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STATE OF THE ART REVIEW

Lead management in patients undergoing percutaneous tricuspid valve replacement or repair: a 'heart team' approach

James K. Gabriels[1]*, Robert D. Schaller [2], Elana Koss[3], Bruce J. Rutkin[3], Roger G. Carrillo [4], and Laurence M. Epstein [1]

[1]Department of Cardiology, Zucker School of Medicine at Hofstra/Northwell, North Shore University Hospital, 300 Community Drive, Manhasset, NY, USA; [2]Electrophysiology Section, Division of Cardiovascular Medicine, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA, USA; [3]Department of Cardiovascular and Thoracic Surgery, Zucker School of Medicine at Hofstra/Northwell, North Shore University Hospital, Manhasset, NY, USA; and [4]Cardiothoracic Surgery, Palmetto Hospital, Miami, FL, USA

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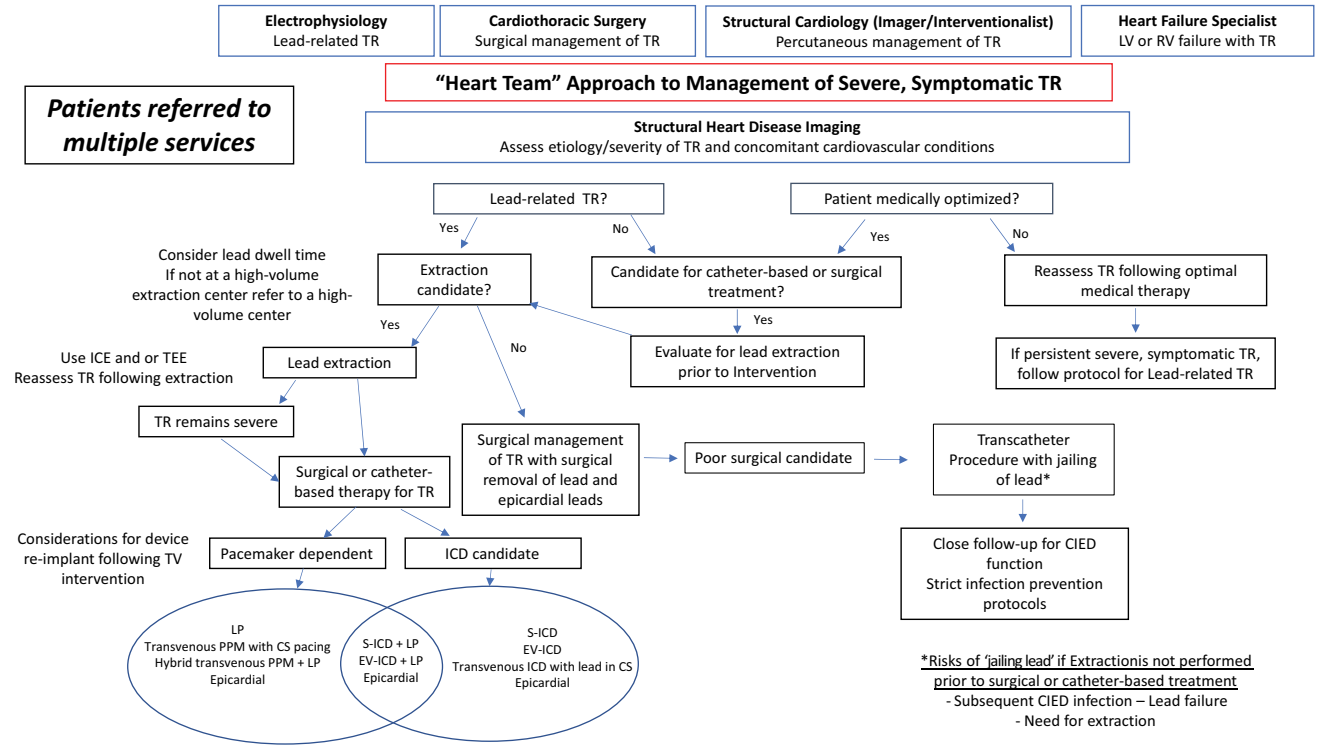
Abstract

Clinically significant tricuspid regurgitation (TR) has historically been managed with either medical therapy or surgical interventions. More recently, percutaneous trans-catheter tricuspid valve (TV) replacement and tricuspid trans-catheter edge-to-edge repair have emerged as alternative treatment modalities. Patients with cardiac implantable electronic devices (CIEDs) have an increased incidence of TR. Severe TR in this population can occur for multiple reasons but most often results from the interactions between the CIED lead and the TV apparatus. Management decisions in patients with CIED leads and clinically significant TR, who are undergoing evaluation for a percutaneous TV intervention, need careful consideration as a trans-venous lead extraction (TLE) may both worsen and improve TR severity. Furthermore, given the potential risks of 'jailing' a CIED lead at the time of a percutaneous TV intervention (lead fracture and risk of subsequent infections), consideration should be given to performing a TLE prior to a percutaneous TV intervention. The purpose of this 'state-of-the-art' review is to provide an overview of the causes of TR in patients with CIEDs, discuss the available therapeutic options for patients with TR and CIED leads, and advocate for including a lead management specialist as a member of the 'heart team' when making treatment decisions in patients TR and CIED leads.

* Corresponding author. Tel: +1 516-562-4100; fax: +516 562 3978. *E-mail address*: jgabriel13@northwell.edu

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Graphical Abstract



Flow diagram of a 'heart team' approach to managing severe symptomatic tricuspid regurgitation. CIED, cardiac implantable electronic device; CS, coronary sinus; EV-ICD, extravascular ICD; ICD, implantable cardioverter defibrillator; ICE, intra-cardiac echocardiography; LP, leadless pacemaker; LV, left ventricle; PPM, pacemaker; RV, right ventricle; S-ICD, subcutaneous ICD; TEE, trans-oesophageal echocardiography; TR, tricuspid regurgitation; TV, tricuspid valve.

Keywords Lead extraction • Tricuspid regurgitation • Trans-catheter tricuspid valve intervention

Introduction

Clinically significant tricuspid regurgitation (TR) has been reported to occur in 0.5–0.8% of the general population.[1,2] The prevalence of TR increases with age and is associated with increased mortality. Higher mortality rates in patients with moderate to severe TR are independent of both left ventricular ejection fraction and pulmonary artery systolic pressures.[1,3] Tricuspid regurgitation can arise due to primary abnormalities in the valvular apparatus but more commonly is due to secondary (functional) causes including left-sided heart disease, pulmonary hypertension, dilated cardiomyopathy, and persistent atrial fibrillation[4–6] and in patients with cardiac implantable electronic devices (CIEDs).[7] Medical management of severe secondary TR includes the use of diuretics, neurohormonal agents, and therapies for pulmonary hypertension.[6] One-year mortality rates for patients with severe TR who are managed using medical therapies alone range from 36% to 42%.[8,9] Class I recommendations for surgical intervention of severe functional TR are limited to patients undergoing left-sided valve surgery.[10,11] Retrospective data suggest that there is improved mortality in patients with severe TR and congestive heart failure who are managed surgically.[12] Given the intra-operative and peri-operative risks associated with surgical management of severe TR in patients with right ventricular (RV) failure and end-organ damage, only a subset of patients with severe TR are treated surgically.[6,13]

Therapies involving percutaneous tricuspid trans-catheter 'edge-to-edge' repair (T-TEER) or trans-catheter tricuspid valve replacement (TTVR) to treat severe TR have emerged as alternatives for patients with high operative risks. Trans-catheter leaflet repair has been demonstrated to safely reduce TR severity and improve clinical outcomes.[14–19] Limitations of leaflet repair techniques include suboptimal results in patients with significant leaflet tethering, patients with torrential TR, and those with a coaptation gap greater than 7 mm.[14,15,17] Initial studies involving TTVR have demonstrated safety and efficacy along with clinical improvements and low rates of mortality and hospitalizations for heart failure during short-term follow-up.[20–24] A significant number of patients requiring treatment of severe TR have CIED lead(s) traversing the tricuspid valve (TV). Data regarding the use of T-TEER or TTVR in this patient population are limited.[25–31] The purpose of this 'state-of-the-art' review is to provide an overview of the currently available data regarding TR in patients with CIEDs and outline management strategies for patients with CIEDs and severe TR. The manuscript will also emphasize the importance of using a 'heart team' approach when considering patients with CIEDs for percutaneous therapies to treat severe TR. We advocate for inclusion of a lead management specialist in the 'heart team' when evaluating patients with severe TR and CIEDs as performing a transvenous lead extraction (TLE) prior to a T-TEER or TTVR can (i) improve TR severity, possibly eliminating the need for a TV intervention if the TR is CIED lead related, (ii) further worsen TR severity, which may alter the decision regarding the optimal device/approach to treat the TR, and (iii) eliminate the risks associated with 'jailing' CIED leads.

