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# INDURE registry: Clinical and Quality of Life Outcomes of surgical aortic valve replacement in 421 patients under 60 years of age



# Study design and objective

**INDURE is a prospective, open-label, multicentre registry to assess the clinical outcomes of SAVR in patients under 60 years of age**

Endpoints: VARC-2 time-related valve safety at 1-year, and freedom from Stage-3 SVD at 5 years

Inclusion: 18–60-year-olds undergoing SAVR ± CABG, with or without root replacement

Exclusion: Redo-AVR, active endocarditis/myocarditis or within 3 months

Follow-up: Core-lab adjudication echo at 1, 3 and 5 years

**Our aim is to report prospectively collected clinical, and quality of life outcomes of 421 patients documented from 21 sites in Europe and Canada (2018–2021) at 1-year follow up**

INDURE data extraction 04.04.2022 / Study design protocol: ClinicalTrials.gov: NCT03666741 ; Meuris B et al. J Cardiothorac Surg. 2020; 15: 119



# Patient and procedural characteristics: Overall, and by gender

Patient characteristics	Cohort (n=421)	Female (n=99)	Male (n=322)	p value
Age, years ± SD	53.5 ± 6.9	53.6 ± 6.7	53.5 ± 7.0	0.975
Female, %	23.5	100	0	0.887
<b>BSA, m<sup>2</sup> ± SD</b>	<b>2.00 ± 0.23</b>	<b>1.79 ± 0.21</b>	<b>2.08 ± 0.20</b>	<b>&lt;0.001</b>
BMI, kg/m <sup>2</sup> ± SD	28.2 ± 5.1	26.1 ± 6.2	28.4 ± 4.7	0.174
EuroSCORE II, % ± SD	1.5 ± 1.6	1.6 ± 1.3	1.5 ± 1.6	0.335
<b>NYHA class III or IV, %</b>	<b>27.2</b>	<b>42.3</b>	<b>22.6</b>	<b>&lt;0.001</b>
Dominating aortic valve:				
Stenosis, %	72.4	76.5	71.1	0.294
Regurgitation, %	23.3	19.4	24.5	0.292
Severe AR w/o stenosis, %	13.6	12.2	14.0	0.661
Bicuspid aortic valve, %	78.7	65.7	75.5	0.054
Coronary artery disease, %	23.6	19.6	24.8	0.285
Diabetes mellitus II, %	13.1	13.1	13.0	0.982
Hypertension, %	49.6	45.5	50.9	0.340

Follow up	
Mean follow up, months	13.7 ± 6.7
Cumulative follow up, patient-years	476.9



# Methods

- Descriptive analysis of categorical variables presented as %, and continuous variables presented as mean  $\pm$  standard deviation or median (IQR)
- Group comparison were performed using t-test or Mann-Whitney U-test for continuous variables, as appropriate depending on distribution, and a Fisher's exact test or Chi-Square for categorical variables
- Test for normal distribution was carried using Kolmogorov-Smirnov-Test



# Results 1: Cumulative safety, and hemodynamic at 1-year follow up

Outcomes, n/N (%)	Discharge	1-year FU
<b>All-cause mortality</b>	<b>1/421 (0.2)</b>	<b>7/354 (2.0)</b>
<b>Valve-related mortality:</b>		
Valve-related	0/421 (0.0)	1/354 (0.3)
Not valve-related	1/421 (0.2)	3/354 (0.8)
Unknown	0/421 (0.0)	3/354 (0.8)
<b>Repeated procedure</b>	<b>0/421 (0.0)</b>	<b>1/349 (0.3)</b>
Stroke	2/421 (0.5)	2/349 (0.6)
<b>Life-threatening bleeding</b>	<b>16/421 (3.8)</b>	<b>16/351 (4.6)</b>
Pacemaker implantation	16/421 (3.8)	19/350 (5.4)
<b>Endocarditis</b>	<b>0/421 (0.0)</b>	<b>1/348 (0.3)</b>
Sub-clinical valve thrombosis	0/421 (0.0)	6/348 (1.7)
<b>SVD stage 3<sup>†</sup></b>	<b>N/A</b>	<b>0/301 (0.0)</b>

