RAPID-DEPLOYMENT AND SUTURELESS AORTIC VALVE REPLACEMENT INTERNATIONAL REGISTRY: A STEP FORWARD IN DEFINING THE IDEAL TARGET PATIENT POPULATION

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TEXT

We would like to congratulate Berretta and co-authors for their article in this issue of the European Journal of Cardio-Thoracic Surgery reporting the outcomes of the Sutureless and Rapid Deployment International Registry (SURD-IR), which represents the largest international independent registry enrolling patients undergoing aortic valve replacement (AVR) with both sutureless and rapid deployment aortic valves (SURD). The procedural results as well as the in-hospital outcomes and the hemodynamic valve performance of patients undergoing AVR with sutureless (Perceval, Livanova PLC, London, UK) and rapid deployment (Intuity Elite, Edwards Lifesciences, Irvine, USA) valves (Group 1) were compared with patients undergoing aortic valve replacement with standard sutured valves (Group 2) [1].

It has recently been confirmed by available scientific literature that the SURD aortic prostheses are not inferior to standard stented valves in patients undergoing AVR, in terms of major adverse cerebral and cardiovascular events at short-term follow-up [2-4]. The SURD Registry real world data confirm initial satisfactory results of these two prostheses (according to VARC-3 criteria), without residual regurgitation or elevated valvular gradients. Of note, the Authors decided to present the outcomes in a cumulative fashion (Group 1), without dividing the sutureless and the rapid deployment valve systems, although the approach to the aortotomy, the implanting technique and the anchoring system differ substantially between them. In fact, the Rapid Deployment valves are essentially Perimount Magna bioprosthesis (Edwards Lifesciences, Irvine, USA) with a modified anchoring technology in the left ventricular outflow tract, thus inheriting the excellent long-term results of the classic stented prostheses. In contrast, the Perceval bioprosthesis is built on a self-expanding nitinol stent, which has the dual role of supporting the valve's leaflets as well as fixing the valve in place by using coaxial forces. Differing from the rapid-deployment Intuity valve, the Perceval valve requires crimping ahead to its implantation and the three guiding sutures are eventually removed from the annulus, defining a truly sutureless bioprosthesis.

Nevertheless, the Registry provides a clear understanding of the in-hospital outcomes of both SURD prostheses, as compared to conventional AVR. Considering the obvious limitations of group-matching, the number of patients enrolled in the study is rather large (more

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than 2000 matched pairs) and the evidence becomes clear. As demonstrated by the Authors, the strength of these devices includes a shorter clamping time (mean time of 49 minutes for Group 1 vs 59 minutes for Group 2). They facilitate either minimally invasive valve surgery or complex and redo cardiac interventions, especially in elderly and high-risk patients, who are more sensible to the detrimental effects of a prolonged heart ischemia and cardiopulmonary bypass time.

To date, with the increase of surgical experience, SURD valves may be implanted in the vast majority of the aortic valve anatomies with satisfactory clinical and hemodynamical results. In particular, adopting a simple intraoperative technique that has been recently described by our group, the so-called “annulus stabilization technique”, some of the anatomical limitations of the rapid deployment valves, such as the risk of paravalvular leak, the commissural misalignment or the risk of pacemaker implantation, can be overcome [5]. Moreover, in pure aortic valve regurgitation or in bicuspid anatomies, where the placement of the three guiding-sutures at the nadir of the coronary sinuses is less straightforward, the suture annuloplasty works as a successful compensatory technique.

Following these considerations, the key question remains the indication for the use of SURD valves: which patients would benefit the most from them? Looking to Registry data, a large number of strokes in the SURD group is reported, which has however been reduced in the last three years of observation, but is still larger compared to standard bioprostheses (2.3% for Group 1 vs 0.9% for Group 2). The Authors' explanation for this event is not very thorough and may be related to the implantation techniques and to the different aortic manipulations. Indeed, this is one of the key aspects to be monitored, especially when treating young patients. In addition, as well as transcatheter aortic valves (approximately 10% of risk), the SURD valves presented a significant higher risk of permanent pacemaker implantation (7.9% for the Group 1 vs 2.5% for Group 2). This is an important issue and makes it mandatory to select patients without any pre-operative rhythm abnormalities [6-7]. As already mentioned, innovative simple techniques can help overcoming these rare side effects of SURD [5].

Last but not least, there is still much we do not know about long-term durability. With only in-hospital and short-term data available for SURD Registry and correlated studies, one study reporting mid-term data [8], only time will tell how these technologies compare with

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the well-established durability of conventional sutured bioprostheses. However, as previously stated, the advantage of the Intuity valve system is to feature a leaflet valve technology directly derived from the Perimount valve that has already been showing a very long durability with low risk of structural valve deterioration for many years [9]. However, long-term follow-up for SURD is needed to demonstrate the optimal durability of this new generation of valve devices.

In conclusion, these observations suggest that SURD valves may be considered one component of a contemporary aortic valve program, favouring either isolated minimally invasive aortic surgery (in patients without any pre-existing rhythm disturbances) or combined complex cardiac procedures in elderly high-risk patients.

Again, the Authors should be congratulated for clarifying this evidence.

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