Lead-related tricuspid regurgitation

Epidemiology and mechanisms of lead-related tricuspid regurgitation

Rates of moderate to severe TR are significantly higher in patients with CIEDs when compared to the general population.[7] The incidence of significant TR in patients with CIEDs ranges between 10–45% and 10–15% of all cases of TR are attributed to CIED leads.[32–35] With the aging population and increased use of CIEDs, the prevalence of lead-related TR will likely continue to rise. Tricuspid insufficiency in this population is associated with an increased rate of heart failure hospitalization and mortality.[3,32,36–38] Lead-related TR can be caused by damage to the valvular apparatus at the time of implant due to direct leaflet perforation or laceration[39–41] or RV papillary muscle perforation.[42] Additionally, and likely more commonly, lead-related mechanical tethering, impingement, or entrapment, along with lead entanglement in the sub-valvular apparatus (chordae tendineae and papillary muscles), can contribute to worsening TR.[40,42–44] As a RV lead traverses the TV, the septal leaflet of the TV is the most frequently impinged leaflet,[45,46] a non-commissural lead position has the greatest degree of interference with TV apparatus,[47,48] and severe TR occurs most often when the lead is implanted between the posterior and septal TV leaflets.[47] Over time, the interaction between the valvular apparatus and lead body can result in an inflammatory response, which causes a fibrotic encapsulation of the lead within the TV and can further limit leaflet mobility.[49–51] Other postulated causes of lead-related TR include changes in RV geometry due to pacing, pacing-induced cardiomyopathy with left ventricular systolic dysfunction that results in elevated pulmonary pressures, and tricuspid annular dilatation, along with chronic thromboembolism from lead-related thrombosis, which can cause pulmonary hypertension.[52–54]

Lead implant-related factors

Many lead implant-related factors impact the likelihood of valvular or sub-valvular trauma and valvular dysfunction. These factors include the type of fixation mechanism (active vs. passive), lead diameter, and the number of leads that are implanted across the TV.[7,33,41,55] Additionally, prolapsing the lead across the valve, when compared with directly crossing the TV apparatus at the time of implant, lowers the probability of damage to the valve.[56] The trajectory of the lead, position of the lead on the ventricular size of the valve (apical vs. septal), and lead slack are also all important considerations.[57] Initial data involving the use of 'physiologic' pacing with left bundle area pacing have been demonstrated to be superior to traditional biventricular pacing.[58,59] The impact of this approach on TV function could be positive by avoiding pacing-induced cardiomyopathy or negative if the septal lead placement interferes with valvular function. Initial studies suggest that the implant location remains an important consideration as a shorter distance between the implant site and the TV has been demonstrated to impact the degree of TR in left-bundle branch area pacing leads.[60,61] Once a lead traverses the TV and causes malcoaptation, the resultant regurgitation can cause progressive right-sided volume overload along with right atrial, RV, and tricuspid annular dilation. This pathophysiology can progress to the point where severe TR results in right-sided heart failure and increased morbidity and mortality.[32,36,62,63]

Other causes of tricuspid regurgitations in patients with cardiac implantable electronic devices

Lead-related TR is only one of many aetiologies of tricuspid insufficiency in patients with CIEDs. Tricuspid insufficiency may also arise for reasons unrelated to the CIED lead. Functional TR can result from left-sided valvular pathology, pulmonary hypertension, atrial fibrillation, and left or RV systolic dysfunction,[64] whereas primary TR can arise from abnormalities in the TV leaflets.[57] Causes of primary TR include congenital malformations (Epstein's anomaly), damage to the TV apparatus from infective endocarditis, medications, radiation, and trauma along with carcinoid or rheumatic heart disease involving the TV.[63,65] Lead management decisions prior to a T-TEER or TTVR should be made in all patients, regardless of whether or not the mechanism of the TR is CIED lead related, given the risk of 'jailing' the lead and the potential impact that the presence of a lead has on the difficulty and success of the TV procedure.

Role of echocardiography in evaluation of lead interaction with the tricuspid valve

Echocardiography is the primary imaging modality used to evaluate the anatomy of the TV, diagnose and quantify TR severity, and elucidate the mechanism of TR. Recent advances in the percutaneous treatment approaches to treat severe TR have been one of the drivers for advancements in TV imaging, including a novel TV nomenclature classification scheme, which defines four TV morphologies.[66] In addition, a new expanded TR grading scheme to more accurately quantify and define the degrees of TR has been proposed.[67] Trans-oesophageal echocardiography (TEE) is easily accessible and allows for visualization of the TV valve from multiple imaging windows. Understanding the complex and highly variable anatomy of the TV has been significantly advanced using three-dimensional (3D) echocardiography. Multi-planar 3D reconstruction, either in real time or offline, allows for understanding the TV leaflet anatomy (morphology, leaflet length, and coaptation gaps) and sub-valvular anatomy and quantifying the degree of TR.[68] Echocardiography, specifically TEE, is instrumental in the initial evaluation of patients with CIED leads and TR. Trans-oesophageal echocardiography can also be used intra-operatively during a TLE, for procedural planning in patients undergoing evaluation for T-TEER and TTVR as well as during percutaneous TV procedures.

As CIED lead–related TR can be both causative and incidental, 3D analysis with both trans-thoracic echocardiography (TTE) and TEE is important when evaluating the relationship between the CIED lead(s) and the TV. The use of 3D echocardiography has been demonstrated to be more reliable than two-dimensional (2D) imaging.[46] The CIED-induced TR should be suspected when a patient with a CIED lead traversing the TV has significant TR, especially when an echocardiogram performed prior to the device implantation did not reveal significant TR. The high acoustic impedance and strong reflectivity of CIED leads can often lead to underestimation of the severity of TR by colour Doppler. This occurs more frequently with TTE when compared with TEE,[69] suggesting that TEE should be performed for TR quantitation in all patients with suspected significant TR and CIED leads. Signs of possible lead-related TR on echocardiography include the jet 'hugging' the lead, leaflet malcoaptation, lead adherence to the sub-valvular structures (lead moves with sub-valvular structures), extreme lead displacement against the septum, and a non-RV outflow tract lead position.[33] The CIED lead may also be present without direct interference with the valvular apparatus. Echocardiography, especially with 3D reconstruction, can be helpful in demonstrating that the lead is 'free floating' and is not interfering with the valvular apparatus. By using full-volume data sets of the right ventricle, it is often possible to follow the trajectory of the lead as it courses through the right ventricle and define the extent that the lead is interacting with the sub-valvular apparatus. The 3D multi-planar reconstruction is often the best tool to evaluate CIED interference with TV as this modality allows for evaluation of lead

impingement, adherence, and entanglement with the TV apparatus.[46] The CEID lead-related TR may also be suspected if the origin of the colour Doppler jet is distal to the coaptation point of the TV leaflets, suggesting that the jet may be caused by interference with the sub-valvular apparatus.[70] Additionally, if the CIED can be seen 'moving with' the septal leaflet or appears attached to the septal leaflet, this is suggestive of CIED lead interference.

It can be challenging to distinguish lead impingement to the valvular or sub-valvular apparatus from lead adherence. Lead impingement interferes directly with leaflet coaptation, while an adherent lead attaches to the TV leaflet or apparatus but still moves along with the apparatus.[70] An alternative nomenclature, proposed by Anvardeen *et al*., defines lead interference as an impediment in the systolic excursion of any of the TV leaflets by the lead. Impingement occurs without direct leaflet tethering, whereas adherence involves direct tethering of the lead to the leaflets, and entanglement is defined as tethering of the lead to the sub-valvular chords.[48] Differentiating between these mechanisms can be challenging. This is where clinical factors such as lead dwell time and the appearance of the lead using alternate imaging modalities such as chest radiography may be of use. Ultimately, real-time TEE imaging [or intra-cardiac echocardiography (ICE); see below] at the time that intra-procedural manual traction is applied during TLE is often needed to fully appreciate the presence and extent that the CIED lead is interacting with the TV.

The European Heart Rhythm Association and the Heart Rhythm Society both endorse continuous monitoring using TEE or ICE during an extraction to improve procedural safety.[71–73] In addition to intra-procedural guidance, post-procedural TEE assessment of the leaflet anatomy and degree of TR can be helpful in planning the next stage of a TV intervention, should it be necessary.

Although 3D echocardiography is a useful tool when evaluating CIED lead–related TR,[46,47] limitations of 3D echocardiography include a lower temporal resolution when compared with 2D echocardiography along with imaging artefacts. These artefacts can occur due to the fact that data acquisition is performed over multiple heartbeats and therefore irregular cardiac rhythms and variations in respiration may impact the image quality. The 3D colour Doppler acquisition is further limited by spatial and temporal resolution. A guideline statement from the American Society of Echocardiography and the European Association of Echocardiography includes recommendations for techniques to improve 3D echocardiographic data acquisition.[74] Alternative imaging modalities to assess TR severity have shown promise including cardiac magnetic resonance imaging and computed tomography. In patients with CIED leads, the artefacts created may impact the imaging interpretation however.[75]

Role of intra-cardiac echocardiography to evaluate lead interaction with the tricuspid valve

In addition to TEE, rotational ICE catheters have been utilized to assess lead adhesions during TLE procedures. However, their restricted manoeuvrability and limited imaging depth pose challenges in visualizing the TV and sub-valvular apparatus. To address these limitations, phased-array ICE catheters have emerged as the preferred imaging modality for a broad range of invasive cardiovascular procedures.[76–78] These catheters offer a range of 2D images with adjustable ultrasound frequencies, thereby enabling optimal imaging quality. Phased-array ICE provides invaluable high-resolution, real-time visualization of cardiac structures. Notably, due to its location within the cardiac chambers and its bidirectional deflection capabilities, phased-array ICE allows for imaging of the route of the lead passing through the TV.

