EuroIntervention 2019;15:e820 published online e-edition October 2019

Reply to the letter to the editor "Are we compromising on value versus performance: time to consider the Portico valve as a third major market player?". Rapid implementation of new therapies, new devices, new procedures... fast but under control: be vigilant!

Francesco Maisano*, MD, FESC

University Hospital Zurich Heart Center, Zurich, Switzerland

We are very thankful to the authors Hirji et al for their comments about access to innovative therapies in the current era of evidence-based medicine[1]. The balance between fast and safe access to innovation in modern society has important ethical, economic and political aspects. In Europe, the new regulatory requirements have been adapted to raise safety standards, and to avoid dissolute and uncontrolled use of new devices without evidence of clinical benefit. At the same time, the Food and Drug Administration (FDA) has changed its policy to allow earlier introduction of new devices in early feasibility studies. As the FDA becomes more liberal, and the EU becomes more strict, the pendulum of innovation will not cease swinging and the two continents will continue to play alternate roles in the introduction of new therapies.

Access to modern therapies is very different among different countries. In an analysis about TAVR adoption rates in western countries, Mylotte et al stated that economic indexes such as healthcare expenditure per capita, sources of healthcare funding, and reimbursement strategies were correlated to the TAVR adoption rate[2].

The introduction of multiple valve technologies from different industrial partners is fundamental in order to foster innovation as well as to enable healthy competition which keeps quality high while reducing device prices.

The Portico® valve (St. Jude Medical [now Abbott], St. Paul, MN, USA) has been demonstrated to be safe and effective in clinical practice. This has been confirmed in a large registry. The results are not different to what is achievable with other approved platforms already available for clinical use in the USA. In addition, its small profile, the special stent design and other features make this device one of the easiest to deliver prostheses in a large variety of patients. We are very happy to have this device available in our armamentarium to take care of patients with horizontal aorta, with a calcific anatomy, with challenging access, or who require subsequent coronary access.

Transcatheter valve interventions are becoming a first-line option for most patients with valve disease. Since these are no longer considered to be experimental methods, a new wave of regulations is needed to adapt to this trend and to enable a wider adoption of therapies, reducing the inequalities seen among countries.

At the same time, we need to remember that healthcare policies should be based on evidence, including the outcomes of preclinical research. According to the new EU law on medical devices, the manufacturer will have to provide evidence for any implantable or high-risk device[3]. New and more strict requirements will help patients and physicians to take better decisions, based on transparency, without delayed access to good therapies in properly selected patients, and under strict vigilance.

Conflict of interest statement

F. Maisano is a consultant for Abbott.

References

1. Hirji S, Leya G, Pelletier M. Are we compromising on value versus performance: time to consider the Portico valve as a third major market player? *EuroIntervention.* 2019;15:e818-9.

2. Mylotte D, Osnabrugge RL, Windecker S, Lefèvre T, de Jaegere P, Jeger R, Wenaweser P, Maisano F, Moat N, Søndergaard L, Bosmans J, Teles RC, Martucci G, Manoharan G, Garcia E, Van Mieghem NM, Kappetein AP, Serruys PW, Lange R, Piazza N. Transcatheter aortic valve replacement in Europe: adoption trends and factors influencing device utilization. *J Am Coll Cardiol.* 2013;62:210-9.

3. Fraser AG, Butchart EG, Szymański P, Caiani EG, Crosby S, Kearney P, Van de Werf F. The need for transparency of clinical evidence for medical devices in Europe. *Lancet.* 2018;392:521-30.

**Corresponding author: University Hospital Zurich Heart Center, Witellikerstrasse 40, 8008 Zürich, Switzerland. E-mail: francesco.maisano@usz.ch*

DOI: 10.4244/EIJ-D-18-00966R