

ranging from 1.6 cm² (size 19 valve) to 2.5 cm² (size 27 valve). These EOAs are slightly higher than those reported from St. Jude Medical, but caution should be taken because the difference could be the variability of the aortic valve area at echocardiography during the early postoperative period. In our study, the gradients at discharge were comparable and even lower than those reported for other stented biological valves [4, 6, 7]. Likewise, the Trifecta valve has shown even better haemodynamic results than those of its predecessor, the St. Jude Medical Epic supra-annular valve [8, 9]. It is important to remember that this is not and cannot be a comparative study. Our data also indicated that the Trifecta valve might have a slightly better performance than recently reported by Dell'Aquila *et al.* [10].

From the clinical point of view, early mortality at 30 days was 2.5% ($n = 5$), which is a low rate compared with other studies [6, 11, 12]. Causes of death were considered valve-related only in 1 patient, who died 7 days after discharge, of unknown reasons. All postoperative unexplained or undefined events or deaths were considered valve-related. Only 1 patient (0.5%) had significant aortic insufficiency because of prosthetic endocarditis. After antibiotic treatment, the prosthesis was replaced with another Trifecta valve. The remaining 99.5% had trivial or no aortic insufficiency. In our experience, the clinical performance of the Trifecta valve is perfectly comparable with the other stented biological valves.

The secondary study endpoint was to evaluate the surgical implantation technique.

After 200 implants, the Trifecta valve allowed a relatively simple implant, and the technique is not much different from that of other supported biological valves. In our opinion, there are two key points. The first is a high and wide aortotomy. The prosthesis has a high profile, so it is advisable to make a high aortotomy, ~1–2 cm above the sinotubular junction. To compensate for the difficulties arising from the high-aortotomy approach, a wide aortotomy is recommended. The second key point and the most important, is to properly size the valve. The intra-annular sizer must fit in the aortic annulus, but it should not be very tight. Oversizing increases the difficulty of implantation, particularly when placing the prosthesis in the valvular plane and when knotting. Oversizing could also produce gradient increases due to an excess of prosthetic leaflet tissue, which could be the reason why our EOAs were slightly higher than the St. Jude Medical data. Care must also be taken not to distort the valve stent when lowering the valve into the aortic annulus.

Although haemodynamic and clinical outcomes at discharge are promising, this study had an important limitation that should be taken into account. Our results are from the early postoperative period, which is a short follow-up time. The results presented here offer an approach to the behaviour of this prosthesis, but it will be essential to re-examine the patients included in this study to test their functional status, observe the incidence of complications and do a new echocardiography at least at 1 year.

CONCLUSION

The St. Jude Medical Trifecta aortic valve is easy to implant, but special care must be taken to avoid oversizing, which can lead to difficulty in implantation and produce gradient increases due to an excess of prosthetic leaflet tissue.

The Trifecta valve offers a good alternative to other biological stented aortic valves. This study establishes excellent early clinical

and haemodynamic performance at discharge, but further evaluation is needed during the follow-up.

Conflicts of interest: Rafael Llorens: St. Jude Medical Lecture fees. The other authors: none declared.

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eComment. Trifecta: the latest generation of bioprosthetic aortic valves

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I read with great interest the paper by Permanyer *et al.*, in which they evaluated the early haemodynamic performance of the St. Jude Medical Trifecta valve, a new biological aortic valve, in 200 consecutive patients in a single-centre experience [1]. The Trifecta valve (St. Jude Medical Inc., St. Paul, MN, USA) was introduced into clinical practice in Europe in 2009. This novel biological prosthesis has a unique valve design that maximizes valve haemodynamics without increasing leaflet stress. It is a three-leaflet stented bovine pericardial valve processed with ethanol-based Linx anticalcification technology, and specially designed to be implanted at the supra-annular aortic position. In addition, the titanium stent may offer supplementary clinical benefit during exercise due to its intrinsic expandability.

Dell'Aquila *et al.* [2] were the first to publish their initial experience with this valve by evaluating the outcomes in 70 patients. They concluded that this novel bioprosthesis offers excellent haemodynamic performance in the early postoperative period. Bavaria *et al.* [3] recently published the results of one of the largest prospective, multicentre clinical study ever performed on any surgical aortic valve prosthesis. This trial aimed to establish the early clinical and haemodynamic performance of the Trifecta valve. They enrolled 1014 patients from 31 centres. The mean age of the population was 72.5 ± 9 years and the median follow-up interval was 0.9 years. Kaplan-Meier survival was 95.8% at 1 year and 94.5% at 2 years. Freedom from valve-related mortality and from valve explant was 99.4% at 2 years. Haemodynamic performance of the valve was excellent in the postoperative period. At 1 year of follow-up, average mean gradients ranged from 10.7 to 4.7 mmHg for valve sizes 19 to 29 mm. Average effective orifice area ranged from 1.41 to 2.35 cm² at 1 year for valve sizes 19 to 29 mm.

In conclusion, in the above-mentioned trial, the St. Jude Medical Trifecta valve demonstrated excellent early and at one year hemodynamic performance. Nevertheless, future studies with long-term outcomes are mandatory to confirm the promising results of this new bioprosthesis.

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