Research Article

Progressive Tricuspid Valve Regurgitation Following Cardiac Rhythm Device Lead Implantation

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Abstract

Introduction

Implantable cardiac rhythm devices are widely used for lethal arrhythmias and atrioventricular dyssynchrony with an increasing number of implantations of these devices. Moderate to severe tricuspid regurgitation is independently associated with increased morbidity and mortality. We hypothesized that implantation of an endocardial device lead by crossing the tricuspid valve will result in an increase in tricuspid regurgitation over a long period of follow-up.

Methods

Retrospective data was analyzed for the patients who underwent permanent pacemaker (PPM), implantable cardiac defibrillator (ICD) and cardiac resynchronization therapy (CRT) devices from January 2012 to April 2014. Transthoracic echocardiography data collected before the procedure and 1, 2, 5 years post-procedure were included in the study. Qualitative assessment was done for TR severity with color Doppler and continuous wave signal density as Grade 0 to Grade 3. Statistical analysis was done by Sign test using IBM SPSS software to assess the significance of the change in TR severity pre and post-procedure.

Results

148 patients underwent device implantation. 85 patients were excluded from the study due to inadequate echocardiographic and device lead data. 63 patients were included in the study. The mean age was 63.3±3.88 years. 33 (52.3%) were male and 30 (47.6%) were female. Echocardiographic data 1 and 2 years post-procedure showed no statistically significant increase in TR severity. 37 patients who had echocardiographic data at 5 years post-procedure, 12 patients (32.4%) showed a 1-grade increase, 8 patients (21.6%) showed a 2-grade increase in TR severity. There was a statistically significant increase in TR severity 5 years post-procedure when compared with pre-procedural TR (P = 0.0004). The impact of PPM, ICD and CRT lead and gender difference on TR severity at 5 years post-procedure was insignificant.

Conclusions

There was a significant increase in TR severity at least by 1 grade when compared with baseline to 5 years post-procedure echocardiography. These changes are not seen in the early follow-up echocardiography at 1 and 2 years post-procedure, which signifies that the device lead-induced TR is a progressive disease and needs long-term follow-up.

Keywords; *Tricuspid valve regurgitation, device lead implantation.*

Introduction

Permanent pacemaker (PPM), implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy (CRT) are the treatment for many arrhythmias and atrioventricular dyssynchrony. In 2016 it was estimated there would be 1.14 million devices implanted globally which would increase to 1.43 million by 2023 **(**1**)**. These implantable cardiac devices have improved quality of life and saved lives by supporting symptomatic bradycardia, improving atrioventricular and biventricular synchronization and preventing sudden cardiac death.

Currently, device implantation involves placing the subendocardial lead in the right ventricle (RV) by crossing the tricuspid valve (TV). The association between RV lead implantation via the TV followed by worsening of TR severity has been shown **(**2**)**. Trivial tricuspid valve regurgitation (TR) is considered physiological, however moderate and severe TR is associated with increased mortality and morbidity in terms of worsening heart failure and recurrent hospital admissions **(**3**)**.

Knowledge of the mechanism of lead-induced TR and differentiating it from secondary tricuspid regurgitation aids in the proper management of the condition. In vivo and post-mortem studies have shown the possible mechanisms of lead-induced TR such as impingement, adherence, laceration, or perforation of leaflets and also interfering with sub valvular apparatus **(**4**)**. Studies focusing on the evaluation of device leads as a cause for worsening TR, the clinical impact of worsening TR, and also whether CRT can prevent TR are ongoing **(**5**)**.

Early detection of the device leads induced TR as well as differentiating it from secondary cause is important as this can change the management e.g. lead extraction or surgical repair of the TV.

Our hypothesis was that implantation of endocardial device lead by crossing the tricuspid valve will result in an increase in tricuspid regurgitation when patients are followed over a period of time.

Methods

Retrospective data was collected from all patients who underwent PPM, ICD and CRT implantation from January 2012 to April 2014 in our cardiac center. Patients without echocardiography data and those who only underwent PPM or ICD generator replacement without the lead implantation were excluded.

