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Editorial

Expanding the Armamentarium to Tackle a Still Unmet Need: New Transcatheter Options for the Treatment of Tricuspid Regurgitation

Más herramientas para una necesidad no cubierta: nuevas opciones para el tratamiento percutáneo de la insuficiencia tricuspídea

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Moderate-to-severe tricuspid regurgitation (TR) is a not uncommon valvular disease with moderate-to-severe forms being present in up to 4% of the elderly population.[1] Such clinically relevant forms of TR have been identified as an independent predictor of worse long-term survival.[1,2] However, treatment options in these patients are limited because surgical mortality has remained high over the years.[3,4] Given the setting of such outcomes, only 0.5% of all 1.6 million patients with moderate-to-severe TR in the United States undergo surgery annually.[5] To be able to address this vast unmet clinical need, several transcatheter devices are currently under development or already in clinical testing.[6]

Most of these devices are focused on reducing annular dilation or on repairing the leaflets. However, many of the patients identified and referred for treatment today are not suitable for such approaches as they present with severely remodeled right ventricles, including extensive dilation and papillary muscle displacement, resulting in leaflet tethering and a large coaptation gap.[7] In the presence of such extreme anatomies, annular and leaflet repair systems have limited efficacy and can result in significant residual regurgitation. To overcome these technical limitations, percutaneous orthotopic and heterotopic tricuspid valve replacement systems are under development to expand the armamentarium of technical and procedural solutions to treat significant TR in extreme and challenging anatomies.

In 2 recent articles published in *Revista Española de Cardiología*, the authors report the latest experiences with 2 devices that are specifically suited to treat later stages of TR with altered anatomies (figure 1).

Íñiguez-Romo et al.[8] present their experience with the Tricento device (NVT AG, Muri, Switzerland), a valved bioprosthesis, used to treat a massive TR in an 81-year-old woman. In brief, the device is a pericardium-covered nitinol stent structure extending from the superior vena cava to the inferior vena cava (IVC) carrying a lateral bicuspid porcine pericardium valve in its middle portion that enables flow into the right atrium. Thus, the Tricento system follows the concept of caval valve implantation (CAVI), which aims to protect vulnerable organs by minimizing TR backflow into the venous system.[9] In addition to the first-in-human experience reported by Toggweiler et al.[10] and a recent description of 2 additional cases (18 performed worldwide overall), Íñiguez-Romo et al. report in *Revista Española de Cardiología* the first successful implantation of the device in Spain with a noticeably simple procedural design and promising clinical outcomes, confirming that the procedure is safe and feasible in advanced TR stages.[11] Specific anatomical criteria must be met to enable the implantation, potentially limiting broader use of the device: Vena cava diameters must be between 16 and 42 mm and IVC outlets of the hepatic veins must be at least 1 cm distant from the right atrium. Furthermore, the device needs to be custom made in a 4-week manufacturing process, resulting in increased costs and limitations in acute settings. As in all CAVI procedures, the heterotopic position of the valve results in ventricularization of the right atrium, potentially leading to progressive right heart dysfunction, which is why the technique should only be considered in palliative settings. However, clinical as well as echocardiographic outcomes of the Tricento CAVI device up to 1 year are promising, thus calling for further evaluation of the technique. Here, the insights provided by Íñiguez-Romo et al. mark important first steps to better elucidate the potential of this device.

Estévez-Loureiro et al.[12] present their experience with the GATE system (NaviGate CSI, Lake Forest, United States), a self-expandable valve for orthotopic tricuspid valve replacement. The authors treated a 76-year-old woman with previous right heart failure and severe TR. The device consists of a conical-shaped nitinol stent with ventricular graspers for anchoring and atrial winglets covered by microfiber polyester cloth for sealing. The stent has a 3-leaflet equine pericardium valve. In the case reported, the device was implanted using a transatrial approach via the fourth intercostal space; the transjugular access has largely been abandoned due the size (42-Fr) of the somewhat archaic delivery system. The authors highlight the feasibility of implantation in challenging anatomies, thus obtaining persistent TR abolition at 3 months of follow-up. The authors performed a 4% oversizing of the implanted valve, facilitating stable anchoring without further damage to the tricuspid annulus. During the early experience with the device, some degree of oversizing was recommended, but subsequently nominal sizing was preferred to minimize the risk of harm to the fragile tricuspid annulus; this was considered feasible without an increased rate of valve displacements due to lower pressures in the right heart.[13] However, a case of valve migration following GATE implantation has recently been reported, highlighting that issues

