

Original Research Article

Post-operative results of tricuspid annuloplasty with teflon felt

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ABSTRACT

Background: Surgical treatment of functional tricuspid valve regurgitation (TR) with left-sided valvular disease still remains a challenge for the cardiac surgeon. We present our observations and results on the usage of Teflon felt as an economic and easily available option for the management for tricuspid disease with an emphasis on the ease of procedure.

Methods: In this study 50 (27 male and 23 female) adult skulls were investigated to determine the type of asterion, its distance from important bony landmarks and also the nearby venous sinuses were measured.

Results: Epidemiological data like age, gender, symptomatic status using NYHA class, intraoperative details including the procedure performed, cardiopulmonary bypass and cross clamp time were noted. Patients' preoperative echocardiograms, postoperative echocardiograms done at 1 month, 3 month and 6 month and yearly follow ups were made note of. Most of the patients in our study group are in 4th decade of life with slight female preponderance. Tricuspid regurgitation secondary to rheumatic valvular disease involving left sided valves is the most common etiology. The average size of the teflon felt was sized to the standard SJM sizer and sized to 28.56 ± 3.7 mm. The average CPB time is 138 min 19 sec and average cross clamp time 89 min 14 sec. Five patients had postoperative RV dysfunction out of which three patients recovered with medical management. Overall in-hospital mortality in our study group is 6 (8%). 3 of them died due to low cardiac output, two patients due to sepsis and MODS and one due to bleeding.

Conclusions: Annuloplasty with customised hard teflon felt is a safe, easily reproducible, economic alternative with good results and less mortality and morbidity.

Keywords: Tricuspid regurgitation, Tricuspid valve repair, Tricuspid annuloplasty, Teflon felt

INTRODUCTION

Cardiovascular diseases are the number one cause of death globally. An estimated 17.7 million people died from cardiovascular diseases in 2015, representing 31% of all global deaths. Over three quarters of these deaths take place in low- and middle-income countries.¹

In India, cardiovascular diseases have now become the leading cause of mortality amounting to almost a quarter of deaths. Ischemic heart disease and stroke are responsible for >80% of cardiovascular disease deaths.

The burden of disease for cardiovascular death rate is 272 per 100 000 population in India and is higher than the global average of 235 per 1,00,000 population.^{2,3} Rheumatic heart disease continues to be a problem in India, with an estimated 88,674 deaths (7 per 100 000 population) in the year 2010. Reliable national-level data on the rheumatic heart disease burden are not available from India because of the differences in definitions used in existing studies. However, the available estimates suggest that rheumatic heart disease prevalence is in the range of 1.5 to 2 per 1000 individuals. Of this, incidence of tricuspid disease is around 9.7%.^{2,3}

The right side of the heart being a low pressure chamber, the primary pathology of the tricuspid valve is rare. It is usually secondarily affected due to disease of the mitral or aortic valve or due to pathology in the right ventricle. Since time immemorial, the tricuspid valve has always posed a dilemma firstly in the diagnosis for the cardiologists and then its management for both the cardiologist and cardiac surgeon. The symptoms of tricuspid disease are systemic and more subtle than the other lesions of the heart. Due to developments in imaging, the pathology is more easily and early picked up and more awareness and emphasis is now on the ignored tricuspid valve. However, for the surgeon it is still a challenge due to its close proximity to vital structures of the heart and the limited modalities of treatment options available and the big question-to operate or not to operate. In this study, we present our observations and results on the usage of teflon felt as an economic and easily available option for the management for tricuspid disease with an emphasis on the ease of procedure.

METHODS

It is a retrospective study done in Nizam's Institute of Medical Sciences, Hyderabad. Data was retrieved from previous records of all the patients who underwent tricuspid annuloplasty with teflon felt. Our database included the admission record, the patients' department record, operation theatre and perfusion record, ICU charts and discharge records and follow up notes. Information noted were the age, gender, class of presentation, date of surgery, pre-operative echo details, intra operative notes, post-operative recovery, medications used, post-operative echo, death and rehospitalisation. Intra-operative details include induction and post procedure CVP, chamber enlargement, cross clamp time and CPB time, anatomy of the tricuspid valve and pre and post procedure degree of regurgitation.

