IOSR Journal Of Pharmacy And Biological Sciences (IOSR-JPBS)
e-ISSN:2278-3008, p-ISSN:2319-7676. Volume 18, Issue 5 Ser. 1 (Sept. – October. 2023), PP 01-05
www.Iosrjournals.Org

Usage Of Biological Valve Prosthesis In Aortic Root Replacement Surgery

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Abstract
Introduction: *Although aortic root replacement surgical techniques have been improved considerably in recent years, the choice of biological or mechanical valve type prosthesis remained a domain of uncertainty. No need for life long anticoagulation is a priority which makes the biological aortic valve more favorable. More research is needed to determine the best approach. This study is supposed to evaluate outcomes of aortic root replacement surgeries using bio prosthesis in patients referred to Shahid Rajaie hospital in Tehran, Iran.*
Methods*: In this single center retrospective prospective cohort study data of all patients underwent aortic root replacement surgery between March 2010 and March 2020 was extracted. All the events and complications after the surgery in addition to postoperative echocardiographic findings were documented. Median follow up time for each patient was 12 days. Approximately 30 different preoperative, operative and postoperative variables gathered and analyzed with SPSS software.*
Results*: 16 patients with mean age of 56 years old underwent aortic root replacement surgery during 10 years in Tehran's Shahid Rajaei hospital. Three operations were emergent and the remainder were elective. Only two patients required re intervention due to life threatening bleeding. While no other early complication was reported. Mortality and reoperation rate in our survey was 0%. Mean of ICU stay was 6.31 days. Improvement of aortic valve function in addition to decreased EF were statistically significant echocardiographic findings.*
Conclusion*: In accord with our study, usage of biological aortic valve prostheses in aortic root replacement surgeries was associated with a lower rate of postoperative complications, reoperation, and mortality.*
Key words: *aortic root replacement, Bentall surgery, biologic valve, mechanical valve, complication, outcome*

Date of Submission: 02-09-2023 Date of Acceptance: 12-09-2023

I. Introduction

Diseases involving Aortic root and adjacent structures may necessitate Aortic root reconstruction surgery. Some examples are aneurismal dilatation of aortic root, dissection of aorta, Marfan's syndrome, aortic valve disease, endocarditis, anuloaortic ectasia [1]. The famous Bentall procedure for replacement of aortic valve, aortic root and ascending aorta first described in 1968 [2]. In this open heart surgery through a sternotomy incision, during cardiopulmonary bypass, part of the aorta in addition to aortic valve is excised and replaced with a composite valve graft then reimplantation of coronary artries in to the graft would be done. Application of a composite aortic graft for combined replacement of the aortic valve and aortic root not only needs less time but also leads to less intraoperative bleeding. It was known as the gold standard method for many years [3]. Before development of Bental technique, supracronary method had been used widely in which aortic valve and ascending aorta were being replaced separately with a supra coronary excision cut of aorta. Therefore re implantation of coronary arteries was not needed.

One of the most recent published articles in this field, proposed the Bental De Bono procedure as the surgery of choice for only the older, high risk patients and suggested AV repair or Ross procedure for every other patient. Newer techniques introduced as valve sparing operations letting native AV cusps to be preserved are becoming a trend in many centers [3]. Except for the valve sparing method in which the native valve will be fixed in the graft, mechanical or biological valve prosthesis will be used in the other techniques named above. Mechanical

type of aortic prosthesis needs lifetime anticoagulation and therefore accompanies with anticoagulants complications. While biologic aortic valve prosthesis with no anticoagulation requirement may contribute to reoperation as destroys earlier comparing to mechanical one. Therefore mechanical type is used for Youngers and biologic type remains for elderly with shorter life expectancy and Youngers with anticoagulants contraindication conditions [4]. Increasing age of patients undergoing aortic valve surgery and the younger patients' preference toward not using anticoagulants lifelong, resulted in a trend toward biological valves. Because the young ones did not want to impair their quality of life with necessitation of life long anticoagulants [5]. Subject of choosing between mechanical and biological aortic root prosthesis was investigated by several earlier studies and resulted in Confusing data. There are different evidences supporting mechanical valve type superiority, biological valve type superiority and even no superiority of mechanical or biological aortic prosthetic valve. The majority of these studies emphasized on complementary future studies in this field.
This research was set to identify characteristics and outcomes of aortic root replacement surgeries using bio prostheses in Rajaei university hospital of Tehran, Iran.

