EDITORIAL

Transcatheter edge-to-edge mitral valve repair: A *clip around the TEER!*

"The truth does not change because it is or is not believed by most people."
- Hipatia of Alexandria –

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Palabras clave: **Anillo protésico de anuloplastía; Anuloplastía; Reparación valvular mitral; Reparación valvular mitral transcatéter; Válvula mitral.**

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The JAMA Cardiology journal has just released the article by Young et al. regarding the trends in the US among Medicare patients, relating to the issue of mitral valve (MV) repair, whether by the transcatheter or surgical technique [1]. However, given the shortcomings of the transcatheter edge-to-edge MV repair (TEER) technique, both the medical community and the general public require greater information on this procedure in context, when disseminating this type of content without specifying the relevant limitations. TEER as a treatment for mitral regurgitation, has emerged as one of the most impactful cutting-edge technologies in structural interventional cardiology in recent years. However, of particular importance are the main differences between percutaneous and surgical techniques, a pivotal one being the absence of a prosthetic annuloplasty ring in the former option, thus rendering the TEER procedure just partially effective.

MV repair is the world-wide accepted treatment of choice for MV regurgitation [2,3]. Regardless of the case or underlying pathology, the most important rule for every MV repair in the adult, is the use of an annuloplasty ring, as previously described by Carpentier [4-9]. For extreme emphasis, is the function of the prosthetic ring to not only correct any annular dilation, but more importantly, to reshape and stabilize the repair, by balancing the forces all along and around the native mitral annulus. Consequently, the annuloplasty ring limits any further dilation of the native MV annulus and thus, is considered to be a mandatory component of every MV repair in the adult [8,9]. Consequently, the annuloplasty ring limits any further dilation of the native MV annulus and thus, is considered to be a mandatory component of every MV repair in the adult [8,9].

Surgical edge-to-edge MV repair underpins the concept of TEER. The edge-to-edge surgical technique to repair the MV regurgitation was first performed by Alfieri on April 25, 1991 [10]. Nevertheless, two main factors relating to this surgical technique must be highlighted. Firstly, despite good results reported over the years by using the surgical edge-to-edge technique, it has never been the gold-standard for surgical MV repair. Secondly, the edge to edge technique is no exception to the rule, regarding the inclusion of an annuloplasty ring as a part of every MV repair [10]. As a matter of fact, the lack of an annuloplasty ring is the most powerful predictor for failure after surgical MV repair [11-15]. Thus, the complete technique known as edge-to-edge is composed by two main elements; viz, the stitch joining both leaflets of the MV, and the prosthetic annuloplasty ring reinforcing the repair [16]. In this regard, De Bonis et al. have studied in depth the function of the annuloplasty ring in the edge-to-edge MV repair [17-20]. They have repeatedly stated that the lack of an annuloplasty ring could affect the TEER results, especially in the long run. As such, special attention must be paid to longstanding TEER outcomes [19].

Although the annuloplasty ring is a *sine-qua-non*-condition for surgical MV repair, TEER is a ringless therapy and is therefore, only partially effective as a treatment for MR, especially in the long-term. As yet, the criteria governing the use of TEER as an "isolated procedure" without an annuloplasty ring, are practically unknown. Hence the impact of potential implications of an imperfect technique such as TEER may have on patients' survival, quality of life, unplanned rehospitalization for heart failure rates, requires in depth considerations.

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Much has been said about the evaluation of the effectiveness after TEER as "optimal" or "acceptable" results. A totally discordant act that is against all logic, is the great Conflict of Interest between some of the authors of the Mitral Valve Academy Research Consortium (MVARC) and the main trials supporting the use of TEER in FMR. MVARC is the consortium which defines the success or failure after TEER in all meanings. A very good case in point is the definition about good results after TEER, which literally states "…reduction of MR to optimal or acceptable levels, without significant mitral stenosis (with a transmitral gradient <5 mm Hg), and with paravalvular MR no greater than mild (1+)". However, in an extremely ambiguous manner, the same document cites only lightly within a figure caption "MR reduction is considered *acceptable* when post-procedure MR is reduced by at least 1 (functional) class or grade from baseline onset and no more than moderate (2+) in severity." [21]. This definition is clearly unacceptable for any surgical or percutaneous approach used to treat MR. It is alarming to see the ease with which these concepts have been widely accepted by interventional cardiological groups around the world, without even the slightest argument for this type of deviation. A well-known fact in cardiac surgery is that the target for any MV repair, regardless surgical or percutaneous, should be residual MR ≤1+ [17,22-24]. The negative impact of residual or recurrent MR 2+ after TEER has been demonstrated by several authors [25-28]. Moreover, nearly the half of the patients after TEER had residual or recurrent MR ≥2+ in the different trials or reports [29,30].

Interestingly, the senior author of the COAPT trial, main randomized controlled trial in favor of TEER in FMR is the same senior author of the MVARC [31]. It is worth highlighting that the only RCT in favor of TEER for FMR is the COAPT trial. Therefore, it is quite clear that there is a serious Conflict of Interest between the TEER transcatheter technique, the COAPT trial, and the definitions emanating from the MVARC. To date, this fact has not been adequately taken into consideration.

Last but not least, are the facts resulting from surgery performed for failed TEER cases. The real incidence for failure after TEER is actually unknown, because of the underreported world-wide data on this outcome. Nevertheless, the STS/TVT/ACC Registry Transcatheter Mitral Valve Therapy in US showed that residual or recurrent MR ≥3+ is in up to 8.7% of patients after only 28 days post TEER [32]. In this meaning, Kaneko et al. reported 11,396 patients who underwent TEER; out of them, 548 (4.8%) required re-intervention for failed TEER after 4.5 months of follow-up. The operative mortality was 8.6%, 30-day readmission was 20.9%, and overall 30-day morbidity was 48.2% [33]. In the CUTTING-EDGE study, 332 cases operated on for MR after TEER failure were analyzed. Operative mortality was 16.6% and 1-year mortality was 31.1%. MV replacement was necessary in 92.5% of cases [34]. Chikwe et al. reported 524 patients who underwent MV surgery after failed TEER. The operative mortality was 10.2%, and MV replacement was required in 95% of cases [35]. Of the greatest significance, is the fact that all these patients who ended up with a post TEER mitral valve replacement, had initially been considered as potential candidates for surgical MV repair at the outset.

In closing, considering all the aforementioned information and despite the ever-increasing interest in using TEER for MR around the world, a word of caution should be stressed. The long-term results of using an imperfect technique such as TEER, can be devastating [36]. This technique must be carefully restricted to extremely select cases, whose surgical option has been ruled out without bias and when GDMT for heart failure has not been sufficient for the management of functional MR. The Heart Team, including the interventional cardiologist, must inform the patients about all these shortcomings, drawbacks and limitations of TEER, before making any decisions.

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