Sequential Implantation of Micra and TriClip for Massive Tricuspid Regurgitation and Sick Sinus Syndrome

Implantação Sequencial de Micra e TriClip em Doente com Insuficiência Tricúspide Massiva e Doença do Nó Sinusal

Nuno Moreno[1], Bruno Melica[1], Luís Puga[1], Mário Jorge Amorim[2], Luís Adão[1]*

***Corresponding Author**/Autor Correspondente
Nuno Fernando Morais Moreno [Numoreno@yahoo.com]
ORCID: https://orcid.org/0000-0003-1410-4057
Hospital Lusíadas Porto, Av. da Boavista 171, 4050-115 Porto, Portugal

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Abstract

Severe tricuspid valve regurgitation (TR) is associated with high cardiovascular mortality. Safe and feasible interventional approaches to treat TR are of clinical relevance. Tricuspid transcatheter edge-to-edge repair (TEER) is a promising therapy for severe tricuspid regurgitation. Herein, we report an 81-year-old woman, with a history of double valve replacement, with recurrent symptomatic massive tricuspid regurgitation and sinus node dysfunction, in need of a permanent pacemaker. After the Heart Team discussion, we considered implanting a leadless pacemaker since such a device would not interfere with TEER. The procedure was successfully performed using the TriClip® device and tricuspid regurgitation was reduced to a moderate degree. In conclusion, TEER, in combination with a leadless pacemaker, is an alternative option for patients with an indication for a permanent pacemaker and massive tricuspid regurgitation to undergo a less invasive treatment rather than a potentially higher-risk reoperation.

Resumo

A regurgitação grave da válvula tricúspide (IT) está associada a alta mortalidade cardiovascular. Abordagens percutâneas seguras e viáveis para tratar a IT são de relevância clínica. A intervenção percutânea na válvula tricúspide (TEER) é uma terapêutica promissora para a regurgitação tricúspide grave. Reportamos o caso de uma mulher de 81 anos, com antecedentes de substituição valvular com dupla prótese mecânica mitral e aórtica, com regurgitação tricúspide massiva sintomática, disfunção do nó sinusal e necessidade de pacemaker permanente. Após discussão em Heart Team decidimos implantar um pacemaker sem elétrodos, uma

1. Serviço de Cardiologia, Hospital Lusíadas Porto, Lusiadas Saúde, Porto, Portugal. **2.** Serviço de Cirurgia Cardiotorácica, Unidade Local de Saúde São João, Porto, Portugal

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vez que tal dispositivo não interferiria na intervenção percutânea. O procedimento foi realizado com sucesso utilizando o TriClip® e a regurgitação tricúspide reduziu para grau moderado. Concluindo, TEER em combinação com pacemaker sem elétrodos é uma alternativa para pacientes com indicação para pacemaker permanente e regurgitação tricúspide massiva, de modo a serem submetidos a um tratamento menos invasivo, em vez de uma reoperação potencialmente de maior risco.

INTRODUCTION

Tricuspid transcatheter edge-to-edge repair (TEER) has developed as a treatment strategy for tricuspid valve regurgitation (TR) within the last few years. This percutaneous procedure involves a transvenous approach and approximates the tricuspid-valve leaflets by deploying a clip to hold the leaflets together and reduce tricuspid regurgitation without needing cardiopulmonary bypass or cardiac surgery. Tricuspid TEER is usually undertaken at shallow risk (less than 1% risk of major complication or death). This technique remains new and is still developing. Studies showed a significant reduction in the severity of TR and was associated with substantial improvements in symptoms and quality of life measures.[1]

CASE REPORT

The patient was an 81-year-old woman with a history of rheumatic heart disease. Twenty years ago, she had undergone double valve replacement with mechanical prostheses without any intervention on the tricuspid valve.

