Savings Associated with Surgical Aortic Valve Replacement with Novel Tissue Valves: An Update Incorporating 7-Year Results from the COMMENCE Trial

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Background

- Surgical Aortic Valve Replacement (SAVR) is a common treatment for moderate to severe Aortic Stenosis.[1,2] Novel RESILIA–treated tissue values reduce calcification and have demonstrated positive health outcomes in pre-clinical and clinical studies.[3] The COMMENCE clinical trial recently yielded 7-year health outcomes data for these novel valves.[4]
- Prior economic estimates of legacy or novel tissue valves have generally found that expected savings are positive despite the larger anticipated reoperation costs.[5-7]

Objective

- Utilizing the 7-year results from the COMMENCE trial, this model updates the estimate of long-run savings of novel tissue valves relative to mechanical valves for up to 15 years.

Methods

- Deterministic and Monte Carlo simulation models estimated disease progression across two hypothetical SAVR cohorts (novel tissue vs. mechanical) of 10,000 patients each in the US over 15 years. The primary comparison calculated the difference in valve-related expenditures associated with each valve type ($US, 2022).
- For novel tissue valves annual health outcome probabilities were based on the COMMENCE trial though Year 7 and projected for an additional 8 years based on prior health outcome studies of tissue SAVR.[3,8-10] Health outcomes were also assessed for legacy tissue valves (without RESILIA treatment).
- For mechanical valves annual health outcome probabilities were calculated based on relative risks of each outcomes for tissue valve versus mechanical valve patients. A 'conservative' scenario generally applied larger rates for bleeding and endocarditis. An 'aggressive' scenario assumed lower rates for reoperation, thromboembolism, bleeding and endocarditis. These rates have been used in prior economic analyses of SAVR.[7]
- As the model focuses on cost offsets (excludes QALYs), the mortality rate was generally assumed equivalent across the cohorts.
- Event cost estimates ($US, 2022) for SAVR operation (Mechanical: $53,970; Tissue:$53,716), Thromboembolism (TE: $23,534), Bleeding ($22,936), Endocarditis (EC:$47,358) were sourced from the literature and updated for medical inflation using the US Federal Reserve PCE Health Care Index.[8] Future medical inflation and the discount rate were both set at three percent.
- Annual cost of anticoagulation monitoring (ACM) were based on an activity-based costing (ABC) economic analysis which accounted for labor effort and medicine costs.[11] Tissue valve patients are assumed to have only 6 months of ACM monitoring (no atrial fibrillation), but mechanical valve patients incur ACM costs in all future periods.
- Probabilistic sensitivity analyses and scenario analyses were conducted to identify key inputs and evaluate robustness of the results under different assumptions.

Figure 1: Total Savings over Time per Initial SAVR Surgery Associated with Novel Tissue vs. Mechanical Valves ($US 2022)
Base Case Simulation Model (n=10,000 draws)

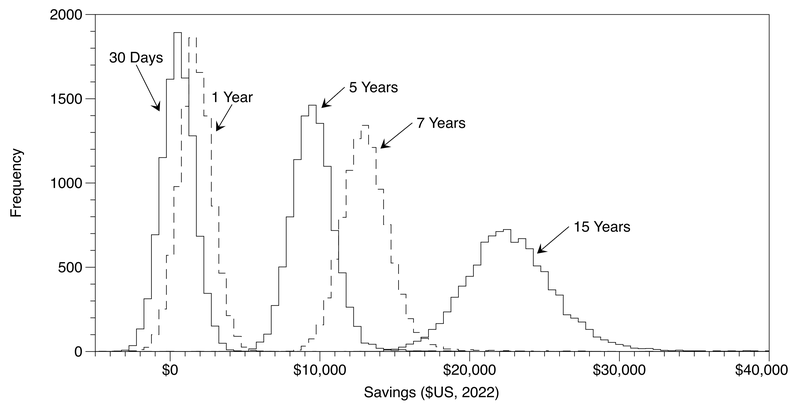


Table 1: Total Savings per Initial SAVR Surgery Associated with Novel Tissue vs. Mechanical Valves ($US 2022)
Base Case and Select Scenario Analyses (Deterministic Model)