II. Methods

In this single center retrospective prospective cohort study, we extracted data of 16 patients undergoing aortic root replacement surgery with biologic aortic valve between March 2010 and March 2020 in Shahid Rajaie hospital in Tehran, Iran. All the events and complications after the surgery were documented. Median follow up time for each patient was 12 days. About 30 different variables including Demographic variables, intraoperative characteristics, surgery outcomes and echocardiographic parameters were obtained.
Echocardiographic study was performed for patients three times; at baseline, after the surgery and follow-up visit.
Baseline characteristics included age, sex, BMI, clinical risk factors and preoperative echocardiographic findings like ejection fraction, pericardial effusion and valve hemodynamic status. Concomitant diseases such as diabetes mellitus, hypertension, coronary heart disease, renal failure, dyslipidemia and COPD as well as smoking were clinical risk factors considered in the study design. Operative data included operation timing (elective or emergent), indication of surgery, history of previous cardiac surgery, concomitant surgery, surgical technique, native valve type (bicuspid or tricuspid), size of tube graft and implanted valve, type of bio prosthetic aortic valve, type of suturing of the implanted valve, type of pump (central or femoral), cardiopulmonary bypass time, aortic cross clamp time and intraoperative blood transfusion. Postoperative variables gathered were early bleeding, early re-intervention, early pleural effusion, early pericardial effusion, ICU length of stay, amount of bleeding during ICU admission, amount of blood transfused in the ICU, Follow-up duration, Re-operation and mortality.
The data were collected from patients' documents according to a prepared checklist.
We entered data to a datasheet of SPSS software version 16 to analyze. Qualitative variables' prevalence is reported as numbers and percentages. Quantitative variables were tested by Kolmogorov–Smirnov Test initially to be identified whether they are normally distributed or not. Normally distributed ones are described by mean, standard deviation and minimum-maximum value as range. Non- normally distributed quantitative data are presented by median, interquartile range [25th-75th percentile] and minimum- maximum value as range in parenthesis. Friedman test was used to analyze all echocardiographic findings in the consecutive visits except ejection fraction variable which was a continuous quantitative variable. Repeated measures ANOVA test was applicated to analyze it instead. Prior its use Mauchy's test of sphericity determined whether this test was suitable or not. Alpha level of 0.05 was used as the cutoff for statistical significance.

III. Ethical issue

We conducted our study in accordance with Helsinki declaration principles for medical research involving human, in all steps. We received ethical license of Iran University of medical sciences committee on ethics for our research project. All data were kept private and used just in line with the research goals. All the patients interviewed to enter the study and informed consent was taken.

IV. Results

16 patients with mean age of 56.19 ± 22.34 undergoing aortic root reconstruction surgery with a bio prosthesis replacing aortic valve between March 2010 and March 2020 in Shahid Rajaie Hospital, Tehran, Iran were included. Pre-operative characteristics including demographic variables and clinical data such as risk factors, Ejection Fraction (EF) and presence of pericardial effusion are shown in Table 1. As illustrated, 25% of patients were female while the majority were male (75%). Mean BMI of the participants was 24.18 ± 7.03 kg/m^2. Prevalence of Concomitant diseases like hypertension, diabetes mellitus, dyslipidemia, coronary heart disease, COPD and Renal failure are listed in table 1. The most prevalent disease was hypertension (43.8%). coronary heart disease was ranked second. Renal failure, Dyslipidemia and Diabetes mellitus were in the next places

