SURVIV

Surgery vs Valve-in-Valve
for Mitral Bioprosthetic Dysfunction

Redo-SURgery vs Transcatheter Valve-In-Valve for Mitral Bioprosthetic Dysfunction: The SURVIV Trial

Dimytri A Siqueira, MD PhD

On behalf of the **SURViV** Investigators

Background

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- Bioprosthetic mitral valve replacement has increased substantially over the past two decades, and deterioration leading to clinically significant bioprosthetic valve dysfunction (BVD) is an increasingly encountered clinical problem worldwide, particularly in regions where rheumatic valve disease is prevalent.

- Redo surgical mitral valve replacement is the standard treatment for failed mitral bioprostheses, with reported 30-day mortality rates of approximately 7% to 22% in contemporary series across different etiologies.[1-4]

- Transcatheter mitral valve-in-valve has emerged as a less-invasive alternative for patients considered at increased surgical risk, but no randomized trials have directly compared these treatment strategies.

1. Kwedar K, et al. Ann Thorac Surg. 2017;104:1516–1521.
2. Mehaffey HJ et al. Heart. 2018 Apr;104(8):652-656.
3. Kilic A, et al. Ann Thorac Surg. 2019;107:754–759.
4. Zubarevich A, et al. J Card Surg. 2021;36:3195-3204.

Study Design

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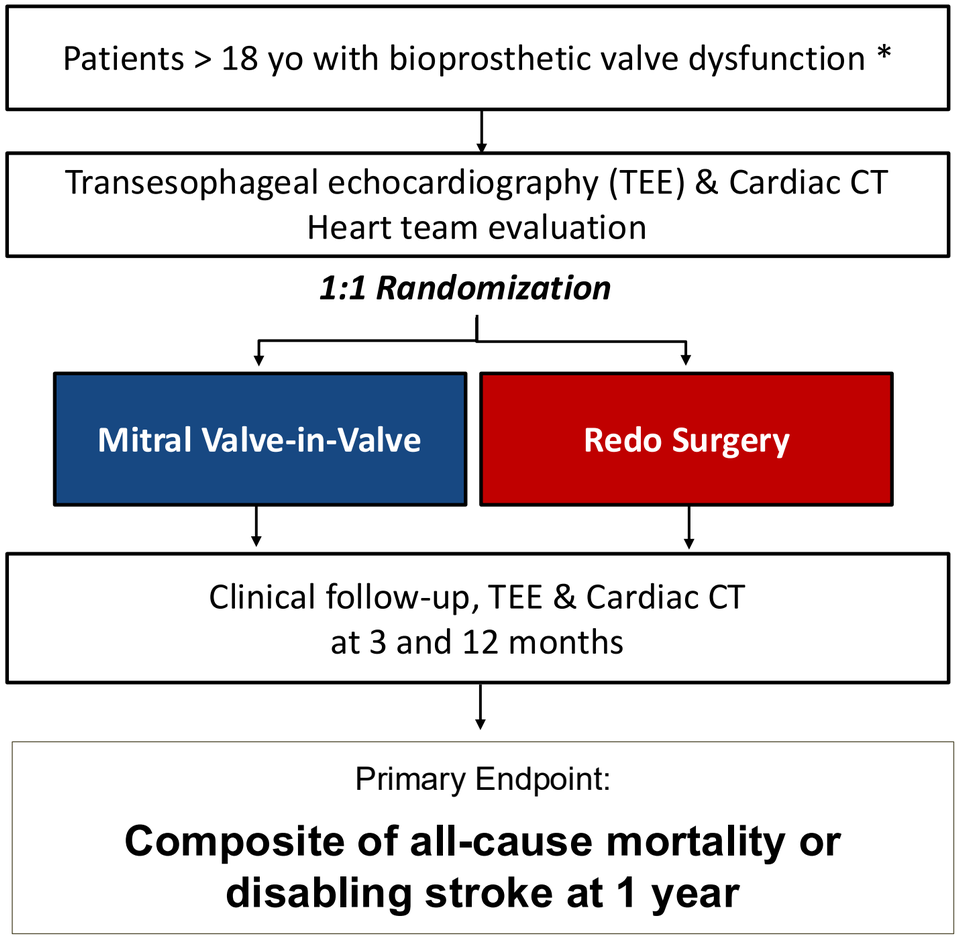
Investigator-initiated, prospective, randomized trial
7 referral cardiovascular hospitals within Brazilian Unified Health System (SUS)



Inclusion Criteria

- Patients > 18 years
- Severe symptomatic bioprosthetic valve dysfunction
- Eligibility for both redo surgery or mitral valve-in-valve

Exclusion Criteria

- Concomitant aortic or complex coronary disease
- Severe (<20%) LV dysfunction
- Intracardiac thrombus or vegetations
- Predicted neoLVOT < 170 mm^2

* Surgical risk-stratification tools (STS and Euroscore II) cut-off values were not utilized as eligibility criteria.

