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Management of Cardiac Implantable Electronic Devices in Patients With Severe Symptomatic Tricuspid Regurgitation—Proposed Algorithm and Selected Case Examples

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ABSTRACT

Severe tricuspid regurgitation (TR) is associated with significant morbidity and mortality. Management of severe TR includes treatment of the underlying cause(s), medical therapy and less commonly surgical tricuspid valve repair. Newer transcatheter tricuspid valve repair devices show promise for those patients who remain symptomatic with severe TR despite such efforts. The presence of a Cardiac Implantable Electronic Device (CIED) with leads across the tricuspid valve poses a significant challenge from both diagnostic and therapeutic standpoints. In this paper, we propose an algorithm to manage patients with CIED leads across the tricuspid valve and symptomatic TR. We include case studies to illustrate implementation of the algorithm in clinical care.

Key takeaway messages: (1) CIED leads across the tricuspid valve (TV) in the setting of TR are often innocent but may be causal and/or interfere with valve imaging. (2) CIED lead extraction often does not reduce TR and is reserved for select patients. (3)Transcatheter TV interventions can be performed in the presence of CIED leads. (4) An algorithm-driven interventional cardiology, electrophysiology and advanced imaging team approach is needed to best manage TR in the setting of CIED leads.

1 | Background

Tricuspid regurgitation (TR) is classified as primary or secondary [1]. Primary TR etiologies include congenital heart disease, leaflet prolapse, rheumatic disease, carcinoid disease, infective endocarditis, and valvular injury [2]. Secondary TR, the most common form, results from annular dilatation and annular flattening due to right ventricular (RV) and/or right atrial dilatation; often due to left heart disease or longstanding atrial fibrillation (AF). TR occurs in 5%–20% of the general population and is associated with up to a 63.9% reduction in 1-year survival [3–5]. TR is also associated with high morbidity, including progressive RV dysfunction, volume overload, liver cirrhosis, and renal impairment.

2 | Medical Management of TR

Medical management of symptomatic severe TR includes diuretics to relieve systemic congestion and volume overload. In secondary TR, therapies to address the underlying cause of heart failure (HF) are recommended. Guideline Directed Medical Therapy (GDMT) is effective for secondary TR caused by left-sided HF. While TR attributed to annular dilatation from AF may benefit from restoration of normal sinus rhythm, such efforts may prove ineffective when the AF is longstanding [6].

3 | Surgical and Percutaneous Interventions for TR

Surgical TV repair is a class I indication for patients with symptomatic severe TR undergoing left-sided valve surgery.

Isolated TV surgical repair, although rarely performed, has a class IIa indication for patients who continue to have severe TR and remain symptomatic despite medical therapy. Despiteinterest in surgical intervention before the onset of severe RV dysfunction or end organ damage to liver and kidney [7–9], The associated high surgical risk and elevated intra- and post-operative morbidity and mortality remain challenging [10, 11]. Percutaneous therapies, including tricuspid transcatheter edge-to-edge repair (T-TEER) and transcatheter tricuspid valve replacement (TTVR), have become alternative options for high-risk surgical patients. The landmark TRILUMINATE trial demonstrated exquisite safety, significant reductions in TR severity, and improved quality of life using the TriClip system (Abbott Vascular) [12]. The TRISCEND II trial found that TTVR with the EVOQUE system (Edwards Lifesciences, Irvine, CA, USA) demonstrated excellent reduction in TR severity with improvement in New York Heart Association (NYHA) classification and quality of life [13]. One year follow-up data from the TRISCEND II showed substantial sustained improvement in patient symptoms, function and quality of life [14]. Existing CIED leads across the TV was not an exclusion criterion in either trial and a significant minority of patients in both trials had CIEDs.

4 | Lead-Related TR

Between 25% to 29% of patients with CIED have TR, and multiple studies have observed worsening TR after implantation of a Permanent Pacemaker (PPM) or Implantable Cardiac Defibrillator (ICD) [15–17].

New or worsening TR after lead placement can occur through different mechanisms, including direct trauma to the leaflets or valvular apparatus during insertion [18–20]. Lead tethering, impingement, entrapment, or entanglement with papillary muscles or chordae tendineae can also increase TR. Other causes include restricted movement of valve leaflets, abnormal coaptation, adhesion, and fibrosis [21, 22].

The septal leaflet of the TV is most frequently impinged. Implantation of the lead between the posterior and septal TV leaflets can confer greater risk of interference with the TV apparatus [23, 24]. Additionally, the inflammatory response resulting from neo-endocardium formation results in adhesion and fibrosis within TV leaflets, further increasing TR [25]. Pacing-induced cardiomyopathy, worsening left ventricular systolic function, worsening pulmonary artery systolic pressure, or tricuspid annular dilatation can alter right ventricular geometry, eventually leading to increased TR [26].

5 | Transvenous Lead Extraction

Transvenous lead extraction is one option for management of lead-related TR; however, no prospective data are available on indications for transvalvular lead removal in patients with severe TR. In a study of 24 patients with lead-related TR, improved TV function was noted in 63% of patients after lead extraction [27]. Another, larger study of 2678 patients showed TR reduction in 35.3% of patients [28]. In a study of 208 patients with 266 ventricular leads, a 37% reduction of TR to mild or moderate was noted after lead extraction [29]. While selection bias likely explains some of these findings.

In a recent meta-analysis of laser lead extraction with over 1700 patients, procedural success rate was 96.8% per patient and 96.3% per lead, clinical success rate was 98.3%, with a procedure-related death rate of 0.08% [30]. Major and minor complications both occurred at a rate of 1.9% [28]. Evidence supports improved outcomes at high-volume extraction centers defined in one study as those performing more than 30 extractions per year [31].

The safety of lead extraction and risk of major complications, including lead-dwell time and comobrid medical conditions, must be considered. Additionally, Lead extraction may lead to worsening of TR. TV damage is especially pronounced for leads with prolonged dwell time, which leads to more fibrosis and scarring. In a study with 208 patients and 237 ventricular leads removed, traumatic TR occurred in 9.1% of patients and was severe in 0.06% of patients [32]. In another study with 2631 patients in high-volume extraction centers, the incidence of TR severity progression was 9.7% and 2.6% experienced significant worsening [33].

6 | Considerations for Percutaneous TV Interventions in Patients With Transvalvular Lead

The first consideration is to assess whether TR is caused by interaction between the lead and the valve as discussed above. If so, then patients should be evaluated for transvenous lead extraction, especially if lead implantation was relatively recent.