Inclusion criteria

All patients who underwent surgery for secondary tricuspid regurgitation using teflon felt between the years 2016-2019, aged between 18-65 years of both genders.

Exclusion criteria

Patients above 65 years of age and below 18 years, with concomitant coronary heart disease and who underwent tricuspid annuloplasty other than teflon felt annuloplasty.

The main indications noted for operating on the tricuspid valve in patients in this study: symptomatic patients with NYHA class III or more, echo indications like grade of TR, tricuspid annulus and severity of PAH, and presence of pre-op medications like diuretics and inotropes.

Due to the high failure rates of suture annuloplasty and the expensive nature of the available rings/bands, teflon felt was chosen due to its easy availability and affordable alternative.

All patients with TR more than moderate TR and more than moderate PAH with a pre-operative tricuspid annulus of more than 40mm were operated. Patients with more than moderate TR were prophylactically started on injectable furosemide at least 3 days pre-operatively. All patients with pre-operative LV dysfunction, severe TR, severe PAH and signs of right heart failure like raised JVP, pedal edema, and palpable hepatomegaly were pre-operatively started on injectable furosemide at least 5 days before the planned procedure whenever possible and were prepared with preoperative injection dobutamine infusion of 5 mic/kg/min at least 24 hours before to optimise the patient for surgery.

As in the institutions protocol, pre-operative 2D echo was performed in all patients after admission and at 5 days post op-which was taken as the post op echo. In an attempt to reduce post op morbidity and mortality, patients who underwent emergency surgeries and redo surgeries, primary packing was the stay of treatment. These patients were planned for secondary closure of the sternum 6hrs post primary procedure. Most patients were extubated within 24 hours of the procedure.

Our main choice of inotropes were injection dopamine at 5 µ/kg/min and injection adrenaline at 0.05 µ/kg/min. In patients with severe pre-operative PAH and RV dysfunction, injection milrinone at 0.33-0.66 µ/kg/min was added. Additional inotropes were added depending on the patients' haemodynamic status. The inotropes were gradually reduced over a period of 48 hours post-surgery.

At the time of discharge, all patients received: angiotensin converting enzyme (ACE) inhibitors-tablet enalapril dose adjusted according to the patients' blood pressure, antiplatelet agents-aspirin at 75 mg, coumarin derivative Warfarin dosed according to the patients INR for valve replacements; class III anti-arrhythmic agents-amiodarone in patients with persistent AF post-surgery; in case of persistent high heart rate, beta blockers- tablet metoprolol was added; selective cyclic GMP inhibitor sildenafil for patients with more than moderate PAH pre-operatively; and diuretics furosemide and aldactone combination for a period of 6 months post op.

During follow up, of 1 month, 3 months, 6 months and yearly all patients underwent 2d echo to monitor the LV and RV function, grade of TR and PAH. The dosages of the medications were adjusted accordingly.

Technique of surgery

The surgery was performed through midline sternotomy and standard aortic and bicaval cannulation. In patients who were undergoing a redo surgery, it is our institute's protocol to electively go on femoro-femoral bypass and then do sternotomy using an oscillating saw. Patient was cooled to moderate hypothermia and after cross clamping aorta, Del nido plegia was our choice of cardioplegia repeated at 45 min intervals. After addressing the

associated lesions and the patient was confirmed to be on total bypass, the right atrium was opened parallel to the AV groove and stayed. The tricuspid valve was checked for regurgitation using the asepto syringe. Once confirmed, 09-12 deep U shaped simple intermittent horizontal sutures were taken using 2-0 Ethibond (Ethicon© Inc, Somerville, NJ) along the tricuspid annulus from the antero septal commissure to the postero septal commissure. The annulus was then sized using St. Jude valve sizer (St. Jude Medical Inc., MN) after visually matching it to that of the native annulus. With this as the guide, a Teflon sheet was taken and a semi rigid ring was fashioned. This was secured in position to the tricuspid annulus using the sutures in situ. At the end of the procedure, tricuspid valve was checked for adequacy of the repair using the saline insufflation technique. After satisfactory result, the right atrium was closed and patient was re warmed and weaned off bypass.

