Mechanical or biological aortic valve replacement in hemodialysis patients: a propensity score matching analysis with long-term results from the TriNetX global network.

Background / Study Objective

- Patients on haemodialysis are at increased risk of cardiovascular disease such as calcified aortic valve requiring replacement.

- In this subgroups of patients prosthetic valve selection remains controversial.

- The latest European Guidelines recommend a mechanical prosthesis in haemodialysis patients (Class I LOE C) because of the early risk of bioprosthetic structural valve deterioration (SVD) due to the end-stage renal disease.

- However, several studies have reported little difference in terms of reintervention between biological and mechanical prosthesis and similar long-term survival.

- The aim of this study is to compare the early and long-term results of biological vs mechanical aortic valve replacement in a large cohort of patients requiring haemodialysis

Methods

- *The TriNetX* global federated health research network was used.

- This platform provides access to electronic medical records (diagnoses, procedures, medications, laboratory values, genomic information) across 99 large healthcare organizations (HCOs), including our own Institution.

- The analysis process includes two main steps:

  1. Defining the cohorts through query criteria: **hemodialysis plus AVR**. All the patients with concomitant cardiac surgery procedures were excluded. The cohort was divided in two groups according to the prosthetic valve used (biological or mechanical). Then a **propensity score matching** analysis was employed.

  2. Setting up and running the analysis. Setting up the analysis requires definitions for the index event, outcomes criteria, and the time frame.

- **Early outcomes included: 30-days mortality, stroke, hemorrhagic events**

- Long-term outcomes were assessed by using Kaplan-Meier estimates for **overall survival**, freedom from **reintervention**, freedom from **stroke,** freedom from **nontraumatic haemorrhage of brain** and freedom from **other hemorrhagic events.**

Patients

- The study population included 1099 patients with end-stage renal failure requiring dialysis who underwent AVR in the TriNetX Global Network from 2005 to 2021. ,

- **500 patients underwent biological AVR and 599 patients mechanical AVR.**

- Patients undergoing other cardiac surgery procedures (MV surgery/CABG/ascending aorta replacement) were excluded.

- To adjust for baseline differences between the two groups, a **propensity score matching** was performed

- Finally, we obtained two well-balanced groups including **398 patients** each.

Variables	Biological AVR 500 patients	Mechanical AVR 599 patients	p-value	SMD	Biological AVR 398 pts MATCHED	Mechanical AVR 398 pts MATCHED	p-value	SMD
Male sex (n, %)	---	---			---	---		
Age (mean ± SD)	61.1±13.5	56.4±13.1	<0.001	0.352	59.1±13.5	59.4±12.7	0.745	0.023
Hypertension (n,%)	413 (82.6)	533 (89.0)	0.002	0.184	346 (86.9)	347 (87.2)	0.916	0.007
Diabetes (n,%)	256 (51.2)	317 (52.9)	0.569	0.034	214 (53.8)	221 (55.5)	0.618	0.035
Atrial fibrillation (n,%)	186 (37.2)	247 (41.2)	0.173	0.083	155 (38.9)	163 (41)	0.563	0.041
Chronic obstructive pulmonary disease (n,%)	99 (19.8)	123 (20.5)	0.763	0.018	84 (21.1)	88 (22.1)	0.730	0.024
Cerebrovascular disease (n,%)	179 (35.8)	243 (40.6)	0.106	0.098	149 (37.4)	169 (42.5)	0.148	0.103
Peripheral vascular disease (n,%)	88 (17.6)	117 (19.5)	0.413	0.050	79 (19.8)	81 (20.4)	0.860	0.013
Heart failure signs or symptoms (n,%)	289 (57.8)	395 (65.9)	0.006	0.168	244 (61.3)	245 (61.6)	0.942	0.005
Acute and subacute endocarditis (n,%)	123 (24.6)	169 (28.2)	0.177	0.082	99 (24.9)	106 (26.6)	0.570	0.040
EF median (mean ± SD) (n,%)	50±14.2	52.3±14.7	0.305	0.157	50.0±14.6	50.9±15.3	0.710	0.062

Results 1

Early results	Biological AVR 398 patients MATCHED	Mechanical AVR 398 patients MATCHED	*p*-values
In-hospital mortality (n,%)	30 (7.53)	30 (7.53)	0.473
Post-operative stroke (n,%)	41 (10.3)	43 (10.8)	0.871
Haemorrhagic events (n,%)	40 (10)	49 (12.3)	0.330