Hemodynamic	Discharge	1-year FU
	mean ± SD	mean ± SD
MPGs, mmHg	11.7 ± 4.3	12.8 ± 5.4
PPGs, mmHg	20.9 ± 7.7	22.7 ± 9.0
EOA, cm <sup>2</sup>	2.1 ± 0.6	1.9 ± 0.6

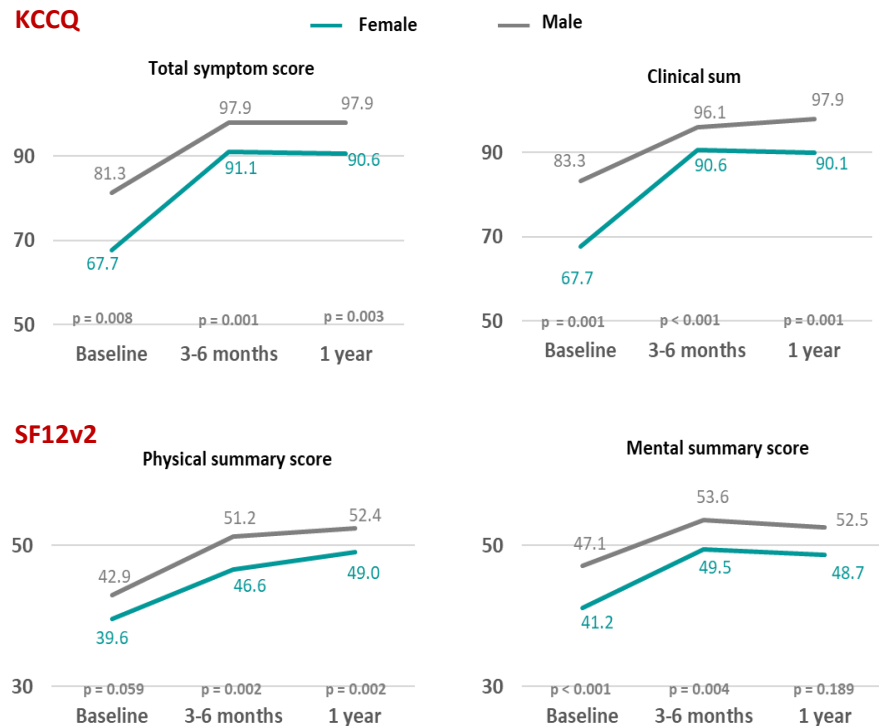
Mean valve size: 24.4 ± 2.3

<sup>†</sup> New/worsening trans-prosthetic regurgitation ≥2 grades OR worsening of MPG ≥20 mmHg + EOA ≥0.6 cm<sup>2</sup> + DVI ≥0.2



# Results 2: Quality of Life assessment up to 1-year follow up

- **QoL is restored** within 3-6 months. Results are excellent, and maintained up to 1-year of follow up (SF12v2 ~50 and KCCQ >90 score)
- **Female-gender shows significantly lower scores vs. male** at each time-point of the physical, symptom, clinical, and mental QoL assessments



SF12v2: >50 score matching QoL of the US general population; KCCQ >90 points = good-to-excellent 75-100 points)



# Conclusions

- Clinical outcomes of patients enrolled in INDURE registry are excellent, including better than predicted hospital mortality (0.2% vs. 1.5%). All-cause and valve-related mortality were 2% and 0.3% at 1-year FU
- Cardiovascular events were low (IE n=1, Stroke n=2, PPI n=19); sub-clinical valve thrombosis (n=6) was detected by CT-scan, and patients did not experience any sequelae or need reoperation
- Inspiris Resilia features satisfactory-stable performance, with no Stage-3 SVD assessed by core-lab (mean  $13.7 \pm 6.7$  months)
- Patients return to the expected Quality of Life, with excellent SF12v2-KCCQ scores within 3-6 months; Female-gender, with a smaller BSA and greater NYHA III-IV class, exhibits significantly lower QoL scores across each time-point of clinical, physical, mental, and symptom components
- **INDURE will continue to inform about the clinical outcomes and QoL of patients < 60 undergoing SAVR**

