Review Article

Interventional Cardiology

Navigating challenges in tricuspid transcatheter therapies for patients with CIED leads: Review of clinical evidence and procedural insights

Sant Kumar[1,2], Mustafa Suppah[1,2], Habib Rahban[1,2], Hursh Naik[2*]

[1]Department of Cardiology, Creighton University School of Medicine, Phoenix, United States of America

[2]St. Joseph's Hospital and Medical Center, Phoenix, United States of America

[*]Author for correspondence:
Hursh Naik, St. Joseph's Hospital and Medical Center, Phoenix, United States of America, E-mail: hursh.naik@imsaz.com

Received date: 01-Jan-2025, Manuscript No. FMIC-25-163372; Editor assigned: 03-Jan-2025, PreQC No. FMIC-25-163372 (PQ); Reviewed date: 17-Jan-2025, QC No. FMIC-25-163372; Revised date: 24-Jan-2025, Manuscript No. FMIC-25-163372 (R); Published date: 31-Jan-2025, DOI: 10.37532/1755-5310.2025.17(1).964

Abstract

Transcatheter tricuspid valve interventions, including Tricuspid Transcatheter Edge-to-Edge Repair (T-TEER) and Transcatheter Tricuspid Valve Replacement (TTVR), have emerged as effective therapies for patients with severe Tricuspid Regurgitation (TR) and Cardiovascular Implantable Electronic Devices (CIEDs). This review examines outcomes in CIED patients undergoing these interventions. Evidence from registries, trials, and case reports consistently shows that both T-TEER and TTVR are feasible and safe in patients with transvalvular leads. These procedures achieve significant TR reduction, symptom improvement, and enhanced quality of life. Lead dysfunction or procedural complications related to the presence of transvalvular leads are uncommon, and routine lead extraction is generally unnecessary. Technical considerations for success include careful echocardiographic evaluation, strategic device placement, and multidisciplinary planning. In challenging cases, lead repositioning or extraction with leadless pacing can be considered. Current evidence supports that transcatheter tricuspid interventions should not be withheld from carefully selected patients with CIED leads.

Keywords: Tricuspid regurgitation • Tricuspid transcatheter edge-to-edge repair • Transcatheter tricuspid valve replacement • Cardiovascular implantable electronic devices

Introduction

TR is common in patients with CIEDs because a transvenous pacemaker or defibrillator lead crossing the tricuspid valve can worsen leaflet coaptation [1,2]. Many patients with severe TR and CIEDs are at high risk for surgery, so transcatheter therapies have emerged as alternatives [3,4]. Two main transcatheter approaches are used: Transcatheter tricuspid edge-to-edge repair and Transcatheter Tricuspid Valve Replacement (TTVR) using valve prostheses. Presented here is a review of case reports, series, cohorts, and registries assessing the outcomes of T-TEER or TTVR in patients with CIED leads. Key details of study design, patient characteristics, device type, procedural data, echocardiographic findings, and clinical outcomes are summarized, with comparisons between patients with and without CIEDs when reported.

Transcatheter Tricuspid Edge-to-Edge Repair (T-TEER) in CIED patients

T-TEER has become the most commonly applied transcatheter therapy for severe TR [5]. A pacemaker/Implantable Cardioverter-Defibrillator (ICD) lead across the tricuspid valve can pose technical challenges: The lead may cause acoustic shadowing on echocardiography or physically interfere with clip delivery and leaflet grasping

[6]. Nonetheless, multiple studies indicate T-TEER is feasible in patients with trans-tricuspid leads when careful planning is undertaken (avoiding cases of severe lead adherence to leaflets).

Taramasso, et al. analyzed a study population of 470 patients with severe symptomatic TR from the TriValve (Transcatheter Tricuspid Valve Therapies) registry who underwent TTVI at 21 centers between 2015 and 2018.7 Among 470 patients who underwent TTVI (mostly edge-to-edge repair) for severe TR, 121 patients (25.7%) had a pre-existing CIED with a trans-tricuspid lead. Baseline comparisons showed CIED patients were slightly more symptomatic (New York Heart Association [NYHA] III-IV in 96% vs. 92%) and had more prior right heart failure episodes than those without leads. The transcatheter therapy was predominantly the MitraClip device for TR (used in 79% of patients, including 87% of those with CIEDs).