ClinicalTrials.gov Identifier: NCT04402931

Siqueira DA et al. *EuroIntervention* 2026;22:e358-e366

Study Organization

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Sponsor	Instituto Dante Pazzanese de Cardiologia, Fundação Adib Jatene
Funding	Brazilian Unified Health System (SUS)
Additional support	Edwards Lifesciences (Irvine, CA, USA) through the provision of 75 transcatheter heart valves (Sapien 3) and 25 surgical valves and technical assistance by clinical field specialists during transcatheter procedures
Steering Committee	Dimytri A. Siqueira, Instituto Dante Pazzanese de Cardiologia Fausto Feres, Instituto Dante Pazzanese de Cardiologia Mario Issa, Instituto Dante Pazzanese de Cardiologia Kleber G. Franchini, Instituto Dante Pazzanese de Cardiologia Roberto V. Botelho, Fundação Adib Jatene Alexandre Abizaid, Instituto do Coração Deepak L. Bhatt, Icahn School of Medicine at Mount Sinai
Study Coordination/Monitoring	Mayara Cortez Silva, Instituto Dante Pazzanese de Cardiologia
Clinical Events Committee	Andreia O Freitas, MD, Luiz F Tanajura, MD PhD, Pedro B de Andrade, MD PhD
Data Analysis	Lucas Petri Damiani, Instituto Dante Pazzanese de Cardiologia

Statistical Analysis

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- **Sample size of 150 patients:**
  - ✓ 80% power, at a two-sided alpha level of 0.05
  - ✓ Incidence of 8% in the mitral ViV and 25% after redo-surgery at 12 months
  - ✓ 10% rate of loss to follow-up at 12 months.
- Primary analysis performed in the **modified intention-to-treat** population
  - ✓ all randomized patients analyzed according to their assigned treatment group
  - ✓ outcomes assessed from the date of the procedure, when performed, rather than from the date of randomization.

Patient Flowchart

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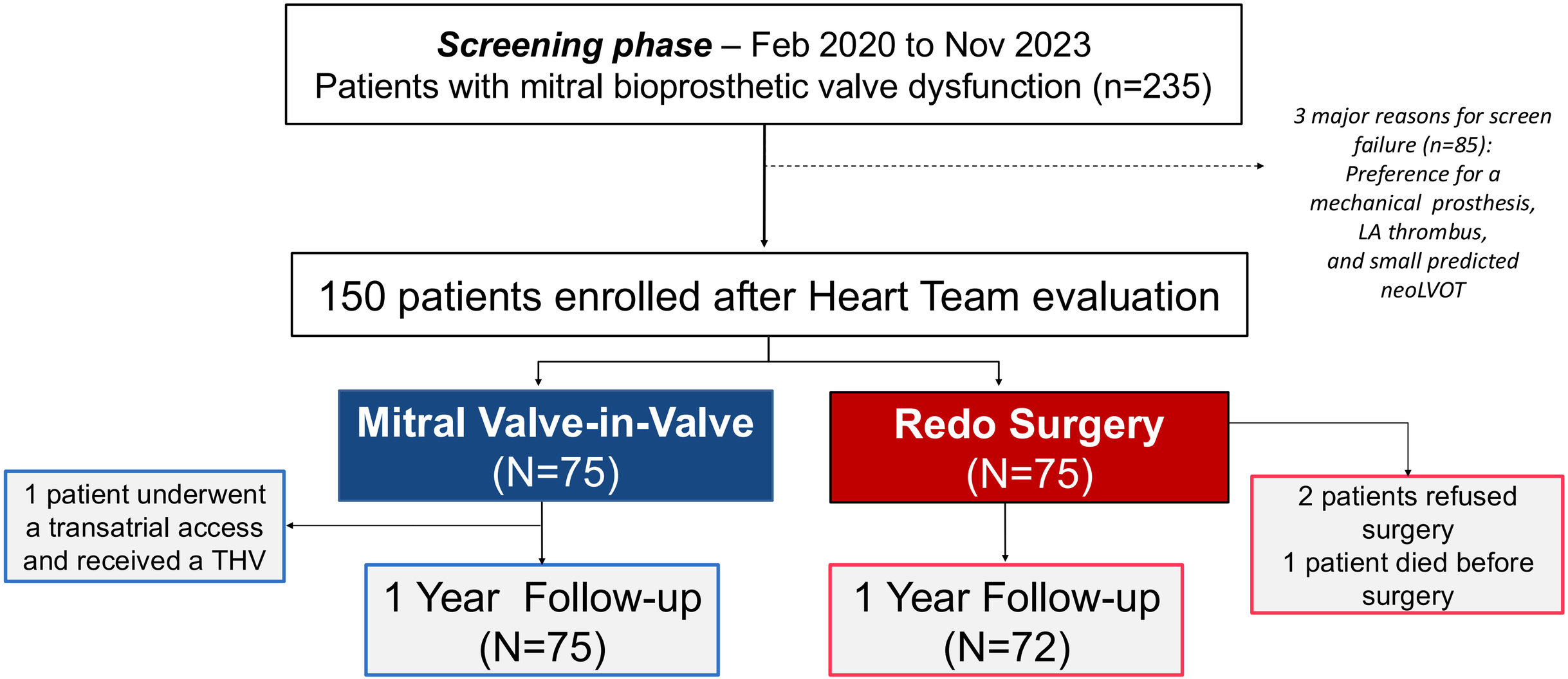

