EDITORIAL COMMENT

Is Annular Reduction the Answer to Tricuspid Regurgitation?*



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ricuspid regurgitation (TR) remains markedly undertreated, with fewer than 10,000 cases treated yearly of the 160,000 to 240,000 incident cases estimated to occur in the United States (1). This estimate is particularly relevant because the supposedly "benign" outcome of tricuspid regurgitation has been proven untrue overall and in each specific cause (2-4). Insidious and progressive symptoms of the disease, occurring especially in an elderly population (5) unsuitable for conventional surgery, make percutaneous intervention one of the most exciting challenges for the near future.

Annular dilation is most often, if not always, the main driving feature of TR. For decades, the lack of leaflet coaptation subsequent to annular dilation has been addressed surgically by ring annuloplasty (6). This surgical method is fast, safe, and efficient and provides good long-term results (7). Unfortunately, only severe TR was, and still is, an indication for most surgeons, leaving patients with lesser degrees of TR untreated (8). This leads in turn, over time, to secondary isolated TR, which is known to be difficult to manage and creates sensitive cases, most of whom are good candidates for percutaneous therapies (8,9).

Tethering of the tricuspid leaflets is an entity of its own, rarely if not seen in degenerative disease most often in ischemic and rheumatic cases, at least at the time of primary surgery for left-sided heart disease. Tethering is not an indication for isolated annuloplasty, as it can even worsen TR (8).

Alfieri and his team, after introducing the edge-toedge concept for the mitral valve, described a similar concept, the Clover technique (10), for the tricuspid valve. It opened the door to percutaneous options such as derived tools for the mitral valve, initially the MitraClip (Abbott Laboratories, Rockville, Maryland) and more recently the TriClip (Abbott) and the Pascal clip (Edwards Life Sciences, Irvine, California). This technology is remarkable but addresses the TR mechanism indirectly by limiting leaflet motion, whereas annular dilation is the main mechanism. Most studies show a decrease of TR grade but not the eradication of TR. Patients show significant clinical improvement, but "no TR" is obviously better than "less TR" (11). The Cardioband (Edwards Life Sciences, Irvine, California), which was initially proposed for the mitral valve, has been successfully used to treat tricuspid annular dilation but in a limited number of cases (12).

This first-in-human case, using a complete ring is truly a breakthrough in addressing the main mechanism, namely the annular dilation (13). The device is not bulky, which is mandatory for a jugular approach. The 2-step procedure is innovative and increases safety. The idea to allow healing is appealing. The second step, to cinch the device after 3 months on a beating heart, allows adjustment to the ring size for each case in a tailored fashion, until TR disappears. There are many unknown issues, among which is the degree of annular reduction without tearing the annulus. Many cases, with various degrees of annular dilation will tell, but the concept is new and makes sense. In addition, in case of recurrent TR, it would ease a valve in ring procedure, which is currently more difficult with previously implanted surgical rigid ring annuloplasty or without any ring at all. The aim of this device is to reduce annular size similarly to that of surgical rings and still allow a free, normal leaflet motion. As most cases of secondary TR do not show tethering, this new tool targets the culprit

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lesion. There can be, with long-lasting TR, some degree of coaptation below the annular plane but rarely >8 to 10 mm as tethering is defined (8,9). In such cases, the tethering is minimal and is not the main mechanism for TR; therefore, dealing with the dilated annulus is the right target. There will obviously be a need for many more cases to validate its efficacy and its durability and reproducibility, but this approach goes in the proper direction.

Addressing the annulus takes into consideration decades of successful surgery showing good longterm results. However, many more questions still have no answers. Moving from this first case to a firstline treatment of TR needs to define the potential pitfalls of the technique.

Patients seen by interventional cardiologists have a long-standing disease with more severe TR than those who are indicated for surgery, and tethering could be a usual finding in such a subset of patients. Therefore, patient selection is an important point for success.

Used in compassionate cases with extreme TR, right ventricular enlargement and torrential TR (aka, "massive" TR) will probably be unsuccessful as some degree of valve tethering may in such cases become part of the TR mechanism and will not be corrected by annulus reduction.

Imaging, and particularly computed tomography and transesophageal echocardiography, require experience from the operators (14).

Tricuspid annulus evaluation is complex, as it is elliptical with a 3-dimensional (3D), but also because the annulus size is dependent on loading conditions and, thus, defining a diameter size fitting to the dedicated device needs to be well established using multimodality before treatment and individualized analysis.

