Tricuspid transcatheter edge-to-edge repair in patients with cardiac implantable electronic device leads

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Cardiac implantable electronic devices (CIEDs) are frequently encountered in patients undergoing transcatheter edge-to-edge repair (TEER) for severe tricuspid regurgitation (TR), with a prevalence exceeding 30%. Transvalvular leads introduce unique anatomic and procedural challenges, including imaging shadowing, leaflet tethering, device-lead interaction, and risk of entanglement during repair. Successful intervention requires careful preprocedural assessment of tricuspid valve anatomy, mechanism of TR, inferior vena cava (IVC) alignment, and the spatial relationship of right atrial, coronary sinus, right ventricular, or leadless systems to the tricuspid apparatus. This manuscript describes a structured intraoperative approach to managing CIED leads during tricuspid TEER (tTEER). The strategy incorporates multi-site femoral venous access, stiff-wire straightening techniques to correct IVC offset, and the use of a steerable sheath to achieve controlled intracardiac lead manipulation. Step-by-step technical considerations are detailed, including lead tethering, commissural repositioning, and controlled release following device deployment. This approach aims to standardize management of CIED-related challenges and provide a reproducible technique for safe and effective tTEER in this complex cohort.

Keywords: Tricuspid regurgitation (TR); transcatheter edge-to-edge repair (TEER); cardiac implantable electronic devices (CIED); lead management; intracardiac lead manipulation

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Introduction

Cardiac implantable electronic devices (CIEDs) remain a major consideration when assessing treatment options for patients with severe tricuspid regurgitation (TR) (1,2). CIEDs are frequently present in patients with TR, with a prevalence exceeding 30% (1,2). With transcatheter edge-to-edge repair (TEER), the goal is to restore coaptation between the native leaflets of the tricuspid valve in patients suffering from significant TR (3,4). As a result, in managing these patients, we are often required to interact with an existing CIED system in order to achieve appropriate TR reduction. Currently, no clear guideline recommendations exist regarding the management of CIEDs in this cohort (5,6); however, data from the TRILUMINATE trial demonstrate similar 1-year procedural outcomes in patients undergoing tricuspid TEER (tTEER) with and without transvalvular leads (7).

Significant considerations must be addressed when performing tTEER in the setting of transvalvular CIED leads (1,2). Preprocedural assessment should include careful evaluation of lead position, commissural interactions, the presence or absence of lead “slack”, and the overall integrity and function of the device system (1,2). Comprehensive preprocedural planning should involve a multidisciplinary heart team approach, incorporating electrophysiology, general cardiology, interventional cardiology, and cardiothoracic surgery (5). Intraprocedural strategies—whether involving lead manipulation, intentional “jailing” of a lead between device components or between the device and native anatomy—carry potential risks, including CIED dysfunction and even lead fracture (1). Alternative