Baseline Characteristics

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Clinical and demographic	Mitral ViV (n=75)	Redo SMVR (n=75)	Overall (n=150)
Mean Age, y, mean (SD)	56.6 (12.4)	59.2 (10.1)	57.9 (11.4)
Female sex	51/75 (68.0%)	57/75 (76.0%)	108/150 (72.0%)
Body Mass Index, mean (SD)	26.3 (5.4)	26.6 (4.5)	26.5 (5.0)
STS mortality score, mean (SD)	3.6 (4.9)	3.7 (4.3)	3.6 (4.6)
EuroSCORE II score, mean (SD)	5.1 (3.3)	6.5 (5.7)	5.8 (4.7)
NYHA functional class III or IV	40/75 (53.3%)	44/75 (58.7%)	84/150 (56.0%)
Number of prior mitral valve surgeries			
One prior surgery	61/75 (81.3%)	51/75 (68.0%)	112/150 (74.7%)
Two or more prior surgeries	14/75 (18.6%)	24/75 (32%)	38/150 (25.4%)
Time elapsed since last surgery, y, mean (SD)	13.3 (5.5)	14.5 (4.1)	13.9 (4.9)
Atrial fibrillation or flutter	35/75 (46.7%)	40/75 (53.3%)	75/150 (50.0%)
Chronic kidney disease	8/74 (10.8%)	11/75 (14.7%)	19/149 (12.8%)
Previous stroke	16/75 (21.3%)	12/75 (16.0%)	28/150 (18.7%)
Previous tricuspid repair or replacement	10/75 (13.3%)	9/74 (12.2%)	19/149 (12.8%)

Continuous variables reported as mean ± standard deviation and categorical variables were presented as percentages.
There were no significant differences ($P<0.05$) in baseline characteristics between groups.

Baseline Characteristics

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Echocardiographic Measurements	**Mitral ViV (n=75)**	**rSMVR (n=75)**	**Overall**
Left ventricular ejection fraction, %, mean (SD)	56.9 (10.1)	57.6 (8.6)	57.2 (9.4)
Mean mitral gradient, mean (SD)	11.2 (4.5)	10.8 (4.7)	11.0 (4.6)
Mitral valve area, planimetry, mean (SD)	1.2 (0.7)	1.2 (0.8)	1.2 (0.7)
Moderate or severe mitral regurgitation	38/75 (50.7%)	50/75 (66.7%)	88/150 (58.7%)
Severe tricuspid valve regurgitation	15/75 (20.0%)	18/75 (24.0%)	33/150 (22.0%)
Mean sPAP pressure, mean (SD)	54.3 (18.5)	59.8 (19.2)	57.1 (19.0)
> 45 mmHg	43/71 (60.6%)	58/74 (78.4%)	101/145 (69.7%)
> 60 mmHg	23/71 (32.4%)	28/74 (37.8%)	51/145 (35.2%)
Computed Tomographic Measurements	**Mitral ViV**	**rSMVR**	**Overall**
Stent external diameter, mean (SD)	29.6 (2.4)	29.5 (2.4)	29.5 (2.4)
Stent internal diameter, mean (SD)	25.7 (2.6)	26.1 (2.3)	25.9 (2.5)
True internal diameter, mean (SD)	23.5 (3.0)	22.4 (2.2)	23.0 (2.7)
neoLVOT area, mean (SD)	383.5 (199.4)	333.6 (132.5)	364.2 (177.5)

Continuous variables reported as mean ± standard deviation and categorical variables were presented as percentages. There were no significant differences ($P<0.05$) in baseline characteristics between groups.