The anatomic feasibility of TV interventions in the presence of transvalvular leads must also be considered. It is notable that 16% of patients enrolled in the TRILUMINATE trial and 38.2% of patients in the TRISCEND II trial had existing transvalvular leads that were not removed before device implantation. Additionally, the incidence of existing transvalvular leads across several studies ranged from 3% to 33% in T-TEER and 14%–36% in TTVR [34–38]. For T-TEER, it is important to evaluate location of the lead in relation to the valve leaflets. Patients with leads that have no involvement with the TR jet ("Innocent leads") may be considered for T-TEER without the need for lead extraction. On the other hand, some may need extraction before T-TEER [39].

7 | Lead Entrapment

Lead entrapment or "jailing" is an important consideration in patients undergoing evaluation for TTVR. Lead extraction may not be an option for these candidates, for example when valve leaflets have adhered to the lead. Risks associated with lead entrapment include lead failure and subsequent lead infection, which preclude future lead extraction; however, data on long-term outcomes of lead condition after TTVR are lacking. In a study of 329 patients undergoing TTVR, 28 patients had RV lead entrapment, one of whom experienced RV lead displacement during the procedure, and two had lead failure during follow-up [40].

Strict infection control is important to prevent lead infection. The risk of CIED-related infections is estimated to be 4.7 per

1000 person years [41]. Risk factors include advanced age and poor renal function [42]. Patients with an infected CIED who are on chronic suppressive antibiotics have high mortality, reaching more than 50% at one year [43].

8 | Lead-Related Imaging Artifacts

CIED leads can cause significant artifacts in both pre-procedural and intra-procedural imaging. From an echocardiography standpoint, leads can cause both reverberation artifact and acoustic shadowing, which can affect valve assessment during pre-procedural planning [44]. T-TEER requires accurate en-face views of the tricuspid apparatus either in the transgastric view or 3D view of the TV. Leads situated more posteriorly are likely to cause significant artifact, preventing accurate assessment of the more anterior anatomy. From a Computed Tomography (CT) perspective, pacemaker leads will cause metal artifact—a combination of beam-hardening artifact, photon starvation, and scatter artifact—which can obscure anatomy and make TV assessment imprecise [45]. Left bundle branch area pacing, in which the pacemaker lead is placed closer to the TV annulus, is becoming more prevalent and is more likely to cause these issues [46].

Intra-procedural imaging may be unable to distinguish between CIED leads and delivery system catheters. For T-TEER, acoustic shadowing from the CIED lead can make it difficult to visualize the leaflets for adequate tissue grasp. Shadowing can obstruct the view of the anterior leaflet in the mid-esophageal four-chamber view or the transgastric view. Shadowing can also obstruct the view of the posterior leaflet depending on the location of the lead and the TR jet. For TTVR, visualizing adequate capture of all tricuspid leaflets with the anchors is similarly affected by CIED leads. Overall, these challenges can increase the procedure length and require increased operator and imager experience. Other investigation TTVR devices may or may not have similar limitations.

9 | Non-Transvalvular CIED Alternatives

In patients who require lead extractions or who develop indications for CIED after TV interventions, nontransvalvular devices should be considered. Pacing options include a leadless RV pacemaker (Micra, Medtronic Minneapolis, MN) or dual chamber pacemaker (AVEIR, Abbott, Abbott Park, IL). Although it has been proposed that leadless pacemakers are associated with TV dysfunction, more data are needed to further elucidate this relationship [47]. Furthermore, given the large sheath size used in leadless pacemaker implantation, it would be preferable to implant the device before TV intervention to avoid potential valve damage. Additionally, it is not known whether a leadless pacemaker would cause difficulties with future percutaneous valve interventions due interactions between the implanted device and the pacemaker. Other options for nontransvalvular pacing include coronary sinus lead implantation.

For patients who have an indication for a defibrillator, the team would need to consider whether this indication still exists. Options for nontransvalvular defibrillators include a subcutaneous, extravascular ICD or a lead placed in the coronary sinus. Additionally, for patients undergoing cardiac surgery, epicardial leads may be used (Figure 1).

10 | Proposed Algorithm for CIED Management in Patients With Severe TR

A heart team approach involving structural interventionist, advanced imager, electrophysiologist, heart failure specialist,

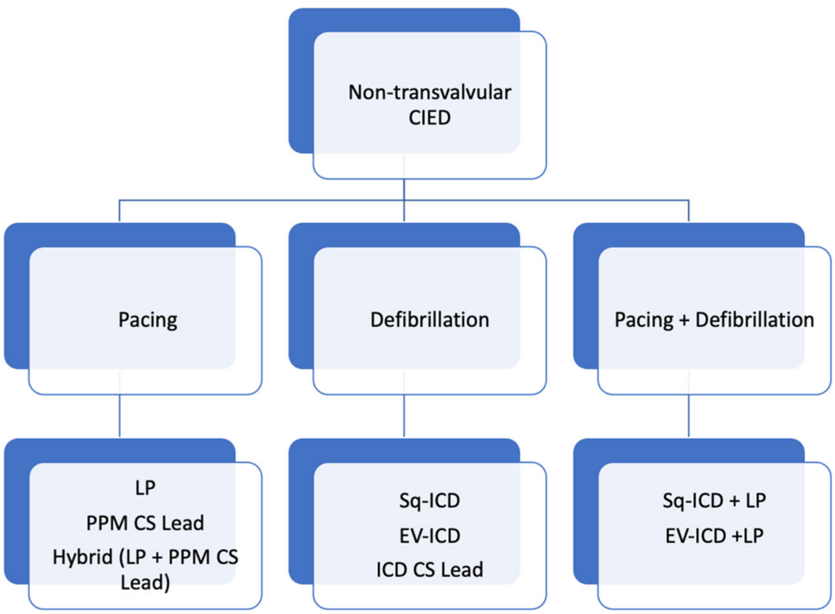

FIGURE 1 | Alternative nontransvalvular CIED. Abbreviations: CIED, Cardiac Implantable Electronic Device; CS, Coronary Sinus; EV, Extravascular; LP, Leadless Pacing; PPM, Permanent Pacemaker; Sq-ICD, Subcutaneous Internal Cardiac Defibrillator. [Color figure can be viewed at wileyonlinelibrary.com]

and a cardiac surgeon is encouraged. After optimizing medical therapy in patients with severe TR, the anticipated efficacy and safety of treatment options should be evaluated.