In case of emergency and redo surgeries, it is the institute’s protocol to electively pack the chest and plan a delayed primary closure after 6 hours to reduce intra op morbidity and mortality. All patients were electively ventilated for atleast a period of 6 hours post op to check for bleeding and stabilize haemodynamics. Supporting inotropes were then gradually reduced over a period of 48 hours.

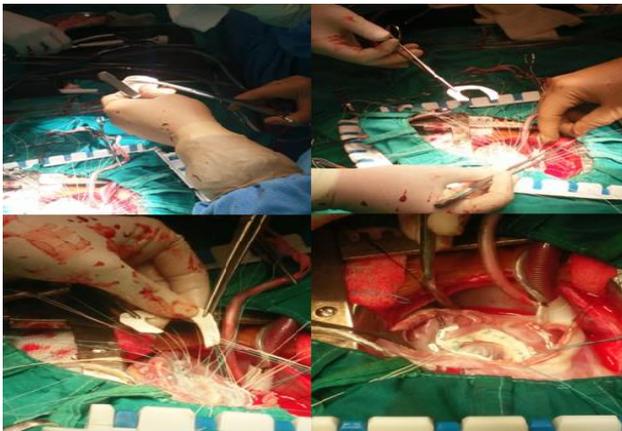


Figure 1: Intra operative images in study.

Statistical analysis

Statistical analysis was performed using the graph pad quick calculation software. Patient demographics were compared with analysis of variance (ANOVA). The study data were analyzed using statistical methods of mean, standard deviation, paired students “t” test (for values within the group at different time stations) and independent unpaired “t” test (for comparison of intergroup values).

RESULTS

In this retrospective study conducted from 2015 to 2019, there have been a total of 189 cases which underwent repair for tricuspid regurgitation. Under these a total of 94

cases underwent teflon felt repair. Out of the 94 cases, we have collected details of 78 cases which fulfil our inclusion and exclusion criteria.

These patients were studied after due consent and clearance from ethical committee of the institution. The different parameters taken into consideration were the age at presentation, gender distribution, the causes, the pre op, post op and follow up NYHA class, degree of regurgitation and echocardiography. The overall mortality and morbidity are compared.

The annuloplasty consideration was moderate to severe tricuspid regurgitation and/or tricuspid annular dilatation. All patients who underwent successful annuloplasty were defined as having no/mild residual regurgitation post-surgery.

Table 1: The pre-operative characteristic of patients who underwent surgery.

Parameter	Value
Age (years)	38.68
Gender-female (%)	40 (51.2)
NYHA class III (%)	40 (51.2)
TR grade severe (%)	45 (57.6)
TA diameter >40 mm (%)	63 (80.8)
Pre-op diuretics (%)	63 (80.7)
Pre-op inotropes (%)	21 (27)

There has been an almost equal distribution of tricuspid regurgitation in the 3rd and 5th decades of life. Gender distribution has been equal for the pathology in our study.

The chief causes for regurgitation have been secondary regurgitation mostly due to a left sided pathology of rheumatic origin. Besides primary surgery there are 12 cases of redo cardiac surgery and 8 cases in which the tricuspid disease was addressed in emergency surgeries.

The average size of the teflon felt was sized to the standard SJM size and sized to 28.56±3.7 mm. The CPB (average 138.32 min) and cross clamp (average 89.24 min) time were also noted. There were 8 patients who developed post op RV dysfunction and 2 with post op tricuspid stenosis. Out of the 8 patients who had developed RV dysfunction, 5 patients showed improvement with Medical management and did not require further hospitalization. Stenosis had reduced with time in subsequent follow ups.

The mean follow up had been 6 months for all the cases with regular 2D echocardiography done at discharge, 1month, 3 months, and the end of 6 months post-surgery and yearly. The NYHA class and the mortality and morbidity with need for readmission and event free survival were noted. The 30 day mortality has been 8%. 6 patients in the follow up had not been relieved of symptoms and required repeated hospitalization for heart failure management.

At follow up, it has been noted that there was a significant improvement of symptoms in patients only at the 3rd month of follow up and there has been a reduction in their regurgitation and NYHA class. No patient was lost to follow up and there has been 2 patients lost due to protracted right heart failure after 2 years and 1 year 3 months of surgery. The event free survival and freedom from readmission has been 4.5%.