Procedural Characteristics

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Mitral Valve-in-Valve	(n=75)
Procedure time, min, mean (SD)	96.1 (41.3)
Transseptal approach	74 (98.7%)
Balloon size for atrioseptostomy	
12 mm	18 (24.0%)
14 mm	56 (74.7%)
THV (Sapien 3) size	
23 mm	3 (4.0%)
26 mm	17 (22.7%)
29 mm	55 (73.3%)
Post-dilation, n (%)	38 (50.7%)
Need for acute iASD closure	0 (0.0%)
Need for THV-in-THV	0 (0.0%)
LVOT obstruction	0 (0.0%)
Conversion to open-heart surgery, n (%)	0 (0.0%)

Redo-Surgical Mitral Valve Replacement	(n=72)
Cardiopulmonary by-pass time, min., mean (SD)	119 (37)
Surgical heart valve size	
23 mm	1 (1.4%)
25 mm	9 (13%)
27 mm	31 (43%)
29 mm	20 (28%)
31 mm	11 (15%)
Concomitant procedure	
Aortic valve replacement	2 (2.8%)
AF ablation	0 (0.0%)
Tricuspid repair or replacement	10 (14%)
LAA closure	19 (26%)

Data are presented as n (%) unless otherwise stated.

Primary Endpoint:
All-cause death or disabling stroke at 1 year

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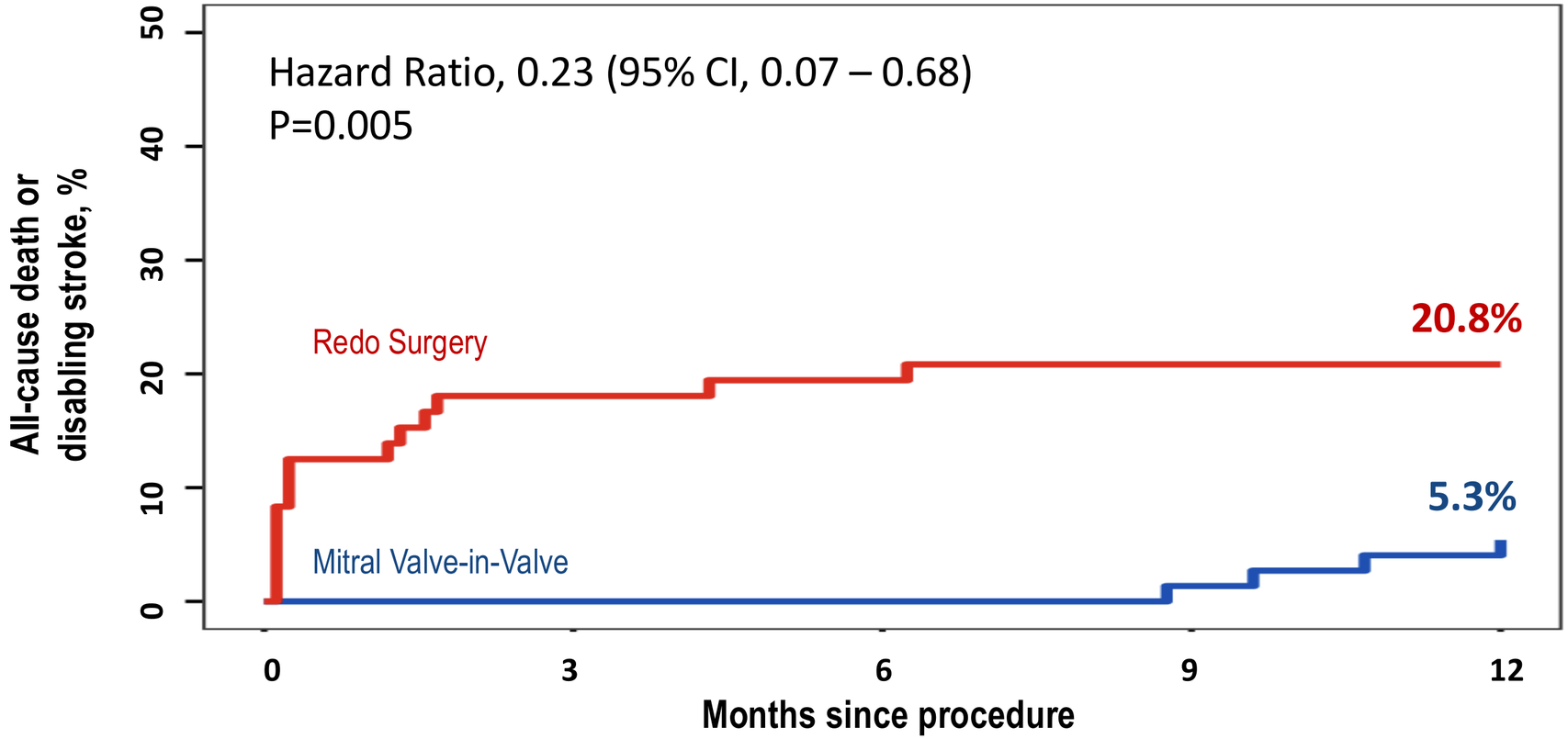