Transthoracic echocardiography data for patients before and at 1, 2, and 5 years after the device implantation was obtained. Analysis of pre and post-procedural echocardiography data was done and

TR was graded qualitatively by color Doppler and Continuous-wave signal density as follows: Grade 0 = No TR or trivial TR (unable to detect or trace of color Doppler / CW Doppler signal), Grade 1 = mild TR (small central TR jet/ faint, parabolic CW signal), Grade 2=moderate TR(Intermediate TR jet/dense parabolic CW signal) and Grade 3=severe TR (Very large central jet or eccentric wall impinging jet / Dense triangular CW signal with early peaking) **(**6**)**.

Statistical analysis was done by using the Sign test with IBM SPSS 25.0 software to assess the significance of the change in TR severity 1, 2 and 5 years after the procedure and compared with pre-procedural TR.

Results

148 patients underwent device lead implantation.85 patients were excluded from the study due to inadequate data (73 patients did not have required echocardiography data, 7 patients had only generator replacement, 5 patients did not have proper RV lead information). A total of 63 patients included in the study. The mean age was 63.3±3.88 years. 33 (52.3%) patients were male, 30 (47.6%) patients were female. 65% (41 patients) underwent pacemaker implantation, 33.3% (21 patients) underwent ICD implantation and 1.5% (1 patient) underwent CRT device implantation.

Echocardiographic data of severity of TR before and 1, 2, 5 years after the procedure were analyzed. (**Table 1**)).

Severity of TR	TR before procedure		TR 1 year after procedure		TR 2 years after procedure		TR 5 years after procedure	
Grade 0	27	42.8%	12	38.7%	18	43.9%	7	18.9%
Grade 1	19	30.1%	12	38.7%	9	21.9%	14	37.8%
Grade 2	15	23.8%	6	19.3%	9	21.9%	11	29.7%
Grade 3	2	3.1%	1	3.2%	5	12.1%	5	13.5%
Total Cases	63		31		41		37	

Table 1: Distribution of Tricuspid valve regurgitation (TR) severity in the study group before and after the procedure

TR severity before the device lead implantation was as follows; 27 patients (42.8%) had no/trivial TR (Grade 0), 19 patients (30.1%) had mild TR (Grade 1), 15 patients (23.8%) had moderate TR (Grade 2), 2 patient (3.1%) had severe TR (Grade 3).

Of the 63 patients, 31 patients had echocardiography data after 1 year of the procedure. (**Figure 1**). 20 patients (64.5%) did not show any change in TR severity, in 7 patients (22.5%) there is a 1-grade increase in TR severity, no patients showed a 2 or 3-grade increase in TR severity. 2 patients who had mild TR resolved completely post-procedure. 1 patient who had moderate TR and another with severe TR showed a decrease in 1 grade of TR post-procedure. However, there is no statistically significant increase in TR severity 1year post-procedure (p= 0.549).

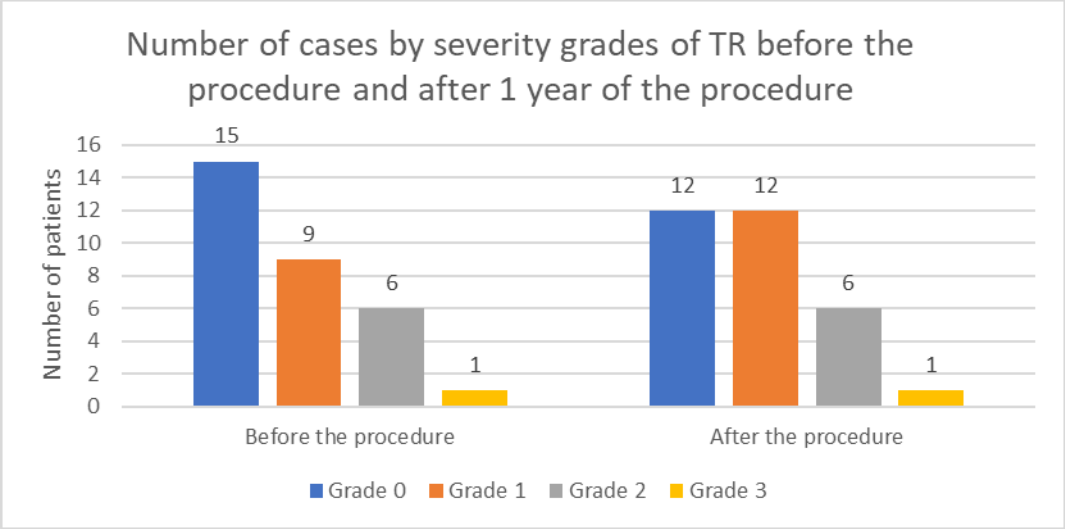

Figure 1.