Acute procedural success (defined as at least one clip implanted with ≥ 1 grade TR reduction) was high and did not differ between groups (78.6% in CIED vs. 80.0% in non-CIED; p=0.74). By 30 days, a significant TR reduction was achieved in most patients -73.7% of CIED patients had residual TR ≤ moderate (grade ≤ 2+) which was comparable to 70.8% in those without leads (p=0.60). On average the tricuspid Effective Regurgitant Orifice Area (EROA) was slightly smaller in CIED patients at baseline (0.6 vs. 0.7 cm^2), and right ventricular function (TAPSE) was slightly worse, but both groups saw substantial TR improvement post-TEER.

In-hospital mortality was low (3.7% in CIED vs. 2.9% in non-CIED, p=0.70). Both groups experienced significant symptomatic benefit: By 1 month about two-thirds of patients improved to NYHA class I-II. One-year survival was 73.6% in the CIED group versus 80.7% in the non-CIED group, a difference that was not statistically significant. The authors concluded that transcatheter tricuspid interventions are feasible in selected patients with pacemaker/ICD leads, with similar short-term efficacy and clinical improvement as in patients without leads.

A single-center retrospective study from Germany specifically evaluated T-TEER outcomes in patients with CIED leads.8 A total of 106 patients underwent tricuspid TEER at this center (mean age 80.1 ± 6.4 years). Of these, 25 patients (23.6%) had a CIED with a right heart lead (transvenous pacemaker or defibrillator). Notably, patients whose TR was primarily due to lead impingement on the valve were excluded from TEER in this cohort-thus all included CIED patients had functional TR (often associated with right atrial enlargement from atrial fibrillation) with the lead considered a contributing factor but not the sole cause. In the CIED subgroup, 68% had a pacemaker, 20% an ICD, and 12% had a Cardiac Resynchronization Therapy (CRT) device; the lead tip was positioned in the Right Ventricle (RV) either centrally (14 patients) or in the posteroseptal commissure (11 patients), and importantly none had a lead in the anteroseptal commissure. Baseline left ventricular ejection fraction was lower in CIED patients (47% vs. 56% in non-CIED, p=0.004) and hypertension was more prevalent (96% vs. 79%), consistent with many CIED patients having underlying cardiomyopathy or heart failure. Other comorbidities were similar between groups.

All patients were treated with edge-to-edge repair, most using the TriClip (Abbott) device; a small number of cases (6 patients overall, 1 with CIED) used the PASCAL device (Edwards). The operators tailored clip placement to avoid interfering with the lead: For example, if a lead was centrally located, the first clip was placed anteroseptally and an additional clip was placed on either side of the lead if needed. On average 1.42 ± 0.6 clips were implanted per patient, and this did not differ between those with vs. without CIED. Procedural success (at least one clip with ≥ 1 grade TR reduction) was achieved in 92% of CIED patients, virtually the same as 93.8% in non-CIED patients (p=0.75). The final TR reduction was also comparable: after TEER, ~92% of all patients had TR reduced to moderate or less (grade ≤ II), with no significant difference between groups (the distribution of post-TEER TR grades I/II/III was similar). Procedure times were similar as well.

Importantly, having a pacemaker/ICD lead did not lead to excess complications. Vascular access complication rates were low and equivalent (12% in CIED *vs*. 8.6% non-CIED, p=0.62). No instances of acute lead dislodgement or device interference were reported. The in-hospital mortality was 4% for CIED patients vs. 9.9% for others, a nonsignificant difference given the small numbers. Overall, this single-center experience demonstrated that tricuspid TEER can be performed safely and effectively in patients with trans-tricuspid leads, with high procedural success and TR reduction rates that mirror those of non-pacemaker patients [7,8].

