post-operative and post-operatively after 3 months is reduced from 79.52mm Hg to 16.19mm Hg to 12.81 mm Hg respectively, for the patients who underwent AVR using Bioprosthetic valve. Both mean and peak aortic valve gradients fell significantly following aortic valve replacement. In all patients, transvalvular gradients decreased to

normal. There was no significant difference between early and late post-op aortic valve gradients. Average peak gradient reduced from 102.11± 30.93 mm Hg to 27.5±9.83 mmHg following AVR. Average mean gradient fell from 59.30±18.26 mm Hg to 15.53±6.18 mmHg. On late follow up, peak gradient was 29.76±11.48 and mean gradient was 15.46±7.52 were observed in the study of T. ***ida et al*** *(*ida al et 2001).

LV internal Diameter, Posterior wall and septal thickness reduced significantly in our patients. LV Mass Index and Relative Regression of LVMI in our patients were higher than western data. Only literature from India shows comparable results. Preop LVMI in our patients were 192.26± 371.14 and post operative LVMI was 142.42± 298.15. In a 3 month follow up study reported by ***Singh et al (Singh et al., 2016)***, mean preoperative LVMI was 199g±79.5 g/m2. At three months post aortic valve replacement, the mean LVMI reduced to 130g±49.0 g/m2. No significant relation was noticed between LVMI regression and early or late post operative gradients. This may be because normal gradients were achieved in all patients after surgery.

Limitations of the study:

1. The study was conducted in a single institute, which may limit the generalizability of the results.
2. The study design was retrospective, which may introduce selection bias.

3. The sample size was relatively small (n=50), which may limit the statistical power of the study.

4. The study relied on phone calls for follow-up, which may introduce response bias.

5. The study did not include a control group, making it difficult to compare the outcomes with patients who did not undergo valve replacement.

6. The study did not account for potential confounding factors such as comorbidities, lifestyle factors, and medication use.

7. The study only looked at early post-operative outcomes and did not assess long-term outcomes and survival rates.

6. SUMMARY AND CONCLUSION

Summary:

Aortic stenosis (AS) and aortic regurgitation (AR), two common valvular heart diseases, affect the aortic valve. AS is more prevalent in developed countries, affecting 2-7% of individuals over 65 years old, while AR has a lower prevalence. Treatment options for both conditions include medical management or surgical aortic valve replacement (SAVR). The choice of treatment depends on severity, symptoms, and patient factors. Regular follow-up and monitoring are essential for disease progression detection and intervention timing.

This retrospective study aimed to analyze and compare aortic prosthetic valve gradient & left ventricular mass regression between metal and bioprosthetic valves of similar size in aortic valve replacement in early postoperative period. The study included 50 patients with aortic valve disease (Aortic stenosis) who underwent Aortic valve replacement between 2017-2021. Patients were selected according to their eligibility criteria and confidentiality was maintained during study settings.

The data was collected through electronic medical records (EMR) and analyzed using International Business Machines, Statistical Package for Social Science. The study examined the Left ventricular mass index after aortic valve replacement using Metal and Bioprosthetic valves in various sizes. Both valves showed reduced Left ventricle mass index, post-surgery. For size 19 and 21 valves, no significant difference in Left

ventricle mass regression index was observed between the two types after 3 months post-surgery. Longer-term follow-up is needed for a comprehensive assessment.

The study included patients aged between 42 to 70 years, with a mean age of 56.70 years and a standard deviation of ±8.627. The New York Heart Association (NYHA) classifications were similar in both Metal and Bioprosthetic valve replaced patients undergoing Aortic valve replacement surgery. In patients undergoing AVR with mechanical valve, the mean peak transvalvular gradient decreased from 83.38 mm Hg (pre-operative) to 16.14 mm Hg (immediate post-operative) and 12.41 mm Hg (post-operatively at 3 months). Similar findings were observed in another group with mean peak gradient reducing from 79.52 mm Hg to 16.19 mm Hg (immediate post-operative) and 12.81 mm Hg (post-operatively after 3 months).

