EDITORIAL
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The NOTION trial: some concerns about structural valve deterioration in surgical bioprosthesis. Fact or fiction?

El ensayo NOTION: algunas preocupaciones sobre el deterioro estructural de la válvula en la bioprótesis quirúrgica. ¿Realidad o ficción?

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Palabras clave: *válvula aórtica, reemplazo valvular aórtico, reemplazo valvular aórtico quirúrgico, implante de prótesis aórtica transcatéter.*

The NOTION 10 years results have been recently presented at the ESC Congress 2023 in Amsterdam. In short, this trial compared TAVI versus SAVR in a large population of patients. The results, by and large, were totally favorable for TAVI in terms of better SVD and PPM.[1] The NOTION trial results at eight years of follow-up showed a significantly higher SVD rate in SAVR than in TAVI (28.3% versus 13.9%, p = 0.0017). In turn, the risk for severe SVD was 6.8% for SAVR versus 2.2% for TAVI (p = 0.068). However, the risk of bioprosthesis valve failure (BVF) did not show any significant difference between them (10.5% versus 8.7%, p = 0.61).[2] Thus, at a glance, SVD seems to be lower after TAVI than SAVR, whilst the two treatments have a very similar risk for BVF.

Nevertheless, there are two crucial points that deserve special scrutiny in this study. First and foremost, let us analyze the endpoints used in the NOTION trial. Bioprosthesis valve dysfunction (BVD) was designed by structural valve deterioration (SVD), defined as moderate SVD (mean gradient ≥ 20 mmHg, increase in mean gradient ≥ 10 mmHg from three months post-procedure, or new or worsening moderate intraprosthetic aortic regurgitation from 3 months post-procedure); and severe SVD (mean gradient ≥ 40 mmHg, increase in mean gradient ≥ 20 mm Hg from 3 months post-procedure, or new or worsening severe intra-prosthetic aortic regurgitation from 3 months post-procedure).

In turn, non-structural valve deterioration (NSVD) was defined as i) moderate to severe patient-prosthesis mismatch (PPM) (indexed effective orifice area ≤ 0.85 cm^2/m^2 for moderate PPM, and ≤ 0.65 cm^2/m^2 for severe PPM) at three months, or ii) more than mild paravalvular leakage (PVL).

From the above, several situations potentially inducing bias in favor of TAVI emerge. A fact that does not represent real life practice is that neither aortic annulus enlargement procedure nor sutureless prostheses were allowed in the NOTION trial. This fact is in line with the result obtained in this trial, up to 28.2% of patients in the surgical arm presented severe PPM.[2]

The definition of SVD using a fixed gradient of ≥ 20 mmHg at any point of cut-off of the study could theoretically affect negatively the SAVR group, if we consider that up to 40% of the patients underwent SAVR had a 19 mm or 21 mm aortic valve bioprosthesis. It has been shown that ≤ 21 mm

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stented bioprosthesis are prone to cause transaortic gradients close than 20 mmHg, without involving SVD.[3]

Regarding the issue related with the use of Trifecta and Mitroflow bioprosthesis up to 40% in the surgical arm of NOTION trial, it is worthy of the following remarks. By means of an issue letter, Abbott announced the decision to withdraw Trifecta and Trifecta GT valves due to the high risk of rapid SVD. "On February 27, 2023, Abbott and the US FDA communicated the potential for early structural valve deterioration (SVD)… for the Trifecta and Trifecta GT valves… Abbott decided to discontinue its Trifecta family of valves".[4] Such information has been also supported by US Food and Drug Administration official website "On July 31, 2023, Abbott announced its decision to stop selling and distributing Trifecta valves, which include the Trifecta Valve and the Trifecta Valve with Glide Technology (Trifecta GT), in the United States".[5]

Several articles have been devoted to the issue of increased rates of early SVD and reoperation for BVD after using Mitroflow aortic valve bioprosthesis.[6-8]

Recently, a report by Mahboubi et al. in which the inherent risk of reoperation for BVF has come to light.[9] This report, the results of 7,037 patients undergoing isolated non-emergent SAVR, between 1980 and 2017 were analyzed. Of the total number of cases, 753 were reoperations and 6,284 were first-time SAVR. Operative mortality was similar in both groups (1.3%). Stroke, sternal infection and renal failure were also similar in both groups. Survival at 1, 5, 10, and 20 years was 94%, 82%, 64%, and 33% for the reoperation group, versus 95%, 86%, 72%, and 46% for primary SAVR.[9] Thus, the risk of mortality and morbidity has decreased considerably in recent years, being similar for SAVR as a primary or reoperation procedure. With this utmost important information, the possibility of reoperation after SAVR should not be taken as a limitation for the selection of the type of prosthesis as well as the type of procedure, whether surgical or percutaneous. This information should be compared in the context of the percutaneous VIV procedure following TAVI or SAVR by BVF.

As a matter of fact, some authors have warned us about the increased number of cardiac operations after TAVI, whilst the interval time between TAVI and operation is decreasing. Main causes for TAVI reoperation were stenosis and/or regurgitation (58%), paravalvular leak (24%) and endocarditis (17%).[10] Operative mortality has been reported as 17.1%.[11] The 8-year cumulative incidence of reoperation was found in 1.9% for TAVI and 14.1% for VIV-TAVI group, respectively.[12] Also, in this report the isolated surgical aortic valve replacement was represented only by 18.2%; all the remainder were related to combined cardiac surgical procedures.[12]

There are still complications after TAVI, which have not been definitively resolved, such as the need for a permanent pacemaker reported as 10.8% at 30-days after procedure.[13]

Thus, the conclusions derived from the NOTION trial must be taken with due caution, and the limitations especially in the surgical arm, must be particularly pointed out. This is of utmost importance when the pursued final objective is the application of TAVI in young and low-risk patients. We need trials being much more representative of reality, both percutaneous and surgical, in order to come to any definite conclusion to be applied in real world practice.

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