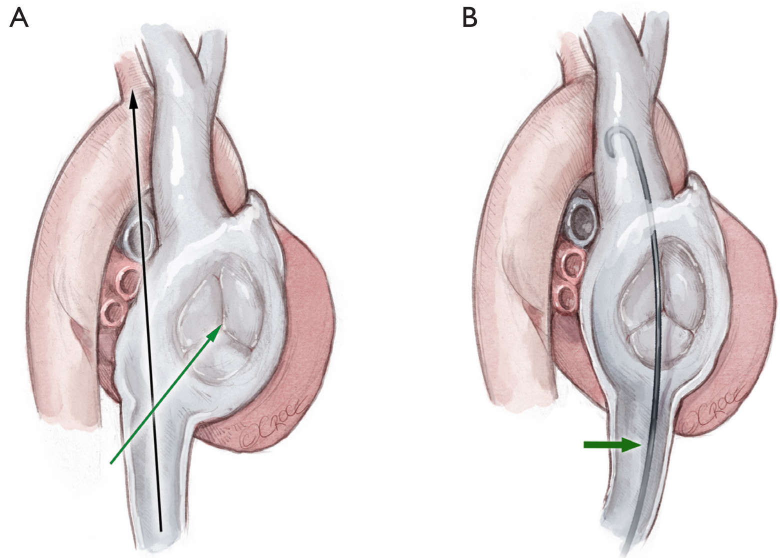

Figure 1 Alignment of the IVC with the tricuspid valve is particularly important, as misalignment can create significant technical challenges in achieving appropriate access and trajectory toward the valve. (A,B) This figure illustrates a patient with IVC offset. Following acquisition of large-bore access, an additional distal right common femoral venous access site is established, and an Amplatz Super Stiff wire is advanced from the IVC into the SVC. This maneuver is performed prior to advancing the secondary guidewire for delivery of the TEER system into the right atrium. Straightening the IVC-SVC axis in this manner corrects any offset and facilitates a more coaxial trajectory, allowing optimal positioning of the TEER device at the level of the tricuspid annulus. IVC, inferior vena cava; SVC, superior vena cava; TEER, transcatheter edge-to-edge repair.

approaches, including lead extraction prior to transcatheter intervention with placement of an epicardial system or transition to a leadless platform, have been proposed for patients undergoing evaluation for tTEER (6). Strategies involving transcatheter manipulation of CIED leads have also been described, although they remain technically challenging. In this illustrative report, we describe a potential technique that may be utilized to perform intracardiac manipulation of CIED leads during tTEER.

Operative technique

Preoperative assessment

Anatomic assessment of the tricuspid valve, the location of CIED leads, the mechanism of TR, and the relationship of the inferior vena cava (IVC) to the tricuspid valve are all critical to procedural success. Beyond valvular morphology, alignment of the IVC with the tricuspid valve is particularly important, as misalignment can create significant technical challenges in achieving appropriate access and trajectory toward the valve (*Figure 1A,1B*). While not mandatory in all cases, three-dimensional evaluation with advanced cardiac computed tomography (CT) can help identify anatomic constraints that may complicate optimal management of tricuspid valve pathology. Although not all patients routinely undergo advanced CT imaging, three-dimensional transthoracic and transesophageal echocardiography remain essential for defining the IVC-tricuspid relationship, anticipating device trajectory, and identifying potential interference with transcatheter tools.

Different types of CIED leads pose unique challenges during tTEER. Right atrial leads can obscure transesophageal and intracardiac echocardiographic imaging when attempting to visualize the tricuspid valve (*Figure 2*). Intracardiac echocardiography (ICE) imaging can often be optimized by steering inferiorly from the IVC. However, there remains a significant risk of entanglement with right atrial leads when advancing equipment from the IVC toward the tricuspid annulus, which may limit maneuverability during device positioning. Excess slack in a right atrial lead can further complicate the procedure by promoting tethering or displacement of the septal leaflet during device manipulation.

Coronary sinus leads may also present substantial

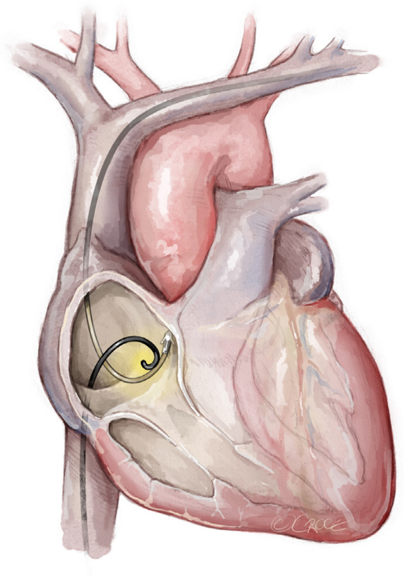

Figure 2 Manipulation of the Agilis sheath allows for reduction of excess lead slack that may interfere with delivery or positioning of a transcatheter edge-to-edge repair or transcatheter tricuspid valve replacement device. If these maneuvers are unsuccessful, lead extraction may need to be considered. For this reason, meticulous preprocedural planning and multidisciplinary evaluation are essential to optimize procedural success and minimize complications.