respectively. None of the patients reported history of chronic obstructive pulmonary disease. 25% of the patients were smoker. Pre-operative echocardiographic studies assessing valve and heart hemodynamics reported pericardial effusion in 2 patients (12.5%). The mean ± SD of baseline Ejection fraction was 47.81 ± 8.55 percent and its change in 3 consecutive visits are demonstrated in figure 1. Other information of performed echocardiographic studies before the intervention are demonstrated in figure 2. As well as the postoperative and follow-up ones. It can be seen from figure 2 that the most common valve malfunction was Tricuspid Regurgitation (TR), Mitral Regurgitation (MR), Aortic Insufficiency (AI), Aortic Stenosis (AS), Mitral stenosis (MS) and Tricuspid stenosis (TS) respectively. While TR was reported in all the patients (100%), no case of TS was seen (0%). The degree of regurgitation was reported to be mild in most patients with TR. The most severe valvular pathology was related to AI. MR presented in all but the one patient (93.7%). About half of them had mild regurgitation degree and the other half had moderate and severe MR. compared to MR, lower prevalence of MS (12.5%) was seen; only one severe and one mild case of MS was recorded. Unlike TR, most of AS cases had severe stenosis. Right ventricular (RV) dysfunction observed in 56.2% of patients and almost all of them were mild. Comparing results of further echocardiographic studies will be discussed later in the text.

Table 2 illustrates operative data. 3 of 16 (18.8%) operations were emergent. One due to aortic dissection, and the other two had endocarditis. Other indications for surgeries were aortic degenerative disease and all were done such elective operations. The prevalence of previous cardiac surgery was 18.8% (3 out of 16). The most frequent concomitant procedure was Mitral valve replacement. The other simultaneous interventions included CABG, TVR and PFO closure. Flanged Bentall technique was used in 10 patients (62.5%) and Supracoronary method performed on the remains (37.5%). The prevalence of patients with bicuspid aortic valve was approximately similar to patients with tricuspid aortic valve. All other surgical details such as tube graft size, implanted biological valve type and size, suture type used for replacing aortic valve, pump type and open-heart surgery related timings are demonstrated in table 2. Early and late post-operative outcomes are given in table 3. Two patients (12.5%) were transferred early back to operating room because of their threating bleeding. Neither early pleural effusion nor early pericardial effusion was seen in the patients. Although early pericardial effusion was not reported in any patient, but its prevalence became a little more after surgery (12.5% to 18.8%). Nevertheless it was not statistically significant (Pvalue=0.867). Exactly the same frequency of pericardial effusion was reported at follow-up visits. While meaningful decrease in Ejection Fraction was seen after surgery (pvalue=0.036). EF changes from baseline can be obtained from Figure 1. Mean, standard deviation and range of ICU stay, ICU bleeding and transfusion are shown in the table 3. With the median of 12 days follow-up, all the patients were found alive (mortality=0%) and none of them needed reoperation. Looking at figure 2 provides valuable information regarding echocardiographic findings from 3 consecutive visits and helps to interpret outcomes. It can be seen that all valve disorders were somehow improved after intervention except MS and TS which was persistent in either assessment. As shown, RV dysfunction became worse and increasing of its prevalence and severity seems to be established even at follow-up visits. As expected frequency of aortic valve dysfunction including AS and AI was significantly decreased after surgery (p value=0.015, p value <0.001, respectively). All the other observed differences were not meaningful statistically. (Pvalue[TR]=0.974, Pvalue[MR]=0.723, Pvalue[RV dysfunction]=0.085).

V. Discussion

Meta-analysis of Studies evaluating Bentall surgery outcomes as the gold standard method for aortic root replacement reported 6% pooled early mortality rate while annual rate for late mortality, Reoperation and hemorrhage was calculated 2.02%, 0.46% and 0.64% respectively during 6 years follow-up. It was also declared that decrease in aortic root reoperation in recent years was seen but some adverse outcomes such as late mortality, major bleeding and thromboembolic events remained concerned [6]. Rate of bleeding in our study was estimated 12.5% which seems far higher from 0.64% but it is explained simply by the few number of cases were studied. While 2 (12.5%) patients underwent early re-intervention due to bleeding, rate of early pleural or pericardial effusion as a surgical complication reported 0% in our surgeries which was a sign of success and reduced the need for early reoperation. Early massive pleural effusion was a reason of early reoperation occurred in 9.8 % of patients in one recent retrospective study while 14% of patients underwent pericardiocentesis postoperatively because of pericardial effusion based on another research [7,8]. Mean ICU stay of 6.31 ± 4.39 days in our survey seems shorter comparing to some previous published studies which reported 9.2 ± 12.5 days as ICU admission period [7]. 0% mortality and 0% reoperation rate in the present study should be interpreted with cautious due to small number of patients and short follow-up duration.