Although ICE has demonstrated utility in identifying TR instigated by CIED lead impingement and ascertaining its severity,[79] the data remain sparse and large-scale supportive studies are lacking. Multi-centre studies evaluating the utility of ICE during TLE would be a welcome addition to the literature. A majority of the theoretical benefits derived from using ICE to evaluate lead-related TR rely on evidence from ICE-guided TLE, where it has proved valuable in detecting intra-cardiac adhesions prior to TLE, which correlate with an increased risk of a 'complex' procedure.[80] In a similar vein, ICE has been used to identify a device lead adhesion to a susceptible 'stalk' that linked the papillary muscle to the RV endocardium, which averted a potentially disastrous complication.[81] Owing to its proximity to the TV, the ICE catheter tip provides a unique vantage point compared with other modalities, but its potential is yet to be scrutinized systematically. In the context of CIED lead–related TR, surrogate markers of lead adhesion are typically employed when the interaction with TV leaflets remains uncertain. These markers include the absence of independent motion between the lead and leaflet, the lead's stationary position affixed to the TV annulus rather than floating freely within the TV, the occurrence of calcium at the lead-TV interface, and the presence of an eccentric TR jet originating from where the lead crosses the TV (*Figures 1* and *2*). Four-dimensional ICE, which has already been studied in the context of interventional valve procedures,[82,83] could afford a more definitive analysis, although it necessitates additional investigation (*Figure 3*). Despite these efficacious tools, evaluating lead adherence during static imaging often poses a challenge, as adhesions frequently only become unmasked with traction during TLE (*Figure 4*). Of significance, the suggestion of lead adherence to the TV also implies a heightened risk of structural damage to the TV during TLE, a consequence that might have significant bearing on the subsequent choice of a percutaneous TV intervention (*Figure 4*).

Surgical management of tricuspid regurgitation

The surgical management of clinically significant TR varies based on the underlying cause and natural progression of the disease. For patients with isolated tricuspid valvular disease and advanced heart failure who are refractory to medical management, surgical intervention is a Class 2a indication.[10] In this context, patients are frequently referred for surgical intervention later in the disease course. These patients are often critically ill and exhibit significant RV systolic dysfunction, which can lead to both renal and hepatic impairment. Due to their co-morbidities, performing surgery on these patients can be challenging with higher rates of peri-operative morbidity and mortality.[12] In contrast, patients who undergo concomitant TV interventions at the time of mitral or aortic surgery are typically in earlier stages of the disease process. They are expected to have fewer right-sided structural changes and lower rates of peri-operative morbidity and mortality.[10]

Surgical treatment of isolated TR includes both repair and replacement options. Tricuspid valve repair is the preferred modality whenever possible, as it allows the preservation of the patient's native valve and avoids the need for long-term anticoagulation. Techniques for surgical repair include (i) suture annuloplasty, which involves tightening the valve ring with sutures; (ii) edge-to-edge repair, which involves suturing together the free edges of the valve leaflets to improve coaptation; and (iii) the use of prosthetic devices such as annuloplasty rings and chords. In cases where repair is not feasible, TV replacement with either a mechanical or bioprosthetic valve is an alternative. In patients undergoing surgical TV repair, it is possible to preserve CIED leads. However, if the patient is undergoing a TV replacement, any lead traversing the TV should be removed to avoid 'jailing' the lead in between the native annulus and the prosthetic valve.

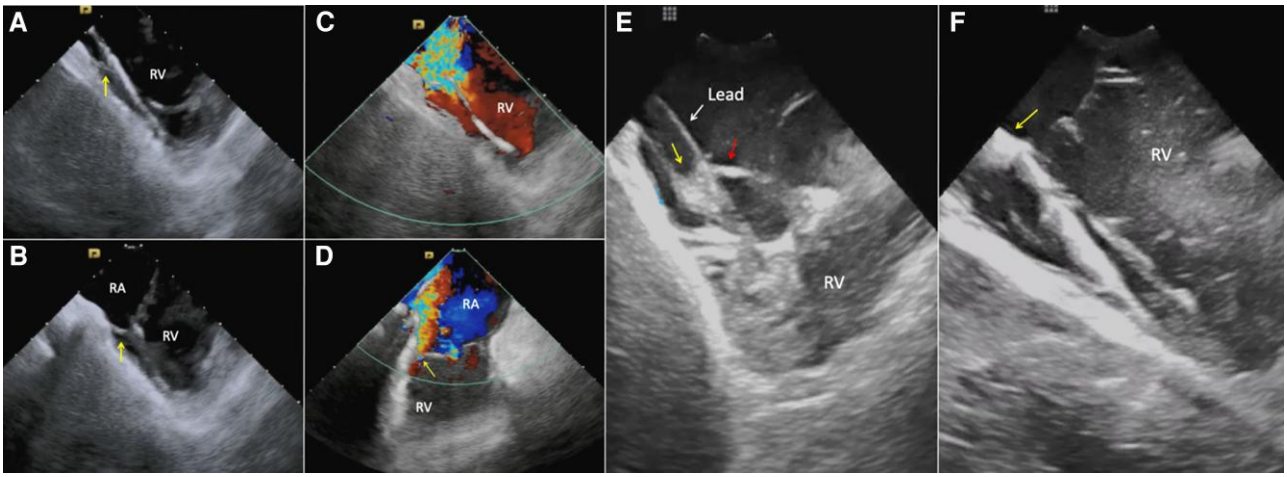


Figure 1 Lead-induced tricuspid. Regurgitation. (*A*, *B*) A TV leaflet is restricted in both systole and diastole (yellow arrows). (*C*) There is severe TR that is emanating from where the lead crosses the TV. (*D*) There are two distinct TR jets: one that tracks the lead (yellow arrow) and one that is central. (*E*) A lead is attached to a papillary muscle (yellow arrow) and a chord (red arrow). (*F*) There is significant calcification (yellow arrow) where the lead crosses the TV, suggesting adherence. RA, right atrium; RV, right ventricle; TR, tricuspid regurgitation; TV, tricuspid valve.

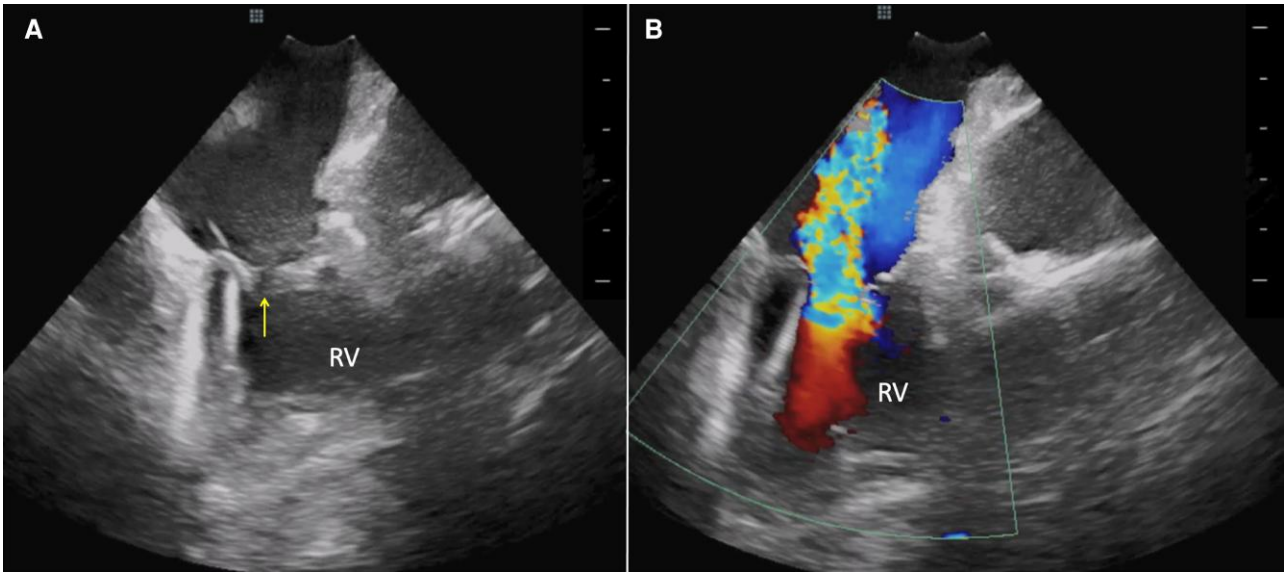


Figure 2 Severe tricuspid regurgitation in a patient with a device lead—mechanism of tricuspid regurgitation not lead related. (*A*) There is no suggestion of lead-related TR with failure of leaflet coaptation (yellow arrow) leading to (*B*) severe, central TR. RV, right ventricle; TR, tricuspid regurgitation.