The patient complained of worsening chest tightness and peripheral edema in the past half a year. Upon admission, the physical examination revealed edema of both lower extremities, arrhythmia, and moderate murmur in the auscultation area of the tricuspid valve. The patient's usual cardiac medication was furosemide 40 mg twice a day and daily spironolactone. The transthoracic echocardiography suggested a normal function of double mechanical prostheses and torrential TR (EROA 0.8 cm^2, VR 93 mL, Fig. 1.A). Besides, both atria (left atrial volume index, 59 mL/m2; right atrial volume index, 71 mL/m2), the right ventricle (right ventricular end-diastolic 3D volume, 75 mL/m^2), and the IVC (33 mm) were severely dilated, whereas the left ventricular volume (52 mL/m^2) was in the normal range. Right ventricular (tricuspid annular plane systolic excursion (TAPSE), 17 mm, ejection fraction 46%, free wall longitudinal strain -23.6%) and left ventricular function (ejection fraction, 53%) were at the lower limit of normality. Furthermore, liver vein congestion with flow reversal and incipient parenchymal liver disease were identified, underlining the significance of present TR (Fig. 1.B). For better characterization, a transesophageal echocardiogram was performed. It showed dilation of the tricuspid ring (47 mm, 28.5 mm/m^2), with significant "tethering" of the leaflets (1.2 cm, 3D volume 6.5 mL) and a type I (3-leaflet configuration) valve with thickened leaflets, with rheumatic involvement but without significant calcification or AD/RV obstruction (3D planimetry area of approximately > 6 cm^2, AD/VD gradient 1.5 mmHg) (Video 1). We also saw a restriction of the septal leaflet (which measured 15 mm), causing a lack of coaptation between the anterior/posterior and septal leaflets (gap 4-5 mm), confirming torrential tricuspid regurgitation (3D vena contracta area 1.2 cm^2).

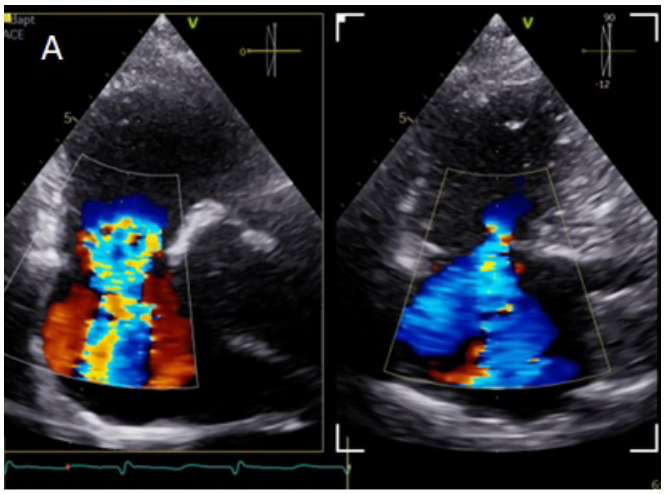


Figure 1.A. Transthoracic echocardiography, modified parasternal short axis showing biplane color Doppler view of tricuspid regurgitation

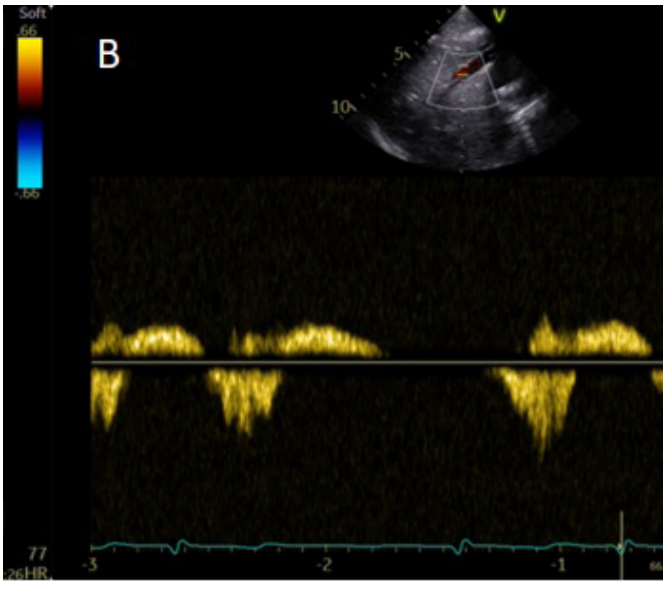
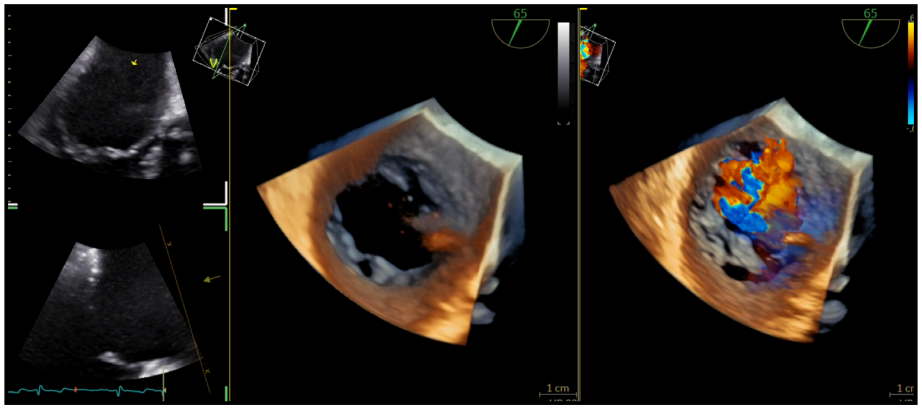