The first step would be to assess lead-valve interactions. If the lead is judged to be the cause of the TR (i.e., due to impingement), then the patient's candidacy for lead extraction should be determined. If the patient is an extraction candidate, then the recommendation

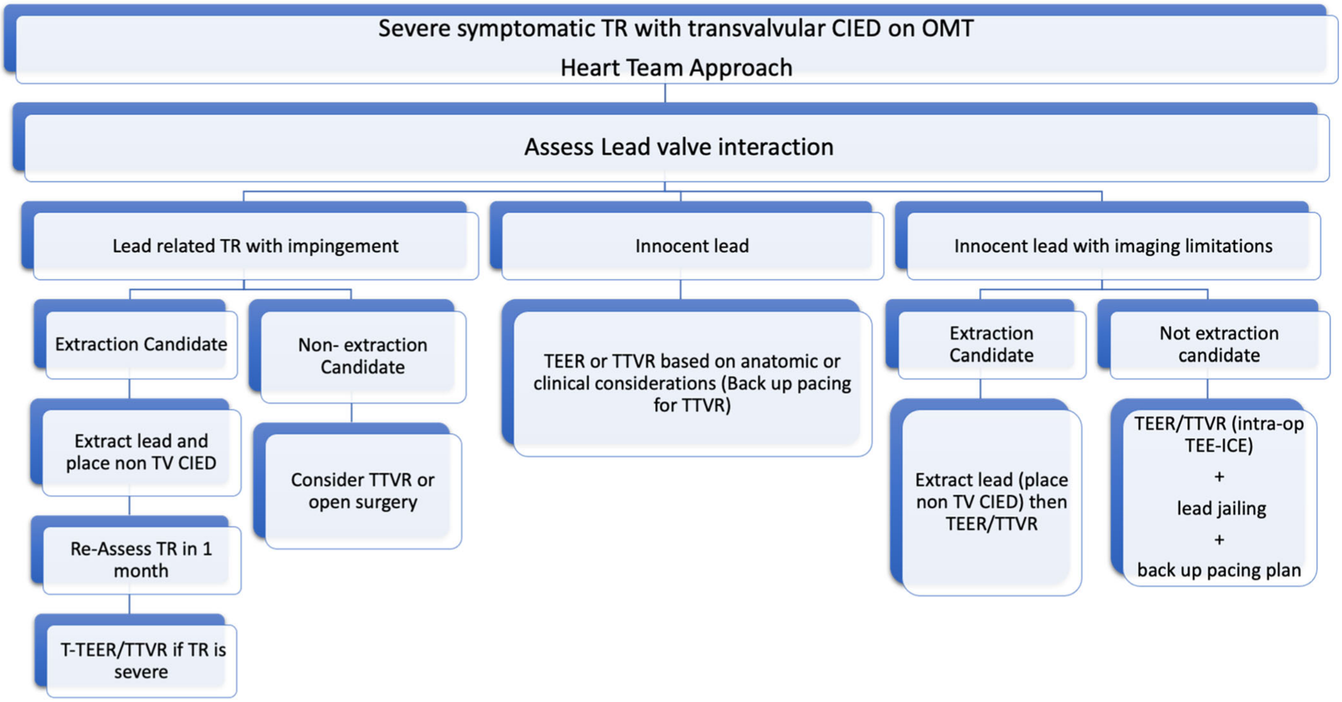

FIGURE 2 | CIED management in severe TR. Abbreviations: CIED, Cardiac Implantable Electronic Device; ICE, Intracardiac Echocardiography; OMT, Optimal Medical Therapy; TEE, Transesophageal Echocardiography; TR, Tricuspid Regurgitation; T-TEER, Transcatheter Tricuspid Edge to Edge Repair; TTVR, Transcatheter Tricuspid Valve Replacement; TV, Tricuspid Valve. [Color figure can be viewed at wileyonlinelibrary.com]

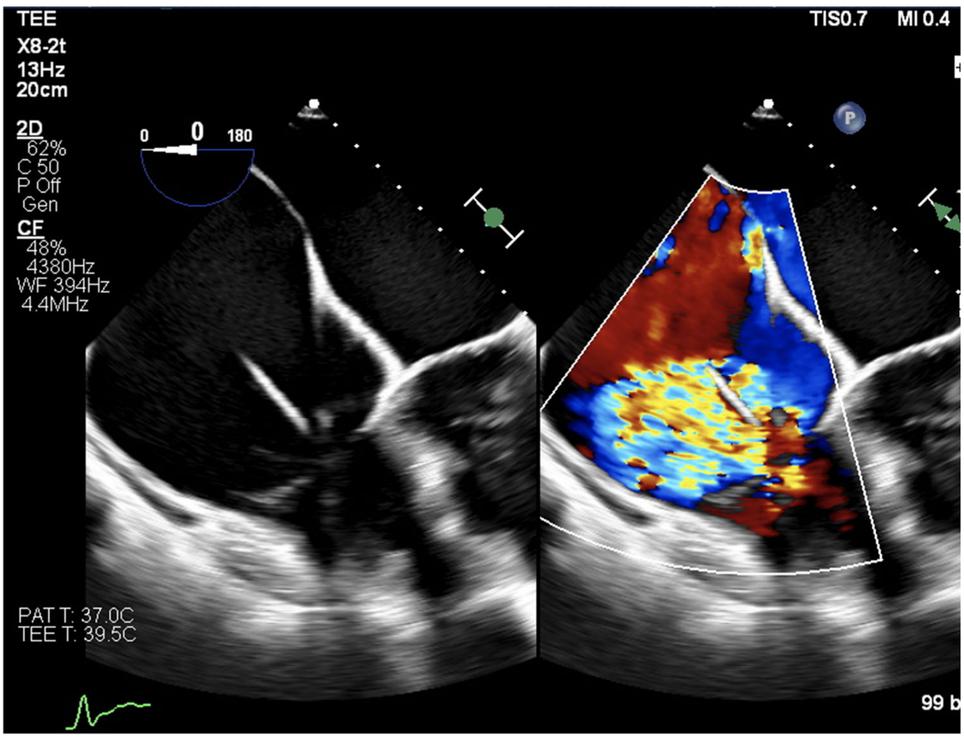

IMAGE 1 | Mid Esophageal 4 chamber view TEE-TR origin appears to be near pacing lead. [Color figure can be viewed at wileyonlinelibrary.com]

would be to extract the lead, place a non-TV device (if the indication for the device still remains) and reassess TR in one month. If TR continues to be severe at that point and the patient is symptomatic, then proceeding with T-TEER or TTVR is reasonable. Alternatively, If the patient is not a candidate for lead extraction, then T-TEER, if feasible or TTVR should be considered, if the risks of lead entrapement are acceptable. Additionally, the team should be ready to place a non-TV device if there is a postoperative lead failure or malfunction, if the indication for the device remains.