Between 2011 and 2020, there were 6507 isolated TV operations for non-endocarditis–related TR registered in the Society of Thoracic Surgeons database. Factors associated with increased operative mortality included age greater than 50 years, chronic lung disease, New York Heart Association Class III and IV heart failure symptoms, non-elective operations, and an increased Model for End-Stage Liver Disease score. The overall operative mortality in this population was 7.3%. In the absence of the aforementioned risk factors, the mortality rate was 1.7%. Isolated TV repair was associated with lower operative mortality when compared with replacement. In addition, on-pump beating heart tricuspid operations, when compared with procedures performed with full cardioplegic arrest or fibrillatory arrest, had worse outcomes. Among patients whose aetiology of TR was identified in this study, 9.8% had CIED lead–related TR.[84]

The volume of surgical TV replacement and repair procedures in the USA has increased in recent years as there has been greater recognition of the importance of treating TV disease.[13,85] Elderly patients are a unique population in which surgical options for TR can be limited due to co-morbidities and frailty. Careful patient selection and consideration of the patient's overall health status are crucial in the decision-making

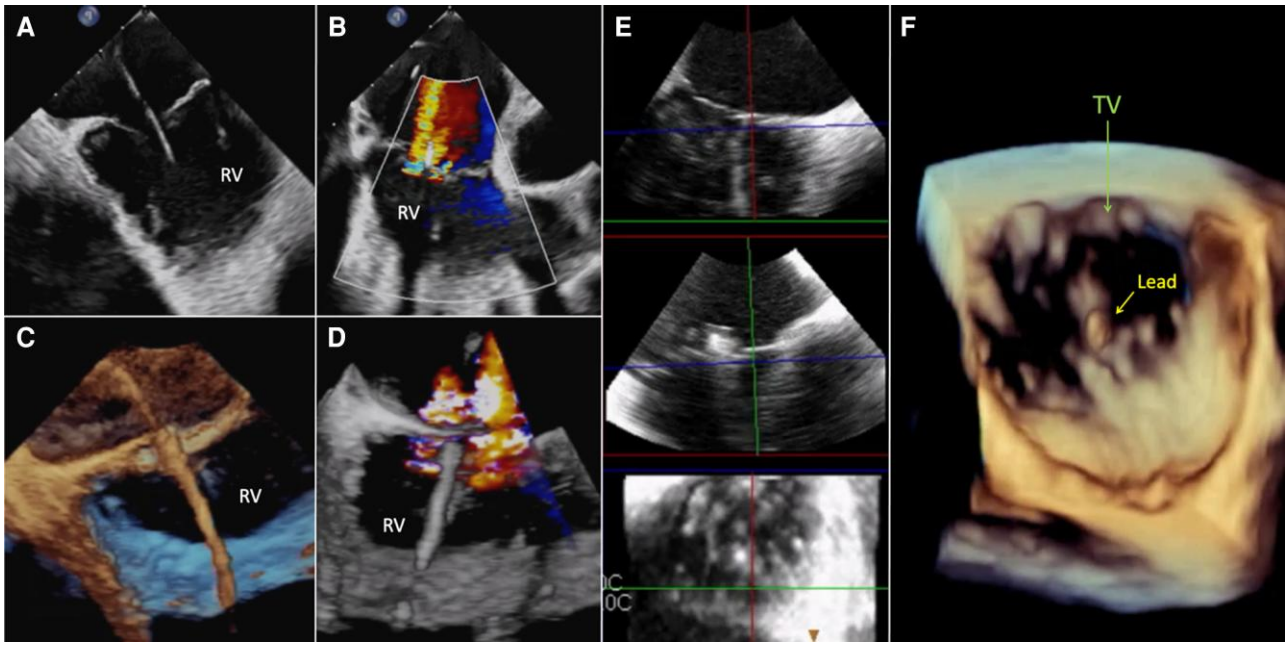


Figure 3 Use of three-dimensional intra-cardiac echocardiography. (*A*) A 2D ICE imaging showing a lead crossing the TV. (*B*) A 2D colour Doppler showing moderate TR. (*C*) A 3D ICE imaging showing a lead crossing the TV. (*D*) A 2D colour Doppler showing moderate TR. (*E*) Multi-plane views of the TV leading to (*F*) a 3D view of the TV with the lead passing through the centre. 2D, two-dimensional; 3D, three-dimensional; ICE, intra-cardiac echocardiography; RV, right ventricle; TR, tricuspid regurgitation; TV, tricuspid valve.

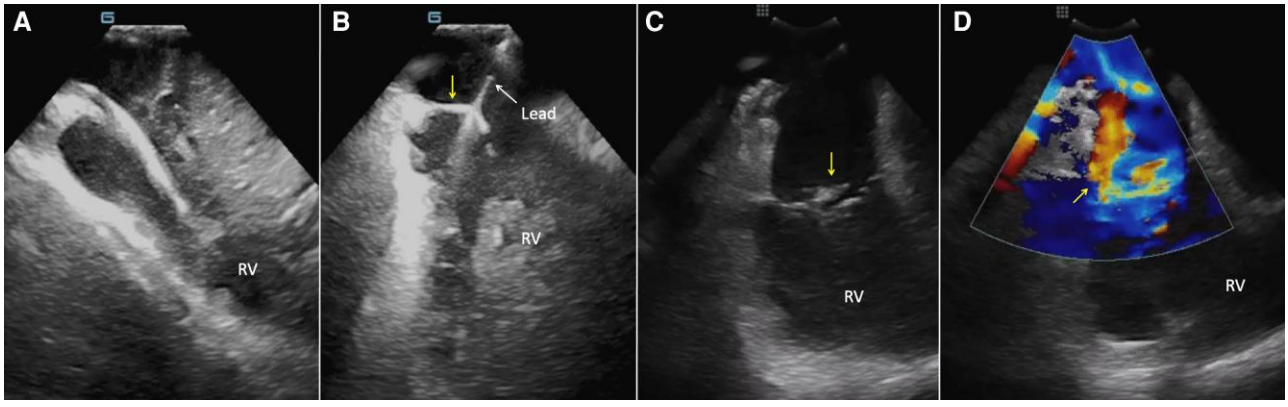


Figure 4 Unmasking adhesions during a trans-venous lead extraction. (*A*) A pacing lead is traversing the TV without clear adhesions. (*B*) Traction on the lead during TLE unmasks an adhesion to a leaflet (yellow arrow). (*C*) Injury to the TV during TLE leading to a flail leaflet (yellow arrow) and (*D*) severe eccentric TR. RV, right ventricle; TLE, trans-venous lead extraction; TR, tricuspid regurgitation; TV, tricuspid valve.

process as elderly patients may have higher rates of morbidity and mortality following surgery. Data from 5005 isolated TV surgeries performed between 2004 and 2013 in the USA demonstrate that patients ages 60 years and older have higher rates of in-hospital mortality (odds ratio: 2.02 95% confidence interval 1.22–3.34, $P = 0.006$).[13] A risk score, proposed by Dreyfus *et al.*,[86] which predicts in-hospital mortality rates for patients following isolated TV surgery assigns additional risk to patients ages 70 years or older. Despite the increased risk, D'Agostino *et al.*[85] reported that 1777 TV surgeries were performed in patients ages 80 years or older in the USA between 2011 and 2016 (1095 TV repairs and 682 TV replacements). Another study by Kundi *et al.* reported outcomes of TV surgery in 5164 Medicare recipients (mean age 68 ± 13 years). Tricuspid valve repair was associated with a lower 1-year mortality when compared with replacement (22.2% vs. 25.9%, $P < 0.001$).[87] These data support the use of TV repair when possible in elderly patients. Modern robotic and minimally invasive techniques are becoming more widely adopted. These approaches yield low rates of peri-operative morbidity, moderate to low rates of TR recurrence, and a low rate of late mortality.[88] Careful patient selection and consideration of the patient's overall health status are crucial in the decision-making process regarding