No. at risk					
Mitral Valve-in-Valve	75	75	74	73	71
Redo Surgery	72	59	58	56	56

In a *modified intention-to-treat analysis*, events were assessed within 12 months after the procedure date, rather than from randomization

Subgroup Analyses:
Primary Composite End Point

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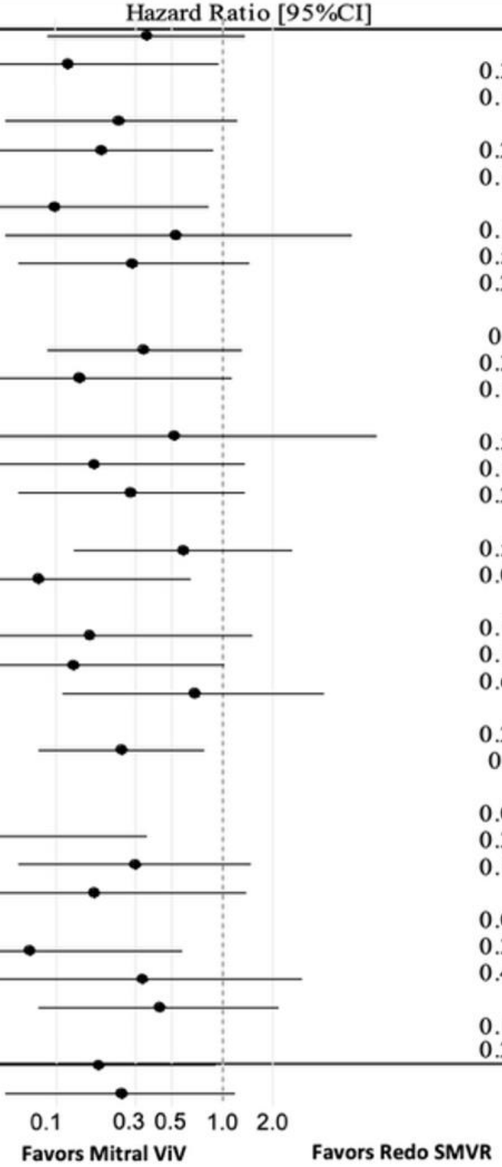
Subgroup	Mitral ViV	Redo SMVR	Hazard Ratio [95%CI]	Interaction p-value
Age, years				0.36
<70	3/66 (4.5%)	7/59 (11.9%)	0.35 (0.09–1.37)	
≥70	1/9 (11.1%)	8/13 (61.5%)	0.12 (0.01–0.95)	
Sex				0.85
Male	2/24 (8.3%)	5/17 (29.4%)	0.24 (0.05–1.24)	
Female	2/51 (3.9%)	10/55 (18.2%)	0.19 (0.04–0.88)	
Body Mass Index, kg/m²				0.54
≤25	1/38 (2.6%)	7/31 (22.6%)	0.10 (0.01–0.82)	
>25 to ≤30	1/21 (4.8%)	2/24 (8.3%)	0.53 (0.05–5.90)	
>30	2/16 (12.5%)	6/17 (35.3%)	0.29 (0.06–1.45)	
STS score				0.60
≤2%	0/28 (0%)	1/25 (4%)	0.00 (0.00–Inf)	
>2% to ≤4%	3/31 (9.7%)	7/28 (25%)	0.34 (0.09–1.31)	
>4%	1/15 (6.7%)	7/19 (36.8%)	0.14 (0.02–1.13)	
Euroscore II				0.80
≤4%	1/34 (2.9%)	1/18 (5.6%)	0.52 (0.03–8.28)	
>4% to ≤8%	1/29 (3.4%)	7/38 (18.4%)	0.17 (0.02–1.36)	
>8%	2/12 (16.7%)	7/16 (43.8%)	0.28 (0.06–1.36)	
NYHA class				0.10
I or II	3/35 (8.6%)	4/29 (13.8%)	0.58 (0.13–2.59)	
III or IV	1/40 (2.5%)	11/43 (25.6%)	0.08 (0.01–0.64)	
Time elapsed from previous surgery, years				0.42
≤10	1/25 (4%)	3/13 (23.1%)	0.16 (0.02–1.51)	
>10 to ≤15	1/26 (3.8%)	8/32 (25%)	0.13 (0.02–1.02)	
>15	2/24 (8.3%)	3/26 (11.5%)	0.68 (0.11–4.07)	
Number of previous surgeries				0.29
1	4/61 (6.6%)	11/48 (22.9%)	0.25 (0.08–0.78)	
2 or more	0/14 (0%)	4/24 (16.7%)	0.00 (0.00–Inf)	
LVEF				0.29
≤40%	1/7 (14.3%)	3/3 (100%)	0.03 (0.00–0.35)	
>40% to ≤60%	2/33 (6.1%)	6/33 (18.2%)	0.30 (0.06–1.48)	
>60%	1/31 (3.2%)	6/35 (17.1%)	0.17 (0.02–1.39)	
Systolic PAP, mmHg				0.34
≤45	1/28 (3.6%)	6/15 (40%)	0.07 (0.01–0.57)	
>45 to ≤60	1/20 (5%)	4/29 (13.8%)	0.33 (0.04–2.98)	
>60	2/23 (8.7%)	5/27 (18.5%)	0.42 (0.08–2.17)	
Tricuspid regurgitation				0.77
Mild/Moderate	2/37 (5.4%)	6/24 (25%)	0.18 (0.04–0.90)	
Severe	2/38 (5.3%)	9/48 (18.8%)	0.25 (0.05–1.17)	