LV Mass Index (LVMI) and Relative Regression of LVMI in the patients of this study were higher compared to western data but comparable to literature from India. Preoperative LVMI was 192.26±371.14, reducing to 142.42±298.15 post-operatively. In a 3-month follow-up study by Singh et al. (2016), preoperative LVMI was 199g±79.5 g/m2, decreasing to 130g±49.0 g/m2 after aortic valve replacement. There was no significant correlation between LVMI regression and early or late postoperative gradients, possibly due to normal gradients achieved in all patients after surgery.

This retrospective study examines early post-operative outcomes of aortic valve replacement in patients with aortic stenosis using metal and bioprosthetic valves. Both

types of replacements improve left ventricular function and structure, but some parameters, such as left ventricular ejection fraction, differ between the two valve types. These insights aid clinicians in selecting the appropriate valve replacement for individual patients.

Conclusion:

The conducted study provides a successful comparison of the early post-operative gradient and left ventricular regression between metal and bioprosthetic valves of similar size after aortic valve replacement in cases of aortic stenosis. The participants, with a mean age of 58.02 years, were slightly older than those in similar studies, possibly due to the lower life expectancy in India and the prevalence of severe aortic stenosis around the age of 75 years.

The gender distribution was nearly balanced, with a marginally higher percentage of females, a pattern that aligns with other studies. The participants' mean values for height and weight were also found to be in line with similar studies. The New York Heart Association classification was comparable across both groups of valve-treated patients, indicating a similar severity of the condition.

The left ventricular ejection fraction showed a slight increase in both metal & bioprosthetic group. The mean value Trans-valvular gradient in peak showed a significant reduction post-operation for both mechanical and bioprosthetic valve replacements, indicating a successful reduction in the pressure gradient across the valve, a positive surgical outcome.

Furthermore, the study found a significant reduction in the LV internal Diameter, Posterior wall, and septal thickness, indicating a reduction in left ventricular hypertrophy. The LV Mass Index and Relative Regression of LVMI in the patients

were higher than western data, pointing to a significant regression of left ventricular mass post-operation.

In conclusion, this study offers valuable insights into the early post-operative outcomes of aortic valve replacement using metal and bioprosthetic valves in patients with aortic stenosis. The results indicate that both types of valve replacements can lead to significant improvements in left ventricular function and structure. However, the type of valve replacement can have different impacts on certain parameters such as left ventricular ejection fraction. These findings can guide clinicians in choosing the most appropriate type of valve replacement for their patients.

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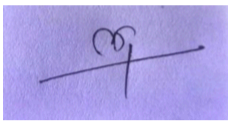
ANNESURES

CV of PRINCIPAL INVESTIGATOR

Format for CV of the Investigators

Pravin	**Narayan**	**Karande**
Date of Birth (dd/mm/yy) 26/07/1982		Sex: Male
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator) Co-investigator:principal investigator		
Professional Mailing Address (Include Institution name)		Study Site Address (Include Institution name)
Dr Pravin Narayan Karande Dept of CVTS SCTIMST Trivandrum		Dr Pravin Narayan Karande Senior Resident , Dept of CVTS SCTIMST Trivandrum
Telephone (Office): -		Mobile Number: 8826943670
Telephone (Residence):-		Email: drpravin.153@gmail.com
Travancore Cochin Medical Council Registration Number - It has been processed and the registration number is awaited.		
Academic Qualifications (Most recent qualification first)		
Degree/Certificate	Year	Institution, Country
MS General. Surgery	2014	Armed Forces Medical College, Pune

M B B S	2004	Maharashtra Institute of Medical Education & Research, Talegaon- Dabhade, Pune, Maharashtra
Details of professional registration : (MCI/State Registration/Bar Council/DCI/etc including Registration Number and Year of Registration: MMC - 2005093493		
Current and previous positions (most recent position first)		
Month and Year	Title	Institution/Company, Country
Jan 2021	SENIOR RESIDENT	SCTIMST.
Brief summary of relevant research experience:		
Current project/s at hand:		
 Signature: Pravin Narayan Karande		Date: 09/04/2023 Place:Trivandrum

CV of Guide

Format for CV of the Co-Investigator

Last Name :Panicker	First Name:Varghese	Middle Name:T
Date of Birth (dd/mm/yy) :29/05/1973		Sex: Male
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator) Co-investigator		
Professional Mailing Address (Include Institution name)		Study Site Address (Include Institution name)
Dr Varghese T Panicker Professor Dept of CVTS SCTIMST		Dr Varghese T Panicker Professor Dept of CVTS SCTIMST
Telephone (Office): 0471-2524551		Mobile Number:9387801642
Telephone (Residence):0471-2443261		Email :vtp@sctimst.ac.in