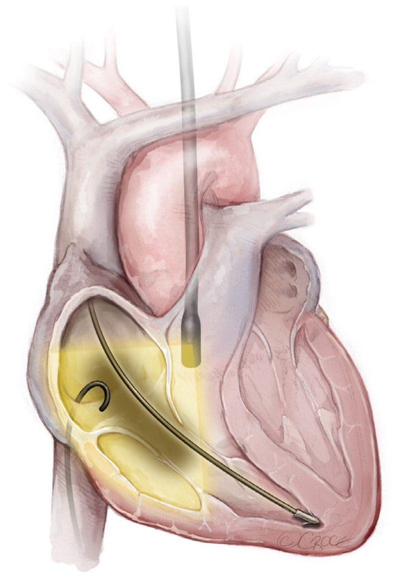

Figure 3 Atrial and ventricular leads may produce significant artifact and acoustic shadowing, limiting adequate visualization of the tricuspid leaflets during edge-to-edge repair. Careful preprocedural planning is therefore essential, and intracardiac echocardiography may help facilitate improved leaflet visualization.

imaging and procedural challenges. These leads frequently course posterior to the tricuspid annulus, creating acoustic shadowing along the posterior-septal commissure and reducing the reliability of leaflet coaptation assessment (*Figure 3*). Similar to right atrial leads, coronary sinus leads carry a risk of interaction with the TEER device. Posterior-septal leaflet grasping may be particularly challenging if the lead is adherent to or impinging upon the posterior leaflet. Any equipment entanglement may result in lead dislodgement, as coronary sinus leads are typically wedged within coronary venous branches rather than actively fixed to the myocardium.

Right ventricular leads introduce challenges that extend beyond imaging limitations. Comprehensive preprocedural imaging is imperative to define the resting position of the right ventricular lead, particularly in transgastric short-axis TEE views. Advanced imaging may be necessary to determine whether the leaflet is adherent to, tethered by, impinging upon, or freely mobile relative to the lead (*Figure 4A-4D*). Right ventricular leads are a well-recognized mechanism of TR and may directly contribute to leaflet malcoaptation. It is therefore essential to determine whether the lead will obscure potential grasping targets or create acoustic shadowing over intended clip positions. Intraprocedurally, there is a substantial risk of entanglement between the repair device and the lead, which may result in lead displacement or device instability. There is also a risk of inadvertent capture of the right ventricular lead between the clip arms.

Leadless pacing systems also present imaging and procedural considerations. Septal implantation may create subvalvular tethering and anchoring of the septal leaflet, thereby contributing to TR pathology (*Figure 5*). During tTEER, such tethering may compromise septal leaflet grasp and limit effective restoration of coaptation.

Several mitigation strategies can be employed when addressing CIED-related challenges. From a preprocedural standpoint, advanced cardiac CT can delineate the course of right atrial, coronary sinus, and right ventricular leads. Identifying anticipated imaging limitations and procedural constraints in advance facilitates intraoperative planning (*Figure 6*). During the procedure, minimizing excessive circumferential rotation and sweeping movements of

