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EDITORIAL COMMENT

Predicting complications for patient suitability

Previsão de complicações para adequação ao doente

Tiago Nolasco

Cirurgia Cardíaca, Hospital de Santa Cruz, CHLO, e Hospital da Luz, Lisboa, Portugal

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Transcatheter aortic valve implantation (TAVI) has seen exponential growth since its first-in-human case 20 years ago, surpassing surgical aortic valve replacement in the USA in 2019 and becoming the predominant treatment for aortic valve stenosis according to the Transcatheter Valve Therapy Registry.[1,2]

With increasing operator and institutional experience, expansion of the treatment indication to intermediate and low-risk patient populations, and the rapid evolution of transcatheter technologies with improvements in TAVI device delivery system profiles and novel percutaneous vascular closure device systems, the rate of major TAVI-related complications has fallen consistently over the past decade.[3]

However, TAVI complications still remain of concern, and have a significant impact on morbidity and mortality. The Valve Academic Research Consortium 3 (VARC-3) Writing Committee[4] highlighted the need to appropriately capture and report these complications, in order to ensure appropriate responses to patient characteristics and ultimately better outcomes. VARC-3 major vascular access site complications, which include vascular injury that leads to major bleeding or death or is life-threatening, visceral ischemia, or neurological impairment, represent a significant proportion of TAVI-related complications, and constitute a significant burden for patients and for health care facilities.

The article by Çakal et al. published in this issue of the *Journal*[5] tackles the important issue of access site-related complications. The proportion of TAVI procedures using transfemoral access has increased to 95.3%. The authors sought to clarify whether the valve manufacturers' recommendations, which are not evidence-based, could predict vascular complications in transfemoral TAVI (TF-TAVI), while studying additional factors that could predict major vascular complications.

Several variables have been described as predictive factors of vascular access site complications, including center and surgeon experience, female gender, femoral artery calcification (especially when circumferential), minimal artery diameter, and sheath-to-femoral artery ratio (SFAR) $\geq$1.05. Hayashida et al.[6] first described SFAR in 2011 as the ratio between outer sheath diameter and minimal femoral artery luminal diameter, claiming that routine application of SFAR would improve patient selection for TF-TAVI and outcome. Markus et al.[7] concluded that manufacturers' recommendations were safe but overly conservative, while SFAR could predict major vascular complications, and circumferential iliofemoral calcifications were associated with increased mortality. Likewise, Fonseca et al.[8] stated that vascular access site complications were frequent in patients undergoing TF-TAVI and that SFAR was the only independent predictor of access site complications and should therefore

E-mail address: tiagodnolasco@gmail.com

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be systematically assessed during pre-procedural imaging study. Durand et al.[9] determined that SFAR predicts vascular complications, but not the need for a stent graft.

In the study by Çakal et al.,[5] although the patient cohort ineligible for TF-TAVI had smaller minimum femoral lumen diameter and higher calcification scores with higher rates of rupture, major and minor vascular complications did not differ between the eligible and ineligible groups. The authors conclude that the manufacturer's guidelines do not provide an individualized risk prediction of major vascular complications, and that only SFAR >0.99 was able to predict which patients were most likely to have major adverse vascular events. The same authors published another article[10] in early 2022 assessing the predictive ability of a modified SFAR to aid patient selection in order to prevent vascular complications and improve outcomes in TF-TAVI procedures.

Therefore, with the rapidly increasing numbers of TAVI patients, it seems appropriate to conclude that the TAVI team should not decide whether the patient is suitable for a femoral approach based solely on the valve manufacturers' criteria, but should instead incorporate additional factors that could predict major vascular complications, in order to be able to choose the most suitable approach (transcatheter or surgical), in all cases following a thorough discussion of the different therapeutic options, aiming for the patient's best interests.

Conflicts of interest

The author has no conflicts of interest to declare.

References

1. Carroll JD, Mack MJ, Vemulapalli S, et al. Registry of transcatheter aortic valve replacement. J Am Coll Cardiol. 2020;76:2492–516.
2. Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT Registry of transcatheter aortic valve replacement. Ann Thorac Surg. 2021;111:701–22 [Epub 16.11.20; PMID: 33213826].
3. Cerillo AG, Voetsch A, Michel J, et al. Editorial: Transcatheter aortic valve implantation: all transfemoral? Update on vascular access and closure. Front Cardiovasc Med. 2022, http://dx.doi.org/10.3389/fcvm.2022.907445.
4. Généreux P, Piazza N, Alu MC, et al. Valve Academic Research Consortium 3: updated endpoint definitions for aortic valve clinical research. J Am Coll Cardiol. 2021;77:2717–46 [Epub 19.04.21].
5. Çakal B, Çakal S, Karaca O, et al. How accurate are manufacturers' recommendations in determining ineligibility for transfemoral transcatheter aortic valve implantation? Rev Port Cardiol. 2022;S0870-2551(22)00369-9.
6. Hayashida K, Lefèvre T, Chevalier B, et al. Transfemoral aortic valve implantation new criteria to predict vascular complications. JACC Cardiovasc Interv. 2011;4:851–8.
7. Reinthaler M, Aggarwal SK, De Palma R, et al. Predictors of clinical outcome in transfemoral TAVI: circumferential iliofemoral calcifications and manufacturer-derived recommendations. Anatol J Cardiol. 2015;15:297–305 [Epub 28.04.14].
8. Fonseca P, Almeida J, Bettencourt N, et al. Incidence and predictors of vascular access site complications following transfemoral transcatheter aortic valve implantation. Rev Port Cardiol. 2017;36:747–53 [Epub 16.07.16].
9. Durand E, Penso M, Hemery T, et al. Standardized measurement of femoral artery depth by computed tomography to predict vascular complications after transcatheter aortic valve implantation. Am J Cardiol. 2021;145:119–27 [Epub 15.01.21].
10. Çakal S, Çakal B, Karaca O, et al. Vascular complications after transcatheter transfemoral aortic valve implantation: modified sheath-to-femoral artery ratio as a new predictor. Anatol J Cardiol. 2022;26:49–56.