Trifecta™ Bioprotheses : Evaluation of the safety based of degenerations according to the VARC-3 classification

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BACKGROUND AND IMPORTANCE

In 2021, cardiologists reported to the medical-devices-vigilance sector serious incidents in four patients with a first-generation Trifecta™ bioprosthesis that resulted in three aortic valve replacement and one death.
→ The question of the degeneration of their bioprosthesis arose.

AIM AND OBJECTIVES

Evaluate the intrinsic imputability of Trifecta™ for dysfunction according to the VARC-3 classification in patients implanted and to reassess their referencing in our center.

MATERIALS AND METHODS

① **Realisation** of a retrospective, single-center and observational study of computerized patient records between February 4, 2011 date of our center's first implantation, and December 31, 2016 to have 5 years of follow-up per patient. This study was approved by our local research department.

② **Extraction** of Trifecta™ valves and data related to the implantation from the traceability software. The collection of echographic and clinical follow-up data were based on the computerized patient records with an extended follow-up period until March 31, 2022.

③ **Classification** of dysfunctions according to the VARC-3 classification criteria[1] : structural valve deterioration (SVD), non-structural valve dysfunction (NSVD), thrombosis and endocarditis.

RESULTS

- Average age : 73,0 (± 9.15) years, 60,7 % male

382 bioprostheses Trifecta® implanted in 378 patients

Perioperative deaths : 15 patients

Missing data : 253 patients

Conclusive data : 114 patients

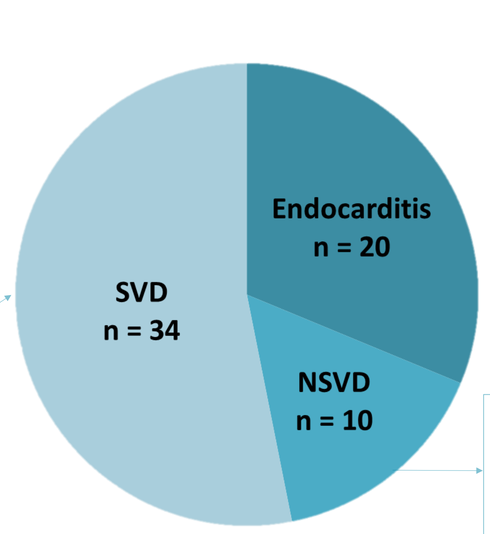
4 of whom had a 2nd Trifecta™ during the study period

Device success : 50 patients

Bioprosthetic valve dysfunction : 64 patients

Mean follow-up time for patients with a **properly functioning bioprosthesis** : **6.6 years**

Aortic valve replacement : **31 patients** during the follow-up period



NSVD were classified as :
- 8 paravalvular regurgitations
- 2 prosthesis-patient mismatches

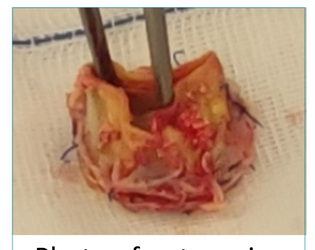


Photo of a stenosing Trifecta™ bioprosthesis

- **20 patients** following SVD within a mean time of **6.7 years**,
- **11 patients** following endocarditis (4 of whom had a 2nd Trifecta™) within a mean time of **3.4 years**.

CONCLUSION AND RELEVANCE

The classification of failures according to VARC-3 allowed us to confirm the intrinsic imputability of the Trifecta™ bioprostheses regarding to the number of SVD-type dysfunctions. Although this study has limitations, it shows the understatement of medical-devices-vigilance cases by the medical staff. The 64 files with dysfunctions were transmitted to the national health authority. The patients will be reviewed to complete the data and perform an echographic follow-up.

According to the manufacturer, degenerations could be related to the expansion system that was improved in the second-generation Trifecta™ marketed in 2016. Since this study, the Trifecta™ has been removed from the hospital formulary.

Nowadays, the French High Authority for Health has removed these bioprostheses from the list of health products financed as hospitalization services mentioned in article L.165-11[2] and R. 165-49[3] of the social security code on the basis of a new safety assessment[4]. These articles condition the purchase of this bioprosthesis by health care institutions. Studies have shown that these valves are less durable than other bioprostheses.

REFERENCES

[1] VARC-3 WRITING COMMITTEE:, Généreux P, et al. Valve Academic Research Consortium 3: Updated Endpoint Definitions for Aortic Valve Clinical Research. J Am Coll Cardiol. 2021 Jun 1;77(21):2717-2746

[2] Code de la santé publique - Article L165-11

[3] Code de la santé publique - Article R165-49

[4] HAS. Avis sur les dispositifs médicaux - TRIFECTA GT Bioprothèse valvulaire aortique avec armature. 2023.

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