

SOCIETY FOR HEART FAILURE AND TRANSPLANTATION'S

# THE RECOVAL Promoting Academics to Improve Clinical Outcomes.

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# EDITOR'S NOTE



**Dr. Manoj Durairaj** Heart Transplant Surgeon, MS, MCh. (AIIMS, New Delhi), FACC. Director, Marian Cardiac Centre and Research Foundation. Program Director, Department of Heart and Lung Transplantation, Sahyadri Hospitals, Pune.

#### Greetings dear Colleagues,

The June 2021 issue of The Revival brings to you a brilliant review addressing the subject of "Valve surgery and heart failure" by Dr Chandrasekar Padmanabhan, Chair, Division of Cardiothoracic surgery, GKNM Hospital, Coimbatore. Dr Chandrasekhar has walked us through the current 2021 definition of heart failure and illustrated the various clinical scenarios wherein heart valve abnormalities can clinically present as acute or chronic heart failure. The treatment choices as per evidence-based medicine have also been lucidly explained. I thank Dr Chandrasekar for being our guest author and for this extremely comprehensive article detailing the current guideline-based standard of care.

Editor's Tip: A Heart Team approach is imperative in valvular heart surgery in this difficult subset of patients. Heart failure can beget valvular regurgitation and vice versa. Patients with heart failure and reduced ejection fraction having significant aortic and mitral regurgitation should be appropriately optimised prior to surgery with the current armentarium of pharmacotherapy (Angiotensin Receptor Neprolysin Inhibitors, Diuretics, Mineralocorticoid receptor antagonists and beta blockers) as per indications and then subjected to surgery.

Results are dependent on patient selection and timing of surgery and in this regard Cardiac MRI is of great help in myocardial viability mapping, quantification of the valvular lesions and chamber volume/dimension measurements. Post-operative course is expected to be stormy in these patients. Levosimendan (especially for ischemic mitral regurgitation), Milrinone and Mechanical Circulatory support like Intra-aortic balloon pump might be necessary in some patients perioperatively.

Dr. Manoj Durairaj
 Editor "The Revival"

# **SUB EDITOR**



**Dr. Talha Meeran** MBBS, MD, FACC, Consultant Cardiologist, Dept of Advanced Cardiac Sciences and Cardiac Transplant, Sir HN Reliance Foundation Hospital, Mumbai.

#### Dear Colleagues,

The editorial team is excited to share the June edition for The Revival. Dr Chandrashekar has provided an excellent review on this vast and challenging topic addressing valvular heart disease in a heart failure population. The preamble of the review itself provides an excellent example of the detail oriented mindset of Dr Chandrasekar. The discussion that follows takes you through each valvular lesion with their accompanying evidence based recommendations. Of particular note is how cutting edge techniques like the Mitra-Clip, BACE device blend well with the discussion of the time-tested valve replacement and repairs.

Sincerely, Dr. Talha Meeran Sub Editor "The Revival"

# PRESIDENTIAL MESSAGE

Dear Colleagues,

Greetings from the Society for Heart Failure and Transplantation!

June issue of 'The Revival' presents 'Valve Surgery and Heart Failure' - a relevant topic well dealt with by Dr. P. Chandrasekhar. Surgical indications for this entity have been addressed in a concise manner. Over the years, I have

observed that preoperative optimization of medical treatment along with hospitalization (from a few days to weeks) prior to surgery aids reduction of pulmonary artery pressure and improvement of RV function. These contribute to a significant improvement in the surgical outcome of patients.

On a positive note, as the second wave of Covid-19 has started to settle down, we hope to get back to our professional activities in full swing soon.

Stay safe!

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Special thanks to Dr. Chandrasekar Padmanabhan for authoring this month's article.

Designed by Maithili Kulkarni

# **VALVE SURGERY AND HEART FAILURE**

## Dr. Chandrasekar Padmanabhan

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- Fellow of IACTS and C S Sadasivan Orator- 2020
- PI for six major trials: STICH/CORONARY/SIRS/BACE/LAAOS/PROMOTE
- · Reviewer for IJCTVS/Asian Annals and EACTS- annual meeting .
- Organized live workshops for 20 consecutive years at GKNMH
- More than 25 years of experience in the practice of specialty with more than 10,000 procedures to credit
- Areas of interest: Reconstructive Valve surgery / Aortic surgery /surgery for heart failure

#### Preamble

The definition of Heart Failure (HF) is very wide and has various gaps. Several recent trials like the PARADIGM, VICTORIA, PARAGON etc. in heart failure have had different definition points. Different Societies have had definitions that are very variable and multi-factorial, some relying on haemodynamic criteria which are very difficult to apply clinically.

