Assessing clinical outcomes in patients with Transcather aortic valve replacement (TAVI) in the Tuscany region, Italy

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BACKGROUND

Surgical aortic valve replacement (SAVR) is the conventional treatment for patients with severe, symptomatic aortic valve stenosis (AVR).

Approximately one-third of patients with an indication for AVR are not eligible for surgery as a result of an increased perioperative risk associated with advanced age, comorbidities, or due to anatomic conditions of the valve or aorta adverse to operability.

TAVI are less invasive procedures originally developed for patients with high surgical risks

OBJECTIVES

- The study aims to provide empirical evidence on the evolution of outcome performance measures in the use of TAVI between 2016 and 2020 via:
- i) Assessment of the number of TAVI procedures performed over time
- Ii) Assessment of temporal trends in outcome indicators

METHODS

Applying the RECOD guidelines to administrative health data, we calculate treatment quality and efficiency indicators.
Patients eligible for the study were identified according to TAVI-specific diagnosis and intervention codes.
The clinical endpoints identified according to the Valve Academic Research Consortium-2 (VARC-2) consensus document[1] are

(a)30-day all-cause mortality;

(b)1-year mortality;

(c)30-day stroke;

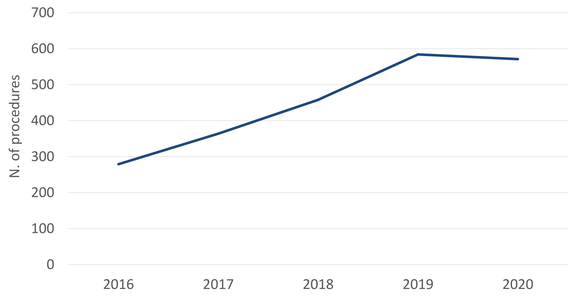
(d)30-day myocardial infarction

(e)30-day conduction disturbances.

RESULTS

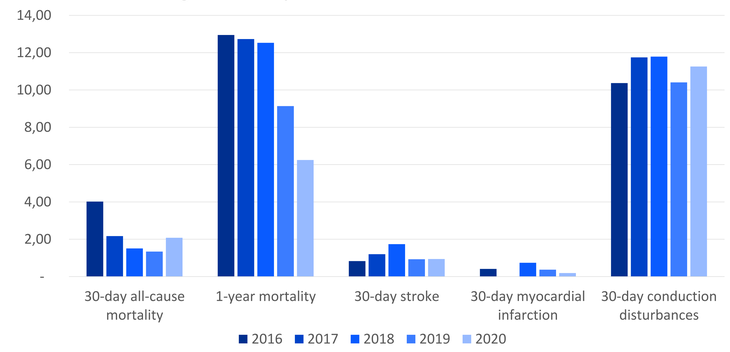
- A total of 2,248 patients with TAVI procedures were identified, with a 102% increase from 2016 to 2020 (Figure 1).

Figure 1 - Temporal trends in number of procedures



- The mean values of 30-day outcomes over the 5-year study period were (a) 2.0%, all-cause mortality (c) 1.1%, 30-day stroke (d) 0.3%, 30-day myocardial infarction, and (e) 11.1%, conduction disorders1-year mortality rates were 11.0%.
- 30-day all-cause mortality rates decreased by 48% from 2016 to 2021, whereas 1-year mortality rates dropped by 52%.
- The reduction in mortality rates is a key outcome indicator, which depends mainly on the implementation of new technologies and interventional procedures.
- Conduction disturbances at 30 days show a 9% increase. Although present among clinical outcomes, they do not represent life-threatening conditions, but important long-term consequences related to TAVI.

Figure 2 - Temporal trends in outcome indicators



CONCLUSION

The increase in TAVI procedures over the five-year study period reflects a change in patient eligibility criteria selection. This study uses real-world data to provide empirical evidence on the primary and secondary endpoints related to the increased use of TAVI. Further studies should be conducted to understand the causes of performance variability among health centers.

References:

[1]Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document (VARC-2). Eur J Cardiothorac Surg. 2012;42(5):S45-S60. doi:10.1093/ejcts/ezs533