In-hospital mortality in our study group is 6 out of 78 patients. The cause of death is low cardiac output in 3 and sepsis in 2 patients and one patient had intractable bleeding. One patient with DVR and TV plasty, 2 with MVR and TV plasty had low cardiac output. A case of emergency DVR with TV plasty succumbed to sepsis and a case of DVR TV plasty had prolonged ventilation, pneumonia and sepsis. Patient of post op DVR who underwent redo sternotomy with redo AVR and TV plasty succumbed to intractable bleeding.

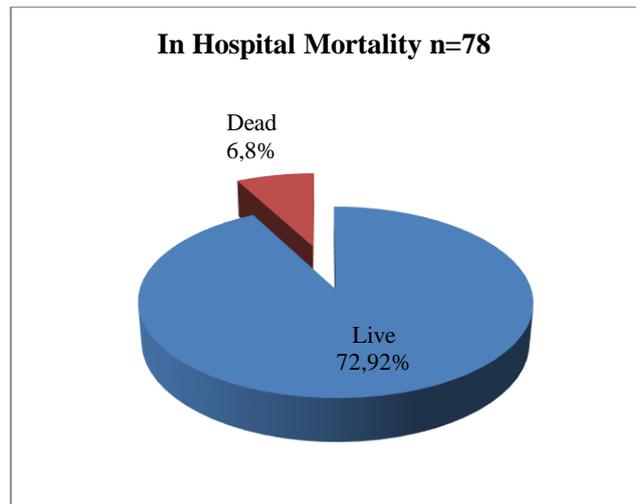


Figure 2: Mortality rate in present study.

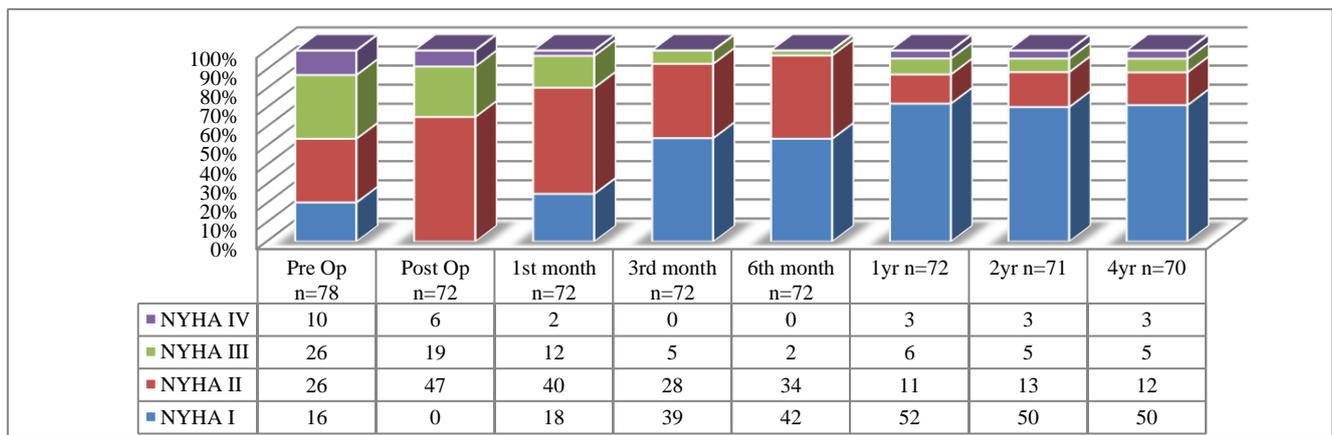


Figure 3: NYHA class in present study.

