

Cost-utility analysis of transcatheter valve replacement using valves with RESILIA tissue for the treatment of aortic stenosis in South Korea

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Background

Transcatheter aortic valve replacement (TAVR) is used to treat aortic stenosis in South Korea. The latest TAVR valves use RESILIA, a bovine pericardial tissue treated with integrity-preservation technology. This involves chemically blocking residual free aldehyde groups to prevent calcium binding and glycerolisation to replace water with glycerol, protecting against structural valve deterioration and enhancing durability. RESILIA is incorporated into the newest balloon-expandable valves on the SAPIEN platform. Although this new tissue increases valve costs, a recent study shows it offers a survival benefit compared to previous valve generations (HR=0.79, 95% CI 0.67, 0.93, p=.004).

Objectives

The study aims to estimate the cost-utility of SAPIEN 3 Ultra RESILIA (S3UR) valve vs earlier SAPIEN valves (S3/S3U) for treating aortic stenosis in South Korea.

Methods

A Markov model with two health states (alive, dead) was developed with 2-week cycles simulating 1000 subjects. Survival curves from a clinical trial were reconstructed through digitisation and a published algorithm. Survival was extrapolated to 10 years using a lognormal distribution; Korean specific health state utilities and disease management costs were obtained from published sources. Deterministic and probabilistic sensitivity analyses were conducted. The influence of survival distribution choice was examined by varying the distribution from lognormal to one of the following alternative distributions: exponential, Weibull, Gamma and Loglogistic. The analyses were performed in Excel.

Results

Outcome and costs from the base case of the cost-utility analysis is presented in table 1.

Table 1. CUA results

	S3/S3U	SU3R	Difference
Outcomes			
Deaths	0.39	0.35	-0.05
Life-threatening bleed	0.20	0.16	-0.05
Years of life lived	6.21	6.47	0.26
QALY lived	5.54	5.77	0.23
Costs			
Valve	KRW 32.1M	KRW 38.5M	KRW 6.1M
Deaths	KRW 0.81M	KRW 0.71M	-KRW 0.98M
Life-threatening bleed	KRW 2.5M	KRW 1.9M	-KRW 0.58M
Annual cost of TAVR	KRW 9.3M	KRW 9.7M	KRW 0.38M
Total	KRW 44.8M	KRW 50.9M	KRW 6.1M

The incremental cost-effectiveness ratios (ICERs) were KRW 23,987,235 per year of life saved and KRW 26,903,584 per quality-adjusted life year (QALY) lived. The lognormal distribution resulted in the highest ICER (see table 2).

Table 2. Structural analysis: varying distributions

Distribution	ICER
Base case: Lognormal	KRW 26,903,584
Exponential	KRW 15,866,310
Weibull	KRW 17,232,124
Gamma	KRW 16,722,807
Loglogistic	KRW 19,975,981

As expected, cost-utility was most sensitive to the price of S3UR and the hazard ratio of the overall survival, while all the other input parameters had little material impact on the ICERs (see figure 1).

