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Debate

Debate: TAVI prosthesis selection for severe calcification. The balloon-expandable technology approach

A debate: Selección del tipo de prótesis para TAVI en presencia de calcificación grave. Visión desde la tecnología expandible con balón

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Question: What are the implications of aortic valve calcification on the outcomes of transcatheter aortic valve implantation (TAVI)?

Answer: Aortic valve calcification has, undoubtedly, been a major influence on TAVI outcomes and the evolving design of heart valves. Severe calcification has been associated with an increased likelihood of complications or poor outcomes, particularly in terms of residual paravalvular leak, need for postoperative pacemaker implantation, or aortic annular rupture, among others.[1] Several generations of TAVI prostheses have mainly evolved with the aim of reducing paravalvular leak,[2] through the use of skirts and coverings that facilitate sealing by adapting to the irregularities caused by annular and outflow tract calcifications. The goal is to balance sealing capacity with the optimal radial force needed, preventing excessive force that could cause conduction disturbances or, more critically, annular rupture. This emphasizes the critical role of procedural planning, which must account for the extent of calcification in all affected tissues. This meticulous planning, combined with experienced judgment and a deep understanding of the behaviour of each prosthesis is crucial for selecting the correct valve size.

Q.: What morphological and quantitative aspects of valvular calcification do you assess at your center?

A.: In addition to the usual annular measurement, in patients with severe calcification it is important to systematically identify the distribution and extent of calcium:

- Sinotubular junction: at this level, it is crucial, especially when using a balloon-expandable valve, to determine whether calcification may compromise balloon inflation and, in the worst-case scenario, trigger balloon rupture, resulting in incomplete valve deployment with the risk of embolization, and the possibility of barotrauma-related dissection or aortic rupture in extreme cases. Therefore, it's important to measure the minimum diameter between the most prominent calcium spicules and the contralateral border to confirm that the size of the balloon inflated with the necessary volume to deploy the selected prosthesis is not larger than that diameter.

- Coronary ostium: Calcified plaques in the aortic wall near the coronary artery origins can increase the risk of coronary occlusion if displaced during valve deployment. Identifying this risk is crucial for implementing appropriate coronary protection strategies.

- Sinuses of Valsalva and leaflets: first, it must be determined whether 3 sinuses are present or if we are facing a bicuspid valve, which has typical calcification patterns. The presence of calcified commissural fusions may require balloon predilatation to ensure passage through the valvular plane with the prosthesis and predict the leaflet behavior relative to the coronary arteries. The calcium will redistribute but will not disappear, so if calcium nodules are present on the leaflets occupying the sinus floor, we must consider the depth of the sinuses, and the association between leaflet length and coronary ostium height. If these sizes are suboptimal, the calcified leaflet may evert and occlude the coronary artery detaching from its base, or perforating the aortic wall if space is extremely limited.

- Aortic annulus: evaluating calcium distribution at this level is crucial, as this is where the prosthesis will exert its greatest radial force. Symmetrical distribution throughout the annular circumference (360°) is rare but undoubtedly one of the most complex scenarios to deal with. In this case, one must assess the depth of calcium into the outflow tract and consider higher

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or lower implantation depths if it achieves sealing in a less calcified area. If not, an additional measurement beyond the annulus in the outflow tract should be taken to determine if the annular/tract anatomy is straight tubular, flared, or tapered. This information can help us oversize or undersize the prosthesis. However, typically, calcium is more focally distributed, with "teeth" extending toward the outflow tract, especially from the left coronary sinus toward the mitral-aortic continuity. A critical point is often a thinning area where the annulus transitions to the outflow tract, which is precisely where the distal end of the valve is usually positioned. This distribution presents one of the highest risks of rupture, specifically at the calcium thinning site, due to a physical principle: denser calcium regions are more resistant to deformation, so if density is not uniform, energy tends to be released where resistance is at its lowest point, potentially causing rupture. Therefore, planning should account for transitions between highly and minimally calcified zones when making decisions on implantation depth. Heterogeneous calcific density likely increases the risk of complications.

Q.: How does the degree of calcification affect valve type selection?