If the lead is judged to be innocent (i.e., not causing TR), and is not interfering with procedural imaging, T-TEER vs. TTVR

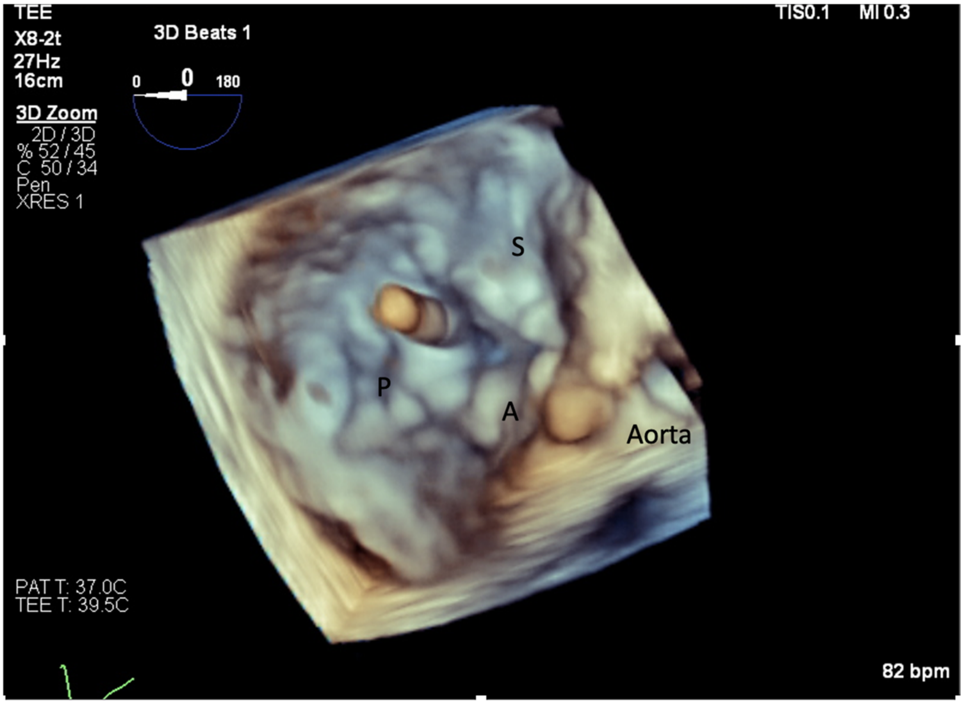

IMAGE 2 | TEE image of three dimensions (3D) tricuspid valve. Note the pacer lead is between the septal and posterior leaflets. A: Anterior Leaflet, P: Posterior Leaflet, S: Septal Leaflet. [Color figure can be viewed at wileyonlinelibrary.com]

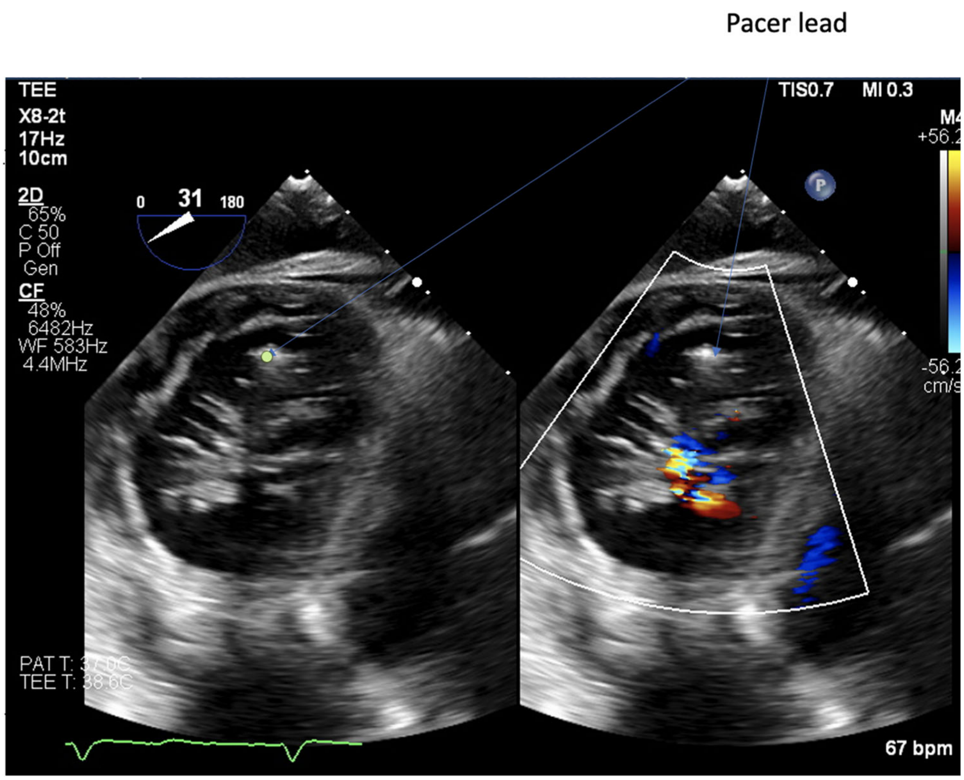

IMAGE 3 | Transgastric TEE showing pacemaker lead away from the TR jet. [Color figure can be viewed at wileyonlinelibrary.com]

