Commentary: Transcatheter tricuspid valve devices—A word of caution

Cipriano Abad, MD, PhD, FEBS (Hon, Gen Surg),^a Stefano Urso, MD, PhD,^b and Bernardino Clavo, MD, PhD^c

From the ^aDepartment of Medical and Surgical Sciences, School of Medicine, University of Las Palmas de Gran Canaria, Las Palmas de Gran Canaria, Spain; and ^bDepartment of Cardiac Surgery and ^cResearch Unit, Hospital Universitario de Gran Canaria Dr Negrin, Las Palmas de Gran Canaria, Spain.

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Address for reprints: Cipriano Abad, MD, PhD, FEBS (Hon, Gen Surg), Department of Medical and Surgical Sciences, School of Medicine, University of Las Palmas de Gran Canaria, Paseo Blas Cabrera Felipe sn, 35016 Las Palmas de Gran Canaria, Spain (E-mail: cprnabad2@gmail.com).

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Cipriano Abad, MD, PhD, FEBS (Hon, Gen Surg)

Central Message

Cardiac surgeons should be cautious at this time to accept an unsupported and unvalidated percutaneous tricuspid device system.

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In this issue of the *Journal*, Carrel and Eberle¹ describe the case of a 77-year-old woman with severe tricuspid valve regurgitation (TR) after a failed transcatheter tricuspid valve repair with a TriCinch technique (4Tech Cardio Ireland Ltd, Galway, Ireland). The patient underwent successful cardiac surgery, in which a tricuspid valve replacement was performed with implantation of a size 33 bioprosthetic heart valve.

In the last decade, the development of new transcatheter systems to treat patients with functional TR represents an innovative, emerging, and ongoing modality of approach to treat these patients. Less invasive percutaneous therapies for patients with severe TR appears as an attractive, modern, and less aggressive technique.

Nowadays, several nonoperative transcatheter tricuspid valve alternatives are in clinical use and under evaluation. These novel interventional cardiology modalities of treatment are (1) leaflet coaptation devices (MitraClip [Abbott Laboratories, Abbott Park, Ill], FORMA [Edwards Lifesciences, Irvine, Calif], PASCAL [Edwards Lifesciences]), (2) annuloplasty systems (Cardioband [Edwards Lifesciences], Trialign [Mitalign Inc, Tewksbury, Mass], TriCinch, IRIS [Millipede, Inc, Santa Rosa, Calif], MIA [Micro Interventional Devices, Inc, Newtown, Pa], pledget-assisted suture tricuspid annuloplasty [PASTA], DaVinci [Cardiac Implants, Tarrytown, NY]), (3) orthotopic valve implantation (NaviGate [NaviGate Cardiac Structures, Inc, Lake Forest, Calif], implantation of percutaneous aortic or pulmonary valves), and (4) heterotopic tricuspid valve implantation (TriValve, Tricentro, percutaneous aortic valves).²⁻⁴

The research, advancement, growth, and expansion in the field of new percutaneous tricuspid valve equipment are expected to continue. Currently, a large range of tricuspid

valve transcatheter systems are available and in use in clinical practice.

The application of these minimally aggressive percutaneous transcatheter tricuspid valve interventions has the following advantages: a less invasive, nonsurgical technique; reduced hospital and intensive care unit stays; avoidance of thoracotomy and cardiopulmonary bypass; less morbidity and risk of infection; a more cosmetic procedure with no surgical scars; and faster recovery and earlier home discharge date. Among the disadvantages are the limited number of cases to treat, the scarce individual experience of the operator, a long learning curve, the need for specific skills (training and dedication), the frequent changes in generation devices, the frequent suboptimal TR correction, the possibility of periprocedural complications, the possibility of an unsuccessful procedure, the need for conversion to cardiac surgery, and the absence of medical reports supporting good long-term outcomes.

We consider that patients with symptoms as a result of severe functional TR and with an acceptable surgical risk can undergo conventional tricuspid valve surgery with cardiopulmonary bypass. In most cases, an effective tricuspid valve repair with a prosthetic ring can be achieved, and very rarely a tricuspid valve replacement with a biologic valve has to be undertaken. The classical tricuspid valve repair by ring annuloplasty and plastic valve repair is a safe, effective and demonstrably long-lasting surgical procedure. Open tricuspid valve repair remains the criterion

standard for patients with severe disabling functional TR. Patients with advanced TR and with a high or prohibitive surgical risk can be candidates for interventional management by means of a percutaneous transcatheter technique.

Nonsurgical percutaneous catheter tricuspid valve technology is still under investigation and clinical evaluation. At present, there is a lack of information about long-term results. The number of medical reports with a significant number of treated cases is limited. There are no comparative demonstrative clinical studies of the effectiveness of the percutaneous tricuspid valve therapy versus the tricuspid standard open surgical repair. Further evaluation of the different transcatheter tricuspid valve modalities of treatment is warranted.²

The development of modern interventional cardiology represent an important advance in medicine. Physicians involved in the care of patients with functional severe TR have to individually evaluate each case. Depending of the

case, the patient may be submitted to pharmacologic treatment, to transcatheter tricuspid therapy, or to conventional tricuspid valve surgery. Percutaneous transcatheter repair does not represent the first and the only path to management of these patients. Cardiac surgeons and cardiologists have to offer the best option to the patients and must also be cautious with the indications of use for unvalidated transcatheter tricuspid valve devices.

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