



EDITORIAL COMMENT

‘‘A momentary lapse of opinion’’: The reader should be aware of the iatrogenic potential of this publication



«Um lapso de opinião momentâneo»: O leitor deve estar consciente do potencial iatrogénico desta publicação

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Available online 23 August 2020

Aortic stenosis is the most frequent native valve disease in Europe, and as the elderly population increases, together with the high prevalence of comorbidities and the extension of indications to low-risk patients, the number of individuals requiring transcatheter aortic valve replacement (TAVR) is likely to increase substantially.^{1–3}

Frailty, dependence and comorbidities affect the lives of some of these patients, raising the question whether the intervention justifies the economic cost. High-quality American and European analyses of TAVR have shown generally acceptable cost-effectiveness, with the higher cost of the procedure being offset by the considerable benefits in quality of life and survival. It is, however, important to examine the specifics at a national level, since large differences have been observed between countries.^{4–8}

The article by Fontes-Carvalho et al. of the Centro Hospitalar de Vila Nova de Gaia in this issue of the *Journal*⁹ points to the need to assess the cost-effectiveness and economic impact of the adoption of new technologies before their dissemination in clinical practice. In this case the time for this objective has passed, which since these

authors are well respected I would suggest should be put down to a momentary lapse of opinion. In fact it is now 18 years since the first TAVR procedure was performed, and it was the Gaia Hospital group that introduced it to the Iberian peninsula in 2007.

The article is of interest because it assesses health technology in structural interventional cardiology from a national viewpoint. On the basis of detailed data from 2017 from a single center, it sets out to estimate the potential impact of expanding the indications for TAVR in three hypothetical scenarios, concluding that public expenditure on this treatment is likely to grow considerably. The authors suggest a centralized approach to the management of the required economic and clinical resources, as well as optimization of the procedure itself.

There are two questions that this study raises in 2020.

The first question is whether economic considerations are paramount for a technique that is considered the first-line treatment for high-risk patients and for which good evidence is emerging for low-risk individuals. The answer is no, for the following reasons:

a) Firstly, since 2017, not only has there been an increase of 33% in the number of TAVR procedures, but in line with

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<https://doi.org/10.1016/j.repc.2020.07.008>

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recommendations there have been improvements in the technique, with simplified protocols for arterial access and sedation. These have led to reductions in costs, complications (stroke, vascular complications, bleeding and valvular regurgitation) and rehospitalizations.^{5,10–12} As Fontes-Carvalho et al. point out in their article, cost-effectiveness studies such as theirs are most valuable before the technique enters clinical practice, which has already happened.

- b) Secondly, in Portugal the laboratories and technicians required to perform TAVR are often unavailable. The European Society of Cardiology (ESC) Atlas¹³ shows that Portugal is lagging in 23rd and 34th place, respectively, among ESC member countries for these two parameters.
- c) Thirdly, there is no sound economic justification for centralization of material acquisition, which was proposed without success some years ago in the area of coronary intervention. The empirical data are inconclusive concerning the advantages and disadvantages of the mixed funding model of a fixed budget and diagnostic-related groups used by the Portuguese national health system (NHS), but this alone does not justify such a change.¹⁴ There are no reports of such attempts in other areas of medicine in Portugal, and the studies referred to are from the UK and the American PARTNER trial, which are of doubtful applicability to Portugal, unlike studies on measures to increase the efficiency of hospital protocols, which are reproducible in any center.^{12,15,16}
- d) Fourthly, times have changed, and it is important to overcome inequalities in regional access to cutting-edge technology, without compromising clinical excellence. In an era of rapidly increasing and improving professional mentoring and interchange, a move toward greater concentration would go against current practice and could hamper the ability of several catheterization laboratories to offer techniques that are becoming simpler and easier. This risks losing one of the main strengths of interventional cardiology, that of universality, the clearest example of which is the coronary fast-track system.
- e) Finally, the true value of a theoretical cost-effectiveness analysis would be seen if it were directed at areas that really are emerging, such as coronary lithoplasty, coronary sinus narrowing, or intervention for structural mitral regurgitation.

The second question is whether the study's methodological limitations are important. I would like to say they are not, but in fact they are, for the following reasons:

- a) The fact that only two of the six devices available nationally are analyzed introduces a selection bias, ignoring around a quarter of the TAVR procedures reported in the Portuguese Registry on Interventional Cardiology (RNCI) run by the Portuguese Association of Cardiovascular Intervention (APIC).
- b) A cautious estimate would have been preferable to the approach of Fontes-Carvalho et al.'s study and its three scenarios, since the difference between their projections and the reality is over three-fold. The RNCI recorded 746 TAVR procedures in 2019, in contrast to the 2516 in the meta-analysis by Durko et al.¹⁷ and the 2488 in Fontes-Carvalho et al.'s scenario 2. It is clear that in this

country the recommended criteria for TAVR in higher-risk patients aged over 65 years are often not followed; the study by Fontes-Carvalho et al. assumes that in such cases patients undergo surgical aortic valve replacement (SAVR). The number of individuals treated by SAVR in Portugal is not known, to the shame of all the country's cardiac surgery departments, but not even the highest estimates could explain the difference of around 1700 cases, which is probably due to patients being neither diagnosed nor referred. Durko et al. include among the limitations of their study the fact that their estimates are based on a model that contains multiple steps, and that it did not consider all local differences in health care systems among individual countries in Europe.^{9,10,17}

