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Editorial

Skirt in TAVI: a toll-free packaging

Falda en la TAVI — un embalaje sin peaje

Bruno García del Blanco,[a,b,*] and Hugo Cuéllar Calabria[c]

[a] *Servicio de Cardiología, Hospital Universitari Vall d' Hebron, Barcelona, Spain*
[b] *Centro de Investigación Biomédica en Red de Enfermedades Cardiovasculares (CIBERCV), Spain*
[c] *Servicio de Radiología, Hospital Universitari Vall d'Hebron, Barcelona, Spain*

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The article signed by García-Guimarães et al.[1] recently published in *REC: Interventional Cardiology* is a living example of how a technical modification of a percutaneous device already being used with good clinical outcomes can have a significant impact not only from the standpoint of the parameters of technical results but also from the clinical viewpoint. Over the past 20 years of development of valves for transcatheter aortic valve implantation (TAVI) procedures we have witnessed a gradual technological progression where 2 different concepts—self-expanding valves and balloon-expandable valves—have initially achieved encouraging clinical outcomes in high-risk or inoperable patients,[1,2] and gradually until achieving better short-term results compared to surgical aortic valve replacement in low-risk patients.[3,4] This successful trajectory is partly due to the interest for developing and improving early and successive TAVI devices. The trials conducted among high-risk patients already found a higher rate of paravalvular leak after TAVI compared to surgical repair. As a matter of fact, it was a common event very much associated with a greater need for pacemaker implantation after TAVI[2] in the early self-expandable valves.

Conceptually this is something that could have been expected since there is no native valve resection or washout of the calcium remaining in the leaflets or the annulus. The need for permanent pacemaker implantation increases due to the implicit mechanism of mechanical fixation due to pressure to the valve annulus and its adjacent structures. We should mention that both phenomena can be inversely associated, that is, the more annular overexpansion we have, the more chances of atrioventricular block and vice versa with paravalvular leak. If we accept that the clinical impact of residual leak—with disparate evidence available—[5,6] can be associated with different degrees categorized as mild, all design changes and those associated with the implantation technique used aim at reducing its rate and severity.

The nature and mechanisms involved with paravalvular regurgitation are obviously different compared to the native valve, which is why several authors propose more categories, and a modification of the analysis technique of transthoracic echocardiography after implantation. This aims at the proper detection of different degrees of paravalvular regurgitation with some potential adverse prognostic effect.[7] The fact of the matter is that the development of TAVI devices mostly aims at reducing the degree of paravalvular leak without compromising the rate of new pacemaker implantation after TAVI, that is, without changing the degree of pressure to the native annulus. Therefore, the «skirts» surrounding the metal structure of the devices where they come into contact with the annulus are not only here to stay but come in longer lengths and have more morphological variations. The history of ACURATE neo (Boston Scientific Corporation, United States) would be a good example of how a modified skirt that is 60% longer can have a benefit that, though may seem spurious, is really a breakthrough with a potential clinical benefit like García-Guimarães et al. proved.[1].

Although the study has some limitations associated with its nature like comparing 2 different, non-homogeneous historic cohorts, it demonstrates something that operators who have tried different models have already confirmed in our routine clinical practice: the segment packaging in contact with the annulus has reduced the rates of leak in TAVI. Also, it proves that designing a device should be a positively toll-free packaging: the ACURATE neo2 valve reduces paravalvular leak without compromising the rate of pacemaker implantation as another similar study that compared 2 consecutive cohorts with the 2 consecutive models of Accurate neo already demonstrated.[8]

In the process of developing new devices for TAVI we have learned to study the size of aortic annuli with the computed tomography (CT) scan much better and be more accurate when adapting the size of the device that should be implanted. More technical options have come up regarding the size of the valve have become available too regarding the size of the valve, its measurement, implantation height, and even the need for pre or postdilatation. The impact of each one of these factors could be statistically figured out, although this is not an easy task between 2 different historic cohorts.

If we conduct an in-depth study of what it means to assess aortic valves with the CT scan, especially the capacity to predict the rate of paravalvular leak after TAVI, we'll find some contradictions along the way. Although the degree or spread of calcification can seem the culprits of paravalvular regurgitation, not everything is so clear or linear. This confusion can be attributed to the different ways valvular calcium can impact the sealing of the valve based on the type (balloon-expandable or self-expanding), specific design (with or without skirt, among other), size selected, and procedural technical issues (implantation height). In the studies of coronary calcification assessed via CT scan there is variability in the technique used to quantify coronary calcium (CT without contrast or coronary computed tomography angiography [CCTA]) and the methods of analysis

*** Corresponding author.**
E-mail address: brunogb51@gmail.com (B. García del Blanco).

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(threshold for the detection of coronary calcium, assessment of Agatston score or calcium volume even the outflow tract, among other).

The standard method to quantify coronary calcium includes a baseline study often before the injection of the iodinated contrast material needed to perform the cardiac and aortic CCTA. When this baseline determination is lacking, the calcium quantification used in the article signed by García-Guimarães et al.[1] includes a dichotomic detection threshold based on the opacification obtained in the outflow tract of CCTA images;[9,10] an easy method with an acceptable correlation that was homogeneously applied to both cohorts.

The size of the valve selected, implantation height, and the distribution of calcium both in the annulus and left ventricular outflow tract may have shared some protagonism in this study and on this regard.

Sealing limitations with TAVI compared to surgical aortic valve replacement may still persist for some time despite the advances made with the former. However, the supravalvular position of coaptation and the worse profile of the bare-metal stents vs surgical valve can be favorable assets for TAVI regarding the study of long-term durability.

Finally, although for the time being there is not a cause-effect correlation, it's striking to see that the group with more residual leak in the aforementioned study[1] and others[9,10] also shows more bleeding at follow-up. It is obvious that since they're historic cohorts, this could be due to other factors involved in the learning curve and the development of the technique like vascular access treatment or use of drugs that may affect bleeding. It could also be that the leak has deleterious rheological effects like some studies have already suggested.[11]

We should say that although there's always a toll to pay with new packagings, this doesn't seem to be the case.

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CONFLICTS OF INTEREST

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