One of Bentall surgery modifications named flanged Bentall was performed in this research which was also the subject of previous literatures. The most recent study showed acceptable outcomes with excellent results in bio-Bentall group. There was no death or significant adverse event to report in 26 cases underwent flanged bio-Bentall surgery during 18 years with mean follow-up time of 75 months [9]. It was also the case in our study which showed 0% of mortality rate.

The most frequent heart anomaly with 2 % prevalence in general population is bicuspid aortic valve. No difference in outcomes between Bicuspid aortic valve and Tricuspid aortic valve groups undergoing aortic reconstructive surgery was seen as said in a recent study comparing outcomes of elective and emergent modified Bentall procedures [10]. Anyway the prevalence of bicuspid aortic valve was approximately similar to that of tricuspid valve in our study (56.3%, 43.8%).

Lower BMI is associated with higher mortality and complications following valve surgery [11]. BMI of two patients was reported lower than normal range in our study and both of them underwent concomitant mitral valve replacement. But it did not contribute to increase mortality rate and it was preserved 0%. Our clinical experience showed far longer aortic clamp time and cardiopulmonary bypass time comparing to the results of a recently published cohort of 456 patients who were replaced their aortic valve due to aortic stenosis during 25 years follow up. Median clamp time of 63 min and mean CBP time of 92.7 min were reported in this study. Longer clamp time was associated with decreased survival rate while longer CBP time did not relate to survival rate. At least in our study these far higher values did not contribute to death in any patient. Maybe our shorter follow-up time made their effect invisible [12]. Although biological or mechanical valve preferences was an interested area to study but the available data is confusing and highlights the need for more researches in this field. The common agreement is on using biological valve prosthesis for the elderly with shorter life expectancy and younger patients having the conditions with anticoagulants contraindication [4]. Whereas the efficacy of mechanical valve seemed questionable in some papers, there are some studies which emphasizes the preference of mechanical type valve even in older patients. Their explanations are mentioned below respectively. A cohort study including 3046 patients aged 50 t0 69 years in Germany revealed similar 5 year survival but higher stroke rate in mechanical valve group comparing to biological one [13].Another investigation with limited selection of elective surgeries of patients with or without aortic regurgitation but without any degree of aortic stenosis predicted 0% early mortality, 3.2% reoperation and 42.7% complication rate for mechanical valve group. Only differences between complication rates were significant. More complications were reported in mechanical valve group comparing to biological valve and valve sparing group [14].

On the other hand some studies presented better outcomes for mechanical aortic valve prosthesis. Like a newly published article in European journal of clinical investigation which reported lower risk of reoperation and myocardial infarction furthermore better survival rate and non-significant difference of stroke rate in mechanical valve group. Even it questioned the accuracy of guideline recommendations because of older age of participants (<65) [15]. Also some evidences support the idea which says other factors rather than prosthetic valve type contribute to higher rate of stroke in mechanical group [16].

Even More confusing, no superiority of choosing between mechanical and biological prosthesis was confirmed in previous systematic review studies [17].

Fortunately more persistent data is available regarding observed higher reoperation rate in biological group and higher bleeding rate in mechanical group [16,17]. Reoperation rate of 0% in our study is in favor of excellent outcomes of biological valve use and is somehow contradictory to pervious evidences. Although its interpretation is limited by shorter follow-up duration.