Figure 1.B. Transesophageal echocardiography. Pulsed-wave Doppler showing systolic flow reversal in supra-hepatic vein.

During hospitalization, electrocardiography monitoring showed sinus bradycardia, sinus pause, AV junctional escape beats, ventricular escape and paroxysmal atrial fibrillation. The longest RR interval was 7.230 s.



Video 1. Transesophageal echocardiography mid-esophageal cut plane showing the tricuspid valve in 3D and 3D color. Orientation is according to the "interventionalist's view," with the aortic valve displayed at around 5 o'clock.

After discussion in the Heart Team, the patient was evaluated as being at high risk for redo surgical; the anatomy of the tricuspid valve was considered amenable to percutaneous intervention. Taking this data into account, an optimal therapeutic approach was considered to be the implantation of a leadless pacemaker (LP) (Micra, Medtronic Inc.) since such a device would not permanently interfere with the percutaneous repair of the valve as a conventional pacemaker lead. Micra LP was successfully implanted in an apical position in the right ventricle (Fig. 2) and percutaneous tricuspid intervention was delayed until at least 6 weeks to allow for the device to settle properly and avoid the risk of embolization.

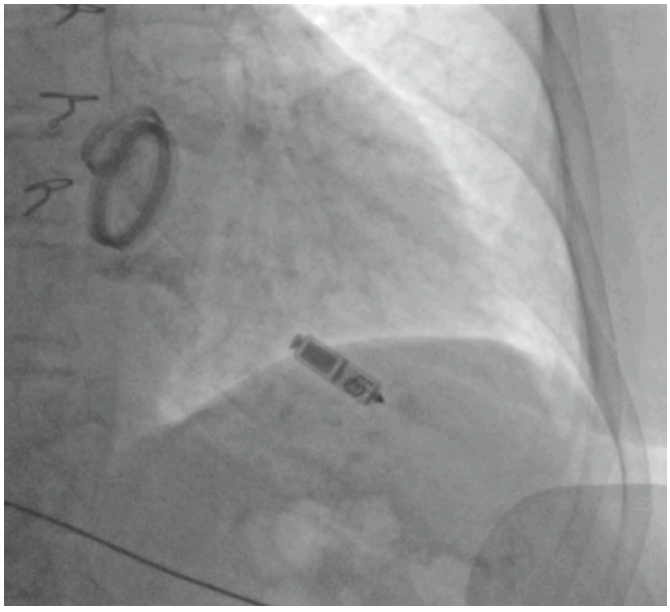


Figure 2. Fluoroscopy image of the final position of the Micra

After therapeutic adjustment and volume overload reduction, the patient was discharged home uneventfully on day two. However, she remained symptomatic, and transthoracic echocardiography (TTE) kept showing torrential TR. Six weeks later, she returned for tricuspid valve repair with the TriClip® (Abbott Laboratories, Abbott Park, IL, USA).

The procedure was performed under general anesthesia with transesophageal echocardiography and fluoroscopic guidance. Distance from the free edge of the LP device to the tricuspid valve plane was estimated as 35 mm and was continuously monitored by fluoroscopy and echocardiography to avoid interaction between the two systems (Fig. 3.C). Implantation of one TriClip® G4 XTW in an anteroseptal position (Fig. 3.D) was attempted with adequate grasping of the leaflets. This clip reduced TR from torrential to moderate with a residual posterior eccentric regurgitation (Video 2). Implantation of a TriClip® G4 XT in a posteroseptal position was tempted several times (Fig. 3.E), achieving a further reduction of TR, but causing significant valve stenosis (mean gradient of 4-5 mmHg). Notably, we intended to reduce the degree of TR rather than eliminate all TR. The risk of tricuspid stenosis and concerns about whether the dysfunctional RV would tolerate a further acute reduction in the degree of TR made us remove the second clip, which was achieved without complications. The final TEE evaluation showed moderate to severe residual TR (biplane vena contracta 6-8 mm) and a mean gradient of 3.3 mmHg (Video 3).

