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EDITORIAL COMMENT

Heterotopic Tricuspid Valve Implantation

With New Procedures, Do We Need to Accept New Complications?*

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Tricuspid regurgitation (TR) has aroused a huge interest over the past years. The latest scientific evidence indicates that: 1) surgery for isolated TR is performed in only a limited number of patients and is burdened by high mortality; and 2) transcatheter therapies are safe and effective and provide better outcomes than medical therapy.[1,2] As a consequence, several transcatheter technologies for TR treatment have been introduced and a therapeutic algorithm proposed (**Figure 1**).[1] These different therapies can address several mechanisms underlying TR, although edge-to-edge and direct annuloplasty technologies have the largest experience for tricuspid valve (TV) interventions so far.

Despite this renewed attention toward TV disease, the best timing for intervention is still an open discussion in TR because patients with severe TR are often referred (too) late for treatment, when irreversible right heart deterioration has already occurred. In such cases, some therapies, such as edge-to-edge or direct annuloplasty, might be precluded and the selection among available devices is limited.[3]

The TricValve system (P+F Products + Features) represents a heterotopic TV implantation device with the objective to improve patient symptoms by protecting the venous system from elevated right atrial pressure and systolic caval backflow in severe TR, without any correction of the TV disease itself. The device is made of 2 self-expanding bioprostheses with bovine pericardium leaflets on a nitinol stent. Although the experience with caval valve implantation is still limited, recent studies have shown high procedural success and significant clinical improvements at 6 months of follow-up.[4]

The case presented in this issue of *JACC: Case Reports* by Custódio et al[5] describes for the first time a case of thrombosis after heterotopic valve implantation on the bioprosthesis implanted in the inferior vena cava, which was successfully treated by anticoagulation (parenteral anticoagulation followed by vitamin K antagonists [VKAs]). Although the authors do not provide information about the antithrombotic regimen before the onset of this complication, this case raises an important issue for both orthotopic and heterotopic replacement for TR, which is the best antithrombotic drug regimen (and its duration) in these patients. Although the same problem occurs in patients submitted to transcatheter mitral valve replacement,[6] the presence of low pressure and slow flow in the right chambers suggest the need for anticoagulation in these patients. In the dedicated trial on this device, all of the 35 enrolled patients were discharged under VKAs or direct-acting oral anticoagulants and no thrombosis was observed, whereas major bleeding was reported in 17% of cases. Looking at data on orthotopic replacement, the rate of anticoagulation (drugs not specified) on discharge was 74%, with bleeding occurring in 13% of cases, but, again, no device thrombosis was observed at 30-day follow-up.[7]

Taken together, these data suggest that in these patients the risk of bleeding is frequently higher than the risk of thrombosis, possibly owing to latent

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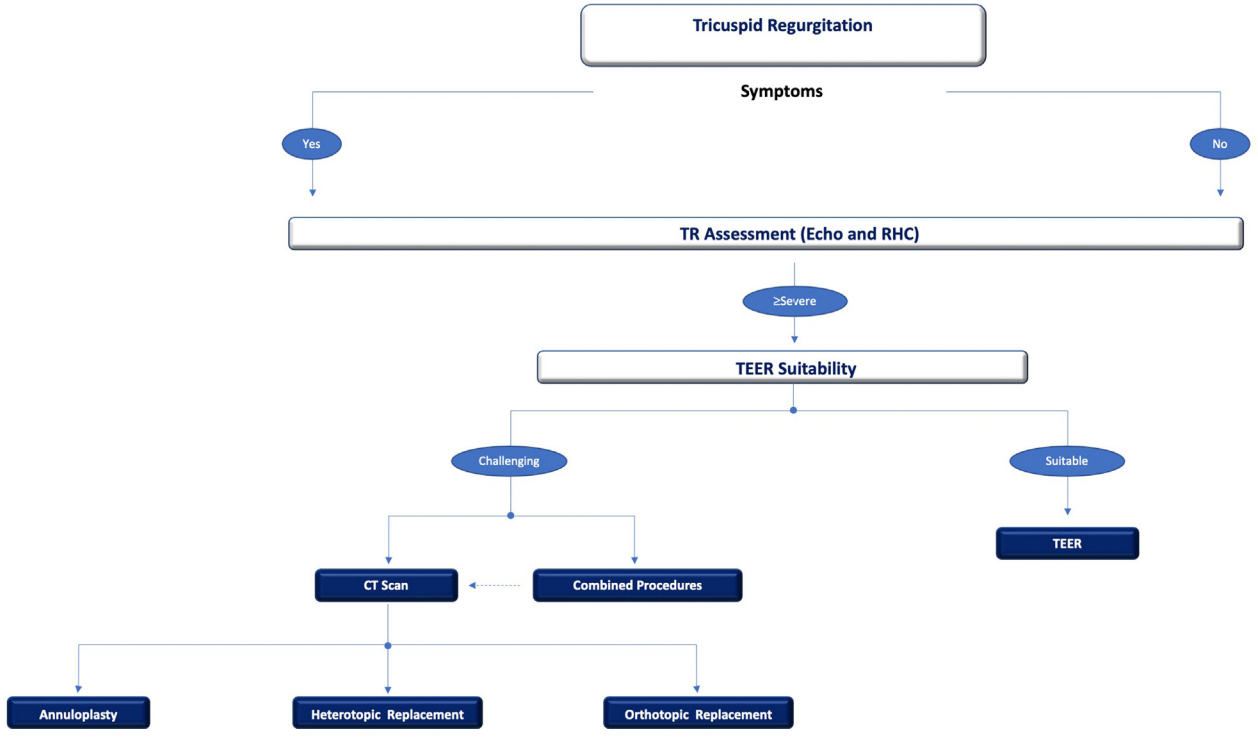
FIGURE 1 Transcatheter Management of TR



Proposed simplified algorithm for the management of percutaneous treatment of TR, according to clinical and anatomic factors. CT = computed tomography; Echo = echocardiography; RHC = right heart catheterization; TEER = transcatheter edge to edge repair; TR = tricuspid regurgitation.

hepatic dysfunction due to stasis and hypersplenism. Therefore, before considering such interventions, the risk of bleeding should be assessed in each patient, especially considering that most of the patients receiving these therapies are at high surgical risk and present multiple comorbidities. In this perspective, experience on mitral valve disease might represent a guide for TV interventions, because mitral valves and TVs have several similarities, despite several anatomic differences.[3] For transcatheter mitral valve replacement, studies adopted different antiplatelet/anticoagulant strategies, although anticoagulation with VKAs was the preferred one.[8] Regarding the risk of thrombotic complications in patients submitted to TV intervention, this should be higher, because, beyond the low pressure and slow flow that are typical of the right heart circulation, this procedure is associated with a possible right atrial ventricularization and an increased risk of acute right ventricular dysfunction due to increase pressure, which may favor blood stagnation and right-chamber thrombosis.

In conclusion, although "a single tree does not make a forest," this single case report reinforces the need to collect more data to find the best antithrombotic regimen (and its duration) in patients submitted to both ortho- or heterotopic TV replacement. Until this information is available, an individualized decision should be done for each patient, before the intervention, balancing both thrombotic and bleeding risks. Furthermore, more work should be done to standardize the definitions of TV intervention end points, such as the work done by the Mitral Valve Academic Research Consortium.[9]

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