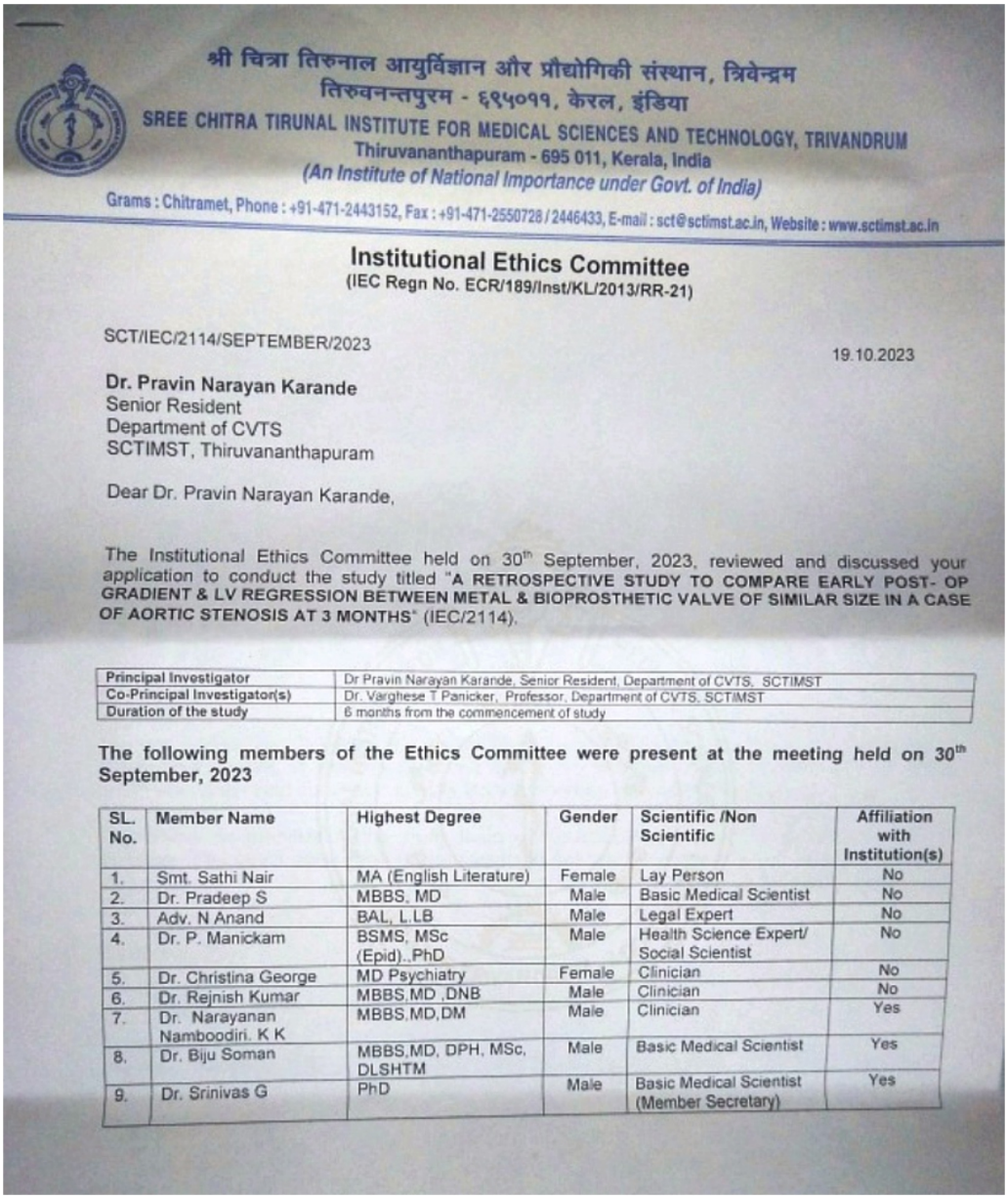
Academic Qualifications (Most recent qualification first)