Long-term results
The seven-year overall survival was **36%** in the biological AVR group and **38%** in the mechanical AVR group (log-rank test *p* 0.257).
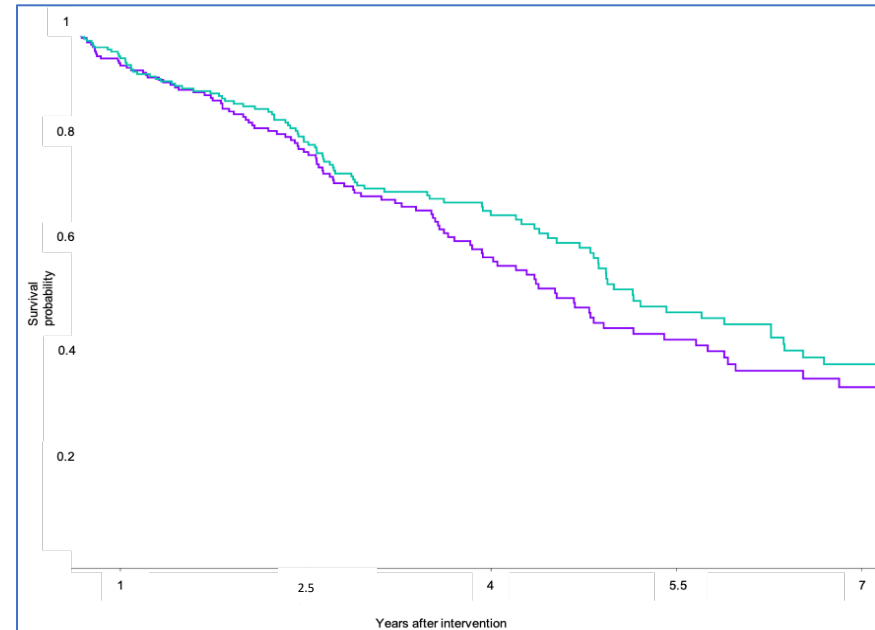
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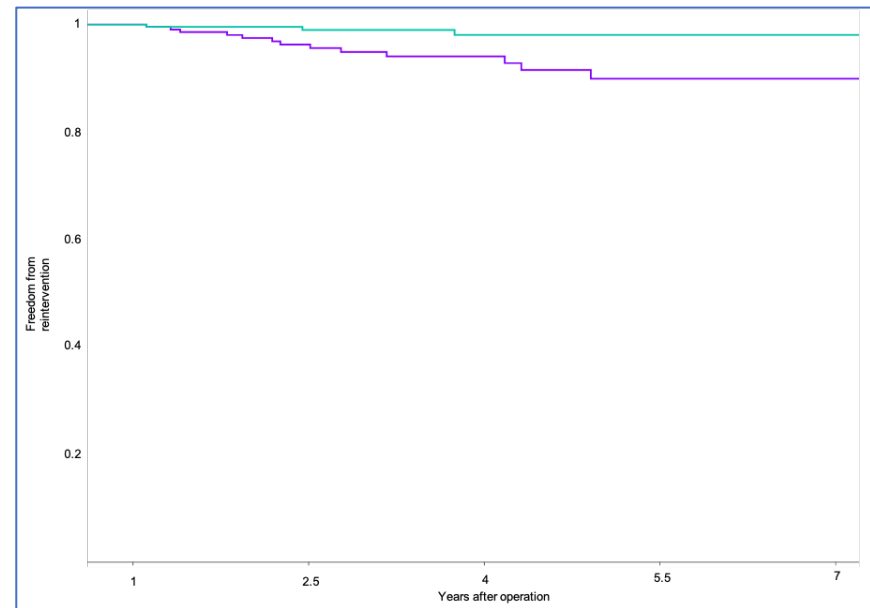
Long-term results
At seven-years, the freedom from reintervention was **89.9%** in the biological AVR group and **98.1%** in the mechanical AVR group (log-rank test *p* 0.006).

At seven-years	Biological AVR 398 patients MATCHED	Mechanical AVR 398 patients MATCHED	*Log-rank test*
Freedom from stroke	82%	78%	0.876
Freedom from nontraumatic haemorrhage of brain	90%	85%	0.516
Freedom from nontraumatic other hemorrhagic events	54%	57%	0.834

Conclusion

- Aortic valve replacement in patients on haemodialysis is burdened by high hospital mortality and morbidity.

- At seven-years, the freedom from reoperation is lower in the bioprosthetic AVR groups whereas the mechanical AVR patients tend to have more embolic/hemorragic events

- *The TriNetX* network data here reported confirm that late survival remains poor but it is not associated to the type of prosthesis implanted.