Based on the nature of surgery, improving of Aortic insufficiency and aortic stenosis was expected to be seen with statistically meaningful difference. Somehow it may be interpreted as an indicator of successful rate of surgery. Right ventricle dysfunction rate seems to get worse during follow-up visits although it was not statistically significant. Transient impairment of right ventricle function was previously reported and evaluated in some studies. A recent published paper determined longitudinal RV systolic dysfunction after non complicated cardiac surgery without conferring RV global function which had been improved during 1 year follow-up [18].

Statistically meaningful decrease of EF observed in present study may be explained by longer aortic clamp time and cardiopulmonary bypass time.

VI. Conclusion

To summarize, biological aortic valve prosthesis use in aortic root replacement surgery was associated with low rate of postoperative complications, reoperation and mortality in our survey unlike the results of some previously published articles. Even with far longer aortic clamp time and cardiopulmonary bypass time of our surgeries, no mortality nor reoperation was reported. Although they probably contributed to decrease in patients' heart Ejection Fraction. Longer follow-up duration may change the results. Confusing data about aortic valve type preferences presented by earlier published papers emerges the need of complementary researches in this field. Studies enrolling much more patients with far longer follow-up duration is needed to exactly determine the better choice between mechanical and biologic aortic valve prosthesis. Our study with measuring numerous different variables before, during and after surgery in addition to echocardiographic findings provides valuable data for future investigations in order to establish the more précised aortic root surgical guidelines.

Table 1 preoperative characteristics

Preoperative characteristics	N (%) or mean ± SD (range)
Age (year)	56.19 ± 22.34 (9-83)
Sex	
Male	12 (75%)
Female	4 (25%)
BMI (kg/m^2)	24.18 ± 7.03 (38.05-12.43)
Clinical risk factor	
smoking	4 (25%)
Hypertension	7 (43.8%)
Coronary heart disease	4 (25%)
Renal failure	3 (18.8%)
Dyslipidemia	2 (12.5%)
Diabetes mellitus	1 (6.3%)
COPD	0 (0%)
EF (%)	47.81 ± 8.55 (30-60)
Pericardial effusion	2 (12.5%)

BMI: Body Mass Index, COPD: Chronic Obstructive Pulmonary Disease, EF: Ejection Fraction

Table 2 Operative characteristics

Operative characteristics	N (%) or mean ± SD (range)
Timing	
Elective	13 (81.2%)
Emergent	3 (18.8%)
Indication	
Dissection	1 (6.3%)
Endocarditis	2 (12.5%)
Other	13 (81.2%)
Previous cardiac surgery	3 (18.8%)
Concomitant surgery	
CABG	2 (12.5%)
MVR	4 (25%)
CABG +MVR	1 (6.3%)
TVR	1 (6.3%)
PFO closure	1 (6.3%)
PFO closure +MVR	1 (6.3%)
Technique	
Flanged Bentall	10 (62.5%)
Supra coronary	6 (37.5%)
Tube graft size (mm)	28.75 ± 4.25 (19-34)
Native valve	
Bicuspid	9 (56.3%)
Tricuspid	7 (43.8%)
Implanted valve type	
PERCEVAL XL	1 (6.3%)
Edwards/Magna	1 (6.3%)
Perimount	13 (81.1%)
Free style	1 (6.3%)
Implanted valve size (mm) [a]	25 [25-25] (23-29)
Suture type	
Continuous	14 (87.5%)
Interrupted	2 (12.5%)
Pump type	
Femoral	0 (0%)
Central	16 (100%)
CPB time (min)	182.63 ± 101.26 (116-490)
Clamp time (min) [a]	104.50 [87-152] (70-1021)
Intraoperative blood transfusion (unit) [a]	0 [0-1.75] (0-5)

CABG: Coronary Artery Bypass Grafting, MVR: Mitral Valve Replacement, TVR: Tricuspid Valve Replacement, PFO: Patent Foramen Ovale, CPB: Cardiopulmonary Bypass

[a] continuous variables with non-normal distribution are described by median, interquartile range [25th -75th percentile] and range presented in ().