Degree/Certificate	Year	Institution, Country
MCh –CVTS	2008	SCTIMST
MS –General Surgery	2004	Medical College,Trivandrum
MBBS	1997	Medical College,Trivandrum

Details of professional registration : TCMC 27238 (1998)		
Current and previous positions (most recent position first)		
Month and Year	Title	Institution/Company, Country
2019- till date	Professor ,CVTS	SCTIMST
2015-2019	Additional Professor ,CVTS	SCTIMST
2012-2015	Associate Professor ,CVTS	SCTIMST
2009-2012	Assistant Professor ,CVTS	SCTIMST
Brief summary of relevant research experience:		
Current project/s at hand: Mitral Annuloplasty in calcified Annuloplasty		
Signature:Varghese T Panicker		09-04-2023 Trivandrum

APPENDIX – APPROVALS & PERMISSIONS

Institutional Ethics Committee (IEC) Approval Letter



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)

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Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/2114/SEPTEMBER/2023

19.10.2023

Dr. Pravin Narayan Karande
Senior Resident
Department of CVTS
SCTIMST, Thiruvananthapuram

Dear Dr. Pravin Narayan Karande,

The Institutional Ethics Committee held on 30th September, 2023, reviewed and discussed your application to conduct the study titled "**A RETROSPECTIVE STUDY TO COMPARE EARLY POST- OP GRADIENT & LV REGRESSION BETWEEN METAL & BIOPROSTHETIC VALVE OF SIMILAR SIZE IN A CASE OF AORTIC STENOSIS AT 3 MONTHS**" (IEC/2114).

Principal Investigator	Dr Pravin Narayan Karande, Senior Resident, Department of CVTS, SCTIMST
Co-Principal Investigator(s)	Dr. Varghese T Panicker, Professor, Department of CVTS, SCTIMST
Duration of the study	6 months from the commencement of study

The following members of the Ethics Committee were present at the meeting held on 30th September, 2023

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
2.	Dr. Pradeep S	MBBS, MD	Male	Basic Medical Scientist	No
3.	Adv. N Anand	BAL, L.LB	Male	Legal Expert	No
4.	Dr. P. Manickam	BSMS, MSc (Epid)..PhD	Male	Health Science Expert/ Social Scientist	No
5.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
6.	Dr. Rejnish Kumar	MBBS,MD ,DNB	Male	Clinician	No
7.	Dr. Narayanan Namboodiri. K K	MBBS,MD,DM	Male	Clinician	Yes
8.	Dr. Biju Soman	MBBS,MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
9.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

1

The following documents were reviewed:

Original submission

1. Responses/Amendments made based on the Reviewer's comments
2. Covering letter addressed to the Chairperson, IEC, SCTIMST
3. IEC Application Form
4. Declaration form
5. Project Proposal
6. Proforma
7. Telephone script in Malayalam
8. CV of PI and Co-PI
9. Checklist Form
10. SRC Recommendation Letter

Revised submission

1. Covering letter addressed to the Member Secretary, IEC, SCTIMST dated 18.10.2023
2. Covering letter addressed to the Chairperson, IEC, SCTIMST
3. IEC Application Form
4. Declaration form
5. Project Proposal
6. Proforma
7. CV of PI and Co-PI
8. Checklist Form

IEC Decision

The IEC approved the conduct of the study in the present form.

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).

Sincerely,

Dr. G. Srinivas
Member Secretary, IEC

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST
THIRUVANANTHAPURAM

APPENDIX – SUPPLEMENTARY TABLES

MASTER CHART (DATA ENTRY)

CHVP Valve (29 patients)

Sr. No.	AGE	SEX	HEIGHT	WEIGHT	NYHA FC	VALVE						
		M=1 F=2			II=2 III=3		LVIDD	POSTERIOR WALL DISAMETER MM in Diastole	Septal thickness in diastole in mm	Transvalvular gradient in Peak	Transvalvular gradient in mean	LVEF
1	50	0	177	69	2	1	48	14	17	89	44	58
2	44	1	168	59	3	1	46	14	17	75	50	50
3	53	0	168	70	3	1	54	15	15	83	42	52
4	50	0	165	68	3	2	48	10	15	86	52	65
5	49	0	165	70	2	2	56	15	14	89	45	60
6	46	0	154	54	3	2	57	16	14	77	45	62
7	53	1	178	90	2	2	47	15	14	85	49	54
8	64	1	156	60	3	2	50	17	18	89	52	60
9	48	0	164	68	3	2	54	15	16	77	50	52
10	55	0	166	70	3	2	50	15	15	99	45	70
11	50	1	174	87	2	2	54	18	15	90	50	68