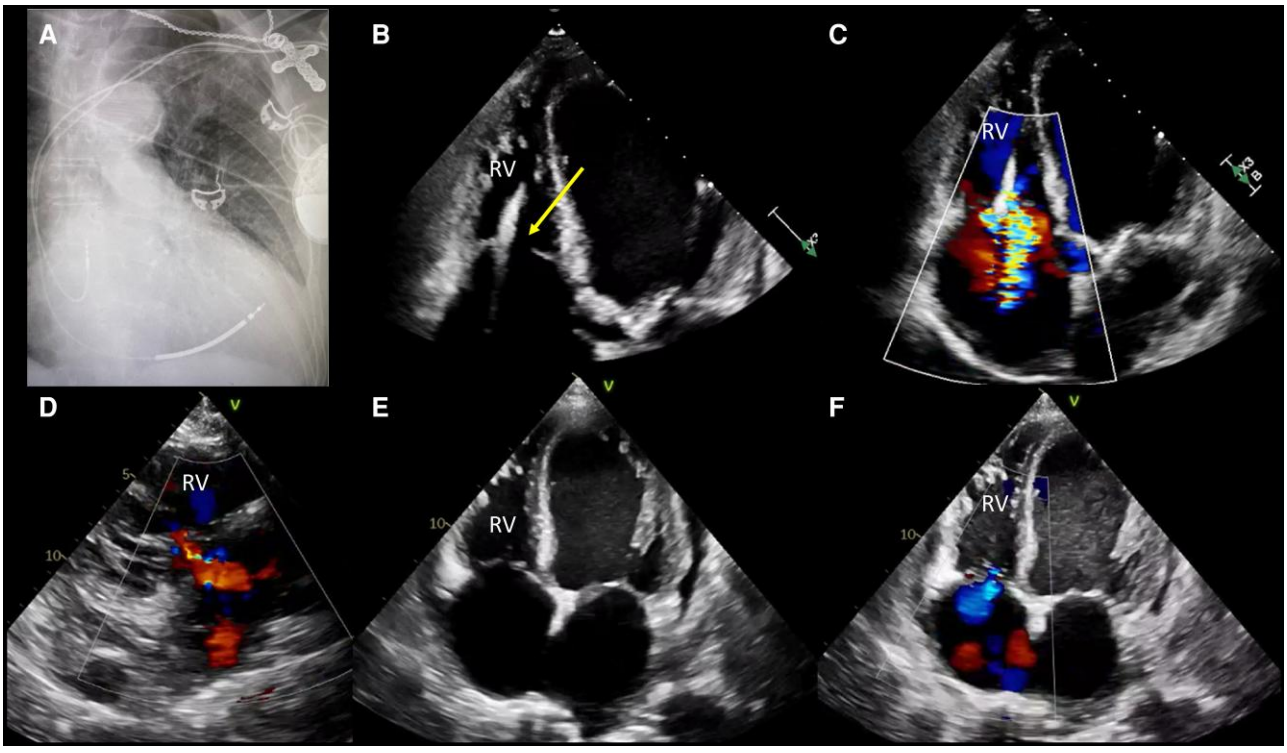


Figure 5 Improvement in tricuspid regurgitation severity following a trans-venous lead extraction. (*A*) Dual chamber primary prevention ICD (leads: 4076 and 6935) implanted four months prior to development of torrential tricuspid regurgitation. (*B*, *C*) Apical four chamber view from transthoracic echocardiogram demonstrating malcoaptation of tricuspid leaflets (yellow arrow) and torrential tricuspid regurgitation. Right ventricular inflow view (*D*) and apical four chamber views (*E*, *F*) following lead removal (using manual traction) with improvement in tricuspid regurgitation to trivial. RV, right ventricle.

whether or not to proceed with surgery in the elderly population. The role of surgical interventions in the elderly population will continuously be evaluated as more safety data emerge regarding the use of percutaneous treatment approaches in this population.

Trans-venous lead extraction and tricuspid regurgitation

As discussed previously, trans-venous CIED leads can cause impingement of and damage to the TV leaflets and sub-valvular apparatus. Trans-venous lead extractions can both worsen or improve the degree of TR (*Figures 4* and *5*). Unfortunately, limited data existing regarding the rates of improvement or progression in TR severity following a TLE as studies and registries have not uniformly tracked changes in the degree of TR following TLE. In addition, for the purposes of this review, we are most interested in the impact TLE has in patients with pre-existing severe TR who are being considered for trans-catheter TV interventions. In this subset of patients, there are two important considerations: does TLE damage the valve to a degree where a trans-catheter TV intervention is no longer possible, and does TLE improve TR severity to the point where a TV intervention is no longer required?

Trans-venous lead extraction worsening tricuspid regurgitation

A variety of small studies have previously found TLE-related worsening of TR in 3.5–15% of cases. Not surprisingly, studies with shorter lead dwell times had a lower incidence of TR progression when compared with studies with longer dwell times.[89–94] This suggests that scarring/fibrosis over time is a critical determinant of TLE-related damage to the TV. The 2018 European Heart Rhythm Association expert consensus statement on lead extraction reported a worsening of TV function in far fewer patients (0.02–0.59%) following TLE. Importantly, they reported the incidence of a flail TV leaflet that required intervention in only 0.03% of patients.[72] In a study of 2631 patients across three high-volume extraction centres, Polewczyk *et al.*[95] found a 9.7% incidence of any progression in TR severity; however, only 2.6% of patients had significant worsening in TR severity, which the authors defined as an increase by two degrees of TR severity. More importantly, only two patients (0.08%) required emergent cardiac surgery, and 10 patients (0.38%) required delayed surgery to treat severe TR. The authors found that longer procedure duration, a higher number of extracted leads, strong lead-to-lead connections due to connective scar tissue, the occurrence of any technical problems during the TLE, the need to use multiple extraction tools, extraction of pacemaker leads (especially unipolar leads, leads with a passive fixation mechanism, or extraction of an abandoned lead), and longer dwell times were all factors that predicted a significant worsening of TV function.[95] Park *et al.* reported on the extraction of 266 ventricular leads in 208 patients. Significant TR was noted in 24 (11.5%) of patients, and the need for emergent cardiac surgery due to TV leaflet avulsion occurred in one patient (0.5%). A multivariate analysis yielded only lead dwell time as an independent predictor of TLE-related acute TR. The age of the oldest lead extracted was divided into quartiles with TV injury essentially non-existent for leads ≤ 7 years old and only rising significantly for leads > 15 years

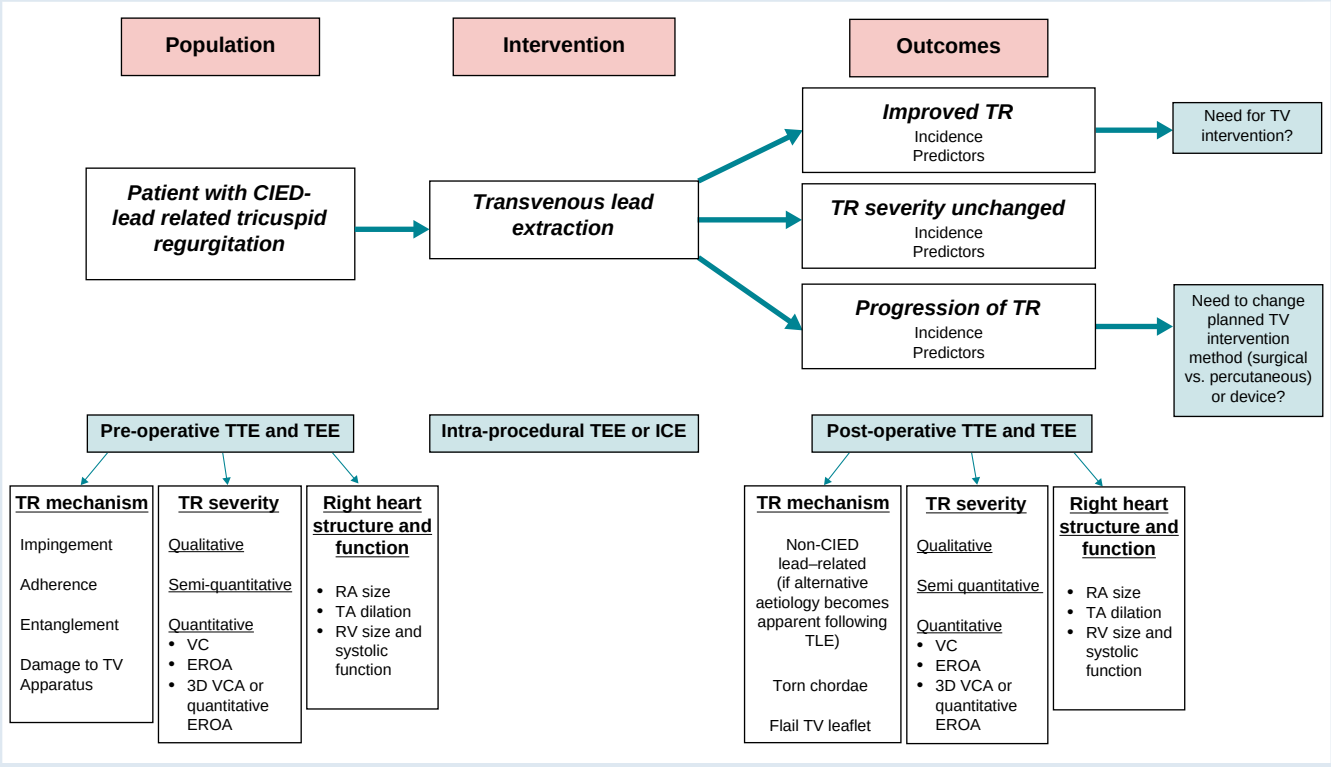


Figure 6 Potential future study design for systematically evaluating the impact of trans-venous lead extraction on CIED lead–related tricuspid regurgitation severity and outcomes. 3D, three-dimensional; CIED, cardiac implantable electronic device; EROA, effective regurgitant orifice area; ICE: intra-cardiac echocardiography; TEE, trans-oesophageal echocardiogram; TLE: trans-venous lead extraction; TR, tricuspid regurgitation; TTE: trans-thoracic echocardiogram; VC, vena contracta; VCA: vena contracta area.

old.[96] Each of these risk factors should be taken into consideration when evaluating a patient for a TLE prior to a TV intervention.