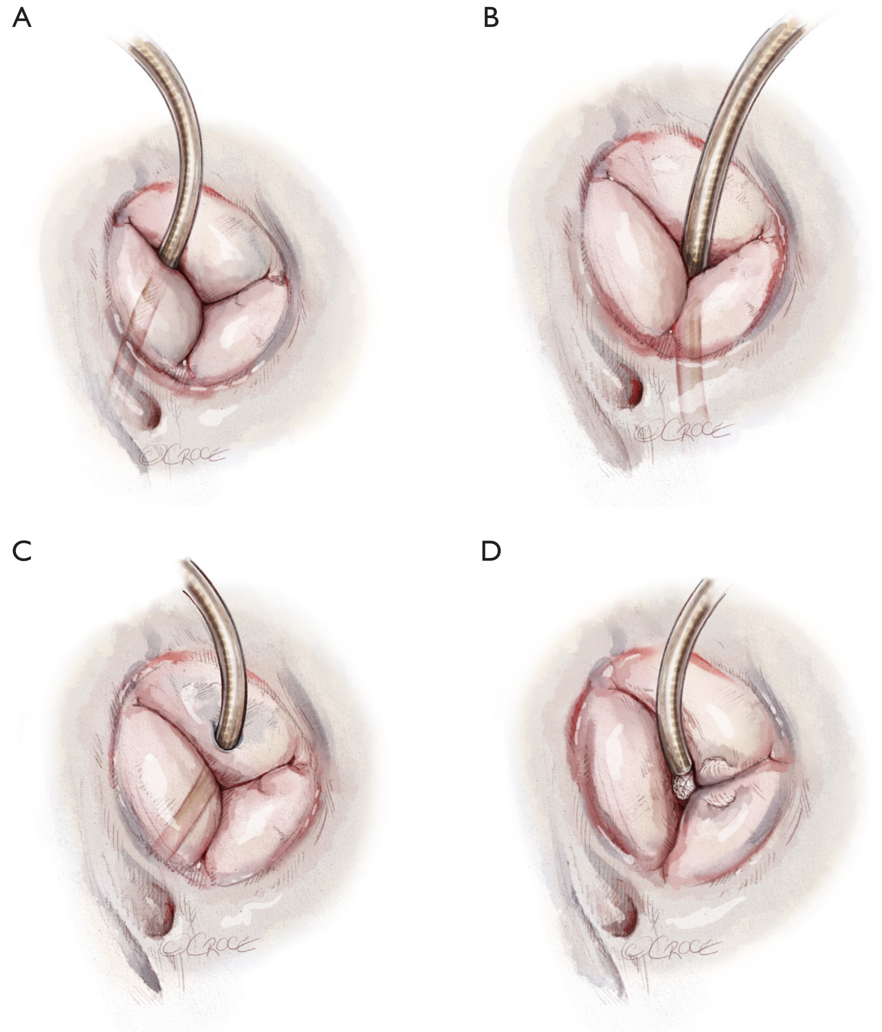

Figure 4 Advanced imaging may be necessary to determine whether the leaflet is adherent to, tethered by, impinging upon, or freely mobile relative to the lead. A freely mobile right ventricular lead with minimal interaction with the valvular apparatus allows for less challenging transcatheter edge-to-edge repair (A). Tricuspid regurgitation may result from lead interaction with the valve preventing leaflet coaptation (B), leaflet perforation by the lead (C), or lead-induced tethering of the subvalvular apparatus preventing appropriate valve closure (D).

delivery systems may reduce the risk of entanglement with right atrial and coronary sinus leads.

Intraprocedural technical approach

Here, we describe an intraoperative technical approach for patients with CIED leads. In patients with CIED systems and challenging anatomy, obtaining multiple venous access points may be necessary. Traditionally, the right common femoral vein serves as the primary access site for transcatheter tricuspid valve procedures, as it reduces the distance to the tricuspid annulus and facilitates a more direct trajectory. In the setting of challenging anatomy and transvalvular CIED leads, it may be necessary to obtain multiple venous puncture sites within the right common femoral vein, as well as contralateral access via the left common femoral vein. Large-bore access for TEER is typically preclosed with two Perclose sutures. Additional access sites are then obtained depending on the procedural challenges encountered. We describe here a technical approach for managing patients with IVC offset as well as those with CIED leads.

In patients with IVC offset, an additional inferior 6-French venous access site can be obtained adjacent to

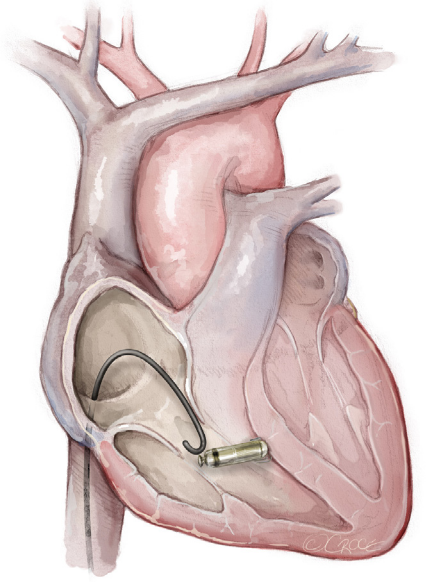

Figure 5 Leadless pacemakers implanted close to the tricuspid valve along the subvalvular apparatus of the septal leaflet may complicate tricuspid TEER. Interaction with the device can impede catheter positioning and septal leaflet grasping, limiting effective treatment of tricuspid coaptation zones. TEER, transcatheter edge-to-edge repair.

