

Isolated Aortic Valve Replacement with Sutureless Prosthesis by Surgical Approach from the Multicentric MANTRA Study

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OBJECTIVE

Minimally invasive approaches to aortic valve replacement (AVR) are recently increasing. However, median sternotomy is still widely used. This analysis aims to **evaluate benefits of minimally invasive (MICS) versus median sternotomy (MS) in AVR using the Perceval Plus sutureless bioprosthesis.**



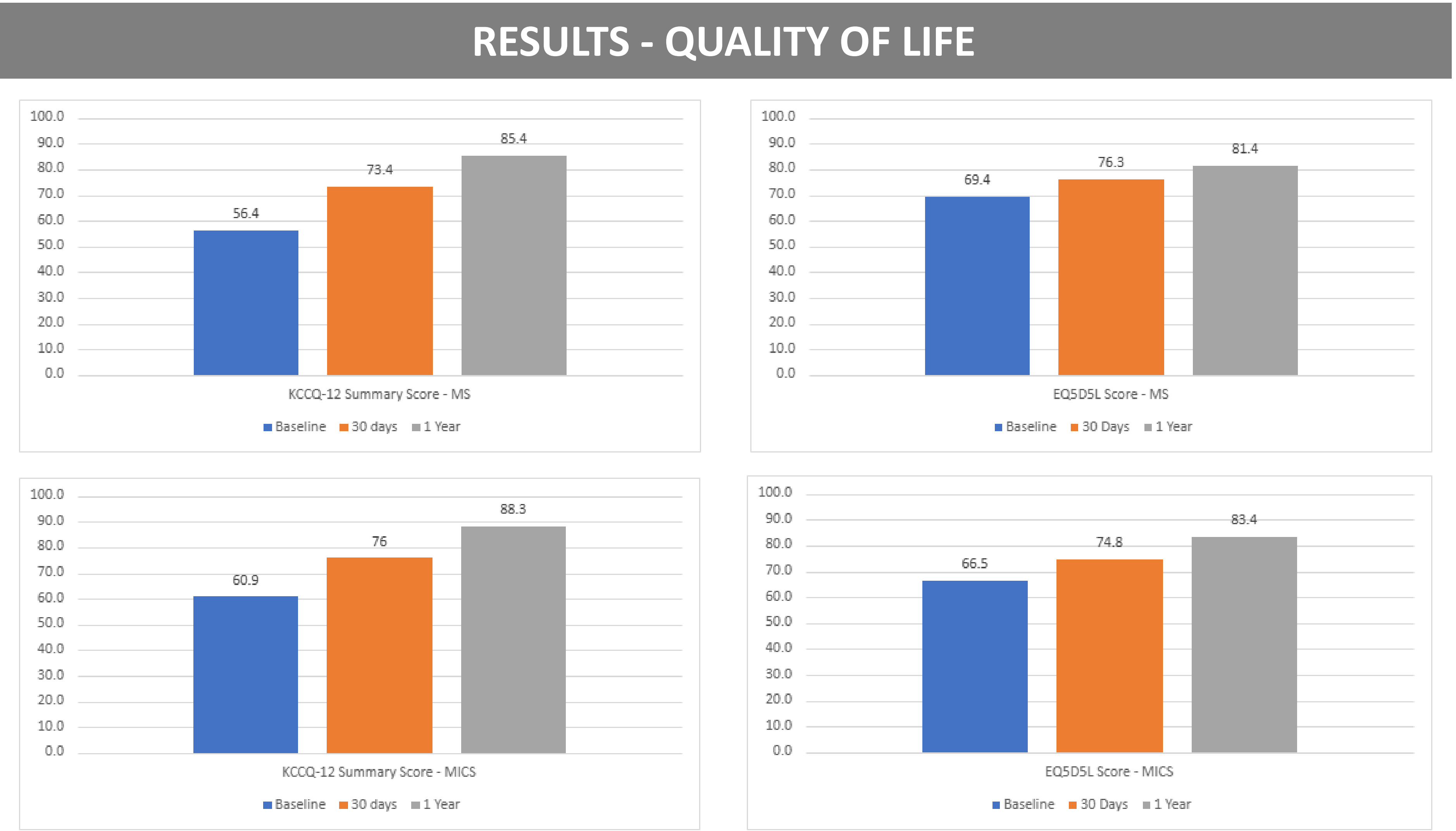
METHODS

MANTRA is a prospective, multicenter study designed to collect clinical and echocardiographic data on various Corcym devices with up to 10 years of follow-up. This analysis focuses on patients who underwent isolated AVR (N=198) using the Perceval Plus between July 2021 and June 2024, comparing those treated with **MS access (N=55)** with those treated with **MICS (N=143)** in 30 centers worldwide. Clinical and hemodynamic outcomes, KCCQ-12 and EQ-5D-5L quality of life (QoL) questionnaires were collected preoperatively, at 30 days, and at 1 year. Serious adverse events, both early (≤30 days) and late, were assessed according to VARC-3 criteria. All patients completed the 30-day follow-up, and 73.3% of the expected 1-year follow-up data were available at the time of this analysis. This study is ongoing.



PATIENTS			
Baseline and operative data	MS (N=55)	MICS (N=143)	P value
Age (year) [mean±SD]	71.1±6.3	71.1±0.6	
Male [n (%)]	28 (50.9%)	68 (47.6%)	
Valve size M/L [n (%)]	37 (67.3%)	83 (58.1%)	
Cross-clamp time (min) [mean±SD]	50.7±19.3	53.1±16.7	N.S.
CPB time (min) [mean±SD]	79.5±39.2	84.2±29.9	N.S.
Ventilation time (hours) [mean±SD]	12.6±21.2	10.1±9.2	N.S.
Red blood cell unit transfusions [mean±SD]	1.9±0.9	1.9±1.2	N.S.
ICU stay (days) [mean±SD]	3.3±3.4	2.0±1.8	p<0.05

N.S. = Not Significant



RESULTS - SAFETY				
	30 Days		1 Year*	
	MS	MICS	MS	MICS
All deaths	0	0	0	0
Re-intervention	0	0	0	0
Permanent pacemaker implantation	4 (7.3%)	5 (3.5%)	4 (7.3%)	6 (4.2%)
Endocarditis	0	0	0	0
Stroke	0	4 (2.8%)	0	4 (2.8%)
Bleeding	0	5 (3.5%)	0	5 (3.5%)
Acute Kidney Injury	3 (5.5%)	2 (1.4%)	3 (5.5%)	2 (1.4%)

*Includes also events occurred within 30 days.

RESULTS - HEMODYNAMICS PERFORMANCE						
	Baseline		30 Days		1 Year	
	MS	MICS	MS	MICS	MS	MICS
MPG [mmHg] [mean±SD]	47.38±16.11	48.46±16.02	10.35±4.46	10.70±4.20	11.18±4.70	12.02±5.56
EOA [cm²] [mean±SD]	0.77±0.19	0.75±0.19	1.84±0.68	1.65±0.48	1.55±0.58	1.70±0.58
PVL mild [n (%)]	-	-	0	4 (3.1%)	0	1 (1.4%)
PVL moderate and severe [n (%)]	-	-	0	0	0	0

CONCLUSIONS

Minimally invasive approach with sutureless prosthesis did not lead to statistically increased surgical times and resulted in a reduced ICU length of stay. No other significant differences were found. **Minimally invasive is safe as sternotomy, with advantages of reduced surgical trauma and cosmetics benefits.**