The 2021 guideline from AHA/ ACC defines the diagnosis of Heart Failure with reduced ejection fraction as anything <40 %.

The 2021 consensus statement by the Heart Failure Societies of America/Europe and Japan tries to address some of the gaps and grey zones and they have proposed a new universal definition for Heart Failure. This consensus statement defines HF *as a clinical syndrome with current or prior* symptoms and/or signs caused by a structural and/or functional cardiac abnormality as determined by EF <50%, and corroborated by *at least one* of the following:

- Elevated natriuretic peptide levels
- Objective evidence of cardiogenic pulmonary or systemic congestion by diagnostic modalities such as imaging or hemodynamic measurement at rest or with provocation.

Most of the definitions have addressed the left ventricle. Right heart failure (RHF) is commonly secondary to left heart failure and is associated with a dilated right atrium and right ventricular dysfunction, associated with WHO group 2 pulmonary hypertension. Most of the time in valvular heart disease there is a component of right heart failure and biventricular failure. Valvular Heart Disease (VHD), especially Aortic stenosis (AS), aortic regurgitation (AR) and mitral regurgitation (MR) can result in heart failure. VHD is acknowledged as a specific disease and so most heart failure clinical trials exclude significant VHD.

The focus of this article is to address valve surgery and heart failure. Primary diseases of the valve will eventually result in heart failure, mostly aortic and mitral regurgitation. Heart failure can itself result in valvular regurgitation which commonly occurs in mitral and tricuspid valves. For the ease of understanding and to have a clear idea the article would address, a clinical situation where the patient has a surgically correctable valvular lesion associated with ventricular dysfunction. This article does not dwell into the surgical techniques and procedures available as it is beyond the scope. The content is based on the current consensus document in heart failure ( Ref 1), the 2020 AHA guideline on Valvular heart disease (Ref 2), and the ACC 2021 Update to Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment (Ref 3).

Heart valve abnormalities can clinically present as acute or chronic heart failure. We will look at each valve separately as the clinical scenario and the cause can be different.

#### **Aortic Valve:**

Critical aortic stenosis and acute aortic regurgitation secondary to endocarditis or acute aortic dissection, can result in acute heart failure. Treatment is pretty straightforward and needs to be addressed based on the underlying condition, which could be either a valve or a root replacement procedure as indicated. Most of the time the left ventricle (LV) fails due to the sudden increase in volume and once the mechanical issue is resolved the LV recovers completely.

In Aortic Stenosis (AS) the timing of intervention is simple i.ewhen the patient is symptomatic. The onset of symptoms is an indication of surgery. Symptomatic AS (stage D1) – Aortic Valve Replacement (AVR) is a **class IA** recommendation. In asymptomatic individuals with critical AS a LV function < 50 % is a class IB-NR indication( Ref 2 ). In asymptomatic AS which is critical ( V max > 5 m/s ) it is also wise to look at BNP levels. If it is elevated greater than 3 times the baseline; it is a class IIa indication for surgery. The simple take-home message is that there is no contraindication for offering a valve procedure to patients with AS based on their poor left ventricular function. The risk stratification may vary but not the indication. The other argument today is whether it is a Surgical AVR (SAVR) or Transcatheter AVR (TAVR). This has to be a Heart Team decision (**IA**).

Aortic regurgitation (AR) again is similar and may present late as it is asymptomatic for long. So one may see more patients with LV dysfunction at the time of presentation. Here again, presence of symptoms is an indication of surgery. If asymptomatic and if the EF <55 % it is an indication. However, even if the EF is >55% one has to look at the Left Ventricle End Systolic Dimension(LVESD). Surgical intervention is indicated if the LVESD is >50 mm or indexed is >25mm/ m2. Another parameter in asymptomatic patients is to look at serial imaging studies to see if there is a drop in EF or increase in Left Ventricle End Diastolic Dimensions (LVEDD) to >65 mm which will signify the development of heart failure and surgery may be indicated (2b). Transcatheter Aortic Valve Implantation (TAVI or TAVR) is a class 3 (Harm) recommendation in patients with AR who have an indication for SAVR. Here as well, the take-home message is again related to symptoms. If the patient is symptomatic - offer surgery irrespective of LV function.