Table 3 Post-operative characteristics

Postoperative characteristics	**N (%) or mean ± SD (range) [median]**
Early bleeding	2 (12.5%)
Early re-intervention	2 (12.5%)
Early pleural effusion	0 (0%)
Early pericardial effusion	0 (0%)
Postoperative pericardial effusion*	3(18.8%)
Postoperative EF (%)	44.69 ± 7.84 (30-55)
ICU stay (days)	6.31 ± 4.39 (2-16)
ICU bleeding (cc)	969.38 ± 521.41 (240-2150)
ICU blood transfusion (cc)	450 ± 298.32 (0-1250)
Follow-up duration (days) [a]	12 [7.75-21] (4-496)
Re-operation	0 (0%)
Follow-up EF (%)	44.06 ± 8.20 (30-55)
Follow-up pericardial effusion*	3 (18.8%)
Mortality	0 (0%)

EF: Ejection Fraction, ICU: Intensive Care Unit

* Pvalue > 0.05

[a] continuous variables with non-normal distribution are described by median, interquartile range [25th -75th percentile] and range presented in ().

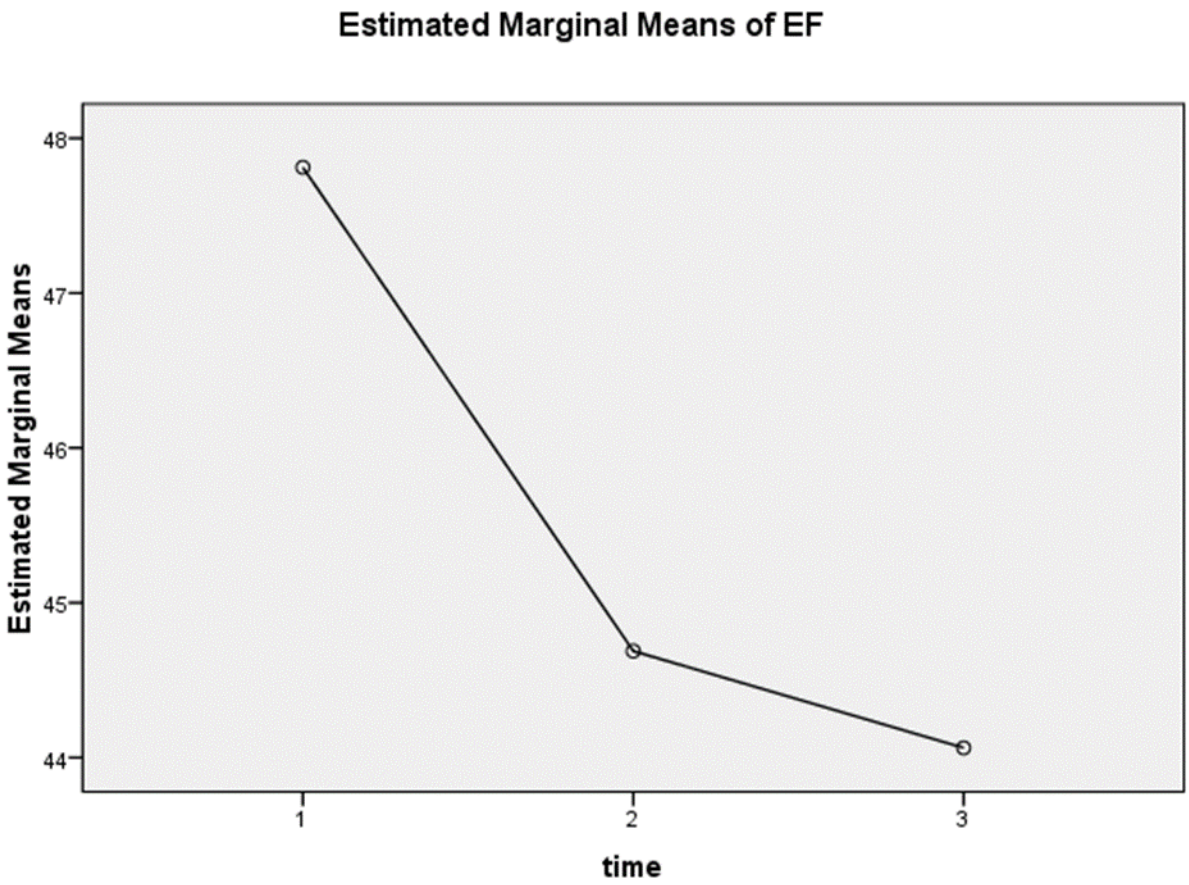

Figure1 EF changes during consecutive visits

EF: Ejection Fraction (%) Pvalue=0.036

1: pre operation 2: post operation 3: follow up

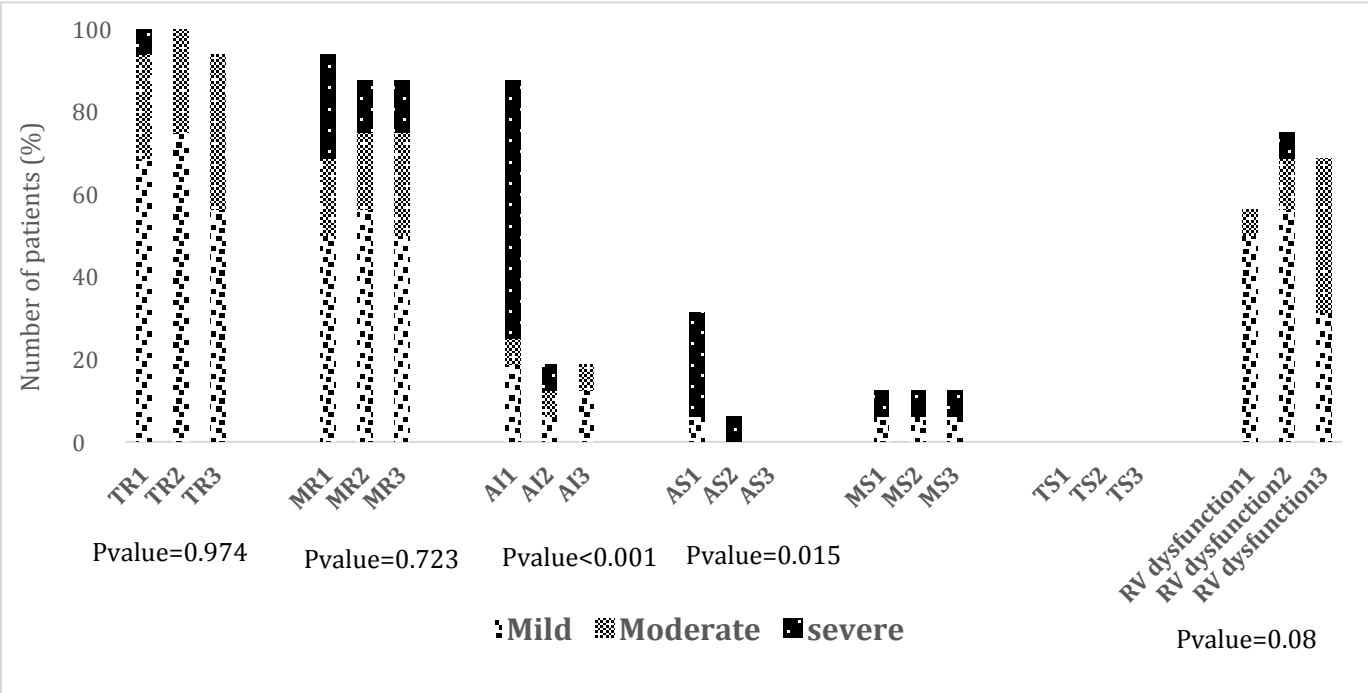

Figure 2 Echocardiographic findings from consecutive visits

1: pre operation 2: post operation 3: follow up

TR: Tricuspid regurgitation, MR: Mitral Regurgitation, AI: Aortic Insufficiency, AS: Aortic Stenosis, AI: Aortic Insufficiency, MS: Mitral Stenosis, TS: Tricuspid Stenosis, RV: Right Ventricle.

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