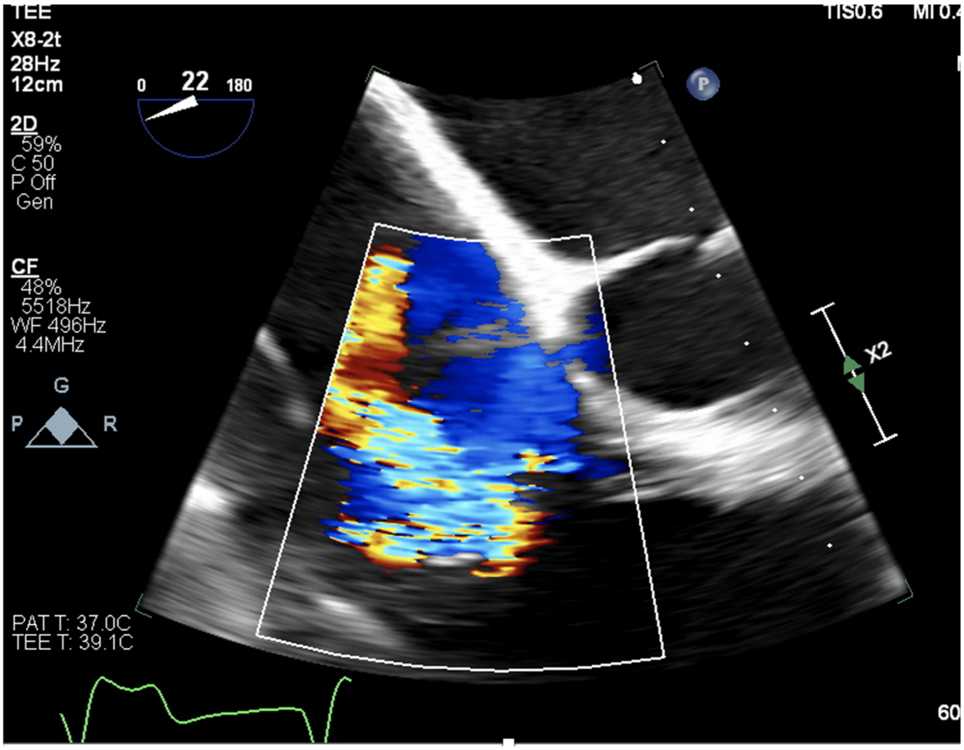

IMAGE 4 | Mid esophageal TEE view. Note how the pacemaker wire is not in the plane of TR Jet. [Color figure can be viewed at wileyonlinelibrary.com]

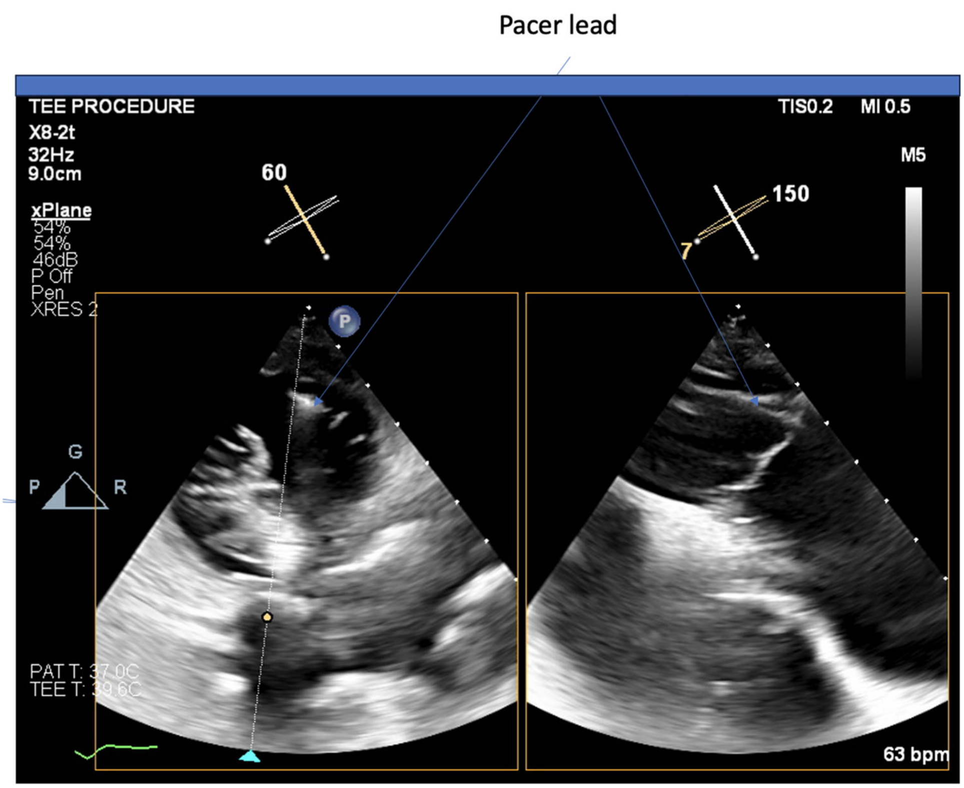

IMAGE 5 | Note how due to shadowing, cannot adequately visualize how ventricular the TEER device is on biplane view from transgastric tricuspid short axis view. [Color figure can be viewed at wileyonlinelibrary.com]

candidacy should be considered. If the patient is a T-TEER candidate, then proceeding with T-TEER is reasonable. If undergoing TTVR, the possibility of lead malfunction should be considered.

If the lead is judged to be innocent but is causing significant shadowing and artifact, extraction candidacy should be evaluated followed by placement of non-TV CIED, then T-TEER or TTVR. If extraction is not feasible, then a combination of