Surgical procedures may vary from valve repair to replacement. If replacement it could be a mechanical or a bioprosthetic valve. In terms of approach, it could be a TAVR or a SAVR. There could be additional procedures that need to be done on the root or ascending aorta depending on associated conditions and genetic background of the patient.

# **Mitral Valve:**

Acute mitral stenosis in a native valve is unknown. Rarely an acute obstruction to a left Atrio-Ventricular valve is due to a prosthetic valve obstruction or a myxoma. They present as acute pulmonary edema and an urgent surgical correction is indicated. Chronic Mitral Stenosis (MS) most commonly is rheumatic in origin and presents quite early before the onset of LV dysfunction. The indications of surgery are clearly defined and depending on the morphology of the valve a Percutaneous Mitral Balloon Commissurotomy (PMBC) or surgical repair/replacement is carried out. There is no contraindication to surgery even with LV dysfunction. Most of the time, these patients have more right ventricular (RV) dysfunction and tricuspid regurgitation (TR) due to a long-standing mitral obstruction.

Mitral Regurgitation (MR) is the focus when it comes to the left ventricle. It can be acute or chronic and can also be primary or secondary.

Acute MR presents as an acute emergency with acute pulmonary edema and varying degrees of LV dysfunction. The causes include Post Myocardial Infarction (MI) MR, an acute chordal rupture in degenerative disease, infective endocarditis, or prosthetic valve dehiscence. Acute post-MI - MR is most commonly seen with inferior wall MI and the majority of patients present with cardiogenic shock. More than 2/3rd of the cases are due to partial rupture of the postero-medial papillary muscle. Left untreated more than 75% of them die within the first 4 weeks. Surgery also carries a high risk close to 15-40% but with a 5-year survival of close to 60%. The management of most cases of Acute MR is surgical which maybe repair or replacement. An acute chordal rupture in a degenerative etiology should be repaired (if possible). Infective Endocarditis (IE) and valve dehiscence are dealt with as the need be. A total chordal preservation mitral valve replacement will be a better option especially in the setting of a partial or complete papillary muscle rupture in Post MI acute MR. Sometimes an Acute MR can be dynamic due to dysfunction secondary to ischemia where revascularization alone may correct the problem.

Chronic MR can be primary or secondary.

Primary MR if symptomatic is an indication for surgery irrespective of LV function. However, if asymptomatic a drop in EF<60% or a LVESD >40 mm is an indication for surgery (**Class I recommendation**). If degenerative in origin then a repair should be attempted in a centre of excellence which is again a **class I recommendation**. All the above recommendations even though class I are all supported by a **LOE B-NR**.

Secondary MR can be ischemic or non-ischemic. Ischemic MR (IMR) is a result of asymmetrical dilatation of the LV whereas non-ischemic is usually symmetrical. Both cases are ventricular disease rather than a valve problem.

The most common clinical scenario is an IMR. It is a surrogate marker of poor outcomes. 5-year survival is only 40% if MR is present and the mortality is also directly related to the quantum of MR. 5-year survival of 47% with Effective Regurgitation Orifice (ERO) <2 cm2 vs 29 % with ERO >2 cm2. Relative risk ratio of cardiac death is 1.56 if ERO <2 cm2 vs 2.38 if ERO >2 cm2.

The mechanism proposed is multifactorial which includes annular and LV dilatation, regional LV dysfunction, papillary muscle dysfunction or displacement and leaflet tethering. Current Magnetic Resonance Imaging (MRI) studies have shown that it is just not a LV dilatation but a loss of balance between systolic torsion and diastolic recoil. Consequent to this the saddle shape is lost with flattening and stretching of the septo-lateral diameter and apical tethering of the posterior leaflet. The tenting height is a marker of severity. The leaflets are not normal. Studies from transplanted hearts have shown that the leaflets are biochemically different with altered extracellular matrix. There is a delayed closure leading to central and commissural leaks. Current echocardiography studies have also shown that papillary muscle dysfunction is protective and decreases MR. Also, LV End Diastolic Volume (LVEDV) has a poor correlation to severity. The ratio of LV mass to EDV is constant in secondary chronic MR. An EF of <55% with severe MR indicates advanced myocardial dysfunction. LV End Systolic Volume Indexed (LVESVI) - is the most accurate indicator of ventricular contractility and the best predictor of outcome and cardiac death.

Echocardiography forms the gold standard for evaluation and assessment of severity. The severity of MR as per the recent guideline is the same as for degenerative etiology. An Effective Regurgitant Orifice Area (EROA) >0.4 cm2 and a Regurgitant Volume >60 cc are suggestive of severe MR. The decision to intervene should be made on preoperative assessment and not under general anaesthesia.