- c) The costs of the artificial valves, which are central to the analysis, were based on figures from a single center in 2017, and are now lower. It should also be noted that estimates of in-hospital costs (human resources and facilities) are complicated by the unreliability of any nationwide analysis, which would be of necessity based on official reports, given the systematic lack of credible analytical data derived from cost-based management, which is commonplace in private practice but practically unheard of in the NHS.¹⁴
- d) Finally, the opinions expressed in the article are not shared by those working in this area in other centers, which significantly limits their validity, especially when the authors were unable to include data from even a second hospital.¹⁸

To conclude, this article seemed promising, but has unfortunately become obsolete. Percutaneous aortic valve implantation is now an established technique, due to its clinical benefit and ever-improving patient selection processes.

The study by Fontes-Carvalho et al. has the merits of originality, of developing credible economic studies in the field of interventional cardiology, and of challenging medical societies to adopt a national strategy.

If the methodology behind their estimates had been solid, I would still disagree with their proposed concentration of resources, due to the 'iatrogenic' impact of blocking the expansion of access to TAVR with no guarantee of adding value to what is most important – clinical outcomes and knowledge of the cost-effectiveness of the technique at national level.

Even so, I remain an optimist.

Conflicts of interest

The author has no conflicts of interest to declare.

References

1. Iung B, Baron G, Butchart EG, et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on valvular heart disease. *Eur Heart J*. 2003;24:1231–43.
2. Popma JJ, Michael Deeb G, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med*. 2019;380:1706–15.

3. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;380:1695–705.
4. Iannaccone A, Marwick TH. Cost effectiveness of transcatheter aortic valve replacement compared with medical management or surgery for patients with aortic stenosis. *Appl Health Econ Health Policy*. 2015;13:29–45.
5. Galper BZ, Baron SJ, Cohen DJ. Cost-effectiveness of TAVR in low-risk patients: do we have more than a NOTION? *EuroIntervention*. 2019;15:e953–5.
6. Kularatna S, Byrnes J, Mervin MC, et al. Health technology assessments reporting cost-effectiveness of transcatheter aortic valve implantation. *Int J Technol Assess Health Care*. 2016;32:89–96.
7. Goodall G, Lamotte M, Ramos M, et al. Cost-effectiveness analysis of the SAPIEN 3 TAVI valve compared with surgery in intermediate-risk patients. *J Med Econ*. 2019;22:289–96.
8. Baron SJ, Wang K, House JA, et al. Cost-effectiveness of transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at intermediate risk: results from the PARTNER 2 trial. *Circulation*. 2019;139:877–88.
9. Fontes-Carvalho R, Guerreiro C, OE, et al. Present and future economic impact of transcatheter aortic valve replacement in the Portuguese national health system. *Rev Port Cardiol*. 2020;39.
10. EAPCI. Valve for life - Portugal; 2020. Available from: [https://www.escardio.org/Sub-specialty-communities/European-Association-of-Percutaneous-Cardiovascular-Interventions-\(EAPCI\)/Advocacy/valves-for-life-portugal](https://www.escardio.org/Sub-specialty-communities/European-Association-of-Percutaneous-Cardiovascular-Interventions-(EAPCI)/Advocacy/valves-for-life-portugal) [accessed 01.06.20].
11. Gialama F, Prezerakos P, Apostolopoulos V, et al. Systematic review of the cost-effectiveness of transcatheter interventions for valvular heart disease. *Eur Hear J Qual Care Clin Outcomes*. 2018;4:81–90.
12. Durand E, Borz B, Godin M, et al. Transfemoral aortic valve replacement with the Edwards SAPIEN and Edwards SAPIEN XT prosthesis using exclusively local anesthesia and fluoroscopic guidance: feasibility and 30-day outcomes. *JACC Cardiovasc Interv*. 2012.
13. Timmis A, Townsend N, Gale CP, et al. European Society of Cardiology: cardiovascular disease statistics 2019. *Eur Heart J*. 2020;41:12–85.
14. Street AD, O’Reilly J, Ward P, et al. DRG-based hospital payment and efficiency: theory, evidence and challenges. In: Busse R, Geissler A, Quentin W, Wiley M, editors. *Diagnosis-related groups in Europe – moving towards transparency, efficiency and quality in hospitals*. Maidenhead: Open University Press and McGraw-Hill Education; 2011. p. 93–114.
15. Llewellyn S, Procter R, Harvey G, et al. Facilitating technology adoption in the NHS: negotiating the organisational and policy context – a qualitative study. *Health Services and Delivery Research*, No. 2.23. Southampton (UK): NIHR Journals Library; 2014.
16. Kasel AM, Shivaraju A, Schneider S, et al. Standardized methodology for transfemoral transcatheter aortic valve replacement with the Edwards Sapien XT valve under fluoroscopy guidance. *J Invasive Cardiol*. 2014;26:451–61.
17. Durko AP, Osnabrugge RL, Van Mieghem NM, et al. Annual number of candidates for transcatheter aortic valve implantation per country: current estimates and future projections. *Eur Heart J*. 2018;39:42–2635.
18. Teles RC, Ribeiro VG, Patrício L, et al. Position statement on transcatheter aortic valve implantation in Portugal. *Rev Port Cardiol*. 2013;32:801–5.