Figure 1. Deterministic sensitivity analysis

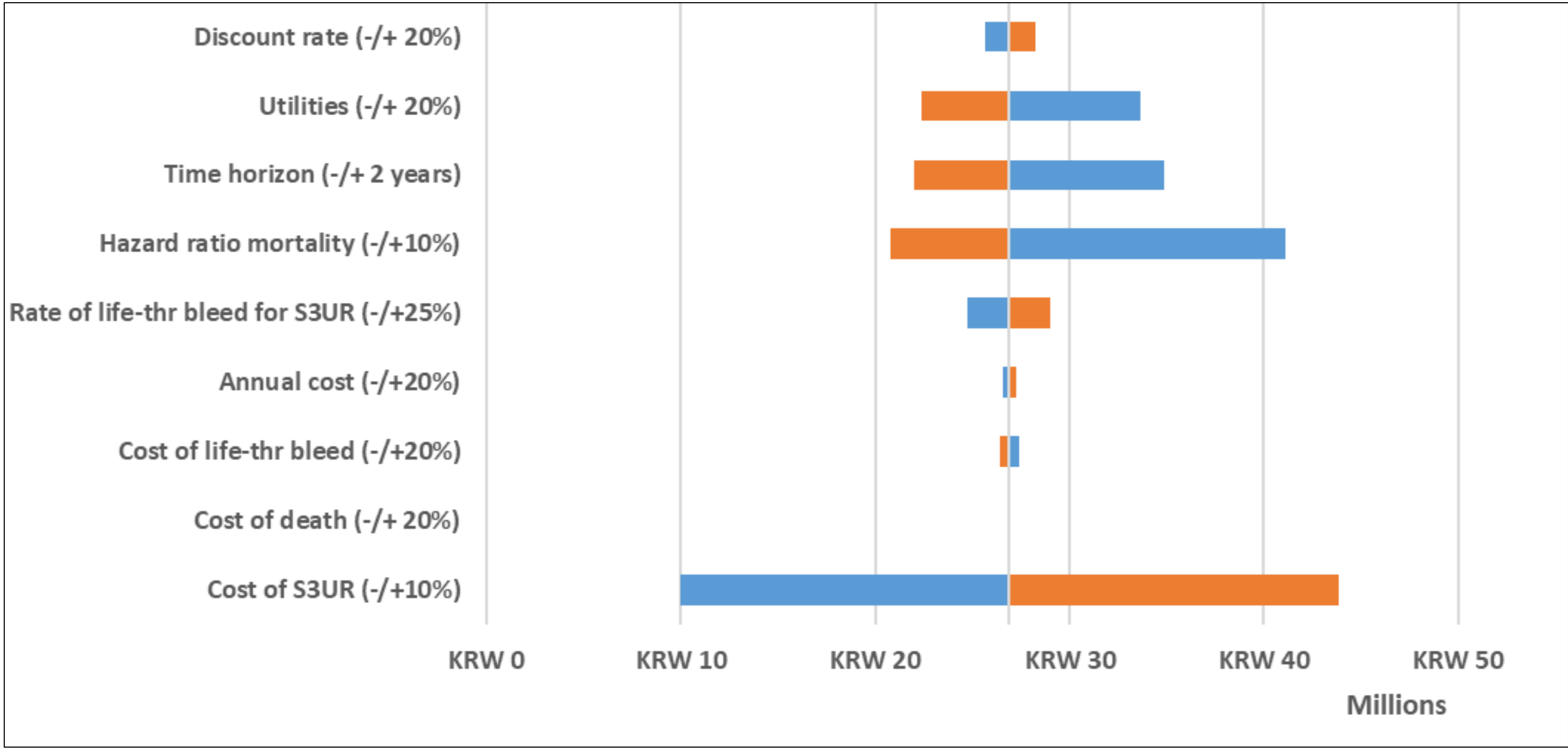
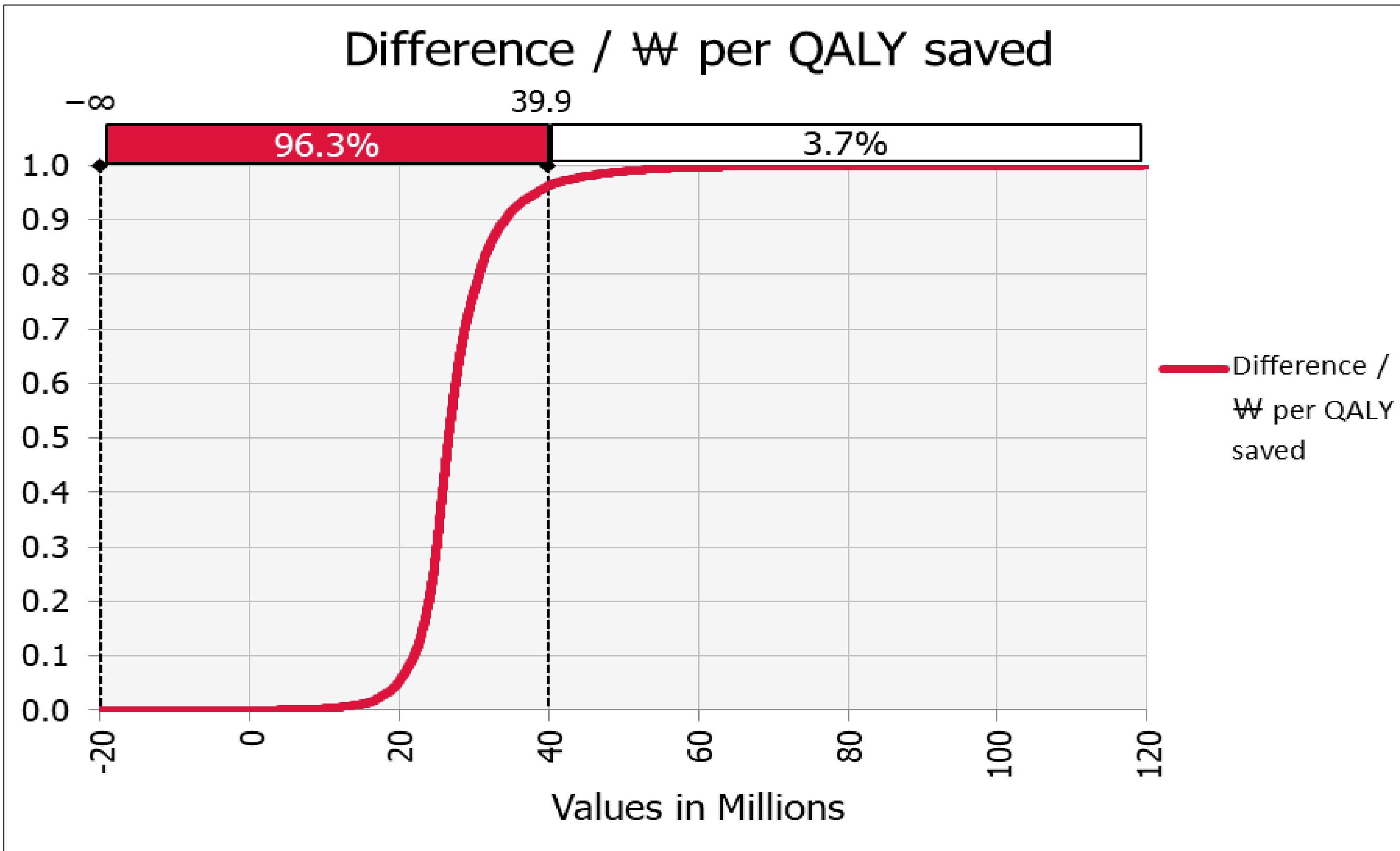


Figure 2. Acceptability curve



More than 96% of the simulations in the PSA were below a KRW 39.9M threshold.

Conclusion

S3UR represents a cost-effective alternative to previous generations of valves with potential improvement in quality of life and survival for aortic stenosis patients in South Korea.