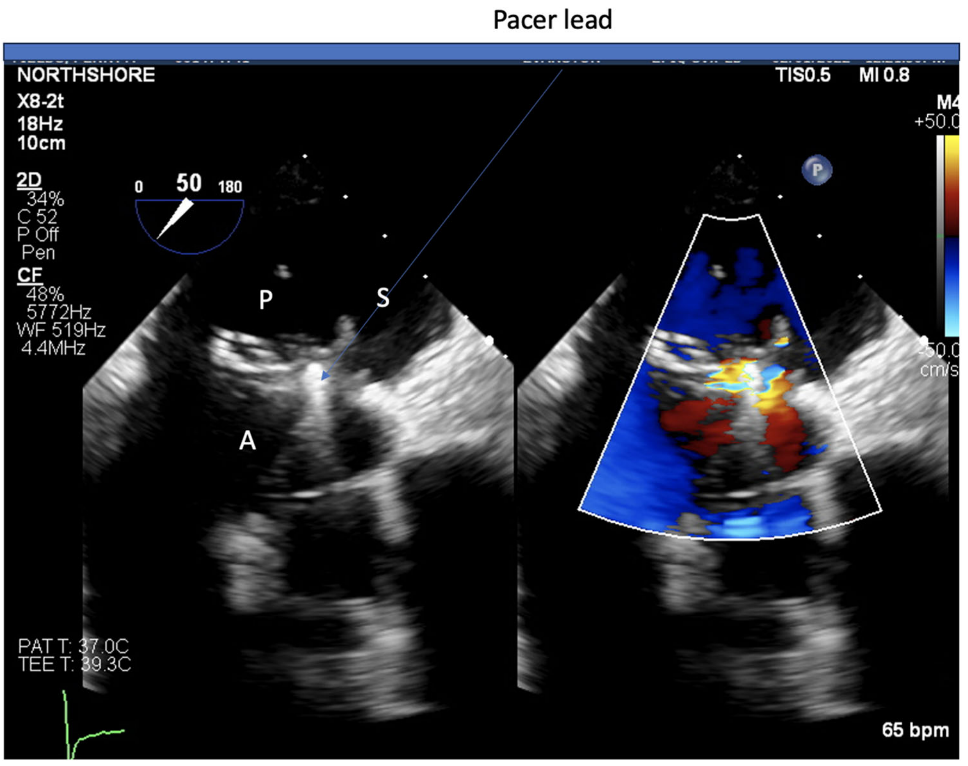

IMAGE 6 | Short axis transgastric TEE view. Pacemaker lead seen to be impinging on septal leaflet of the tricuspid valve. A: Anterior Leaflet, P: Posterior Leaflet, S: Septal Leaflet. [Color figure can be viewed at wileyonlinelibrary.com]

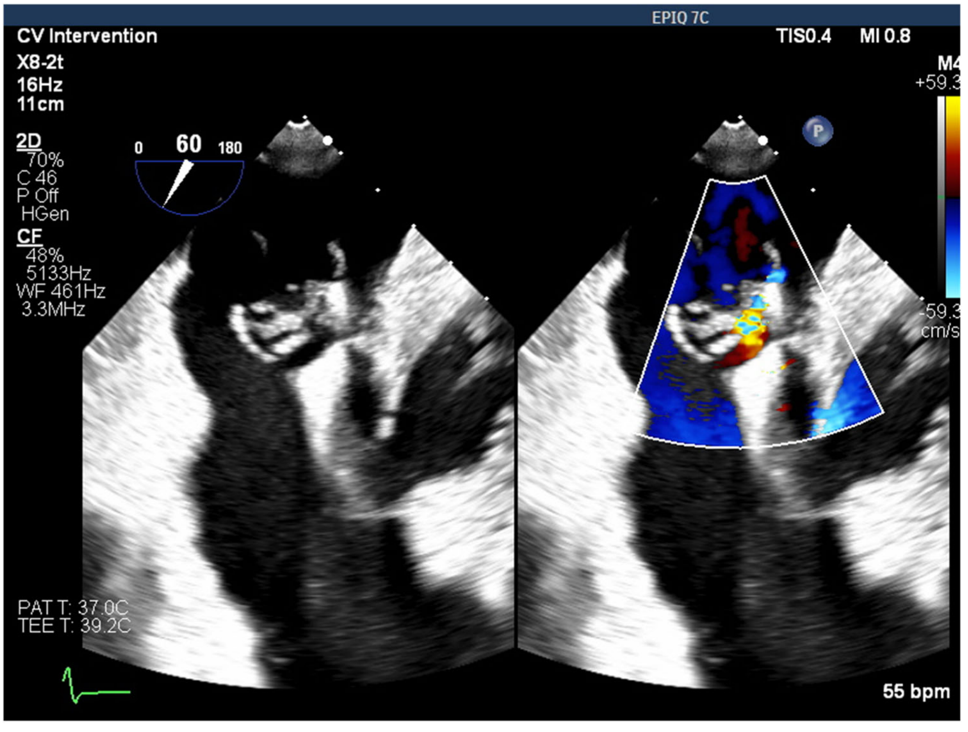

IMAGE 7 | T-TEER device placed anterior to the lead. [Color figure can be viewed at wileyonlinelibrary.com]

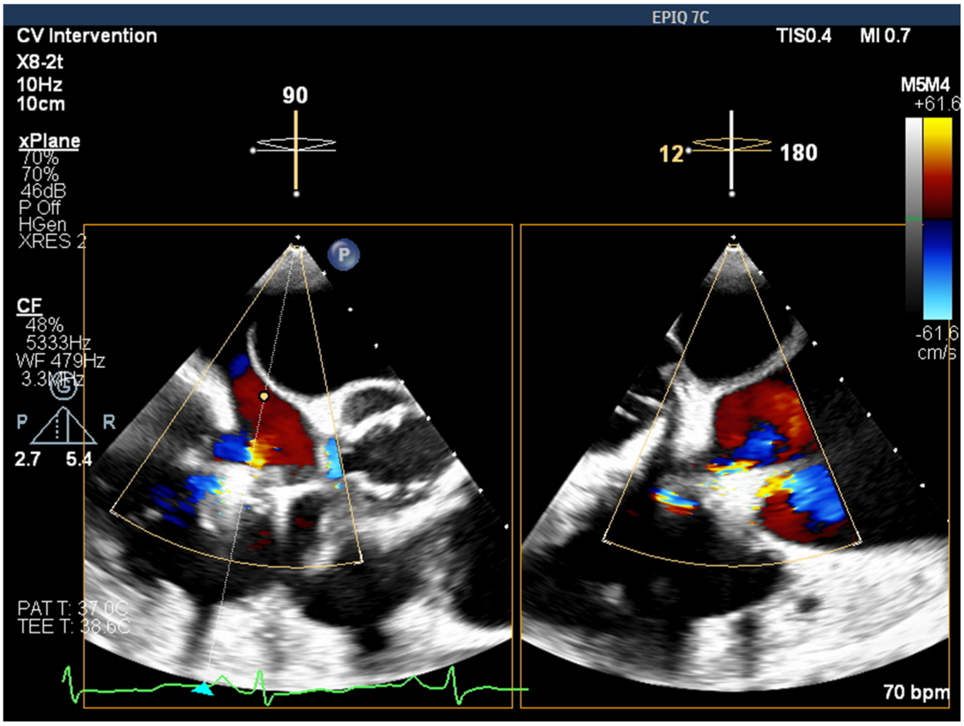

IMAGE 8 | Reduction in TR from severe to mild-moderate. [Color figure can be viewed at wileyonlinelibrary.com]

