Myval balloon-expandable prosthesis in Argentina: Time to grab the bull by the horns

Prótesis Myval balón-expandible en Argentina: Tiempo de tomar el toro por los cuernos

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In biomedical research, all therapeutic innovation that reaches the market is aimed at improving patient quality of life and life expectancy compared with current available treatment options, as well as reducing costs so as to support the sustainability of the healthcare system. The fast pace of 21st-century innovations results in a paradox as far as the medical field goes: its regulatory framework, while necessary, also slows down the expansion of new therapies. Exclusive marketing rights are an essential piece of the current system of incentives for private innovation, whose purpose is to ensure the profitability of its investments. However, the current patents system is not the most beneficial alternative for society as a whole, especially in the case of innovations such as transcatheter aortic valve implantation (TAVI), which originated from research at a government-funded university and whose patent was financed by the Danish government until its patent rights were acquired by a private company due to its marketing potential. Society rightfully wonders and questions whether it is actually paying twice for innovation: first through public funding of research, and then through the premium price typically associated with patented products. Every physician and researcher should undergo the peculiar experience of reading the article *How Transcatheter Aortic Valve Implantation (TAVI) Was Born: The Struggle for a New Invention*, by Henning Rud Andersen[1], who describes the struggle of those (including himself) who developed TAVI from an idea to one of the most significant advancements in our field, one that has already saved hundreds of thousands of lives, and the obstacles that the current patents system posed for the process of going from the first experimental implant in an animal (1989) to the first implant in a human being (2002)[2], and its commercialization (2006) (**Figure 1**).

In this context, the new Myval balloon-expandable prosthesis (Meril LifeSciences Pvt. Ltd., Vapi, Gujarat, India)[3] has been available in international markets since 2019, with favorable results in patients at any level of surgical risk[4, 5]. This intra-annular prosthesis with three bovine pericardium leaflets has allowed for the expansion of the therapy worldwide due to a reduction in costs. Preliminary data suggest similar efficacy compared to currently available alternatives, particularly with the Edwards Lifesciences balloon-expandable prosthesis series[6]. However, given its novelty as the first balloon-expandable alternative, proper documentation of its results is crucial. To date, there have been more than 15,000 implantation procedures worldwide with the aforementioned device, and the Argentine cardiology community holds a prominent position in the use of this technology, its training, and its expansion to the rest of Latin America and the world. In an article published in the *Argentine Journal of Cardiology*, [RACI 2024:15(2):51-57], Blanco et al. report the precise results derived from the initial experience with the new Myval prosthesis in this country, thus providing highly valuable scientific information. This is a prospective multicenter registry that included in a non-randomized basis the first 300 patients with some form of symptomatic valve disease, either native or prosthetic, whether regurgitation or stenosis, treated percutaneously with this innovative technology (95% in aortic position, 2.6% in tricuspid position, 1.3% in pulmonary position, and 1% in mitral position). The average age of the study population was 78.7±6.3 years; 39.6% of subjects were men, and the average surgical risk according to the EuroSCORE II scale was 6.2%±2.3%. The procedural outcomes presented are satisfactory. There was a need for post-dilation in 18.6% of cases, a permanent pacemaker implantation rate of 6.6%, and only 8 cases of in-hospital mortality (2.7%). These results reflect the high efficacy and safety of this treatment, with particularly interesting data on conduction disorders. It should also be noted that intermediate sizes were used in 44.3% of

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Conflicts of interest: Dr. Ignacio J. Amat-Santos is a proctor for Medtronic, MerilLife, and Boston Scientific.

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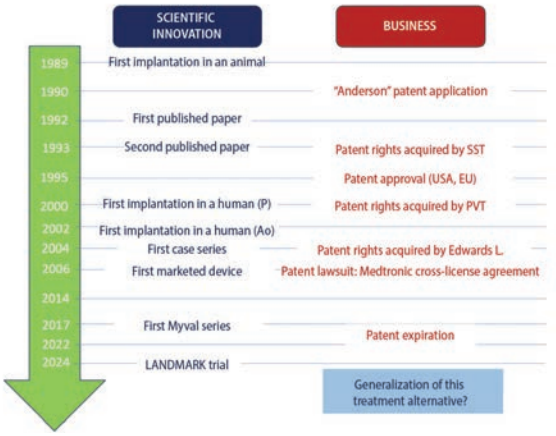

Figure 1.

all implantations and extra-large sizes in 3.3% of cases. These data reflect the clear need for this new therapeutic alternative in clinical practice. In the case of aortic valve disease, the hemodynamic behavior of the Myval prosthesis was optimal, with a residual mean gradient of 5±3 mmHg and no residual regurgitation greater than moderate. Finally, a point of particular interest for new operators is that the article includes a subjective assessment scale by Argentine interventional cardiologists regarding this new technology, which highlights trackability (4.16/5), valve deployment (4.16/5), and hemodynamic outcome (4.48/5) as specifically outstanding aspects of this device.

The Myval technology thus is a very attractive option that also offers promising results in off-label scenarios such as bicuspid aortic stenosis[7, 8], pure aortic regurgitation[9], or mitral[10], tricuspid[11], or pulmonary[12] valve disease with large-size rings. Additionally, current accumulated experience with Myval use has demonstrated device safety for the treatment of dysfunctional biological prostheses or surgical rings in valve-in-valve or valve-in-ring procedures[13].

Thanks to the results presented by Blanco et al., it is possible to expand the treatment options for percutaneous interventionism in Argentina, as it includes a sample of unselected patients, and it therefore has external validity. However, it should be noted that this initial experience only reports in-hospital results, without a description of long-term clinical or hemodynamic follow-up results. Furthermore, this is a non-randomized and non-monitored study, which may allow for the inclusion of errors. On the other hand, the global experience with Myval, as well as the results of the LANDMARK clinical trial and from an experience of over three years that will be presented soon, could soon provide the evidence that is still missing from the authors' experience.

Innovation and criticPeal analysis must continue if we want to improve the treatment of our patients. The Argentine school, with this article, takes a leadership role in that.

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