41 patients had echocardiography data at 2 years post-procedure. (**Figure 2**). 19 patients (46.3%) showed no change in TR severity, in 10 patients (24.3%) there is a 1-grade increase in severity, 4 patients (9.7%) showed a 2-grade increase in TR severity. 5 patients (12.1%) with mild TR and 2 patients (4.8%) with moderate TR before the procedure showed trivial or no TR 2 years post-procedure.1 patient with severe TR became moderate TR 2 years post-procedure. All the above changes did not show any statistically significant increase in TR severity (p =0.286).

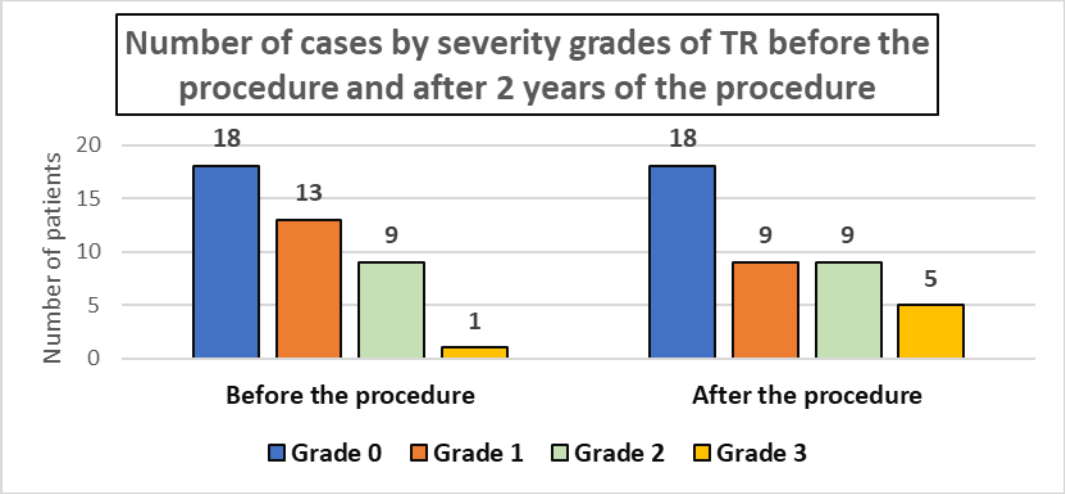

Figure 2

37 patients had echocardiography data 5 years post-procedure. (**Figure 3**). Among them,15 patients (40.5%) did not show any change in TR severity, 12 patients (32.4%) showed a 1-grade increase, 8 patients (21.6%) showed a 2-grade increase in TR severity. 1 patient with moderate TR and another with mild TR before the procedure showed trivial or no TR 5 years post-procedure. There is a statistically significant increase in TR severity 5 years post-procedure when compared with TR severity before the procedure (P-value 0.0004)

