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Transcatheter, sutureless and conventional aortic-valve replacement: a network meta-analysis of 16,432 patients

Lloyd D, Luc JGY, Indja BE, Leung V, Wang N and Phan K.

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Key points

- The rates of 30-day all-cause mortality and postoperative stroke were similar for the conventional, transcatheter and sutureless AVR.
- Transcatheter and sutureless AVR were associated with higher PPI rates compared with conventional AVR.
- Transcatheter and sutureless AVR are feasible alternatives to conventional AVR in selected patients.

Background information

- According to recent RCTs, the outcomes of TAVR and sutureless AVR are non-inferior to conventional AVR for high-risk patients with aortic stenosis.
- However, multi-arm analyses comparing the perioperative outcomes of the three techniques are lacking.

Aim

- To compare Valve Academic Research Consortium-2 (VARC-2) clinical outcomes for transcatheter, sutureless and conventional AVR.

Type of study

- A Bayesian network analysis.

Endpoints

- Eight VARC-2 postoperative outcomes:
  - Thirty-day all-cause mortality
  - Stroke
  - Myocardial infarction
  - Major bleeding or bleeding requiring surgical re-exploration
  - Mild/trace paravalvular regurgitation
  - Moderate/severe paravalvular regurgitation
  - Acute kidney injury
  - PPI.

Edwards

Methods

- Searches of electronic databases identified seven two-arm RCTs and 25 propensity score-matched studies comparing clinical outcomes of transcatheter, sutureless and conventional AVR.
- Bayesian Markov chain Monte Carlo modelling was used to analyse VARC-2 clinical outcomes.

Results

Patient characteristics

- The 32 studies recorded outcomes for 16,432 patients:
  - Conventional AVR: 8,138 patients
  - Sutureless AVR: 1,238 patients
  - TAVR: 7,056 patients.
- Baseline characteristics were similar for the three matched groups, except for diabetes, which was more common in patients receiving sutureless *versus* conventional valves (OR 0.64, 95% CI 0.44–0.93, p=0.02).

VARC-2 outcomes

- The ORs for the VARC-2 outcomes are shown in Table 1.
- The rates of 30-day all-cause mortality and postoperative stroke were similar for the three groups.
- Compared with conventional AVR, TAVR was associated with lower rates of myocardial infarction (OR 0.59, 95% CI 0.04–0.86) and major bleeding (OR 0.41, 95% CI 0.28–0.59).
- Both sutureless (OR 0.05, 95% CI 0.02–0.09) and conventional AVR (OR 0.09, 95% CI 0.06–0.14) were associated with lower rates of trace/mild paravalvular regurgitation when compared with TAVR.
- Similarly, rates of moderate/severe paravalvular regurgitation were lower for sutureless (OR 0.08, 95% CI 0.03–0.17) and conventional AVR (OR 0.11, 95% CI 0.07–0.16) *versus* TAVR.
- Compared with conventional AVR, sutureless AVR was associated with lower rates of major bleeding (OR 0.56, 95% CI 0.30–0.99) and acute kidney injury (OR 0.60, 95% CI 0.42–0.86).

Table 1. Comparison of VARC-2 outcomes for conventional, transcatheter and sutureless AVR.

VARC-2 outcome	OR		
	Transcatheter *versus* conventional	Sutureless *versus* conventional	Transcatheter *versus* sutureless
Mortality	0.93	0.79	1.18
Stroke	0.94	0.81	1.16
Myocardial infarction	0.59	0.65	0.91
Major bleeding	0.41	0.56	0.72
Trace/mild paravalvular regurgitation	11.11	0.50	20.00
Moderate/severe paravalvular regurgitation	9.09	0.72	12.50
Acute kidney injury	0.59	0.60	1.01
PPI	3.03	2.70	1.12

Table reports ORs as random effects with informative priors to minimise the impact of diversity in the patient populations and study designs. Where the publication reported ORs for the converse associations to those in the table headings (e.g. conventional *vs* transcatheter), the reciprocal of the published OR is presented. Significant associations are highlighted grey.

OR: odds ratio; PPI: permanent pacemaker implantation; VARC-2: Valve Academic Research Consortium-2

- PPI rate was lower for conventional AVR than for both TAVR (OR 0.33, 95% CI 0.24–0.45) and sutureless AVR (OR 0.37, 95% CI 0.22–0.61).
- Heterogeneity levels were high for acute kidney injury, PPI, trace/mild paravalvular regurgitation and major bleeding.

Limitations

- Pooling of data contributes to the heterogeneity observed between the studies.
- The three broad categories of AVR were unable to account for different practices, vascular access routes and types of valves implanted.

Conclusion

This analysis found no differences in perioperative mortality or stroke between patients who underwent transcatheter, conventional or sutureless AVR, suggesting that transcatheter and sutureless AVR are feasible alternatives to conventional AVR in selected patients. However, TAVR was associated with increased paravalvular regurgitation compared with conventional AVR, although developments in TAVR technology, such as the outer skirting of the EDWARDS SAPIEN 3 valve (Edwards Lifesciences), may minimise paravalvular regurgitation. Both TAVR and sutureless AVR were associated with increased PPI; heart teams should consider this increased risk when choosing an appropriate intervention for their patients.

Several trials comparing these techniques are underway and should inform the use (if any) of transcatheter and sutureless AVR in low- and intermediate-risk patients. These trials include PERSIST-AVR (NCT02673697), PARTNER 3 (NCT02675114) and EVOLUT (NCT02701283). One-year data for PARTNER 3 are available at http://bit.ly/PARTNER3. Two-year data for EVOLUT are available at http://bit.ly/EVOLUT. Data from both trials were presented at the American College of Cardiology Annual Scientific Session in 2019.

This document is a summary of the Lloyd D et al. *paper and covers key information including aim, type of study, methods, results, limitations and conclusions.*

The full publication is available at:
http://bit.ly/lloyd2019

Abbreviations

AVR: aortic valve replacement
CI: confidence interval
OR: odds ratio
PPI: permanent pacemaker implantation
RCT: randomised controlled trial
TAVR: transcatheter aortic valve replacement
VARC-2: Valve Academic Research Consortium-2

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