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Are we compromising on value versus performance: time to consider the Portico valve as a third major market player?

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We found the recent study by Maisano et al very thought-provoking, given the focus on the commercial experience using the Portico™ bioprosthetic valve (Abbott, Santa Clara, CA, USA) in the multicentre PORTICO-1 study[1]. We applaud the authors for conducting this important study which further adds to a growing body of evidence demonstrating the overall safety (low mortality) and acceptable clinical and haemodynamic outcomes (low transvalvular gradients and low rate of moderate-high paravalvular leak) of the Portico valve[2-4].

While innovation in transcatheter aortic valve replacement (TAVR) devices and adoption of the procedure have occurred rapidly, it appears that this innovation is most tightly regulated in the USA, what we describe as "Controlled Innovation". This may, in part, be due to the predominance of two "major" players, namely Edwards Lifesciences (Irvine, CA, USA) with their SAPIEN technology, and Medtronic (Minneapolis, MN, USA) with their CoreValve® and Evolut™ R/PRO technologies, who together occupy the majority of the TAVR market space[5]. As TAVR expands to a wider, younger population, it is estimated that the market share for emerging transcatheter devices for aortic valve replacement will increase to 76% by 2021, with a global market value of US $8.1 bn[6]. Thus, with these forecasts suggesting increased market size and profit opportunities, many new players are trying to enter the market.

In particular, the Portico valve, an acceptable and viable option in many countries, is gaining appreciable interest and has shown comparable haemodynamic performance to the newer-generation valves[2-4]. Unfortunately, the lack of head-to-head comparison has hindered its growth due to concerns over safety and performance. We reviewed our own institutional experience in a matched comparison of the Portico valve and the SAPIEN valve and found that mean valve gradients were comparable, although statistically lower for the SAPIEN valve (10.1 mmHg vs 5.9 mmHg). Nonetheless, rates of at least mild-moderate aortic insufficiency, operative mortality, permanent stroke and new-onset renal failure were similar.

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Considering the changing competitive and reimbursement landscape of the US healthcare system, TAVR technologies ought to be cost-effective and more readily accessible to a wider population, what we define as "value proposition". We propose a focused effort from various stakeholders, including the Food and Drug Administration agency, to act swiftly to accelerate the evaluation and approval of these newer valves in order to ameliorate the existing market imbalances. The existing market share of these two major players appears to have had substantial impact from an economic standpoint, in terms of discouraging price competition. At the same time, from a health policy standpoint, there is limited accessibility to TAVR valves in many centres, due to their high cost, compared to standard surgical valves. By softening regulatory guidelines, similar to the Europeans and Canadians, and by allowing other valves to enter the market, we may see more competitive pricing. We believe the effect would be to improve access to this procedure, which in turn would increase the availability of this procedure to many Americans, while maintaining quality and cost of care.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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