International Journal of Cardiology 294 (2019) 37–38

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Editorial

Aortic valve replacement in intermediate risk patients in the international community: Time to hop on the TAVI train

Abdallah El Sabbagh [a,*], Mohammed Al-Hijji [b], Mohamad Alkhouli [c]

[a] Department of Cardiovascular Diseases, Mayo Clinic, Jacksonville, FL, United States of America
[b] Heart Hospital, Hamad Medical Center, Doha, Qatar
[c] Department of Cardiovascular Disease, Mayo Clinic, Rochester, MN, United States of America

Keywords:
Transcatheter aortic valve implantation
Cost-effectiveness
Aortic stenosis

Transcatheter aortic valve implantation (TAVI) has emerged as a disruptive treatment modality for severe aortic stenosis. Several factors led to the success of TAVI including ease of its use, tolerance of the patients to the procedure, rapidity of recovery and robustness of the data proving its efficacy and safety. As a result, TAVI has become the treatment of choice in high risk and inoperable patients, which led to its rapid adoption in these patient populations [1]. Recent clinical trials showed favorable survival and quality of life outcomes in lower risk patients undergoing TAVI [2]. As the indication for TAVI continues to expand, the question of cost-effectiveness becomes a vital one, particularly in the international community where resource allocation is often a challenging and meticulous process.

During the early days of TAVI, published analyses reflected equipoise regarding its cost-effectiveness. Reynolds et al. showed that patients undergoing TAVI using a balloon expandable valve in both PARTNER A (high risk) and PARTNER B (inoperable) trials, as well as those undergoing self-expandable TAVI had an acceptable gain in incremental cost-effectiveness ratio (ICER) per quality of life adjusted years (QALY) [3–5]. To our knowledge, only one single center study by Osnabrugge et al. has challenged the growing evidence on the cost-effectiveness of TAVI vs. SAVR [6]. Subsequent studies looked at drivers of cost in TAVI. Arnold et al. showed that presence of complications during TAVI was associated with a higher cost [7]. A study by Babaliaros et al. revealed that the "minimalist approach", whereby TAVI is performed in the catheterization laboratory under conscious sedation, as oppose to general anesthesia in the hybrid operating room, was associated with significant reduction in costs [8].

With the evolution of safer transcatheter valve systems that lowered complication rates, improvements in pre-procedural planning, and inclusion of lower risk patients who have less comorbidities that can negatively impact the procedure, the cost-effectiveness of TAVI became evident. In the most recent analysis, Baron et al. looked at the cost-effectiveness of TAVI in intermediate risk patients in the PARTNER 2A trial and PARTNER S3i registry, from the USA healthcare system perspective [9]. This study showed clear economic superiority of TAVI over SAVR, particularly with the use of the contemporary and safer Sapien S3 valve design and transfemoral access, which led to the decrease in nonprocedural costs, such as the shorter length of stay.

Despite the data proving cost-effectiveness of TAVI, many international communities outside Europe and the US have been slower in adopting TAVI in intermediate risk patients, with costs being a major concern. With the rising costs of healthcare and limited resources, policy-makers are posing stringent requirements for supportive evidence of cost-effectiveness of medical devices before approving resource allocation for their utilization.

In the paper published in the current issue of the IJC by Zhou et al., the authors raised this particular issue as an obstacle for expanding TAVI to intermediate risk patients in the Australian medical system [10]. In order to estimate cost effectiveness of TAVI in intermediate risk patients in Australia, the authors used data from the PARTNER S3i registry, which compared intermediate risk patients undergoing TAVI using the contemporary Sapien S3 balloon expandable valve to the surgical arm from the PARTNER 2A trial. They performed cost-effectiveness analysis using a Markov model, estimating costs from the Australian Medicine Benefits Schedule. They found that the higher procedural cost of TAVI compared to SAVR was offset by the economic savings from shorter length of hospital stay. More importantly, the projected 10-year costs were lower in TAVI than SAVR by ~10,000 Australian dollars, and the gain in QALY and life years was higher in TAVI than SAVR (0.31, and 0.33, respectively).