Patient's further evolution was uneventful and the patient was discharged in day 3.

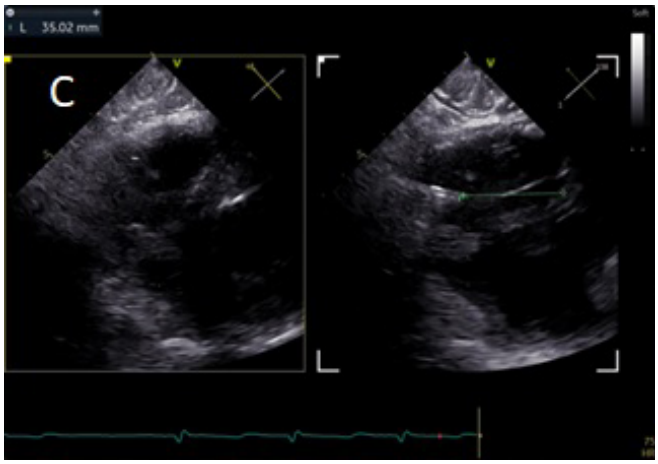


Figure 3.C. Transesophageal echocardiography transgastric view measuring the distance from the tip of the Micra leadless pacemaker to the tricuspid valve plane (35 mm).

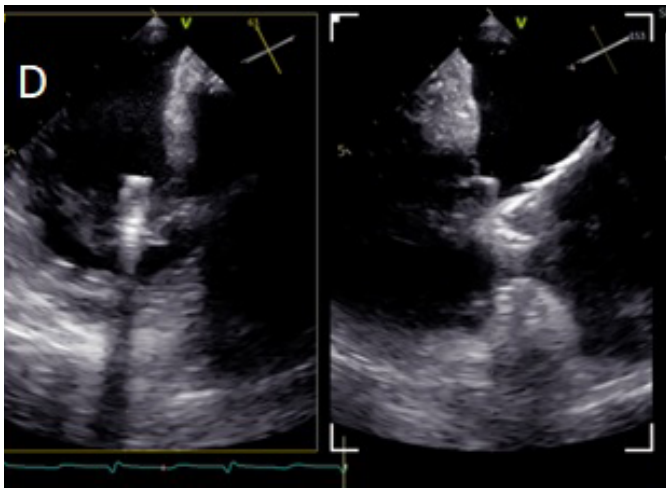
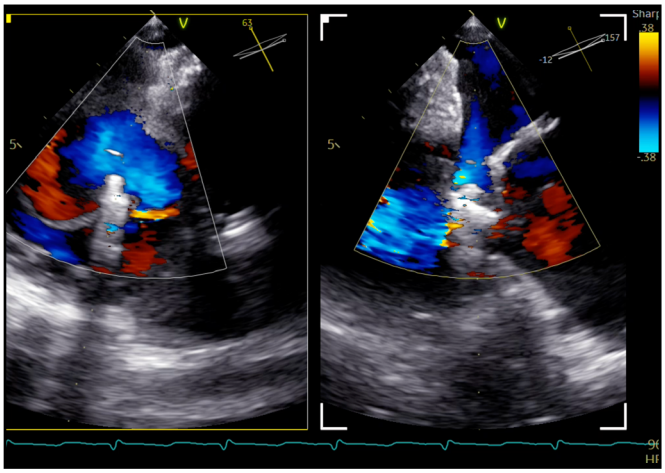


Figure 3.D. Transesophageal echocardiography. Deep esophageal cut plane for optimization of the device trajectory to the anteroseptal part of the tricuspid valve. Left pane showing the inflow/outflow view and the right pane shows the device aligned to the valve plane with both arms opened.



Video 2. Transesophageal echocardiography. Deep esophageal biplane color mode on the tricuspid valve during the closure of the device shows a significant reduction of the tricuspid regurgitation in the antero-septal part of the valve.