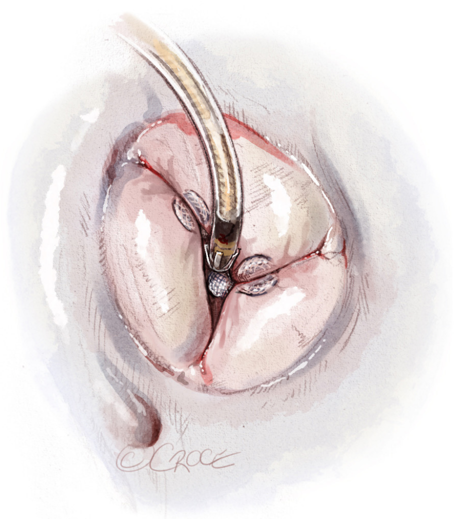

Figure 6 Manipulation of the right ventricular lead may permit edge-to-edge repair around the lead, facilitating effective reduction of tricuspid regurgitation.

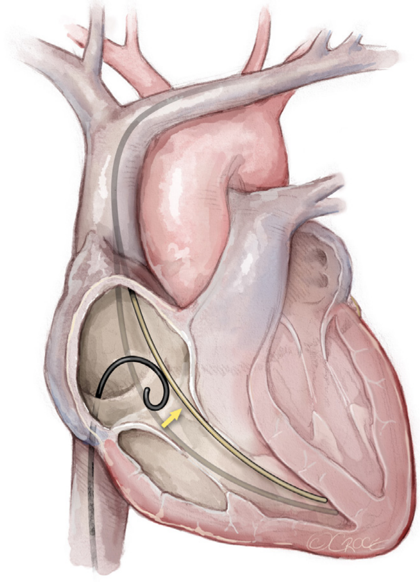

Figure 7 This figure demonstrates use of a steerable Agilis sheath with a 6-French pigtail catheter. The pigtail is advanced through the Agilis sheath and used to encircle and secure the right ventricular lead at the sheath ostium. This controlled tethering permits deliberate repositioning and stabilization of the right ventricular lead before advancing the transcatheter edge-to-edge repair device toward the tricuspid annulus, thereby facilitating safe device delivery and reducing the risk of lead-device interaction.

the primary large-bore access. An Amplatz Super Stiff wire (Cook Medical, Bloomington, USA) can be advanced from the IVC into the superior vena cava (SVC) to help correct IVC offset and facilitate improved alignment toward the tricuspid valve (*Figure 1B*). Placement of one or more stiff wires from the IVC into the SVC may straighten the venous course and allow a more coaxial trajectory for devices approaching the tricuspid valve from below. Contralateral 11-French access via the left common femoral vein is typically obtained for placement of three-dimensional ICE.

In the setting of significant obstruction from right atrial, coronary sinus, or right ventricular leads, an additional distal 12-French venous access site can be obtained in the right common femoral vein, separate from the primary edge-to-edge repair access. Through this site, an Agilis sheath (Abbott Vascular, Santa Clara, USA) may be advanced into the right atrium with significant anteflexion to maneuver around right atrial or ventricular leads (*Figure 7*).

A 6-French pigtail catheter inserted through the Agilis sheath can then be used to encircle the right atrial or right ventricular lead, effectively tethering and securing the CIED lead at the ostium of the Agilis sheath.

Once the TEER device is advanced from the IVC toward the tricuspid valve, the Agilis sheath can be repositioned—moved anteriorly or posteriorly and rotated superiorly or inferiorly—to optimize the spatial relationship between the CIED lead and the transcatheter device. This allows controlled manipulation of the CIED lead, particularly the right ventricular lead, and facilitates positioning within a specific commissure to preserve an adequate coaptation gap while minimizing the risk of entanglement.

After device deployment and withdrawal of the delivery system from the tricuspid valve, the pigtail catheter within the Agilis sheath can be unwound to release any tethering of the CIED lead. The Agilis sheath is then returned to its neutral configuration and safely removed. Postprocedural assessment of CIED lead function, including threshold testing, should be performed in collaboration with electrophysiology to ensure no device dysfunction has occurred.

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Footnote

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