Case reports

Beyond larger studies, many published case reports illustrate specific scenarios and techniques for managing TR in the presence of device leads. A case series described three distinct patient scenarios, each with a pacemaker and severe TR, managed by different transcatheter strategies [9]. All patients were in their 80s with multiple comorbidities and long-standing CIEDs. In Case 1, an 83-year-old woman with an RV pacemaker lead causing a secondary TR jet underwent T-TEER. The team first implanted a TriClip XT in the posteroseptal commissure to intentionally grasp and retract the pacemaker lead toward that commissure, moving it out of the septal leaflet's way. In Case 2, an 87-year-old with a pacemaker and massive TR had the lead tethering the septal leaflet centrally, making her anatomy unfavorable for clipping. Instead, a transcatheter annuloplasty (Cardioband) was performed. This

percutaneous tricuspid band cinching reduced TR from massive to mild. Case 3 was an 84-year-old with torrential TR (huge coaptation gap ~13 mm) and a pacemaker; TEER or annuloplasty were not feasible (large gap and the right coronary artery was too close to allow Cardioband). She was treated with a heterotopic caval valve implantation (TricValve system-placing venous valves in the SVC and IVC). This procedure does not interact with the tricuspid leaflets or lead, but it relieves systemic venous congestion. After the two caval valves were implanted, the patient's symptoms improved dramatically with a 10-kg diuresis and NYHA class II at 1 month follow-up.

In a complex case of pacemaker-induced TR, Tang, et al. described a fully percutaneous staged strategy [10].The patient was pacemaker-dependent with severe lead-induced TR and also had significant mitral regurgitation. First, a MitraClip was placed on the mitral valve to address the MR. Next, to address the TR, the existing transvenous pacemaker lead was removed with laser extraction and replaced with a leadless Micra pacemaker, thus freeing the tricuspid valve from any hardware. Finally, a T-TEER was performed with the MitraClip device. After this sequence, the patient's TR grade improved from severe to moderate and her MR was reduced to mild. The report highlighted that removing the trans-tricuspid lead can "un-tether" the leaflet and facilitate a more effective tricuspid repair. This innovative case illustrates that in select situations, converting a transvenous pacemaker to a leadless system can enable a successful transcatheter TR intervention.

Transcatheter Tricuspid Valve Replacement (TTVR) in CIED patients

TTVR refers to catheter-based implantation of a replacement valve in the tricuspid position. This can be orthotopic (placing a new valve at the native tricuspid annulus)-for example, in a failed surgical tricuspid bioprosthesis (valve-in-valve) or the native valve *via* dedicated devices-or heterotopic (implanting valves in the vena cavae to alleviate TR as in the caval valve approach). TTVR is an emerging therapy with several devices in early trials (e.g. Edwards Evoque, Navitor, LuX-Valve). A key consideration is what to do with existing pacemaker leads during replacement. During surgical TVR, any trans-tricuspid leads are usually extracted to avoid entrapment between the sewing ring and annulus. In TTVR, however, extraction is high-risk and often avoided; thus, the catheter-delivered valve is typically implanted with the lead left in place, which results in the lead being "trapped" between the new valve frame and the tricuspid annulus or valve. This raises concern for lead dysfunction or difficulty accessing the lead afterward. The following studies report outcomes in such scenarios.

The largest analysis comes from the Valve-in-Valve International Database (VIVID) registry, examining patients who underwent transcatheter tricuspid valve-in-valve or valve-in-ring replacement (i.e. TTVR in a failed surgical tricuspid repair/replacement) [11]. Among 329 patients in the registry who had TTVR for a degenerative tricuspid bioprosthesis or ring, 128 patients (39%) had a pre-existing cardiac pacing system. Most of those had epicardial leads (n=70), but 58 patients had transvenous leads in place across the tricuspid valve. In 3 cases the transvenous RV lead was prophylactically extracted prior to TTVR, but the remaining 55 patients went to TTVR with the lead in situ. Ultimately, 31 patients in the cohort ended up with a lead crossing the new tricuspid valve after the procedure (i.e. entrapped in the TTVR device). The most common scenario was a transcatheter valve-in-valve implantation that snared the existing RV lead between the new valve and the old surgical valve frame.