Vena contracta width is more predictive of severity than EROA. EROA in secondary MR has its limitations as it is affected by loading conditions of the LV and a stress echo paradoxically decreases EROA and MR severity in Functional MR (FMR) and IMR. EROA estimation based on doppler flow convergence is also affected because of the crescentic shape of the regurgitant orifice.

#### Severity of MR: AHA 2020 Guideline

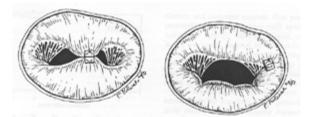
Parameter	Mild	Moderate	Severe
EROA ( cm2)	< 0.2	0.2 - 0.4	> 0.4
Regurgitant Vol ( ml )	< 30	30 - 60	> 60
Vena Contracta ( mm )	< 3	3 - 6.9	>7

Treatment of secondary MR is primarily GDMT (Guideline Directed Management and Therapy). This is a **Class I recommendation (2020)**. In patients undergoing CABG with severe MR, mitral valve procedure is indicated as a **2a** recommendation. In patients with severe MR who are symptomatic in spite of GDMT and if EF >50% MV surgery is a **2b-B-NR** indication. In patients with severe MR with EF <50 % Transcatheter Edge-to-Edge (TEER) is a **2a-B-NR** indication provided the LVESD<70 mm and the PA systolic<70 mm Hg. Surgical options are MV Repair or Replacement. The 2020 guidelines give a **2b-B-R** recommendation for a chordal preserving MVR in symptomatic MR with EF <50 % against an undersized annuloplasty. Repair is the most commonly done procedure as the operative mortality is significantly lower than MVR when CABG is associated. The mechanism is complex and the fact that the recurrence of MR is high suggests that most of the time the exact mechanism is not addressed.

Two standard techniques are a) an undersized annuloplasty (Figure 1a) and b) an edge-to-edge repair (Fig 1b).



Figure 1a) Schematic diagram showing an undersized annuloplasty performed



*Figure 1b) Schematic diagram showing an edge-to-edge repair performed* 

The choice of rings is many and there is no ideal one. The choice between a band and ring is also not very clear and largely depends on the surgeon's choice and comfort. The general consensus is in favour of a complete rigid ring, however not supported by any definitive studies. There are other techniques like neo-chords, chordal cutting, papillary muscle traction to correct displacement etc. but are not standardized.

There are certain situations where the controversy or lack of clear consensus still exists-

1) Should moderate MR be addressed during CABG ? There have been many trials and the recent CTSN RCT is the only definitive trial that compared this. 300 patients were randomized to either CABG only or CABG plus undersized annuloplasty. The primary endpoint was not clinical but LVESVI. There was no difference between the two groups in terms of MACE also. MV repair group had less MR at two years but no clinical difference. They also observed that improvement in lateral wall motion correlated with improvement in MR irrespective of treatment arm. Hence, the answer to the question is NO. However, there are a few caveats. If the lateral wall is scarred and is not grafted added then fixing the MR may be a good option to improve symptoms and quality. On the contrary, if the lateral wall is viable with a good target vessel that is graftable then one may defer fixing the moderate MR. Probably, it is not justified to replace the valve for sure in moderate MR. Either repair it or leave it alone. Poor predictors of recurrence include a LVEDV >5, coaptation depth of <10 mm and AP diameter >37 mm and a tenting area >1.6 cm sq.

#### 2) MV Repair or Replacement?

This question arises in the setting of severe MR and symptomatic patients. The CTSN looked at it. They randomized 251 patients to either MV repair or a total chordal preserving MVR. At one year the degree of residual or recurrent MR was higher in the repair group but the perioperative mortality was higher in the replacement group. At one year there was no other difference however in clinical outcomes. The CORE group from Australia in their metaanalysis also observed the same. Repair may be preferred if there is significant viable myocardium on the inferolateral wall and if the target vessel is grafted. A scarred lateral wall probably will dictate a choice of replacement.

The current 2020 guideline gives a **2b-B-R** recommendation in favour of total chordal preserving replacement in this setting as against an undersized annuloplasty.

#### 3) Role of Percutaneous Techniques?

The Mitra-clip which is based on the principle of Alfieri stitch is the only percutaneous repair technique now approved for MR. Initially applied for a degenerative disease it is extended to secondary MR as well based on the COAPT trial. It is a **2a-B-R** recommendation in FMR in patients with LVEF of 20-40 % and LVESD<70 mm and PA pressure<70 mm Hg.