Trans-venous lead extraction in patients with pre-existing tricuspid regurgitation

Can a TLE improve TV function in patients with lead-related TR? Polewczyk *et al.* reported an improvement in TV function in 15 of 24 patients (63%) with lead-related TV dysfunction treated with percutaneous TLE. Importantly, clinical improvements were noted in 75% of these patients at 1.5 years of follow-up.[97] In a subsequent study from the same group involving 2678 patients undergoing TLE, 119 (4.4%) had pre-existing lead-related TR. Trans-venous lead extraction was associated with a reduction in TR in 35.3% of patients. Improvement was more likely in elderly patients with ischaemic heart disease and in patients with a smaller RV size.[98] Nazmul *et al.* did not find benefit in four patients who underwent TLE for relatively 'young leads'. However, significant tricuspid annular dilatation was present in all cases.[99] Wardell *et al.* described six patients with CIED lead–related TR who underwent TLE. Four of these patients (67%) demonstrated clinical improvement. One patient required surgical repair for iatrogenic TV damage.[100] In the study by Park *et al.*,[96] a significant finding was in patients undergoing TLE with pre-existing severe TR (the population we are interested in); 37% had a reduction to either moderate or mild TR post-extraction. It is very likely a trans-catheter TV procedure would no longer be required in these patients. It is important to evaluate the potential risks and benefits of TLE in patients with severe TR. There are some who believe that the risks of extraction preclude extracting leads as this may render the patient not a candidate for a trans-catheter intervention or result in excess morbidity and mortality. They strongly advocate 'jailing' the lead as a safer alternative. Although limited, the existing data suggest the risk of avulsing the valve is quite low, especially for younger leads, and the risk of mortality even lower (see below). In addition, there are clearly patients who benefit from extraction. Trans-venous lead extraction can obviate the need for a TV intervention (*Figure 5*), which has its own inherent risks. Ultimately, each case must be evaluated on an individual basis considering the patient's goals of care, age and co-morbidities, lead dwell time, number of leads present, and the imaging findings. Further multi-centre prospective studies that include a systematic evaluation of mechanism of CIED lead–related TR along with both qualitative and quantitative assessments of the severity of TR[67] as well as the rates of improvement and progression of TR following TLE would be a welcome addition to the literature (*Figure 6*).

Safety of trans-venous lead extraction

There are those who believe that only infected leads should be extracted. This is based on two assumptions: first, that TLE is a highly dangerous procedure with a significant rate of major complications including death; and second, that lead abandonment/jailing is benign. We believe that both these assumptions are at best inaccurate. The risks of abandonment and 'jailing' leads will be reviewed subsequently. The perception of the high-risk nature of TLE originated at a time when extractions were limited to manual traction and very rudimentary tools. With the development of the 'counter traction' technique pioneered by Byrd *et al.*[101] and newer tools, including powered sheaths,[102] TLE has become a relatively safe and predicable procedure. The

reported risk of major complications across a range of studies is 0.4–3.4% with the risk of death, 0.00–1.86%. These rates have continued to improve over time.[71–73,103–106]

The LExICon study[107] evaluated the safety and efficacy of consecutive TLE procedures in 13 high-, medium-, and low-volume centres. Sites were specifically chosen to evaluate the 'real world' experience and not the results only from the highest volume centres. A total of 2405 leads were removed from 1449 patients with a clinical success rate of 97.7%. Major procedure-related complications occurred in 1.4% of patients. There were four (0.28%) procedure-related deaths. The Electra Study[108] was a prospective registry of patients undergoing TLE at 73 centres across Europe. The study reported on TLE in 3555 consecutive patients and found a clinical success rate of 96.7%. The major complication rate was 1.7% with a 0.5% mortality rate. A subsequent study of the Electra data set by Sidhu *et al.* examined the impact of procedural volume on outcomes. They defined low-volume centres as <30 TLE/year and high-volume centres as ≥30 TLE/year. Procedures performed by low-volume operators were more likely to be unsuccessful (93.5% vs. 97.1%; $P < 0.0001$) and complicated by death (1.1% vs. 0.4%; $P = 0.0417$).[109] While safer than many believe, TLE can have catastrophic complications. It is important to recognize that all major complications do not result in death. Trans-venous lead extraction should only be performed in centres that are prepared to rapidly intervene when complications arise. The requirements for personnel, equipment, venue, and techniques for performing safe TLE procedures have been clearly delineated.[71] In addition, the development of a compliant balloon that can be deployed in the event of a superior vena cava tear (Bridge, Philips Colorado Springs, CO, USA) has had a major impact on mortality.[110]

Individualized approach when considering risks and benefits of trans-venous lead extraction

Patients with structural heart disease are often older with multiple co-morbidities. This has been suggested as a justification for not extracting and 'jailing' leads at the time of a TV intervention. However, multiple studies have demonstrated the safety of TLE in elderly patients with multiple co-morbidities.[111–115] Giannotti Santoro *et al.*,[115] for example, demonstrated comparable rates of clinical success and major complications when comparing patients ages 80 years and older to younger patients undergoing TLE. Lead dwell time is a reproducible risk factor in studies that have evaluated risk factors for major complications during TLE procedures. Other factors include prior failed TLE procedure, female gender, age < 30 at the time of implant, anaemia, an elevated international normalized ratio, low platelet count, a dual coil implantable cardioverter defibrillator (ICD) lead, previously abandoned leads, and renal failure.[116–120] As with any invasive procedure, the risks and benefits must be weighed on an individualized basis. However, it is crucial that the actual risks to the individual patient be considered. Extraction of a single lead with a dwell time between 1 and 5 years in a 65-year-old patient with severe TR to avoid or facilitate a trans-catheter procedure is very different than a palliative procedure in a 90-year-old patient with a 25-year-old lead across the TV.

Current and future percutaneous trans-catheter treatment approaches for tricuspid regurgitation

Preliminary data regarding the use of T-TEER and TTVR for treating clinically significant TR are promising.[14–24] Based on these data, a variety of catheter-based therapies for the treatment of patients with symptomatic moderate to severe or greater TR are being evaluated. Trans-catheter therapies include devices to perform T-TEER (TriClip, Pascal), orthotopic TTVR (Evoque, Intrepid), and the use of heterotopic devices, which utilize caval valve implants (single and bicaval).

The T-TEER employs the use of devices to capture the leaflets of the TV to restore normal coaptation and reduce TR. These devices are placed between the anterior, septal, and posterior leaflets, depending on the location and aetiology of the TR (most commonly between the anterior and septal leaflets). Favourable results from the first randomized trial involving T-TEER were recently published by Sorajja *et al.* (TRILUMINATE Pivotal Trial).[121] This study, which randomized patients to treatment with the TriClip device (Abbott) in addition to guideline-directed medical therapy (GDMT) vs. GDMT alone, demonstrated that the use of the TriClip resulted in significant improvements in TR severity and patient-reported quality of life. Patients are currently being enrolled in the TRILUMINATE Continued Access Study to further investigate this device in the USA and Europe (NCT03227757). Another T-TEER study that is actively enrolling patients is the CLASP II TR trial (NCT04097145). Similar to TRILUMINATE, this study is randomizing patients to an intervention arm (T-TEER using the PASCAL platform, Edwards Lifesciences, with GDMT) vs. GDMT alone.

Similar to trans-catheter aortic valve implantation, orthotopic TTVR involves complete replacement of the TV by placing a new valve within the native TV; these valves have nitinol frames with bovine pericardial tissue leaflets. Trans-catheter TV replacement is being evaluated in the TRISCEND II study (NCT04221490), which was also initially randomized (TTVR with the Edwards EVOQUE valve + GDMT vs. GDMT alone) and is now in Continued Access. Trans-catheter TV replacement is also being evaluated as part of a non-randomized feasibility study using the Intrepid™ Valve system (Medtronic, NCT04433065). Each of these studies allows for implantation of these devices in patients with existing CIED leads without consulting with a lead management specialist.

From a procedural standpoint, when considering T-TEER and TTVR in patients with a CIED lead, it is critically important to evaluate the location of the lead and its impact (or lack thereof) on the aetiology of the TR and to, the extent possible, predict how the lead may impact the ability to successfully perform the procedure (from both a device interaction perspective and an intra-procedural imaging perspective). If, for example, the pacing lead is positioned in the commissure between the posterior and septal TV leaflets and has no involvement in the TR jet, T-TEER may be considered without TLE. If, on the other hand, the lead is impinging upon the septal leaflet of the TV and is creating a significant jet of TR, or the lead is located centrally and is between the two leaflets that are the target of the TEER, consideration should be given to performing a TLE prior to the TV intervention. If TLE is undertaken prior to an anticipated T-TEER, consideration must also be given to the type of CIED that will be re-implanted (see section below). In patients whose anatomy is not amenable to T-TEER (e.g. due to large coaptation gaps or short/retracted leaflets that cannot be grasped), TTVR may be an option. However, there are patients who are also not suitable for TTVR under the current study protocols (e.g. anatomic exclusions, such as a large annular diameter, or clinical exclusions, such as severe RV dysfunction).

In patients who are not candidates for either T-TEER or TTVR, a number of new devices that are considered heterotopic (i.e. not treating the TV directly) can be deployed in the inferior vena cava or both the superior and inferior vena cava (bicaval) to mitigate the sequelae of severe TR and the symptoms of right heart failure. This approach is based on a series of historic cases in which a balloon-expandable valve (Sapien, Edwards) was deployed in the vena cava for palliative purposes in patients with refractory right heart failure that had no other surgical or catheter-based options.[122] There are now dedicated caval devices being studied in Europe and the USA. One such device is the

TricValve, which completed an early feasibility study[123] and will be evaluated in the USA as part of the TRICAV study, which will randomize patients to either TricValve or GDMT. The TricValve trans-catheter bicaval valves consist of two self-expanding nitinol biological valves that are implanted under fluoroscopic and echocardiographic guidance via femoral venous access. The valves are implanted percutaneously into the inferior and superior vena cava without involving the native TV. In addition to the heterotopic therapies, there are a number of other devices also in development, including annuloplasty devices and spacers.