Hazard Ratios and interactions were evaluated by Cox proportional Hazard models.

Secondary Endpoints:
Clinical adverse events at 30 days

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	Mitral ViV (n=75)	Redo Surgery (n=72)	p value
Death	0 (0.0%)	9 (12.5%)	**0.001**
From cardiovascular causes	0 (0.0%)	6 (8.3%)	**0.012**
Disabling stroke	0 (0.0%)	1 (1.4%)	0.49
Life-threatening, extensive, or major bleeding	1 (1.3%)	8 (11.1%)	**0.016**
Major vascular complications	2 (2.7%)	1 (1.4%)	>0.999
Myocardial infarction	0 (0.0%)	0 (0.0%)	>0.999
Acute kidney injury — stage 2 or 3	0 (0.0%)	11 (15.3%)	**<0.001**
New-onset atrial fibrillation	8 (10.7%)	16 (22.2%)	0.08
Reoperation or re-intervention	0 (0.0%)	2 (2.8%)	0.24
Endocarditis	0 (0.0%)	1 (1.4%)	0.49
Index length of stay, days, median [quartiles]	4 [1 - 6]	14 [11 - 19]	**<0.001**

In a *modified intention-to-treat analysis*, events were assessed within 30 days after the procedure date, rather than from randomization

Secondary Endpoints:
Valve performance at 3 and 12 months

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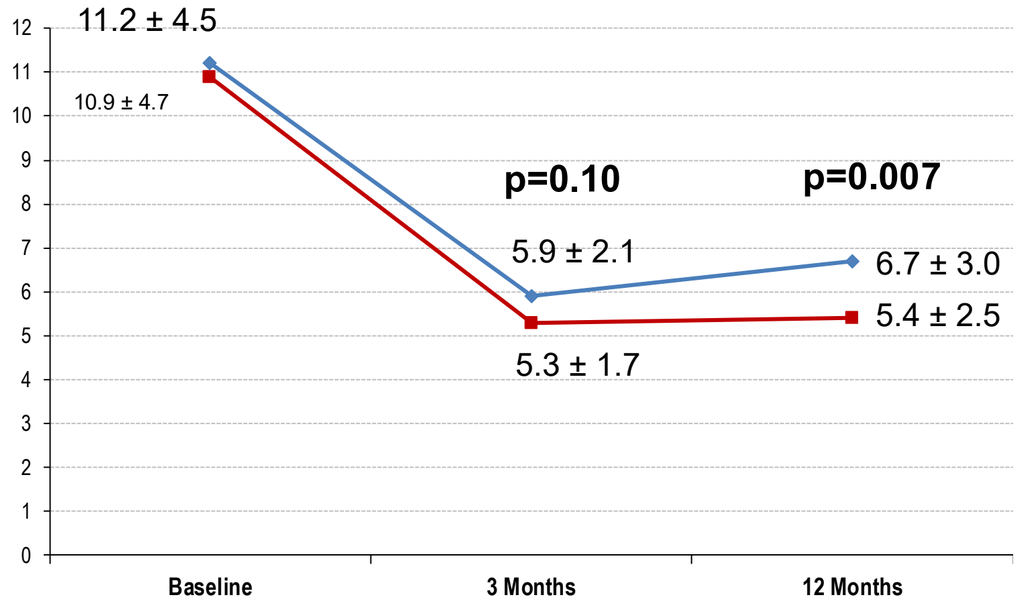
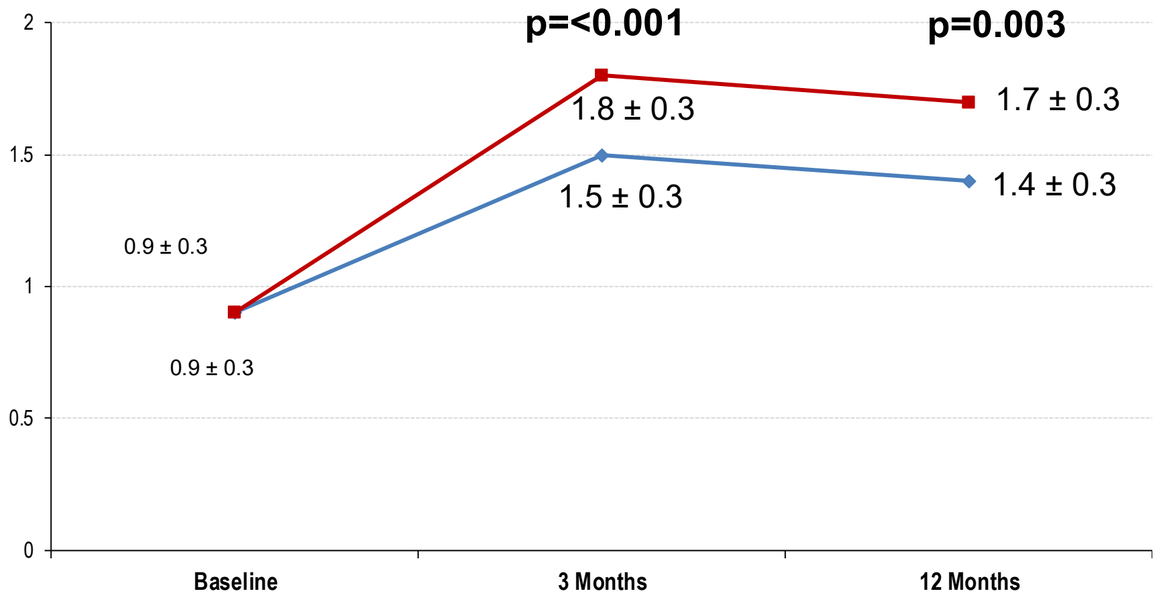
Mitral valve-in-valve Redo Surgical Mitral Replacement