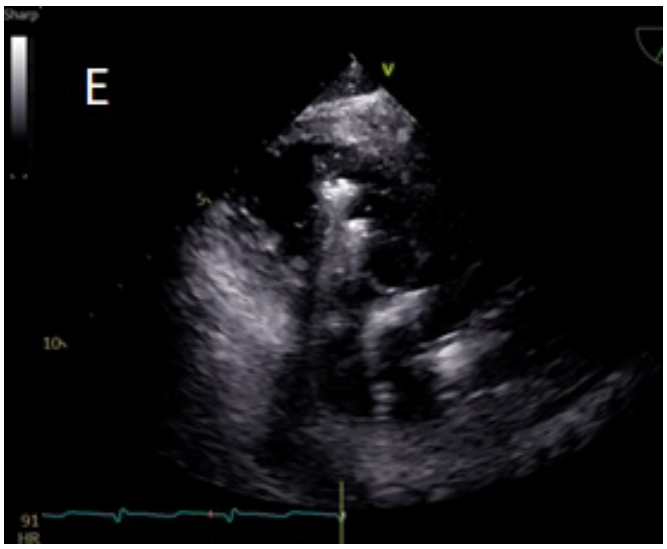
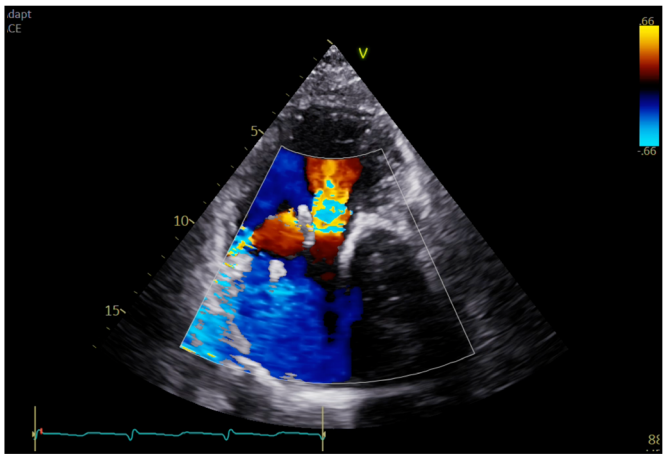


Figure 3.E. Transesophageal echocardiography – transgastric short-axis plane of the tricuspid valve showing the two devices (TriClip® XTW) in anteroseptal and posteroseptal part of the valve

At 1-month follow-up, symptomatic improvement and TR reduction were significant (Fig. 4). There was mild ankle edema and no ascites. Diuretics use was reduced to furosemide 40 mg twice a day, while regular daily spironolactone was no longer required.



Video 3. Transthoracic echocardiography, modified parasternal short axis showing tricuspid valve color Doppler of the final result after removal of the second device (catheter still visible in the right atrium).

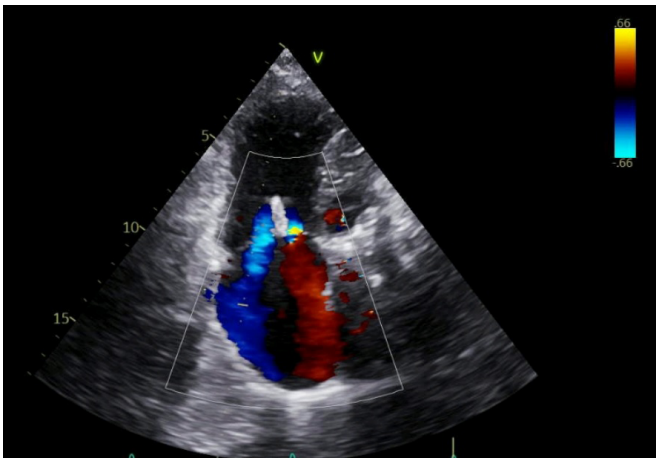


Figure 4. The postinterventional transthoracic echocardiogram shows significant reduction of tricuspid regurgitation

Discussion

This case emphasizes the safety of a sequential planned implantation of Micra LP and a TriClip® in a patient with an indication for permanent pacemaker and tricuspid valve edge-to-edge repair.