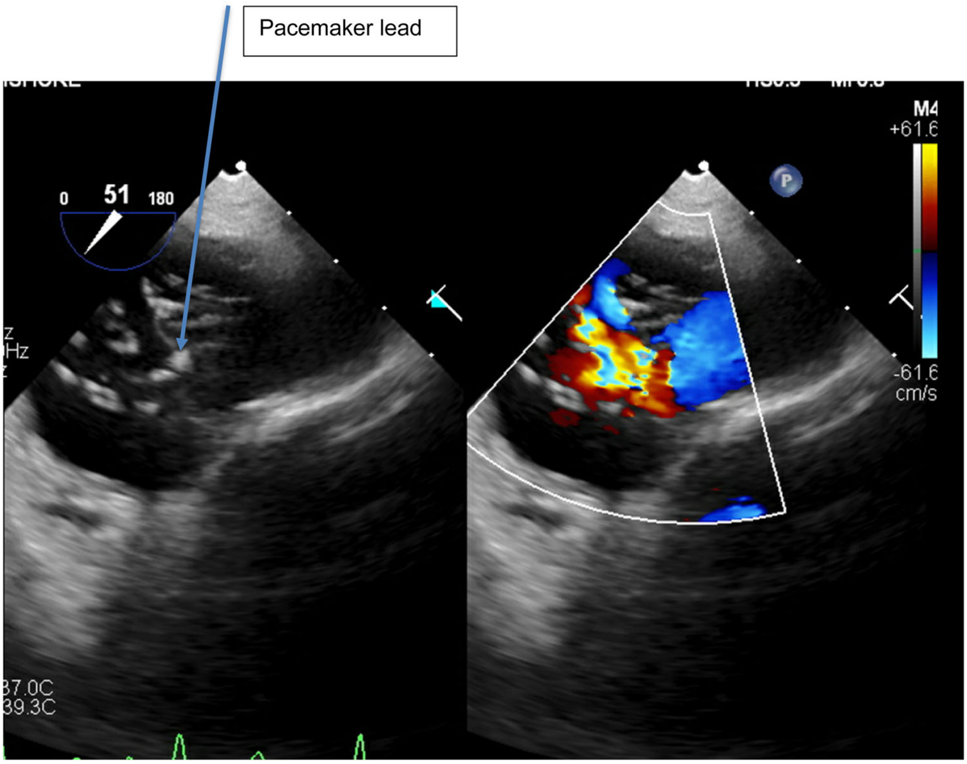

IMAGE 9 | Transgastric TEE image showing severe TR due to malcoaptation of septal and anterior leaflets and pacemaker lead tethered to the septal leaflet. [Color figure can be viewed at wileyonlinelibrary.com]

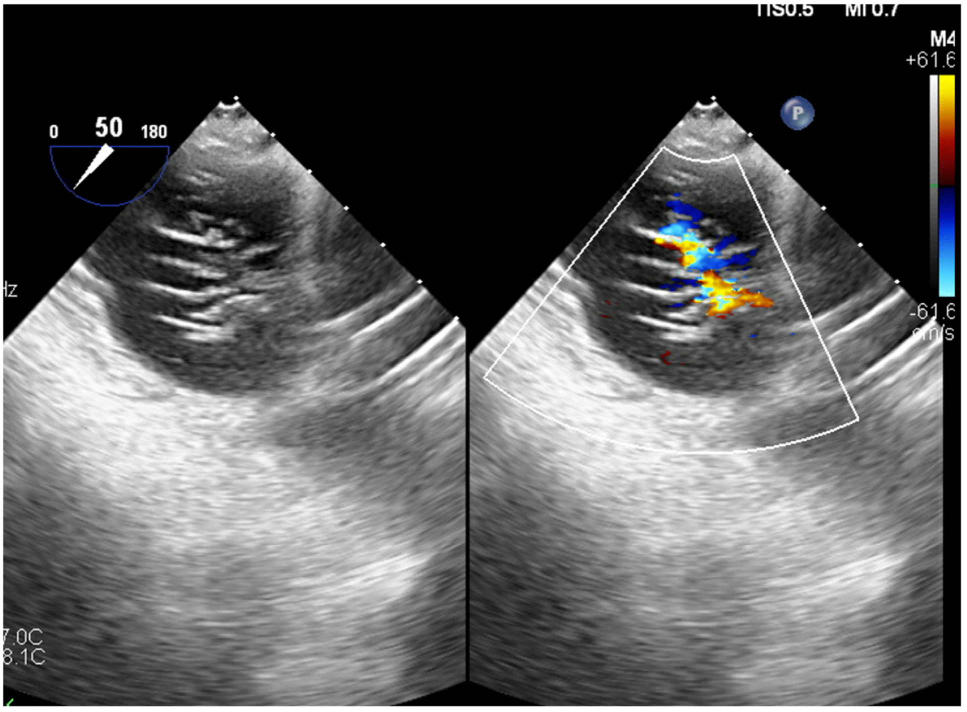

IMAGE 10 | Transgastric TEE showing severe TR despite lead removal- Septal leaflet is no longer impinged and coaptation gap has been reduced. [Color figure can be viewed at wileyonlinelibrary.com]