Mean mitral gradient, mmHg



Mean prosthetic valve area (planimetry), cm^2



No. at risk						
Mitral Valve-in-Valve	74	73	67	38	56	50
Redo Surgery	71	58	56	29	40	39

Secondary Endpoints:
Rehospitalizations at 1 year

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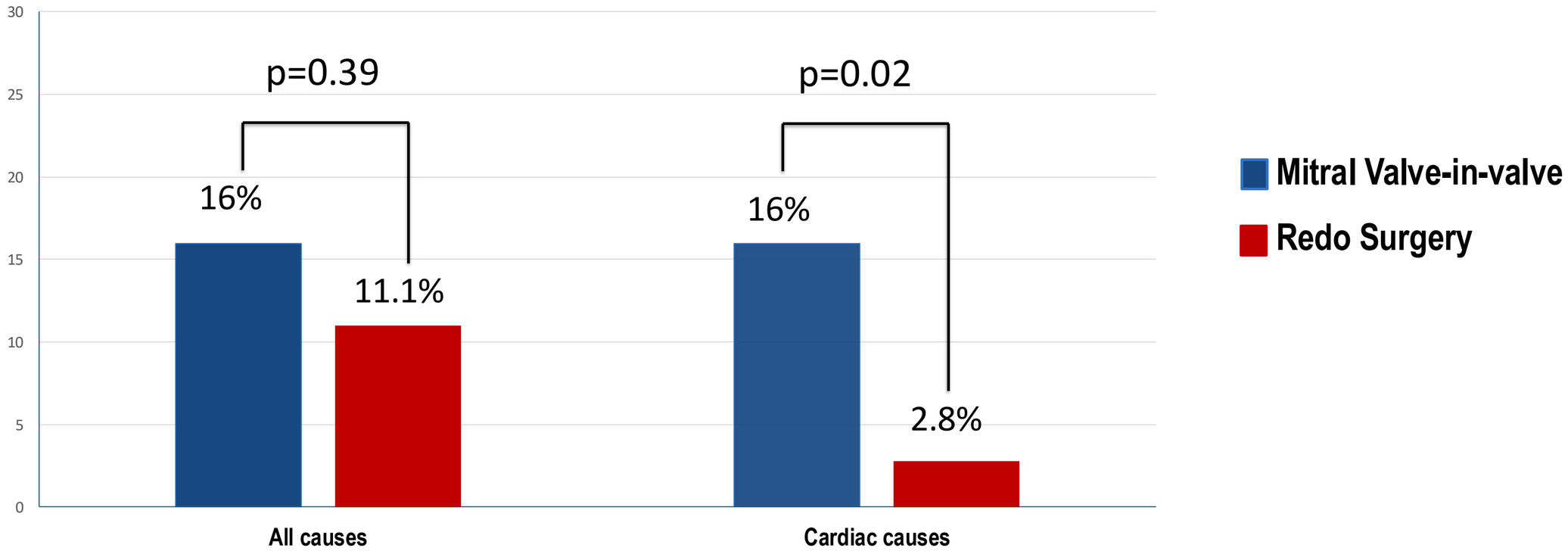