12	56	0	156	88	3	2	55	16	18	88	48	70
13	47	0	170	55	2	3	53	14	11	84	55	72
14	59	1	174	58	2	3	45	15	18	95	58	56
15	45	0	180	78	3	3	49	14	16	65	38	58
16	52	1	180	77	2	3	55	13	18	100	49	60
17	44	0	155	50	3	3	53	13	16	77	42	62
18	55	0	153	50	2	3	48	15	16	85	50	68
19	43	1	173	80	3	3	55	15	17	75	42	72
20	48	1	175	79	2	3	57	16	14	82	43	55
21	53	0	174	88	2	3	48	13	18	68	43	70
22	48	0	169	70	3	3	46	12	15	94	50	54
23	55	1	176	80	3	3	48	14	15	79	50	68
24	53	0	163	69	3	3	48	16	14	89	50	55
25	41	0	170	68	3	4	49	19	17	94	50	56
26	57	0	170	67	3	4	58	17	15	79	43	70
27	48	1	167	50	3	4	52	11	15	67	43	54
28	47	0	166	56	3	4	52	17	13	86	46	70
29	55	1	178	89	2	4	45	15	17	72	45	58

Sr No	Transvalvular gradient in Peak	Transvalvular gradient in mean	LVIDD (mm)	Posterior wall diameter in diastole	Septal thickness in diastole in mm	Transvalvular gradient in Peak	Transvalvular gradient in mean	LVEF	Pre LV Mass Lvmass =0.8 {1.04[([LVEDD +IVSD =PWD] 3-LVEDD3)]}+0.6	Post LV MASS	Pre RWT= 2*PWD /LVEDD	Post RWT =2*PWD /LVEDD	PRE LVMI=Lvmass/BSA	POST LVMI=Lvmass/BSA	Actual LV mass regression =Pre-opLVmass-Post-opLVmass
1	14	9	42	12	12	12	6	62	318.20	177.56	0.58	0.57	172.76	96.40	140.64
2	20	9	42	12	15	14	6	55	298.85	211.68	0.61	0.57	180.11	127.57	87.17
3	18	9	50	13	13	15	8	54	362.12	261.23	0.56	0.52	200.36	144.53	100.89
4	15	6	46	9	13	4	2	60	231.65	180.62	0.42	0.39	131.22	102.31	51.03
5	15	8	42	12	13	12	7	65	364.84	188.59	0.54	0.57	203.69	105.29	176.25
6	16	8	50	12	12	14	6	64	393.79	233.15	0.56	0.48	259.10	153.40	160.65
7	16	10	40	13	12	15	7	58	278.85	175.24	0.64	0.65	132.19	83.07	103.61
8	20	12	45	15	16	15	7	65	406.95	289.41	0.68	0.67	252.38	179.49	117.54
9	10	4	43	14	14	8	4	56	379.94	231.63	0.56	0.65	215.87	131.61	148.31
10	20	9	40	14	13	15	7	72	321.98	196.99	0.60	0.70	179.22	109.64	125
11	18	10	53	15	13	14	7	70	416.87	318.29	0.67	0.57	203.29	155.22	98.57
12	10	4	48	13	16	9	4	60	448.11	287.82	0.58	0.54	229.47	147.39	160.29
13	8	4	52	13	10	9	4	72	270.96	234.01	0.53	0.50	168.13	145.21	36.95
14	15	8	44	14	14	12	6	60	319.01	239.67	0.67	0.64	190.53	143.14	79.34
15	19	10	48	12	15	15	8	60	312.33	258.99	0.57	0.50	158.15	131.14	53.34
16	15	5	50	11	17	14	7	62	390.78	290.83	0.47	0.44	199.16	148.22	99.95
17	15	6	45	12	15	15	7	64	334.87	234.73	0.49	0.53	228.23	159.98	100.15
18	21	11	40	12	14	15	6	70	318.20	185.95	0.63	0.60	218.28	127.56	132.25