In patients with a prior surgical TV replacement or repair using an annuloplasty ring, some centres have used an off-label technique wherein a balloon-expandable valve is implanted in the tricuspid position.[124] This is similar to current techniques using a balloon-expandable valve in the mitral position in patients with a prior mitral valve replacement or mitral annuloplasty ring, which was approved for on-label use in 2017.

In summary, there are a number of devices being studied (and many more in development) to treat patients with symptomatic severe TR. These devices address the TR using a variety of methods: either by repairing the TV leaflets, replacing the TV, or intervening on the vena cava to mitigate the sequelae of TR. Further clinical data are needed to determine which of these approaches are best suited for an individual patient. Current data, and the authors' clinical experience, suggest that the optimal solution to treat clinically significant TR with trans-catheter devices will not be a 'one size fits all' approach given the complexity of this patient population.

Conduction abnormalities related to percutaneous trans-catheter treatment approaches for tricuspid regurgitation

As is the case with surgical interventions on the TV, percutaneous approaches can also result in conduction disturbances that necessitate permanent pacing. The incidence of new conduction disturbances requiring permanent pacing immediately following a TTVR or T-TEER ranges from 8% to 11% based on the currently available data.[22,23,125] Conduction disturbances have also been noted during follow-up including a single patient (4%) that was implanted with the EVOQUE system. This patient required permanent pacing between 30 days and 1 year of the device implant.[20] Similarly, a single patient (3%) implanted with the Cardioband™ tricuspid system (Edwards Lifesciences) developed a conduction disturbance during the first year of follow-up.[126] Additionally, five patients (2.9%) in the T-TEER group in the study by Sorajja *et al.* received a permanent pacemaker or ICD within 1 year of the TV intervention. As the rate of CIED implantation in this study was identical in the control group at 1 year, and the details regarding the indications for the device implants in this study are not available, it is unclear if these devices were implanted due to conduction abnormalities that directly resulted from the TV intervention.[121] Clearly, further data regarding conduction disturbances, both acutely and during follow-up, are needed following TV interventions.

The risk of lead entrapment ('jailing' leads)

A significant limitation of T-TEER and TTVR devices is that in patients with existing CIEDs, implantation results in lead entrapment or 'jailing'. The published incidence of lead(s) being 'jailed' in clinical studies involving TTVR or T-TEER ranges from 3% to 36% (*Table 1*).[15–17,19–24,121,127–134,136] Entrapment of endocardial leads by stented valves carry significant considerations pertaining to lead functionality and patient safety. Despite its importance, there is a scarcity of data concerning the fate of leads after TV interventions due to variable follow-up, although instances of lead malfunction have been documented in prior reports.[31] In the most extensive series to date, a 10% rate of lead failure was observed, including a case of acute dislodgement and subsequent lead failure in two patients at an average time of 15.2-month post-procedure.[137] The overall risk of lead damage in this context remains unclear, being contingent on factors such as lead dwell time, composition, and location, in addition to the properties of the valve used. In addition, the impact of lead compression/abrasion and the creation of a 'hinge point' on long-term lead function are unknown. In the setting of pacemaker-dependent patients, lead damage may result in syncope, the urgent need for an alternative form of pacing, and the possibility of death due to asystole or pause-dependent polymorphic ventricular tachycardia. While it is possible to place a new lead within the TTVR following its deployment, lead revision increases the risk of developing a pocket infection. Moreover, the reported incidence of unanticipated venous occlusion can be as high as 25.7%, potentially necessitating the use of advanced recanalization techniques or the use of leadless devices or lead tunnelling from the contralateral side.[138] In such scenarios, the entrapped lead is potentially irremovable preventing extraction to regain venous access, a well-documented technique for addressing venous occlusion.[71] The extraction of leads that are not entrapped within the TTVR also poses similar challenges due to the frequent occurrence of lead-to-lead binding, which often requires the unexpected extraction of adjacent leads for a successful intervention.

While there are limited data specifically addressing leads entrapped in percutaneous TTVRs, useful insights may be extrapolated from experiences with leads confined within venous stents in both the innominate vein and superior vena cava (similar to the superior vena cava stent valves currently under investigation). These scenarios typically arise in the treatment of CIED-associated central vein stenoses, in which case balloon venoplasty alone is preferred. If stents are required, the prevailing protocol involves the extraction of leads prior to stent placement. This has been demonstrated to be a safe approach[139] and is one that is endorsed by multiple societies.[71,140] Subsequently, either leads are then placed within the stents, or other pacing modalities are utilized such as leadless, or epicardial systems.[141,142] While smaller series have reported symptomatic success and short-term lead safety in the context of entrapped leads,[143,144] the long-term behaviour and implications of confined leads remain largely unexplored. To acquire a comprehensive understanding of the long-term risks associated with entrapped leads, be it in a percutaneous TTVR or within a stented valve in the superior/inferior vena cava, systematic long-term follow-up of patients' post-percutaneous TV interventions is crucial.

Cardiac implantable electronic device–related infections in patients with 'jailed leads'

Cardiac implantable electronic device–related infections necessitate complete system removal, inclusive of all leads.[71] Although lead entrapment does not inherently elevate the infection risk, it prohibits lead extraction through conventional percutaneous techniques, mandating the exploration of complex surgical extraction methods or chronic antibiotic suppressive therapy, alternatives that increase morbidity and mortality in a high-risk patient population. While the annual risk of endocarditis in this population is low, the risk of a pocket infection, at the time of generator change ranges from 0.5% to 2.5%.[145] As with systemic infection, pocket infections require complete system

Table 1 Percutaneous options for managing tricuspid valve insufficiency and incidence of 'jailed' leads in clinical studies

Device	Vendor	Design	Implant route	Study (Number of patients)	Patients with jailed leads Number (%)
Percutaneous TV Replacement					
EVOQUE	Edwards Lifesciences	Self-expanding bovine pericardial valve, nitinol frame, fabric skirt	Trans-femoral	Fam *et al.* [22] (25)	9 (36)
				Webb *et al.* [20] (27)	9 (33)
				Kodali *et al.* [23] (56)	19 (34)
Lux-Valve	Jenscare Biotechnology Co.	Bovine pericardium valve with self-expanding nitinol atrial disc, fabric skirt, graspers, inter-ventricular septal anchor	Right thoracotomy, trans-atrial approach	Sun *et al.*[24] (6)	Not reported
GATE	NaviGate Cardiac Solutions	Equine pericardium, nitinol alloy stent	Right thoracotomy, trans-atrial approach	Hahn *et al.*[21] (5)	1 (20)
TRICENTO	New Valve Technology	Bicaval stent graft with pericardial valve	Trans-femoral	Wild *et al.*[127] (21)	3 (14)
Sapien Valve	Edwards Lifesciences	Balloon-expandable valve	Trans-femoral	Lauten *et al.*[128] (25)	9 (36)
				Dreger *et al.*[129] (28)	Not reported
Percutaneous TV Repair					
MitraClip XTR (TriClip)	Abbott	Edge-edge repair with clip	Trans-femoral	Braun *et al.*[130] (31)	Not reported
				Lurz *et al.*[131] (85)	12 (14)
				Sorajja *et al.*[121] (175)	28 (16)
MitraClip	Abbott	Edge-edge repair with clip	Trans-femoral	Mehr *et al.*[15] (249)	74 (30)
				Besler *et al.*[17] (117)	38 (33)
PASCAL	Edwards Lifesciences	Central spacer with two clasps, paddles	Trans-femoral	Fam *et al.*[22] (28)	1 (3)
				Kodali *et al.*[132] (34)	4 (12)
Forma Repair System	Edwards Lifesciences	Passively expandable, foam-filled balloon spacer	Left sub-clavian or axillary vein	Campelo-Parada *et al.*[133] (7)	Patients with leads excluded from study
				Perlman *et al.*[134] (18)	3 (17)
Tricinch	4Tech Cardio	Corkscrew anchor fixed to the anterioposterior commissure, attached to a stent in the IVC using a Dacrond band	Trans-femoral	Denti *et al.*[135] (24)	Not reported
Trialign	Mitralign	Pledgets fixed at the posteroseptal and anteroseptal commissures are cinched together	Trans-jugular	Hahn *et al.*[19] (15)	Patients with leads excluded from study
Cardioband	Edwards Lifesciences	17 anchors and a Dacrond band cinch the tricuspid annulus	Trans-femoral	Nickenig *et al.*[24,126] (30)	4 (13)

removal. In the rare incidence, a patient is judged to be unsuitable for a surgical intervention; options include extensive pocket revision by experienced operators, delivery of continuous, *in situ*-targeted, ultrahigh concentration of antibiotics, or severing of the leads, facilitating retraction into the bloodstream, and all suboptimal solutions.[30,146,147] In the setting of a CIED infection, the use of chronic suppressive antibiotics has a mortality rate of 25% at 1 month, more than 50% at 1 year, and nearly 90% at 5 years.[148] Data regarding percutaneous extraction of entrapped leads under unusual circumstances are limited, with such operations predominantly undertaken at specialty centres due to their precarious and unpredictable nature (*Figure 7*). One case study reports the percutaneous removal of both pacing and ICD leads that were externalized between the sewing ring and the TV annulus during bioprosthetic valve surgery.[149] While using traditional equipment, it was possible to retract the lead prior to the sheath traversing the TV annulus, which was a fortunate occurrence.[149] Similar experiences have been described including a jailed lead in a patient with mustard circulation, which was similarly removed without the extraction sheath crossing the stent.[150] In the most comprehensive study to date, seven leads previously stented to the wall of the left innominate and sub-clavian veins were extracted. Three leads were extracted with basic traction, while the remainder necessitated an unconventional femoral approach, occasionally requiring 10–20 min of continuous traction without the stent being crossed.[151] Given the potential risks of subsequent infections in patients with existing CIED leads and the aforementioned risk of lead damage, prior to 'jailing', a lead at the time of a T-TEER or TTVR consultation with a lead management specialist should be obtained (see 'heart team' approach section).