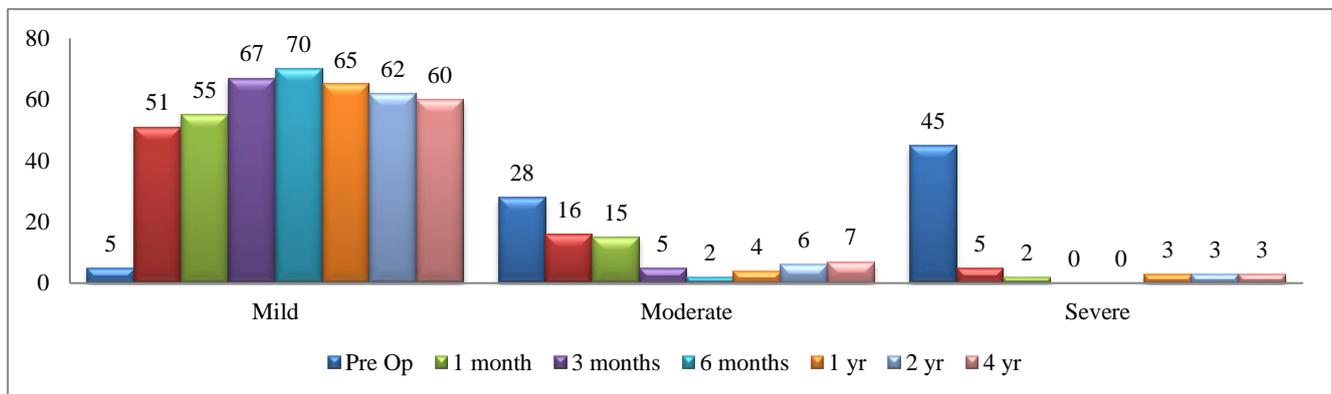


Figure 4: 2D ECHO in patients of study.

DISCUSSION

There has been a dramatic decline in the incidence of rheumatic heart disease and its sequelae in the developed countries, but we in India being a developing country still face the consequences of it. As a result of this, tricuspid regurgitation as a result of left sided disease of the mitral

and aortic pathology still is very much prevalent in the Indian sub-continent. Besides secondary functional regurgitation, there are various causes of TR like infective endocarditis, tumours, congenital causes, intra-cardiac lesions, prolapse, radiation, carcinoid, trauma and others that do form the spectrum of diseases that contribute to tricuspid insufficiency.

There have been many studies and publications earlier that advocated that the tricuspid valve be left alone and the adequate treatment for the left sided lesions reduces the pulmonary hypertension and hence the tricuspid insufficiency.^{9,11,13,15} However these same studies over the long term have also noted that there was no improvement of the right sided lesion, reduction in signs and symptoms and improvement of quality of life in patients who were not dealt with tricuspid regurgitation in the initial surgery.^{9-15,30}

The latest guidelines by the American heart society in 2014 clearly states that the tricuspid valve has to be addressed in any patient with moderate to severe TR and/or annular dilatation who is undergoing surgery for left sided valve surgery or redo surgery in case of failed medical management.³²

Over time there have been many ring and non-ring based procedures for the management of tricuspid insufficiency. And they have produced varied results each having its own fair share of advantages and disadvantages. The non-ring techniques like the de Vega's annuloplasty and Peri Guard procedure have the advantage of being easy to perform and low cost procedures with promising results in the short term. But long term results have shown recurrence of insufficiency for these surgeries. Ring based surgeries-rigid, flexible and the 3D based ring, have definitely surpassed the results for achieving adequate repair, however the cost and technical challenges are still yet to be overcome and long term results are awaited (Figure 1).^{5,7,8,30}

Tricuspid regurgitation is the second most common form of valvular insufficiency after mitral insufficiency. And the Framingham study also states that the prevalence of this disease is also same in both men and women. The same has been reflected in our study. The age do not match the international standards, as the most common reasons for tricuspid regurgitation is secondary to left sided valvular lesions. This is more prevalent in India in the 3rd to 5th decade. While in international registry this is more common in the 6th-7th decade.¹²

Various studies have already proven that though the initial results of the de Vegas technique are acceptable, the results of the ring annuloplasty technique fare better.^{13,14,26,28,30} And taking a leaf out of this and a technique first reported for mitral regurgitation repair by Mohan et al we have developed a technique which uses teflon felt as a pseudo ring to strengthen the annulus and reduce its diameter without compromising the RV capacity.¹⁷ So far as per our knowledge, there has been only one case report that supports the use of teflon felt but that has been a modification of the de Vegas technique and uses intermittent strips of felt.^{16,18}

In comparison with international studies by Chang et al and Navia et al, patients who underwent ring annuloplasty fared better with less reoperation rates and less incidence

of readmission and recurrence rates. In these studies, the freedom from residual more than moderate tricuspid regurgitation has been as high at 97%, which in our study is at 96%.^{4,5} Though there are 6 deaths in our study for the patients who underwent this procedure, the cause of death was not the tricuspid lesion or the surgery over it (Table 1).