Isolated tricuspid valve surgery should be considered in symptomatic patients with severe functional TR (with or without prior left-sided valve surgery) who have right ventricular dilation and preserved ventricular function. Nowadays, surgical tricuspid valve repair using an annuloplasty ring to reduce the tricuspid ring dimension under cardiopulmonary bypass remains the mainstream, but it carries high risks for elderly patients and those who require reoperation or have right ventricular dysfunction. As for these patients, transcatheter edge-to-edge (TEER) is a feasible option for treating primary and functional TR with acceptable safety and simplicity.[2] In a recent trial, TEER had sustained benefits at 2 years, especially associated with improvement in quality of life and repair efficacy was durable at 2 years in 75% of the patients.[1] TEER devices, such as TriClip® and PASCAL system, aim to restore coaptation by leaflet approximation.[3,4] As for direct annuloplasty devices, cardioband has been the only system to be approved for clinical use, yet.[5]

Characterization of the main morphologic and/or functional abnormalities resulting in TR is an essential aspect of transcatheter TV device selection. Primary TR results from an anatomical abnormality of the TV apparatus and is observed in only 8%-10% of patients with TV disease. Secondary TR (STR) is more common and arises as a result of annular dilation caused by RV enlargement and dysfunction due to pressure/volume overload as a consequence of pulmonary hypertension (PHT), often caused by left-sided heart disease, or atrial fibrillation (AF) with normal RV pressures (atrial/ atriogenic or isolated TR). A favorable anatomy compiles a small septolateral gap (≤7 mm), anteroseptal jet location and confined prolapse or flail in a tri-leaflet morphology valve.[6]

In addition to the anatomical characteristics of the valve, the presence of a good result is strongly associated with patient management and selection. The indication for any TV intervention and its timing should take into account of multiple factors, including the patient's clinical characteristics, disease severity, concomitant end-organ function and anatomical considerations. Those who remain symptomatic and fluid-overloaded despite diuretic treatment with mild or moderate left ventricular impairment, preserved RV function, no evidence of pre-capillary PHT, and only mild/moderate renal and liver dysfunction may derive the greatest benefit from TV intervention. Also, we have dedicated risk score models that help to inform patients and physicians regarding the risk of TEER and guide the clinical decision-making process of patients with severe TR. Compared to conservative management, an early and successful surgical or transcatheter intervention improved 2-year survival in patients at low and, to a lower extent, intermediate TRI-SCORE, while no benefit was observed in the high TRI-SCORE category.[7]

TR secondary to device leads has long been a problem since implantation rates have increased and the incidence of new or increasing severity of TR after the implantation of CIEDs varies between 10% and 39%.[8] Echocardiographic guidance during device implantation may help early identification of lead-associated TR and improve lead placement, but additional studies are needed to quantify improvement/detection.[9] Lead-associated TR is always a challenging scenario for percutaneous treatment and often results in worse outcomes. Even if the TR is not directly related to the lead, it may affect leaflet engagement, delivery system interaction and image quality. Thus, LP appears as a good solution in the cases of indication for permanent pacemaker and percutaneous tricuspid valve treatment. Unexpectedly, some trials associated LP therapy with an increase in TV dysfunction.[10] This may be caused by acute implantation-procedure-related damage of the tricuspid valve and it has been hypothesized that a septal instead of an apical implantation site may be a mechanical contributor to tricuspid valve dysfunction. Changes in the severity of TR after LP implantation are not uncommon but the majority of

patients show unchanged (71%) or improved (10%) tricuspid valve function. In conclusion, data regarding this functional impact on TR are conflicting but a meta-analysis of available data shows no evidence for an increase in the prevalence of significant TR up to one year after LP implantation.[11] In our case, TR remained unchanged after Micra implantation despite an apical implantation that was sought to avoid potential interaction with the TriClip® system. This approach seems to be safer to avoid the risk of device interaction and potential detachment/embolization of the previously implanted LP. Moreover, a delay of percutaneous tricuspid intervention for a couple of weeks after the LP implant sounds reasonable to allow for proper endothelization and fibrosis around the implant site and reduce the risk of embolization.

Regarding our decision to remove the second clip due to fear of significant stenosis, it has been the subject of debate. In the case of TV and TEER, it has been established that an "acceptable" gradient after clipping was arbitrarily defined as a TVG < 3 mmHg. In TriValve registry,[1] an increased discharge TVG was not significantly associated with adverse outcomes after tricuspid TEER but further investigations on higher gradients and longer follow-up are needed to better guide the intraprocedural decision-making process.