The current analysis provided supportive data to extend the TAVI practice into intermediate risk patients. However, there are certain limitations that need to be considered. The data used in the study is extracted from clinical trials done in Europe and the USA, thus there can be potential confounders such as: 1 — the patient demographics and comorbidities may differ, 2 — Cost of pre-procedural testing, consultations and pre-TAVI percutaneous coronary interventions may differ, 3 — procedural considerations such as implanter experience, achieved results, cost of managing complications (e.g. pacemaker placement), availability of nursing conscious sedation, and total procedural time may differ; and 4 — Post-procedural considerations including post procedural monitoring protocols and related costs of monitoring units,

* Corresponding author at: Mayo Clinic, Department of Cardiovascular Disease, 4500 San Pablo Road, Jacksonville, FL 32224, United States of America.
E-mail address: elsabbagh.abdallah@mayo.edu (A. El Sabbagh).

https://doi.org/10.1016/j.ijcard.2019.07.088

length of stay as well as rehabilitation needs can also differ. Despite this, and given the challenges of replicating a clinical trial, proof of cost-effectiveness using the methodology demonstrated by Zhou et al. serves as a springboard to support expansion of TAVI into intermediate risk patients in the Australian healthcare system as well as other international communities.

If TAVI gains approval in intermediate risk patients in Australia, several measures can be taken to economize the costs such as: 1 — Adopting a total percutaneous approach to TAVI in the cardiac catheterization laboratory, favoring transfemoral TAVI as the primary access route; 2 — Using nurse conscious sedation and transthoracic echocardiography in the majority of cases; 3 — Aiming for a shallow implantation (90% aortic and 10% ventricular) to minimize pacemaker implantation and paravalvular leak rate. This has been feasible with contemporary devices without affecting the quality of device seal; 4 — Overnight monitoring in a non-ICU setting and next day dismissal in uncomplicated cases; 5 — Seeking proctorship programs for clinical support and guidance during cases to achieve optimal results; and 6 — Approving multiple percutaneous valve systems in the market to avoid monopoly.

The rapidly evolving field of TAVI will continue to witness developments not only in the valve and delivery system design and indications, but also with the concomitant procedures such as embolic protection devices and newer pacemaker systems. These can have impact on cost-effectiveness, and raise the importance question of whether national registry inclusive of cost data is needed to keep outcomes and costs under check. In the meantime, the study by Zhou et al. showed another encouraging reason for the international medical communities to hop on the TAVI train for intermediate risk, and perhaps soon low risk patients.

Disclosures

None.

Declaration of Competing Interest

The authors report no relationships that could be construed as a conflict of interest.

References

[1] M.B. Leon, et al., Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery, N. Engl. J. Med. 363 (17) (2010) 1597–1607.
[2] M.B. Leon, et al., Transcatheter or surgical aortic-valve replacement in intermediate-risk patients, N. Engl. J. Med. 374 (17) (2016) 1609–1620.
[3] M.R. Reynolds, et al., Cost-effectiveness of transcatheter aortic valve replacement compared with surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results of the PARTNER (Placement of Aortic Transcatheter Valves) trial (Cohort A), J. Am. Coll. Cardiol. 60 (25) (2012) 2683–2692.
[4] M.R. Reynolds, et al., Cost-effectiveness of transcatheter aortic valve replacement compared with standard care among inoperable patients with severe aortic stenosis: results from the placement of aortic transcatheter valves (PARTNER) trial (cohort B), Circulation 125 (9) (2012) 1102–1109.
[5] M.R. Reynolds, et al., Cost-effectiveness of transcatheter aortic valve replacement with a self-expanding prosthesis versus surgical aortic valve replacement, J. Am. Coll. Cardiol. 67 (1) (2016) 29–38.
[6] R.L. Osnabrugge, et al., Costs of transcatheter versus surgical aortic valve replacement in intermediate-risk patients, Ann. Thorac. Surg. 94 (6) (2012) 1954–1960.
[7] S.V. Arnold, et al., Costs of periprocedural complications in patients treated with transcatheter aortic valve replacement: results from the placement of aortic Transcatheter valve trial, Circ. Cardiovasc. Interv. 7 (6) (2014) 829–836.
[8] V. Babaliaros, et al., Comparison of transfemoral transcatheter aortic valve replacement performed in the catheterization laboratory (minimalist approach) versus hybrid operating room (standard approach): outcomes and cost analysis, JACC Cardiovasc. Interv. 7 (8) (2014) 898–904.
[9] S.J. Baron, et al., Cost-effectiveness of transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at intermediate risk, Circulation 139 (7) (2019) 877–888.
[10] J. Zhou, et al., Cost-effectiveness of transcatheter aortic valve implantation compared to surgical aortic valve replacement in the intermediate surgical risk population, Int. J. Cardiol 294 (2019) 17–22.