Impressively, the incidence of lead-related problems was low. During the TTVR procedures, only one patient (of 55 with transvenous leads in place) experienced displacement of the RV lead. Over follow-up (which exceeded 1 year for many patients, median of ~15 months), 2 patients developed lead failure (loss of capture) that was attributed to the lead being immobilized in the valve frame. These three cases correspond to about a 10% rate of lead dysfunction among those with entrapped leads. However, most leads continued to function normally after being jailed by the new valve.

The overall safety and efficacy of TTVR were not diminished by the presence of pacing leads. There were no significant differences in survival, need for re-intervention, or device failure between patients with no lead, epicardial leads, or entrapped transvenous leads. In fact, the cumulative incidence of adverse outcomes (death, repeat TV intervention, or tricuspid valve dysfunction) was statistically similar across these subgroups during follow-up. This suggests that doing a transcatheter tricuspid valve-in-valve with a lead in place did not impart a detectable negative effect on mid-term prognosis. The authors concluded that TTVR can be performed safely in patients with trans-tricuspid pacemaker leads without routine extraction, offering a less invasive alternative to surgical TVR in this challenging group.

Case reports

Because dedicated TTVR devices are still in trial phases, published data in CIED patients are limited mostly to cases of valve-in-valve or compassionate use. Fam, et al. reported a case of transcatheter tricuspid valve replacement specifically for pacemaker-induced TR [12]. In that case, a Sapien 3 valve was implanted in the tricuspid position, capturing the offending pacemaker lead against the annulus, which resolved the severe TR without disturbing lead function (the pacemaker thresholds remained stable after implant). The patient's symptoms improved with the resolution of edema and fatigue on follow-up.

Another aspect of TTVR is the risk of heart block from the procedure

itself since the tricuspid annulus is near the atrioventricular node. In the Edwards EVOQUE Tricuspid Valve Replacement: Investigation of Safety and Clinical Efficacy after Replacement of Tricuspid Valve with Transcatheter Device (TRISCEND) study of the Evoque tricuspid valve replacement (a prospective trial not focused specifically on CIED patients), 11% of patients required a new permanent pacemaker within 30 days due to procedural AV block [13]. Notably, surgical tricuspid valve replacement carries an even higher pacemaker rate (>20%) [14,15]. This highlights that new CIEDs may be needed after orthotopic TTVR in some cases. Thus, when considering TTVR, one must plan for possible pacing needs-and somewhat paradoxically, a patient without a pacemaker before TTVR might end up with one after, whereas a patient with a pacemaker before TTVR might end up with that lead trapped by the valve.

Preliminary evidence suggests that TTVR is feasible even in the presence of transvenous leads, particularly in valve-in-valve scenarios. For new-generation investigational TTVR devices (for native TR), data are still emerging; the need for backup pacing is notable (around 1 in 9 patients for Evoque at 30 days), but having a pre-existing pacemaker does not appear to contraindicate participation.

A prior epicardial or leadless pacemaker could be advantageous to avoid the issue of an entrapped lead. In cases where an existing transvenous lead is present, the decision to extract it versus entrap it in the new valve must be individualized-current practice leans toward leaving leads in place given the acceptable outcomes

Table 1: Studies on outcomes in patients with cardiovascular implantable electronic devices undergoing tricuspid transcatheter interventions.