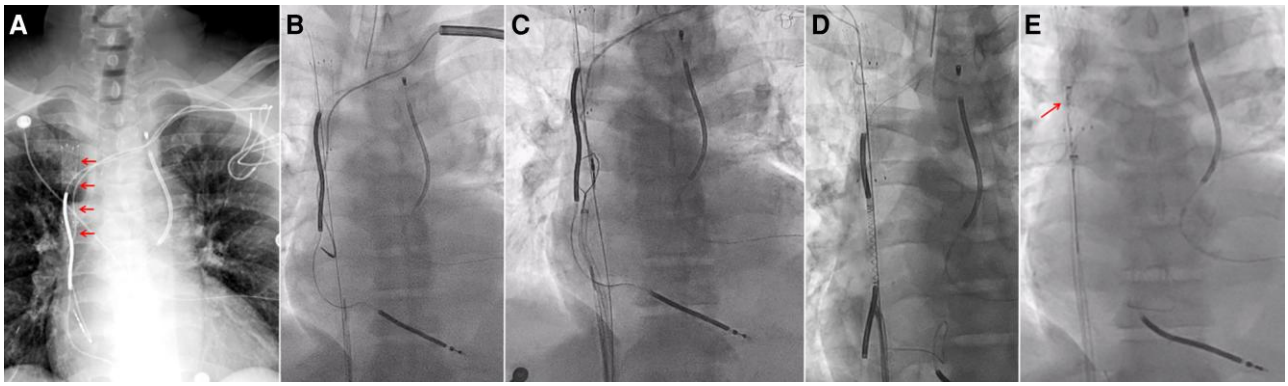


Figure 7 Incomplete extraction in a patient with entrapped leads. (*A*) Radiograph of a patient with multiple leads entrapped between the SVC and a stent (red arrows). (*B*) Traditional extraction sheaths are used to dissect the leads within the innominate veins. (*C*) The atrial lead is snared from below in an attempt to slide it past the stented portion of vein. (*D*) The SVC coil, which has now lacerated, is snared and pulled from below. (*E*) The remaining portion of the SVC coil is unable to be removed. SVC, superior vena cava.

Cardiac implantable electronic devices options following tricuspid valve intervention

Patients may require pacing or defibrillator therapy prior to or as a result of a TV intervention. Considerations should include understanding the indication for the CIED in patients with pre-existing devices. Pacing indications include isolated sinus node dysfunction requiring atrial pacing alone, atrioventricular block requiring ventricular or dual chamber pacing, and biventricular pacing in patients with a reduced ejection fraction, atrioventricular block, and a left bundle branch block. In patients with an ICD, it is important to know whether the indication was primary or secondary prevention. In addition, for primary prevention patients, there have been therapies for ventricular arrhythmias and if the underlying indication for ICD therapy still exists (such as a significant improvement in ejection fraction).

For patients who are in need of ventricular pacing, either before the procedure or as a result of the tricuspid intervention, leadless pacemakers capable of RV pacing,[152,153] RV pacing with atrioventricular synchrony,[154] and left ventricular endocardial pacing[155] are currently available. In addition, a dual-chamber leadless pacing system recently received approval from the Food and Drug Administration.[156] Given the size of the delivery systems, and the need to cross the TV, for both the Micra™ (Medtronic) and Aveir™ (Abbott) devices, it may be preferable to implant these devices prior to the TV intervention. The implant location of a leadless pacemaker (basal vs. apical) and the potential impact of the leadless pacemaker on the sub-valvular apparatus can also both impact the ability to successfully perform a future T-TEER. Further studies are required to understand the best approach.

In addition to traditional leadless pacemakers, hybrid approaches using a combination of a trans-venous device for atrial pacing and a leadless pacemaker for ventricular pacing have also been reported.[157–159] Single-site coronary sinus pacing with a traditional trans-venous device is another alternative in patients to avoid placing a trans-venous lead across the newly instrumented TV.[160] Current data suggest that implanting CIED leads across a bioprosthetic TV or following a tricuspid ring annuloplasty does not significantly change the incidence of TR when compared to controls who did not receive trans-valvular leads.[161,162] However, this is contrary to the impact of leads on native valves, as reviewed above, and may be a result of limited follow-up. Further studies are needed to determine if these findings will be similar in patients who have undergone T-TEER or TTVR.

For patients who require ICD therapy, alternatives to replacing a CIED lead across the TV include implanting a subcutaneous[163] or extravascular defibrillator.[164] Another option involves placing a pace/sense lead in the coronary sinus along with a defibrillator coil in the coronary sinus or azygous vein. This solution is less desirable as these defibrillation coils can be difficult and dangerous to extract.[165] Investigation is currently underway examining the combination of a subcutaneous ICD with a leadless pacemaker that is capable of providing antitachycardia pacing.[166] In patients undergoing open surgical tricuspid repair or replacement, placing epicardial leads at the time of surgery obviates the need to cross the repaired/replaced TV. In patients who underwent a TLE, or in whom placing leads across the newly intervened TV is to be avoided, an epicardial approach for pacing and/or defibrillation is an option.[167–170] However, many in this patient population are not ideal surgical candidates given their medical co-morbidities and/or prior history of cardiac surgery.

'Heart team' approach to management of tricuspid regurgitation in patients with cardiac implantable electronic devices

There are many examples of the 'heart team' approach to patient care. This is especially true in the world of structural heart disease. The Centers for Medicare and Medicaid Services mandates a 'heart team' approach for patients being considered for trans-catheter aortic valve interventions. Most if not all the current studies involving TTVR procedures also require a 'Heart Team'. These teams include the structural interventionalist, an interventional echocardiographer, a cardiac surgeon, and a heart failure specialist to optimize medical management. Unfortunately, these studies do not mandate the involvement of an electrophysiologist. Given that a significant number of patients with TR have existing CIEDs, and the possibility of new conduction system abnormalities following TTVR procedures, it seems prudent that an

electrophysiologist be a part of the 'heart team'. In this case, it is important to include an electrophysiologist who is well versed in lead management.

A team approach is also important as patients can be referred to various members of the team for a multitude of reasons. Some patients are referred directly to the structural or surgical teams, while other may first be referred to a heart failure specialist. It is not uncommon for patients with TR who have CIED leads to be referred to a lead management specialist for consideration of TLE. If a decision is made to proceed with TLE, except for cases involving very 'young leads', it should only be performed at an experienced TLE centre that adheres to published protocols and procedures.[71]

At our centres, we have the following approach (*Graphical Abstract*). All patients are evaluated by the structural team, which includes a structural interventionalist, a cardiac surgeon, and an interventional echocardiographer. They are then evaluated by a heart failure specialist to ensure optimization of medical therapy. If they have a CIED, they are also seen by our extraction team. Complete details of the CIED system are obtained. This includes information on each lead (model, age, and location), the need for pacing (atrial, ventricular, and resynchronization), and, if applicable, the need for ICD therapy (primary prevention, secondary prevention, and device history). The extractor and interventional echocardiographer carefully review all imaging modalities to evaluate, if possible, the relationship of the lead(s) to the TV annulus, leaflets, and valvular apparatus. The various treatment options are then discussed as a group, and decisions are made on a case-by-case basis weighing all potential variables. In some cases, the decision may be a surgical intervention, in others TLE and T-TEER/TTVR. Rarely, in high-risk patients, a decision is made to 'jail' a lead and proceed with a T-TEET/TTVR. If the patient is to undergo a TLE, the interventional echocardiographer is present during the extraction to evaluate the TV along with the lead before, during, and following the TLE. If, during the TLE, it is determined that extraction of the lead poses a significant risk of damage to the valve, the procedure can be abandoned. Using this approach, we have been able to obviate the need for TTVR in some cases due to improvement in the degree of TR to the degree that intervention was no longer indicated (*Figure 5*). In addition, TLE has simplified the TTVR procedure in some patients by eliminating having to 'work around' the lead(s). We believe this approach offers the best chances for optimal patient outcomes.

Conclusions

Trans-catheter approaches to treat clinically significant TR have emerged as alternative solutions to medical therapy and surgical interventions. The use of these treatment modalities in patients with existing CIED leads is not without risk. A 'heart team' approach that includes a lead management specialist should be strongly considered when making management decisions in patients with leads and TR as TLEs can, in some patients, obviate the need for a TV intervention. Additionally, an extraction prior to a TV intervention may facilitate the procedure and extracting the lead eliminates the risks associated with lead 'jailing'.

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Data availability

Not applicable as this is a review article.

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