19	16	9	45	13	15	12	4	74	409.45	247.85	0.55	0.58	208.83	126.41	161.6
20	18	11	55	13	12	14	8	60	393.79	287.56	0.56	0.47	200.95	146.74	106.23
21	17	10	45	12	16	14	6	72	318.20	247.85	0.54	0.53	154.29	120.18	70.35
22	17	8	40	11	13	14	6	60	242.68	164.86	0.52	0.55	133.87	90.94	77.82
23	14	6	45	13	13	12	6	70	287.82	221.97	0.58	0.58	145.54	112.24	65.86
24	10	4	44	15	12	6	3	60	302.82	226.91	0.67	0.68	171.32	128.38	75.91
25	16	8	48	16	15	10	5	60	413.07	318.20	0.78	0.67	230.51	177.57	94.87
26	22	10	50	15	13	12	5	70	444.20	290.83	0.59	0.60	249.73	163.50	153.37
27	20	10	43	10	13	13	6	60	277.84	173.05	0.42	0.47	182.43	113.62	104.79
28	15	9	45	15	12	12	7	72	341.75	234.73	0.65	0.67	212.67	146.07	107.03
29	18	10	40	13	15	14	7	60	304.02	208.36	0.67	0.65	144.93	99.33	95.3

Perimount Magna Valve (21 patients)

Sr. No.	AGE	SEX	HEIGHT	WEIGHT	NYHA FC	VALVE							Immediate Post-op	
		M=1 F=2			II=2 III=3	19PM =1 21PM =2 23PM =3		LVIDD	POSTERIOR WALL DIAMETER MM in Diastole	Septal thickness in diastole in mm	Transvalvular gradient in Peak	Transvalvular gradient in mean	LVEF	Transvalvular gradient in Peak	Transvalvular gradient in mean
1	62	0	169	60	3	1		58	19	16	79	45	73	12	8
2	79	1	152	64	2	1		50	17	15	78	45	56	20	6
3	62	1	175	88	3	1		58	14	16	68	46	55	15	8
4	64	0	161	60	2	1		53	17	16	76	40	74	15	8
5	64	1	182	90	2	1		49	14	16	65	42	68	15	8
6	61	0	161	50	3	1		53	13	16	69	46	60	10	5
7	65	0	155	76	2	2		48	17	15	104	70	70	15	7
8	65	1	167	66	2	2		54	15	15	87	50	58	12	7
9	66	0	175	82	3	2		59	18	13	77	50	54	20	11
10	67	0	160	52	3	2		55	18	16	76	40	70	17	9
11	68	0	168	63	3	2		55	14	18	67	45	58	20	8
12	63	0	164	53	2	2		51	14	18	80	48	56	17	8

13	64	0	163	66	3	2		49	16	16	59	46	68	18	11
14	64	1	175	88	3	2		46	17	18	87	46	66	16	7
15	62	1	170	78	2	3		42	18	16	149	96	64	18	10
16	61	1	155	55	3	3		50	13	12	77	40	72	18	7
17	61	1	182	90	3	3		50	13	17	88	46	78	18	9
18	67	0	153	67	3	3		50	16	13	90	54	54	17	9
19	65	1	183	90	3	3		42	16	16	67	45	66	18	9
20	67	0	167	77	3	3		47	13	17	68	48	64	17	10
21	70	1	165	70	2	3		57	15	17	59	44	65	12	6

Perimount Magna Valve (21patients)

Sr No	LVIDD (mm)	Posterior wall diameter in diastole	Septal thickness in diastole in mm	Transvalvular gradient in Peak	Transvalvular gradient in mean	LVEF	Pre - LV Mass Lvmass=0.8{1.04[([LVEDD+IVSD=PWD]3-LVEDD3)]}+0.6	Post - LV Mass Lvmass=0.8{1.04[([LVEDD+IVSD=PWD]3-LVEDD3)]}+0.6	Pre - RWT=2*PWD/LVEDD	Post - RWT=2*PWD/LVEDD	PRE LVMI=Lvmass/BSA	POST LVMI=Lvmass/BSA	Actual LV mass regression =Pre-opLVmass-Post-opLVmass
1	50	18	14	13	8	70	506.89	354.74	0.66	0.72	302.03	211.37	152.15
2	45	15	13	15	8	60	354.74	247.85	0.68	0.67	215.80	150.77	106.89
3	44	13	14	13	6	60	404.65	226.91	0.48	0.59	195.65	109.71	177.74
4	40	15	14	12	6	72	405.33	220.07	0.64	0.75	247.44	134.35	185.26
5	45	12	14	13	6	70	312.33	221.97	0.57	0.53	146.42	104.06	90.36