Percutaneous mitral valve replacement is still under trial and innovation. There are close to 20 plus devices under investigation for native valve disease. However, a valvein-valve is being done fairly regularly in many centres for bioprosthetic valve failure in patients who are unfit for a reoperation.

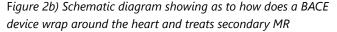
#### 4) BACE Device

The BACE or the Basal Annuloplasty of Cardia Externally is a collar around the base of the heart with silicone bags that can be filled with saline and adjusted remotely under TEE guidance. This addresses the mitral annulus and also supports the infero-basal wall of the ventricle as a containment device. This can be done off-pump and has currently got the CE mark (Fig 2a-b).



Figure 2a) Photograph of a BACE device





#### **Tricuspid Valve:**

The most common cause of tricuspid regurgitation (TR) is secondary to left-sided valve disease.

#### Severity of TR :

Parameter	Progressive TR	Severe TR
Jet area	<50 % of RA	>50 % of RA
Vena Contracta	<7 mm	>7 mm
ERO	<0.4 cm	>0.4cm
Rvol	<45ml	>45 ml

In patients with severe TR who are undergoing left-sided surgery fixing the tricuspid valve is a **Class I –B-NR** recommendation today. In progressive TR who is undergoing a left-sided surgery if the tricuspid annular end-diastolic dimension is >40 mm or with symptoms of right-sided failure then the TV has to be addressed as a class **2a-B-NR** recommendation.

Isolated TV surgery may be considered in the absence of left-sided disease if the patient has symptoms of right-sided failure, either due to primary or secondary TR if there is no pulmonary hypertension. Progressive RV dilatation is also a **2b** indication in asymptomatic cases.

The common scenario is a severe TR a few years after a left-sided surgery. In this setting, if the patient has symptoms of right-sided failure isolated TV surgery can be advised as a **2b-B** recommendation provided there is no pulmonary hypertension and severe RV systolic dysfunction.

The choice of procedure is most often a repair. Repair of the TV valve should be undertaken with the same systematic

process that is done for a mitral valve. An incomplete ring annuloplasty is a preferred technique. There are special rings which may also be used. Sometimes, especially when going in as a redo after a left-sided surgery one should have a low threshold to replace the valve.

#### TR in Transplanted hearts:

TR in transplanted hearts is a very common occurrence. The majority of the cases range from mild to moderate and are managed medically. Sometimes, it can be severe and causes severe right heart failure symptoms. Concomitant TV annuloplasty in donor's hearts is advocated by some but is not universally accepted. The decision to surgically correct the tricuspid valve should be taken with extreme caution even if the RV function is good. Anatomical etiologies do better than functional ones. There is emerging data that suggest that replacement with a biological valve is more durable and also gives access to Endo-Myocardial Biopsy (EMB).

#### **Salient points:**

- Valvular heart disease is one of the established causes of heart failure. As it is a separate entity, most HF trials do not address primary valve disease. It can also be the effect, especially in mitral and tricuspid valves.
- The definition of heart failure is constantly changing and as per the 2021 consensus statement, it is defined as: symptoms and signs with EF <50 % (HFrEF), elevated NP levels and evidence of pulmonary or systemic congestion. (AHA/ACC 2021 <40 %)</li>
- Symptomatic aortic stenosis or regurgitation is a class I indication for intervention irrespective of left ventricular function. Critical AS is a **Class I-A** recommendation (2020).
- Acute MR of whatever etiology is a surgical disease and needs emergent intervention.
- Symptomatic Chronic MR should be surgically corrected irrespective of ventricular function.
- Secondary MR most commonly is ischemic in origin and surgical correction provides symptomatic relief but does not improve survival. No concrete evidence to show that correction of moderate MR helps.
- Standard repair commonly involves a reducing annuloplasty with a rigid complete ring and an edge-to-edge repair if need be as an adjunct. A total chordal preserving MVR for severe MR may be preferred.
- TEE can be done in patients who are high risk for surgery provided EF>20 % and PA pressure <70 mm Hg
- TMVR is still not a validated procedure, however, Valve-in-Valve is a practiced option in patients who are at high risk for a redo-procedure.
- BACE device is an external annuloplasty system that addresses the MR as well as the basal LV.
- Tricuspid Valve disease is mostly secondary to left-sided disease. Severe TR or moderate TR with an annulus
  >40mm should be corrected during left-sided surgery.

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