Conclusion

TEER has recently emerged as a safe and effective intervention for patients with severe TR and heart failure. The TriClip® system is an alternative approach for high-surgical-risk patients to repair severe TR. The high probability of lead-associated TR makes a leadless pacemaker a good solution in case of permanent pacemaker need and transcatheter tricuspid valve intervention. Further device iteration combined with procedural innovation may expand the number of patients eligible for TEER.

Ethical Disclosures

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MJA and LA: Review of article

All authors approved the final version

Declaração de Contribuição

NM, BM e LP: Pesquisa e redação do artigo

MJA e LA: Revisão do artigo

Todos os autores aprovaram a versão final

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References

1. von Bardeleben RS, Lurz P, Sorajja P, Ruf T, Hausleiter J, Sitges M, et al. Two-Year Outcomes for Tricuspid Repair With a Transcatheter Edge-to-Edge Valve Repair From the Transatlantic TRILUMINATE Trial. Circ Cardiovasc Interv. 2023;16:e012888. doi: 10.1161/CIRCINTERVENTIONS.122.012888.
2. Davidson LJ, Davidson CJ. Transcatheter treatment of valvular heart disease: a review. JAMA. 2021;325:2480–94. doi: 10.1001/jama.2021.2133.
3. Baldus S, Schofer N, Hausleiter J, Friedrichs K, Lurz P, Luedike P, et al. Transcatheter valve repair of tricuspid regurgitation with the PASCAL system: TriCLASP study 30-day results. Catheter Cardiovasc Interv. 2022;100:1291–9. doi: 10.1002/ccd.30450.
4. Lurz P, von Bardeleben RS, Weber M, Sitges M, Sorajja P, Hausleiter J, et al. Transcatheter edge-to-edge repair for treatment of tricuspid regurgitation. J Am Coll Cardiol. 2021;77:229–39. doi: 10.1016/j.jacc.2020.11.038.
5. Bruoha S, Mangieri A, Ho EC, Goldberg Y, Chau M, Latib A. Transcatheter annular approaches for tricuspid regurgitation (Cardioband and others). Interv Cardiol Clin. 2022;11:67–80. doi: 10.1016/j.iccl.2021.09.002.
6. Praz F, Muraru D, Kreidel F, Lurz P, Hahn RT, Delgado V, et al. Transcatheter treatment for tricuspid valve disease. EuroIntervention. 2021;17:791-808. doi: 10.4244/EIJ-D-21-00695.
7. Dreyfus J, Galloo X, Taramasso M, Heitzinger G, Benfari G, Kresoja KP, et al. TRI-SCORE and benefit of intervention in patients with severe tricuspid regurgitation. Eur Heart J. 2024;45:586-97. doi: 10.1093/eurheartj/ehad585.
8. Anvardeen K, Rao R, Hazra S, Hay K, Dai H, Stoyanov N, et al. Prevalence and significance of tricuspid regurgitation post-endocardial lead placement. JACC Cardiovasc Imaging. 2019;12:562-4. doi: 10.1016/j.jcmg.2018.07.009.
9. Vij A, Kavinsky CJ. The clinical impact of device lead–associated tricuspid regurgitation: need for a multidisciplinary approach. Circulation. 2022;145:239–41. doi: 10.1161/CIRCULATIONAHA.121.055019.

10. Hai JJ, Mao Y, Zhen Z, Fang J, Wong CK, Siu CW, et al. Close Proximity of Leadless Pacemaker to Tricuspid Annulus Predicts Worse Tricuspid Regurgitation Following Septal Implantation. Circ Arrhythm Electrophysiol. 2021;14:e009530. doi: 10.1161/CIRCEP.120.009530.

11. Haeberlin A, Bartkowiak J, Brugger N, Tanner H, Wan E, Baldinger SH, et al. Evolution of tricuspid valve regurgitation after implantation of a leadless pacemaker: A single center experience, systematic review, and meta-analysis. J Cardiovasc Electrophysiol. 2022;33:1617-27. doi: 10.1111/jce.15565.

12. Coisne A, Scotti A, Taramasso M, Granada JF, Ludwig S, Rodés-Cabau J, et al. Prognostic Value of Tricuspid Valve Gradient After Transcatheter Edge-to-Edge Repair: Insights From the TriValve Registry. JACC Cardiovasc Interv. 2023:S1936-8798(23)00452-1. doi: 10.1016/j.jcin.2023.01.375.