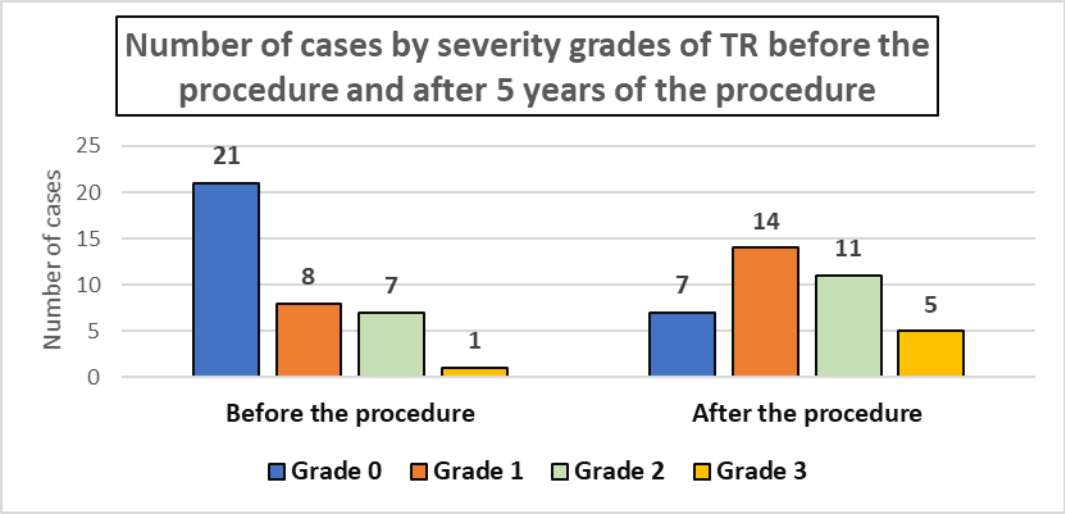

Figure 3

While comparing different devices and their impact on TR after 5 years of device implantation, out of 26 patients who had PPM, 17 patients (65.3%) had at least 1-grade increase in TR severity, whereas among patients who underwent ICD (total 10 patients) 4 patients (40%) showed at least 1-grade increase in TR severity. The changes were not statistically significant (p =0.440)

The difference in TR prevalence in gender 5 years post-procedure was as follows: 5 male patients (28%) out of 18 and 9 female patients (47%) out of 19 had no change in TR severity. 12 male patients (67%) vs. 9 female patients (47%) had at least a 1-grade increase in TR when compared to pre and 5 years post-procedure.1 male patient who had moderate TR and 1 female patient who had mild TR prior to the procedure had completely resolved TR at 5 years post-procedure. This difference in TR severity was not significant (p =0.219).

Discussion

There was no significant increase in TR severity 1 and 2 years post-procedure when compared with respective pre-procedure echocardiography data. The significant increase in TR severity at least by 1 grade was only noted 5 years post-procedure echocardiography. (2 patients who had mild TR pre-implantation of the device developed severe TR after 5 years and 6 patients who had no/trivial TR at baseline developed moderate TR). This difference in the time course could be possibly due to progressive fibrosis, thickening of the leads and impingement of valve leaflets over a long course of time or due to underlying disease process.

Early progression of TR was not seen and this excludes implantation technique-related causes of TR.

The prevalence of an increase in TR severity grade was more in patients who underwent PPM compared to those who had ICD implantation. This difference was however not significant. This finding is contrary to most of the retrospective studies which showed a higher incidence of worsening TR in patients with ICD lead compared to PPM lead due to its thickness and stiffness **(**4**)**, however, these findings in our study could be possibly due to disparity in the sample size of PPM and ICD patients and the use of new smaller ICD lead devices which are available in the recent years.

There is a difference in the distribution of TR among the gender in our study. Male patients had more TR post-procedure compared to female patients. This difference was again not significant.

Conclusion

There was a significant increase in TR severity at least by 1 grade when compared with baseline to 5 years post-procedure echocardiography. These changes are not seen in the early follow-up echocardiography at 1 and 2 years post-procedure, which signifies that the device lead-induced TR is a progressive disease and needs long-term follow up.

Limitation of the study

Transthoracic echocardiography has a lower sensitivity for quantifying the severity of TR in case of device lead-induced TR due to interference of Doppler signal by the lead, eccentricity of the TR jet. One of the studies showed 63% sensitivity of transthoracic echocardiography for detecting device lead-related severe TR **(**2**)**. The lack of the control group and the indications of device implantation could have had an impact on finding the cause of worsening TR over the long period of follow-up. This could be looked at in subsequent studies.

Recommendations

Thorough screening to exclude the patients who have conditions predisposing them for secondary TR would give better and clear final results.

Future studies should focus on transoesophageal or 3D echocardiography with focussed TV views which are ideal imaging modalities for better delineation of the mechanism as well as the severity of the device lead-related tricuspid regurgitation and may aid in the decision of future device implantation techniques.

Future trends towards the device implantation may also change in terms of implanting leadless pacemakers or pacing without crossing the tricuspid valve like in His bundle pacing.

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