A: Perhaps the operator's experience with the chosen valve model is the most influential factor in minimizing complications in heavily calcified scenarios, as operators know the limits of the technology they're using. However, assuming comparable experience, in my opinion, balloon-expandable valves offer an advantage in expansion capacity and deployment control, allowing for more precise positioning. The combination of a low-recoil alloy and a balloon that inflates progressively and uniformly provides the necessary radial force to overcome calcium resistance while enabling control to stop inflation if high resistance or asymmetry is detected, preventing complications. While the idea that the prosthesis adapts to annular morphology is attractive, despite many self-expanding valves having supra-annular valve mechanisms, the risk of underexpansion is likely high[3] requiring aggressive pre- and post-dilatations to create space and prevent recoil. Balloon-expandable technology allows for better sphericity indices in a more controlled and progressive way when appropriate proper implantation technique is used.

Q.: And how does the degree of calcification affect valve sizing?

A: Generally, in these scenarios, the goal with a balloon-expandable valve should be to avoid exceeding 5% oversizing, achieved by adjusting the inflation volume based on the valve nominal size, which usually leads to choosing smaller sizes or inflation volumes than usual for the same annular size in the absence of calcium. Caution in size and inflation volume selection is a great ally in avoiding complications. You can always opt for more aggressive inflations later if necessary and if the initial calcium modification allows. Of note, these valves will gradually expand and modify calcium, so controlled inflation is arguably more important than the final volume used.

Q.: Does the procedure differ based on valve calcification?

A: Technically, several peculiarities should be considered in the presence of a heavily calcified valve:

– Predilatation: in standard cases, direct implantation of the balloon-expandable valve without predilatation is typical. In high calcium scenarios, predilatation offers several advantages, such as assessing calcium behavior in the sinuses of Valsalva and its relationship with coronary arteries, especially with simultaneous contrast injection. If calcification affects the sinotubular junction, predilatation may help determine the actual risk of balloon rupture during valve release. Most importantly, in cases of calcified commissural fusion, effective predilatation facilitates passage through the valve plane without the need fr aggressive push maneuvers. However, balloon predilatation in such situations may theoretically increase the risk of embolizing calcium debris during inflation, making it a potential indication for cerebral protection devices. Non-homogeneous calcium distribution can cause the asymmetric expansion of the prosthesis, thus shortening more in areas with less or no calcium compared with denser regions. While this does not compromise the functionality of valve, it should be considered when planning very high implantation depths. With balloon-expandable valves, residual leak is usually absent in standard implantation. In cases of high-grade calcification, we must be cautious in pursuing this goal, as it may involve forcing expansion that endangers the patient, especially during postdilatation. Remember that in reducing paravalvular (not central) regurgitation, skirt design is highly effective, and its effect may take a few minutes. Therefore, before aggressive postdilatation, it is advisable to allow time for the distal skirts to take effect.
– Postdilatation: the first postdilatation should be performed with the same volume as deployment inflation, keeping it fully inflated for, at least, 5 seconds before increasing the volume in subsequent inflations.

If planning reveals a real risk of coronary artery occlusion, protection techniques should be considered.

Q.: What are the advantages of self-expanding prostheses in the most severely calcified valves?

A.: In addition to previously discussed aspects, of note, the ability of balloon-expandable technology to yield excellent results in reducing paravalvular leak,[4,5] which is one of the main causes of poor outcomes in calcified prostheses. Moreover, with good planning and proper sizing, highly precise implantations can be achieved, with direct and progressive calcium modification, minimal recoil risk, and less need for postdilatation. The ability to achieve more precise implantations reduces the need for pacemaker implantation as well. Additionally, excellent outcomes have been demonstrated in patients with bicuspid valves, even though these often present with high calcium loads and varied distributions. In conclusion, balloon-expandable technology offers potential advantages in these patients due to its radial strength, control, implantation precision, and lower rates of paravalvular leak and need for pacemaker implantation,[6] provided that proper planning goes beyond simple annular sizing, including thorough assessment of calcium distribution and correct size selection, and, above all, adequate knowledge of the prosthesis and the experience needed to handle this complex scenario. Undoubtedly, scientific evidence is needed to determine, beyond opinions, what technology is better, an answer that must come from ongoing clinical trials comparing the new TAVI valves under specific clinical conditions, such as extensive valve calcification.

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STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

No artificial intelligence was used.

CONFLICTS OF INTEREST

Cristóbal A. Urbano-Carrillo is a proctor for Edwards Lifesciences and participates in advisory groups for Medtronic Spain.

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