6	52	12	14	8	4	64	334.87	277.84	0.49	0.46	223.94	185.80	57.03
7	44	16	14	10	6	70	333.97	266.27	0.71	0.73	184.62	147.20	67.7
8	44	15	13	10	6	60	362.12	239.67	0.56	0.68	206.95	136.97	122.45
9	50	16	12	14	8	60	435.65	290.83	0.61	0.64	218.20	145.67	144.83
10	45	15	15	13	7	72	448.11	275.18	0.65	0.67	294.76	181.01	172.93
11	53	12	16	15	6	60	455.86	318.29	0.51	0.45	265.86	185.63	137.57
12	42	12	16	13	6	60	365.36	223.74	0.55	0.57	235.13	143.99	141.63
13	40	15	14	14	7	70	344.28	220.07	0.65	0.75	199.16	127.31	124.2
14	44	15	16	12	5	70	361.18	280.13	0.74	0.68	174.63	135.44	81.05
15	38	16	14	13	4	65	303.59	215.95	0.86	0.84	158.19	112.52	87.63
16	48	11	10	15	8	70	247	181.31	0.52	0.46	160.51	117.82	65.69
17	43	12	15	13	6	72	321.98	219.23	0.52	0.56	150.95	102.78	102.76
18	45	14	12	14	8	58	306.21	221.97	0.64	0.62	181.46	131.54	84.24
19	40	16	14	15	7	70	275.51	232.13	0.76	0.80	128.81	108.53	43.38
20	45	12	15	14	8	66	293.46	234.73	0.55	0.53	155.27	124.20	58.73
21	50	14	15	10	6	66	432.45	306.21	0.53	0.56	241.43	170.95	126.25

APPENDIX – Plagiarism Check Report

Document Information

Analyzed document	Dr. Pravin semifinal thesis for plagarism.docx (D173175883)
Submitted	2023-08-28 05:26:00
Submitted by	Dr P K Dash
Submitter email	dash@sctimst.ac.in
Similarity	6%
Analysis address	sadh.sctims@analysis.urkund.com

Sources included in the report

W	URL: http://www.sctimst.ac.in/ Fetched: 2023-08-28 05:26:00	3
SA	**120000261-Diss-1691368.pdf** Document 120000261-Diss-1691368.pdf (D17982163)	1
SA	**Eight-year+outcomes+for+patients+with+aortic+valve+stenosis+at+low+surgical+risk+randomized+to+transcatheter+vs+surgical+aortic+valve+replacement.p** Document Eight-year+outcomes+for+patients+with+aortic+valve+stenosis+at+low+surgical+risk+randomized+to+transcatheter+vs+surgical+aortic+valve+replacement.pdf (D160820636)	
SA	**Transcatheter aortic valve implantation.docx.pdf** Document Transcatheter aortic valve implantation.docx.pdf (D155613235)	12
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SA	**701903020_jesreman.docx** Document 701903020_jesreman.docx (D114825196)	1

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SYNOPSIS

Aortic stenosis (AS) is a common valvular heart disease affecting the aortic valve, impeding blood flow from the left ventricle to the aorta. The prevalence of AS increases with age, affecting 2-7% of individuals over 65 years old. The most common cause of AS in older individuals is degenerative calcific aortic stenosis, which occurs due to age-related degeneration and calcification of the aortic valve leaflets. Bicuspid aortic valve disease (BAV) is another significant etiology of AS, accounting for a substantial proportion of cases in younger individuals. Other less common causes include rheumatic heart disease, congenital abnormalities, and radiation-induced valvular disease.