The relationship between the adjacent structures, especially the right coronary artery, also need to be considered. The small size of the reported Da Vingi (Cardiac Implant LLC, Tarrytown, New York) cardiac implant stakes compared to the anchors of the other annuloplasty devices, such as the CardioBand (Edwards Lifesciences, Irvine, California), is probably an advantage regarding coronary injury risk.

The simultaneous delivery of all the stakes needs a rigorous check by visualizing the correct position of each launcher and confirming its contact with tissue. However, in the reported case, 1 stake placement was suboptimal without consequence in the annular reduction and procedure success.

The tricuspid annulus is not as fibrotic as the mitral annulus. How much annular reduction will be possible in some very dilated annuli, without dehiscence or, even worse, tearing the tricuspid annulus? The other concern is that, being a complete ring, there should be evenly distributed anchors, and this may lead to secondary heart blocks requiring implantation of a pacemaker. If there are no anchors at the bundle of His area, it will create excess tension and promote dehiscence. Only more clinical trials will tell.

Once this device has shown its feasibility and efficacy in reducing or abolishing TR, there will be a need for comparative trials especially with restricting leaflet motion devices to show at least noninferiority and, if possible, superiority.

However, addressing annular dilation directly is undoubtably the way to go and the answer to most cases of secondary functional TR.

AUTHOR DISCLOSURES

Dr. Dreyfus has held teaching courses for Edwards Lifesciences. Dr. Caussin has been a proctor for Edwards Lifesciences, Abbott Laboratories, Medtronic, and Boston Scientific. Dr. Dulguerov has reported that he has no relationships relevant to the contents of this paper to disclose.

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REFERENCES

1. Enriquez-Sarano M, Messika-Zeitoun D, Topilsky Y, et al. Tricuspid regurgitation is a public health crisis. Prog Cardiovasc Dis 2019;62:447-51.

2. Topilsky Y, Maltais S, Medina Inojosa J, et al. Burden of tricuspid regurgitation in patients diagnosed in the community setting. J Am Coll Cardiol Img 2019;12:433-42.

3. Topilsky Y, Nkomo VT, Vatury O, et al. Clinical outcome of isolated tricuspid regurgitation. J Am Coll Cardiol Img 2014;7:1185-94.

4. Benfari G, Antoine C, Miller WL, et al. Excess mortality associated with functional tricuspid regurgitation complicating heart failure with

reduced ejection fraction. Circulation 2019;140: 196-206.

5. Essayagh B, Antoine C, Benfari G, et al. Functional tricuspid regurgitation of degenerative mitral disease: a crucial determinant of survival. Eur Heart J 2020;41:1918-29.

6. Chikwe J, Itagaki S, Anyanwu A, et al. Impact of concomitant tricuspid annuloplasty on tricuspid regurgitation, right ventricular function, and pulmonary hypertension after repair of mitral valve prolapse. J Am Coll Cardiol 2015;65:1931-8.

7. Dreyfus G, Corbi P, John Chan KM, et al. Secondary tricuspid regurgitation or dilation: which

should be the criteria for surgical repair? Ann Thorac Surg 2005;79:127-32.

8. Dreyfus GD, Martin RP, Dulguerov F, et al. Functional tricuspid regurgitation: a need to revise our understanding. J Am Coll Cardiol 2015;65: 2331-6.

9. Muraru D, Hahn RT, Badano LP, et al. 3-Dimensional echocardiography in imaging the tricuspid valve. J Am Coll Cardiol Img 2019;12:500-15.

10. De Bonis M, Lapenna E, LA Canna G, et al. A novel technique for correction of severe tricuspid valve regurgitation due to complex lesions. Eur J Cardiothorac Surg 2004;25:760-5. **11.** Nickenig G, Weber M, Lurz P, et al. Transcatheter edge-to-edge repair for reduction of tricuspid regurgitation: 6-month outcomes of the TRILUMINATE single-arm study. Lancet 2019;394: 2002-11.

12. Nickenig G, Weber M, Schueler R, et al. 6-month outcomes of tricuspid valve recon-

struction for patients with severe tricuspid regurgitation. J Am Coll Cardiol 2019;73: 1905-15.

13. Reddy VY, Abbo RAA, Ruiz CE, et al. First-in-Human Percutaneous Circumferential Annuloplasty for Secondary Tricuspid Regurgitation. J Am Coll Cardiol Case Rep 2020;2:2176-82. **14.** Hahn RT, Thomas JD, Khalique OK, et al. Imaging assessment of tricuspid regurgitation severity. J Am Coll Cardiol Img 2019;12:469-90.

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