Time Since Initial SAVR	Base Case Analysis	Conservative Scenario	Aggressive Scenario
30 Days	$497	$384	$923
1 Year	$1,614	$1,199	$2,518
5 Years	$9,244	$7,575	$12,129
7 Years	$12,693	$10,535	$16,286
10 Years	$16,935	$14,525	$21,300
15 Years	$22,300	$19,565	$28,333

Results

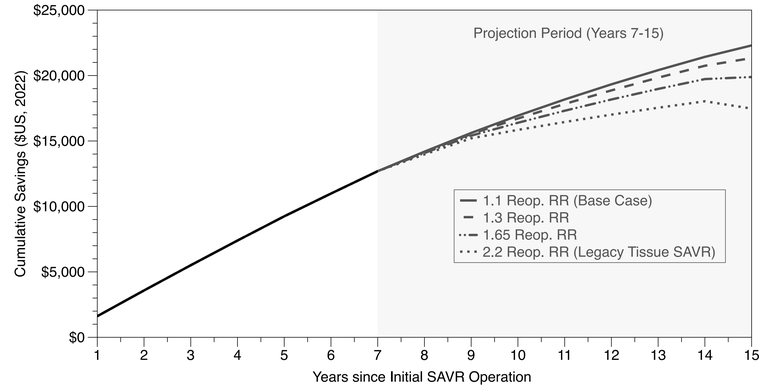
- At year seven savings in the deterministic (simulation) model are $12,693 (Median: $13,023; 95% CI: $10,090-$16,849). Savings increase to $22,300 (Median: $22,613; 95% CI: $17,194-$29,501) at 15 years.(Figure 1 and Table 1)
- In both the 7-year and 15-year durations the 'probability of reoperation' (COMMENCE trial), 'probability of bleeding' (COMMENCE trial) and 'cost of tissue SAVR operation' are the top three inputs impacting savings.
- Across almost all evaluated time periods, savings associated with ACM cost constitute a substantial share of overall savings. If ACM costs are excluded from the analysis, savings persisted in patients receiving novel tissue valves, albeit at lower levels.
- In a comparable model for legacy tissue valves (which have higher reoperation rates than novel tissue valves) the savings relative to mechanical valves are $9,342 ($14,040) at year 7 (year 15)--These are $3,351 ($8,260) less than the 7-year (15-year) savings in the base case model for a novel tissue valves. (Table 2)
- Sensitivity analyses which assumed larger reoperation relative risk for tissue valves (up to 2.2 vs. mechanical valves) for the 'projection period' still yield net savings (Figure 2).

Table 2: Disaggregated Savings per Initial SAVR Surgery Associated with A) Novel Tissue vs. Mechanical Valves and B) Legacy Tissue vs. Mechanical Valves ($US 2022)
Base Case Deterministic Model

Time Since Initial SAVR	Model	Initial SAVR Surgery	Reoperation SAVR	TE	Bleeding	EC	ACM	Overall Savings
7 Years	A	$254	-$120	$562	$1,896	-461	$10,562	$12,693
	B	$254	-$1,641	$1005	$556	-$415	$9,590	$9,342
	Difference	$0	$1,521	-$443	$1,340	-$46	$972	$3,351
15 Years	A	$254	-$604	$826	$2,229	-$841	$20,435	$22,300
	B	$254	-$6,070	$1,752	$1,008	-$732	$17,828	$14,040
	Difference	$0	$5,466	-$926	$1,221	-$109	$2,607	$8,260

Model A: Comparison of Novel Tissue SAVR vs. Mechanical SAVR
Model B: Comparison of Legacy Tissue SAVR vs. Mechanical SAVR

Figure 2: Savings over Time per Initial SAVR Surgery Associated with Novel Tissue vs. Mechanical Valves ($US 2022)
By Reoperation Relative Risk Estimate (projection period)



Conclusions and Discussion

- While not causal, this analysis builds on prior studies that compare long-run tissue and mechanical SAVR costs. Based on the 7-year COMMENCE data projected savings associated with novel tissue valves are significant.
- The lower anticipated reoperation rates for novel valves relative to legacy tissue valves improve marginal savings.

References and Disclosure

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