Study (Year)	Design/Patients	Intervention	Key Findings (CIED patients)
TRILUMINATE Pivotal Trial [4]	Prospective trial; 469 patients (98 CIED leads, 371 without)	T-TEER (TriClip)	Procedural success was high (88% TR ≤ 2 + at 30d, 81% at 1yr). Shorter procedure (133 vs. 156 min, p=0.004), fewer clips (1.9 vs. 2.2, p=0.0018). No lead revisions are needed; comparable mortality/HF hospitalizations. Significant symptom/QOL improvement.
Alachkar, et al. [8]	Single-center cohort; 106 T-TEER patients (25 with CIED, 23.6%)	T-TEER (TriClip/Pascal)	Success 92%; similar TR improvement vs non-CIED. In-hospital mortality is low (4%). Demonstrated feasibility with leads without outcome differences.
Sanchis, et al. [9]	Case series (3 patients, all pacemaker, severe TR)	T-TEER, annuloplasty, caval valve	Tailored interventions successful (massive → mild TR); symptom improvement at 3-12 months.
TriValve Registry [7]	Multicenter registry; 470 patients (121 CIED leads, 25.7%)	T-TEER (mostly MitraClip)	Success ~79%. TR ≤ 2+ in 73.7% at 30 days. 1-year survival comparable (73.6%). Significant symptom improvement; no increased complications.
VIVID Registry [7]	Multicenter registry; 329 valve-in-valve/ring TTVR (128 CIED, 39%)	TTVR (valve-in-valve/ring)	Lead entrapment is common but rarely problematic (10% lead dysfunction at 1 year). No mortality difference. Demonstrated safety and efficacy without lead extraction.
Tang, et al. [10]	Case report (pacemaker-induced TR, pacer-dependent)	Staged lead extraction + Micra leadless pacer + T-TEER	TR improved (severe → moderate), clinical improvement post-procedure. The first use of leadless pacer facilitating T-TEER.

Note: Abbreviations: CIED=Cardiovascular Implantable Electronic Device; HF=Heart Failure; T-TEER=Tricuspid Edge-to-Edge Repair; TR=Tricuspid Regurgitation; TRILUMINATE=Trial to Evaluate Cardiovascular Outcomes in Patients Treated With the Tricuspid Valve Repair System; TriValve=Transcatheter Tricuspid Valve Therapies; TTVR=Transcatheter Tricuspid Valve Replacement; QOL=Quality of Life; VIVID=Valve-in-Valve International Database

reported. Table 1 below compares key findings across the major studies.

Technical tips for tricuspid transcatheter interventions in patients with CIED leads

Performing transcatheter tricuspid interventions, such as T-TEER or TTVR, in patients with transvalvular CIED leads requires meticulous pre-procedural planning and tailored intraprocedural strategies to optimize outcomes and minimize complications. Echocardiographic imaging, particularly Transesophageal Echocardiography (TEE) or Intracardiac Echocardiography (ICE), should be leveraged to accurately assess the interaction between leads and tricuspid leaflets, identify lead adherence, and evaluate leaflet mobility. During T-TEER, operators should strategically select clip placement to avoid lead entrapment, often employing initial clip placement away from the lead followed by additional clips as needed. In cases where the lead directly impinges leaflet captation, intentionally capturing or repositioning the lead with the clip device may enhance procedural success. For TTVR procedures, existing transvalvular leads typically do not require routine extraction; however, operators must cautiously deploy the valve to prevent lead displacement. Post-procedural interrogation of the CIED is essential to confirm lead integrity and function. In selected complex cases where the lead significantly compromises procedural feasibility, lead extraction followed by leadless pacing systems or alternative transcatheter approaches (e.g., caval valve implantation) can be considered. Given the risks of "jailing" a CIED lead during percutaneous TV intervention, a transvenous lead extraction may be considered beforehand. Ultimately, a multidisciplinary heart-team approach is critical in tailoring procedural strategy and lead management decisions to the individual patient's anatomy and clinical needs [16].

Conclusion

Patients with CIEDs can safely undergo transcatheter tricuspid interventions, as evidenced by multiple studies ranging from single-case reports to multicenter registries. Tricuspid Edge-To-Edge Repair (T-TEER) in the setting of pacemaker or defibrillator leads has shown high success rates with significant TR reduction and symptom improvement, with no significant increase in procedural risk, intrahospital mortality, or early recurrence of TR compared to patients without leads. Key baseline differences do not translate into worse procedural outcomes in these reports. Operators have developed techniques to work around leads, and in some cases even use the repair device to mitigate lead interference. CIED presence should not exclude patients from transcatheter tricuspid therapies. High-risk patients with severe TR and pacemaker/ICD leads have been successfully treated with T-TEER, transcatheter annuloplasty, valve-in-valve replacement, and even caval valve implantation, with most reporting improved hemodynamics and clinical status. A multidisciplinary heart team evaluation is essential to choose the optimal strategy (repair vs replacement, and whether any lead modification is needed). While longer-term outcomes beyond 1-2 years remain to be studied, current evidence indicates that both T-TEER and TTVR are promising and effective options for managing TR in patients with CIED leads. Continued follow-up and reporting are needed to further inform best practices for lead management and to monitor the durability of these interventions in this unique population.