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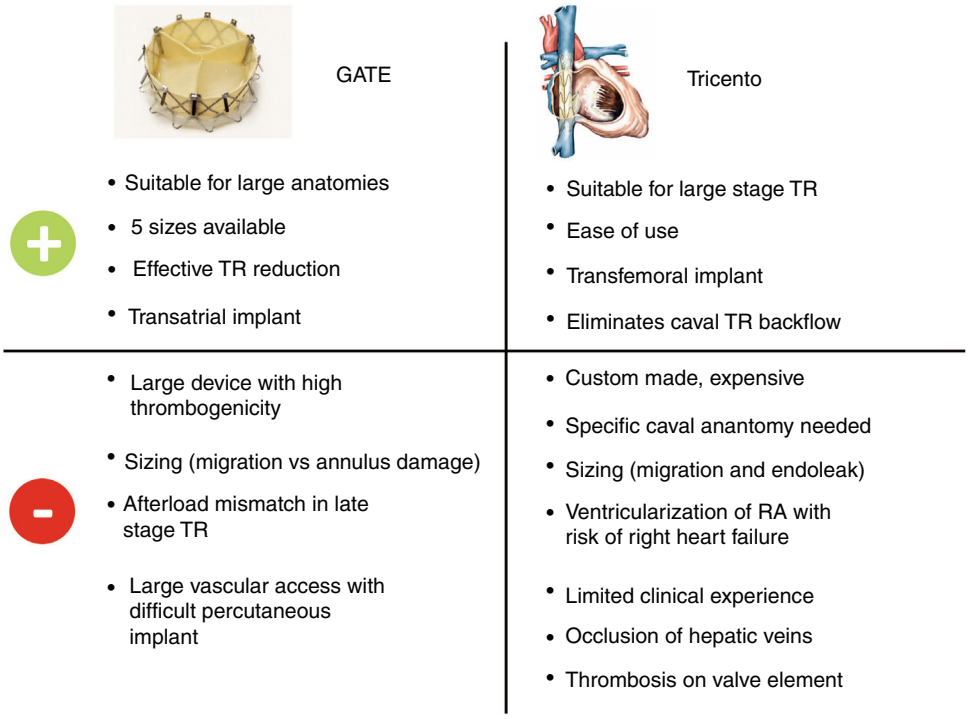

Figure 1. Summary of the technical features of the Tricento and GATE devices. RA, right atrium; TR, tricuspid regurgitation.

about the optimal sizing of transcatheter valves are not fully adressed.[14] Another currently discussed issue of orthotopic replacement in such late-stage patients is potential afterload mismatch following absolute reduction of TR, eventually resulting in acute right heart failure with worsening of the patient's clinical condition and fulminant right-sided heart failure. Thus, the future role of replacement in late phases of TR needs further careful evaluation and, here, after 40 implantations performed worldwide, Estévez-Loureiro et al. provide valuable additional insight.

The authors of both articles should be congratulated not only for providing this young field with additional data and experience, but also for successfully conducting such challenging innovative procedures to help patients in need.

Several issues remain to be addressed in the development of the devices discussed above and other replacement techniques under investigation:

a) Current devices often are massive and bulky, resulting in the need for large introducers and sheaths. This technical feature can lead to a nonnegligible number of vascular complications; moreover, the bulky profile of the current devices can be prone to an increased thrombogenicity (additionally aggravated by lower pressures on the right side). This is complicated by the need for aggressive anticoagulation that could result in serious bleeding events in these frail patients.
b) The implantation technique, especially with regard to sizing, needs further refinements to balance the risk of valve migration with the risk of damage to the tricuspid annulus, while enabling adequate sealing of the prosthesis. A significant proportion of patients also have a venous pacing lead across the tricuspid valve and the feasibility of valve implantation in the presence of a lead has not been evaluated. As the tricuspid valve apparatus is significantly more fragile than valvular structures on the left side of the heart and as pressures are significantly lower, experiences can hardly be derived from other valve replacement procedures but need to be made from scratch in this new implant position. Furthermore, the risk of atrioventricular block needs more careful evaluation.
c) Currently referred patients are often at very late stages of TR, leading to impairment of anatomic structures with huge ventricular cavities and dilated annuli. In such patients, replacement devices are often the last option. However, these procedures would probably perform even better in more preserved anatomies at earlier disease stages. Moreover, orthotopic or heterotopic valve treatment to mitigate symptoms of advanced right ventricular failure can even cause acute afterload mismatch, thus resulting in a further worsening of right ventricular function.

In conclusion, there is a need for further development and clinical testing, to which the authors reporting cases in this issue greatly contribute. There is also a need to increase awareness among health care providers and patients of the early phases of severe TR in order to allow accurately timed treatment with these promising new transcatheter approaches.

CONFLICTS OF INTEREST

A. Latib has served as a consultant for Medtronic and Abbott Vascular. The other authors have nothing to declare.

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