Residual tricuspid regurgitation during follow up and over time has reduced from 57% initially to 4% at 1yr post op. In a study by Patrick et al they quote a residual TR of severe grade in all forms of annuloplasty to be 14%.

Ren et al reported in their study that increased left atrial pressures causes a reversed increased PAP, which changes the RV volume and dimensions, leading to TA dilatation and regurgitation. Hence repairing such pathologies, will improve the haemodynamic and quality of life.^{7,10-14,28} This has been demonstrated in our study, where preoperatively we had 88% with moderate to severe PAH and 96% more than moderate TR and 84% of tricuspid annular dilatation. This at the time of discharge has reduced to 82% with mild or less TR and 78% of moderate or less PAH. And there has been a gradual improvement in the 6 month follow up with 4% of patients with residual severe TR and severe PAH.

So far no studies report the incidence of TS post annuloplasty surgeries, however we had an incidence of 2 such patient and 8 patients with post op RV dysfunction. The TS reduced over time. And among the 8 patients who developed RV dysfunction post operatively only 2 (4.5%) required hospitalization and treatment for heart failure. And 2 patients succumbed to right heart failure. In contrast international studies report a heart failure and hospitalization to the rate of 18% in non-ring based surgeries and 2.7 % in ring based surgeries.^{4,5,8,1,26,28}

Indian literature for supporting tricuspid annuloplasty is rare and hard to find. In a study by Gupta et al who describe a modified tricuspid annuloplasty technique in 50 patients, they noted results as 8% mortality not related to the disease, and 17.3% with no regurgitation, 78.2% with mild and 4.3% with moderate regurgitation in their 70 month follow up. The TRACET study, which compares the de Vegas technique, rigid ring and teflon felt annuloplasty at one year, demonstrates good results with ring based technique compared with the suture based surgery. They have reported a failure rate of 6% in the felt TV plasty.^{27,30} In the present study, the mortality is 8% not related to the disease, and favourable outcomes as comparable with ring based techniques in the limited period follow up. The failure rate in this study is 4% (Figure 2).

If NYHA class is an indicator for improvement in quality of life, there has been an improvement of patients in NYHA class III or more in 24% of patients at the end of 4 yrs. as reported by Sunil et al.^{5,14} In this study there has been a good progressive improvement over time of our patients from a pre-operative NYHA class of III or more

with 46% to 34% at discharge and 12% at 4 year follow up (Figure 3 and 4).

Tricuspid regurgitation of more than moderate has to be repaired to prevent progression of the disease. This is not only beneficial for immediate post-operative recovery but shows good symptomatic improvement in the long term also. There is a high failure rate of surgery in suture based annuloplasty techniques, and rings and bands are costly and an economic burden for developing nation such as ours. In a study by Kumar et al they have proven that Customised Teflon felt has given good results in the mitral position where interchamber pressures are high. The same has been studied to see if similar successful results can be obtained in the tricuspid position.

The limitations of this study include that it is a single centre and single unit retrospective study, with all the limitations that come with such investigations. There has been no adequate data available in this study with respect to the right atrial and right ventricular volume and dimensions pre and post operatively, something that will definitely influence the result of the repair.

CONCLUSION

Tricuspid valve is no longer the neglected valve. Tricuspid insufficiency generally is secondary to diseases of the left heart pathology. Regurgitation of moderate or more with or without annular dilatation should be addressed at the time of the primary surgery to avoid late complications.

More Indian studies are required to highlight the importance of tricuspid insufficiency, its complications and the various modalities of surgical treatment available and the results of such in short and long term. As mentioned in the TRACET study, annuloplasty with customised hard teflon felt is a safe, easily reproducible, economic alternative with good results and less mortality and morbidity.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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