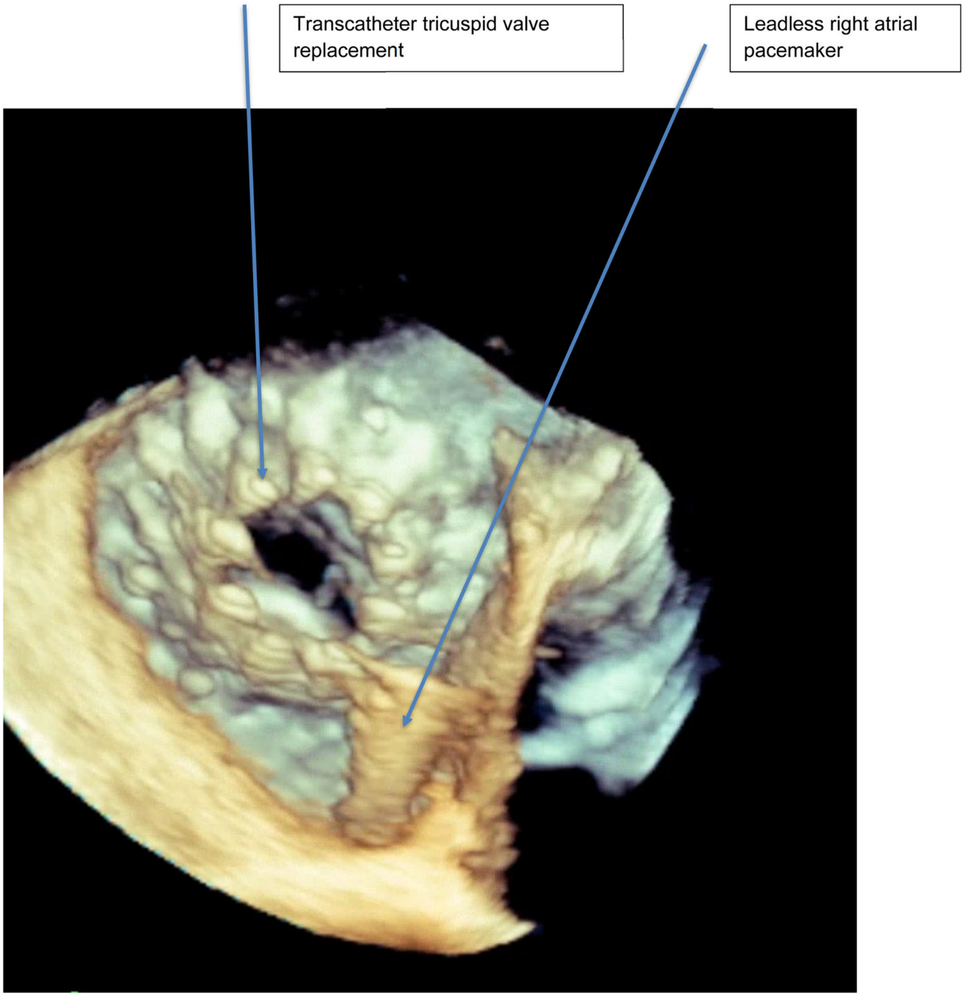

IMAGE 11 | Mid esophageal TEE image showing transcatheter tricuspid valve replacement (Evoque system)- Leadless right atrial pacemaker in place. [Color figure can be viewed at wileyonlinelibrary.com]

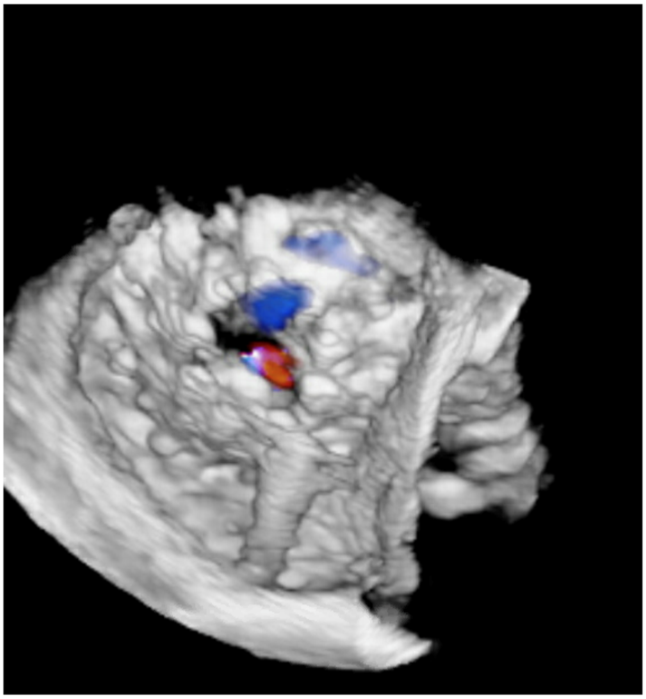

IMAGE 12 | Mid esophageal TEE image showing transcatheter tricuspid valve replacement (Evoque system) with trace TR. [Color figure can be viewed at wileyonlinelibrary.com]

intracardiac echocardiography (ICE) in addition to TEE imaging should be considered. A backup pacing plan should be in place in case of lead failure (Figure 2).

11 | Case Examples

11.1 | Case 1: Lead-Related TR Improvement After Lead Extraction

A 78-year-old male with a past medical history of AF, tachy-brady syndrome status post single chamber PPM (placed 12 years prior) and symptomatic severe TR. Transesophageal Echocardiogram images shown (Image 1) show lead-related TR. Device interrogation showed 0.1% pacing burden. Patient was an extraction candidate and lead was extracted. Repeat transthoracic echocardiogram (TTE) showed improvement in TR from severe to moderate. His symptoms improved and TV intervention was no longer indicated. Patient was monitored for pacing needs and no pacing device was placed as the patient did not require any pacing post extraction (Image 2).

11.2 | Case 2: Innocent Lead Causing Shadowing

An 89-year-old male with a past medical history of cardiac amyloidosis, paroxysmal atrial fibrillation status post ablation, sick sinus syndrome status post single chamber PPM implanted 10 years prior and severe symptomatic TR. TEE imaging (Images 3 and 4) demonstrated an innocent pacemaker lead not impinging on TV leaflets. Lead shadowing was seen preoperatively. Lead extraction was considered, however, the patient was not a candidate for lead extraction. The patient underwent T-TEER. Shadowing was also seen intraoperatively (Image 5). Combination of TEE and ICE was used for imaging. T-TEER was successful, resulting in reduction of TR from severe to mild.

11.3 | Case 3: Lead Related TR and Successful TEER Despite Lead Remaining In-Situ

An 80-year-old female with a past medical history of nonischemic cardiomyopathy and ventricular tachycardia status post internal cardiac defibrillator who has severe symptomatic TR which was lead related (Image 6). Lead extraction was considered but she was not deemed to be a candidate. She underwent T-TEER with jailing of the lead (Image 7). TR improved from severe to mild-moderate (Image 8).

11.4 | Case 4: Lead Related TR in a Pacemaker Dependent Patient Who did not Improve After Lead Extraction Followed by TTVR

A 76 years-old female with a past medical history of hypertension, surgical aortic valve replacement complicated by bioporosthetic aortic stenosis status post re-do sternotomy with mechanical aortic valve replacement, complete heart block status post dual chamber pacemaker (dependent) and severe symptomatic TR. TEE showed severe TR due to malcoaptation of the septal and posterior leaflets due to pacemaker lead that is tethered to the septal leaflet (Image 9). She was referred for laser lead extraction followed by a dual chamber leadless pacemaker (Aveir, Abbott TM). However, she continued to have symptomatic TR which progressed to torrential despite lead extraction (Image 10). She then received a TTVR (Evoque system- Edwards life sciences) resulting in TR improvement to mild and symptomatic relief (Images 11 and 12).

Conflicts of Interest

Mark Metzl, Consulting fees from Abott, Atraverse, Biosense Webster, Boston Scientific, Haemonetics, Phillips, Medtronic, Sanofi and Zoll Medical. Mark Ricciardi, Consulting and speaker fees Abbott Vascular. The other authors declare no conflicts of interest.

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