Statements and Declarations

Dr. Naik has consulted for Abbott and Edwards Lifesciences.

References

1. Al-Bawardy R, Krishnaswamy A, Bhargava M, et al. Tricuspid regurgitation in patients with pacemakers and implantable cardiac defibrillators: A comprehensive review. Clin Cardiol. 36(5):249-254 (2013).
2. Chang JD, Manning WJ, Ebrille E, et al. Tricuspid valve dysfunction following pacemaker or cardioverter-defibrillator implantation. J Am Coll Cardiol. 69(18):2331-2341 (2017).
3. Andreas M, Bartko PE, Zirlik A, et al. CIED and tricuspid regurgitation-a LEADing problem? EuroIntervention. 21(5):e245-e246 (2025).
4. Naik H, Price MJ, Kapadia S, et al. Tricuspid transcatheter edge-to-edge repair in patients with transvalvular CIED leads: The TRILUMINATE Pivotal trial. JACC Clin Electrophysiol. (2025).
5. Taramasso M, Alessandrini H, Latib A, et al. Outcomes after current transcatheter tricuspid valve intervention: Mid-term results from the international TriValve registry. JACC Cardiovasc Interv. 12(2):155-165 (2019).
6. Hausleiter J, Braun D, Orban M, et al. Patient selection, echocardiographic screening and treatment strategies for interventional tricuspid repair using the edge-to-edge repair technique. EuroIntervention. 14(6):645-653 (2018).
7. Taramasso M, Gavazzoni M, Pozzoli A, et al. Outcomes of TTVI in patients with pacemaker or defibrillator leads: Data from the TriValve registry. JACC Cardiovasc Interv. 13(5):554-564 (2020).
8. Alachkar MN, Schnupp S, Eichelsdoerfer A, et al. Feasibility and efficacy of transcatheter tricuspid valve repair in patients with cardiac implanted electrical devices and trans-tricuspid leads. J Clin Med. 12(15):4930 (2023).
9. Sanchis L, Sitges M, Abdul-Jawad Altisent O, et al. Tailored treatment of patients with intracardiac leads and tricuspid regurgitation. JACC Case Rep. 12:101781 (2023).
10. Tang GH, Kaple R, Cohen M, et al. First percutaneous Micra leadless pacemaker implantation and tricuspid valve repair with MitraClip NT for lead-associated severe tricuspid regurgitation. EuroIntervention. 12(15):e1845-e1848 (2017).
11. Anderson JH, McElhinney DB, Aboulhosn J, et al. Management and outcomes of transvenous pacing leads in patients undergoing transcatheter tricuspid valve replacement. JACC Cardiovasc Interv. 13(17):2012-2020 (2020).
12. Fam NP, Eckstein JS, Gandhi S, et al. Transcatheter tricuspid valve replacement for pacemaker-associated tricuspid regurgitation. EuroIntervention. 14(15):e1556-e1557 (2019).
13. Kodali S, Hahn RT, George I, et al. Transfemoral tricuspid valve replacement

in patients with tricuspid regurgitation: TRISCEND study 30-day results. JACC Cardiovasc Interv. 15(5):471-480 (2022).

14. Jouan J, Mele A, Florens E, et al. Conduction disorders after tricuspid annuloplasty with mitral valve surgery: Implications for earlier tricuspid intervention. J Thorac Cardiovasc Surg. 151(1):99-103 (2016).

15. Jokinen JJ, Turpeinen AK, Pitkänen O, et al. Pacemaker therapy after tricuspid valve operations: Implications on mortality, morbidity, and quality of life. Ann Thorac Surg. 87(6):1806-1814 (2009).

16. Gabriels JK, Schaller RD, Koss E, et al. Lead management in patients undergoing percutaneous tricuspid valve replacement or repair: A 'heart team'approach. Europace. 25(11):euad300 (2023).