Treatment options for aortic stenosis include surgical and transcatheter interventions. Aortic valve replacement is the standard surgical approach, involving the use of mechanical or bioprosthetic valves. Medical management focuses on regular monitoring and controlling associated risk factors such as hypertension and hyperlipidaemia. Aortic valve replacement (AVR) includes surgical AVR (SAVR), transcatheter AVR (TAVR), and balloon valvuloplasty.

The study aims to compare the early post-operative gradient & left ventricular mass regression between metal and bioprosthetic valves of similar size after aortic valve replacement in a case of aortic stenosis. It is important to consider individual patient characteristics, including age, comorbidities, and valve morphology, when deciding on the most appropriate treatment strategy. Regular follow-up and monitoring of patients with aortic stenosis or aortic regurgitation are essential to detect disease progression and determine the optimal timing for intervention. After relevant permission taken from the Institute of Ethical Committee (IEC) of a of a

76% **MATCHING BLOCK 1/27** W

Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivendrum (SCTIMST) prior to

the study conduction. A retrospective, observational study design is performed by utilizing a secondary recorded data from the Department of Cardiovascular and Thoracic Surgery. We got total 110 number of patients with aortic valve replacement, which underwent surgical management between the 2017-2021 years. From those 50 numbers of cases only participated in our study according to our eligibility criteria. Written informed or telephonic verbal consent was taken prior to the study setting. Confidentiality is maintained during study settings. Study included patients, who underwent aortic valve replacement surgery, having aortic stenosis only. And excluded the patients having aortic valve redo surgeries, aortic regurgitation, valve repair, double valve replacement surgery, coarctation, aortic aneurysms and combined with coronary artery bypass graft. Preoperative, immediate post-operative and postoperatively after 3 months follow up data was collected through electronic medical records (EMR). Retrospective analysis of data and clinical examination of the post-operative follow-up was performed by the principal investigator and co-investigators.

Compilation of data was done in a systematic manner. Using a Microsoft excel worksheet (Microsoft, USA, version 8.1) A master table was made, accordingly, the data was subdivided and distributed which was presented in the form of individual tables and figures. Statistical analysis using International Business Machines, Statistical Package for Social Science (Statistics for Windows, version 25.0, Armonk, NY: IBM Corp.) was done and the comparison of data was carried out by applying statistical tests in order to find the statistical significance of the results.

PATIENT INFORMATION

SUBJECT CODE NO:

AGE:

GENDER:

HEIGHT:

WEIGHT:

BSA:

PRE-OPERATIVE PARAMETERS:

RISK FACTORS / COMORBIDITIES:

Hypertension
Diabetes
Thyroid dysfunction
Chronic Kidney disease
NYHA Functional Class
Blood Pressure

IMAGING

ECHOCARDIOGRAPHY

- Annular Size
- Ascending aortic size
- Valve function
- As gradient
- LVID/LVIDS
- Septum S
- Septum D
- LVEF
- PW S/ PW D
- RWMA

INTRA OPERATIVE PARAMETERS

Total cardiopulmonary bypass time
Duration of surgery
Immediate valve gradient
Emergency /elective surgery

POST OPERATIVE PARAMETERS

Aortic valve gradient
Need for surgery
Anticoagulation regimen
Arrythmias
Hospital Stay

FOLLOW UP

- **Blood Pressure**

- ECHO:
  1. Aortic valve function
  2. Aortic valve gradient
  3. LVID/LVIDs
  4. PW S/ PW D, Septum S/Septum D
  5. RWMA
  6. Left ventricle function

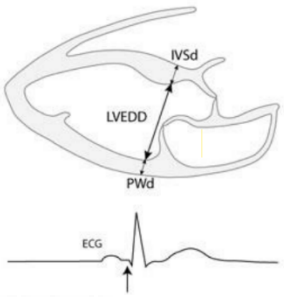
  - **LV MASS**

  - LV Mass was calculated using the equation

  - LV Mass (g) =0.8{1.04[([LVEDD + IVSD +PWD]3- LVEDD3)]} + 0.6

  - Values were interpreted as per following chart suggested Yby Lang et al.

	Female	Male
o Reference Range	43-95	49-115
o Mildly Abnormal	96-108	116-131
o Moderately Abnormal	109-121	132-148
o Severely Abnormal	≥122	≥149



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