4 rehospitalizations *in the mitral ViV group were related to leaflet thrombosis: 2 asymptomatic patients with HALT; 2 patients with HF symptoms, RELM, and elevated gradients*

Secondary Endpoints:
NYHA class and quality-of-life at 3 and 12 months

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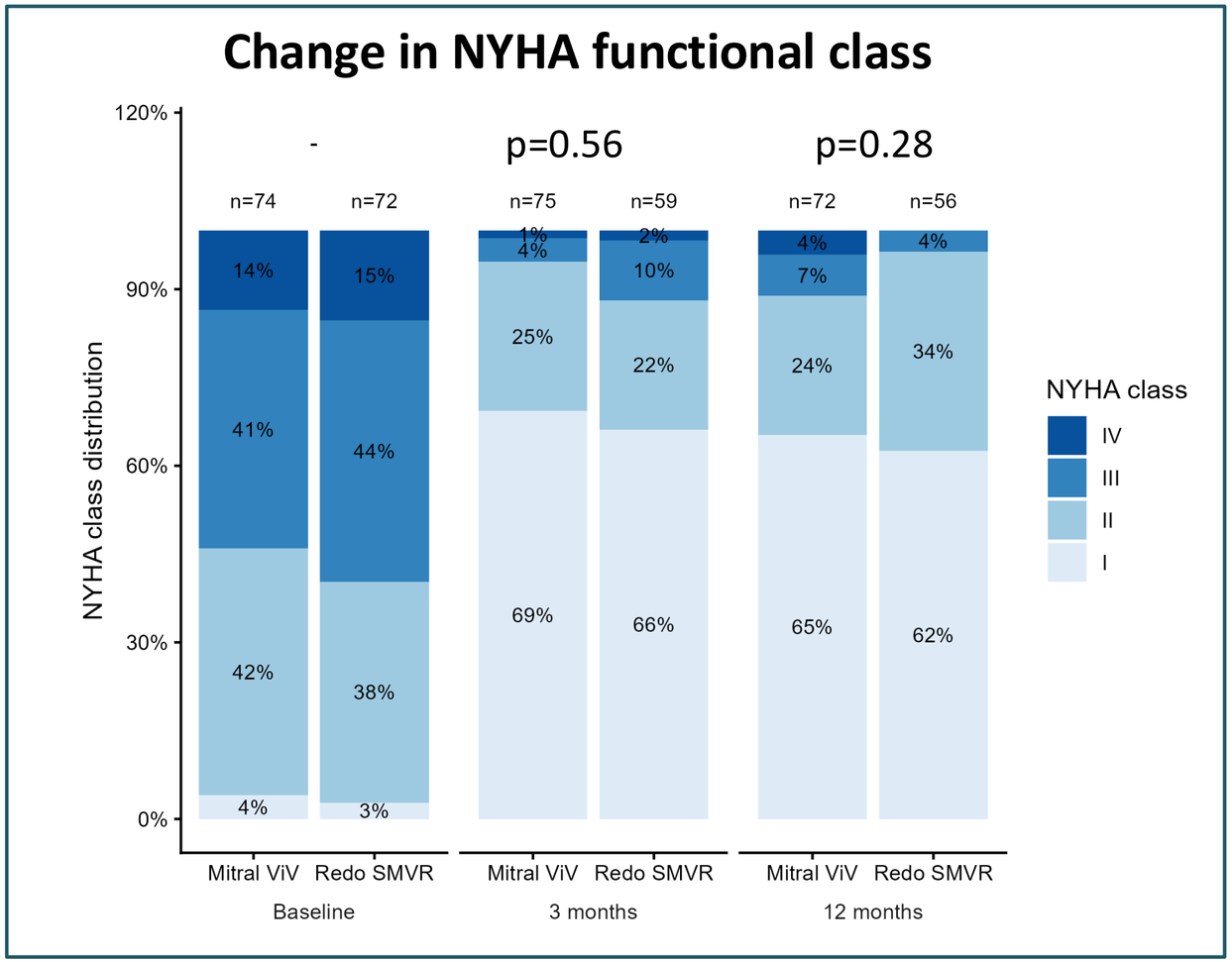

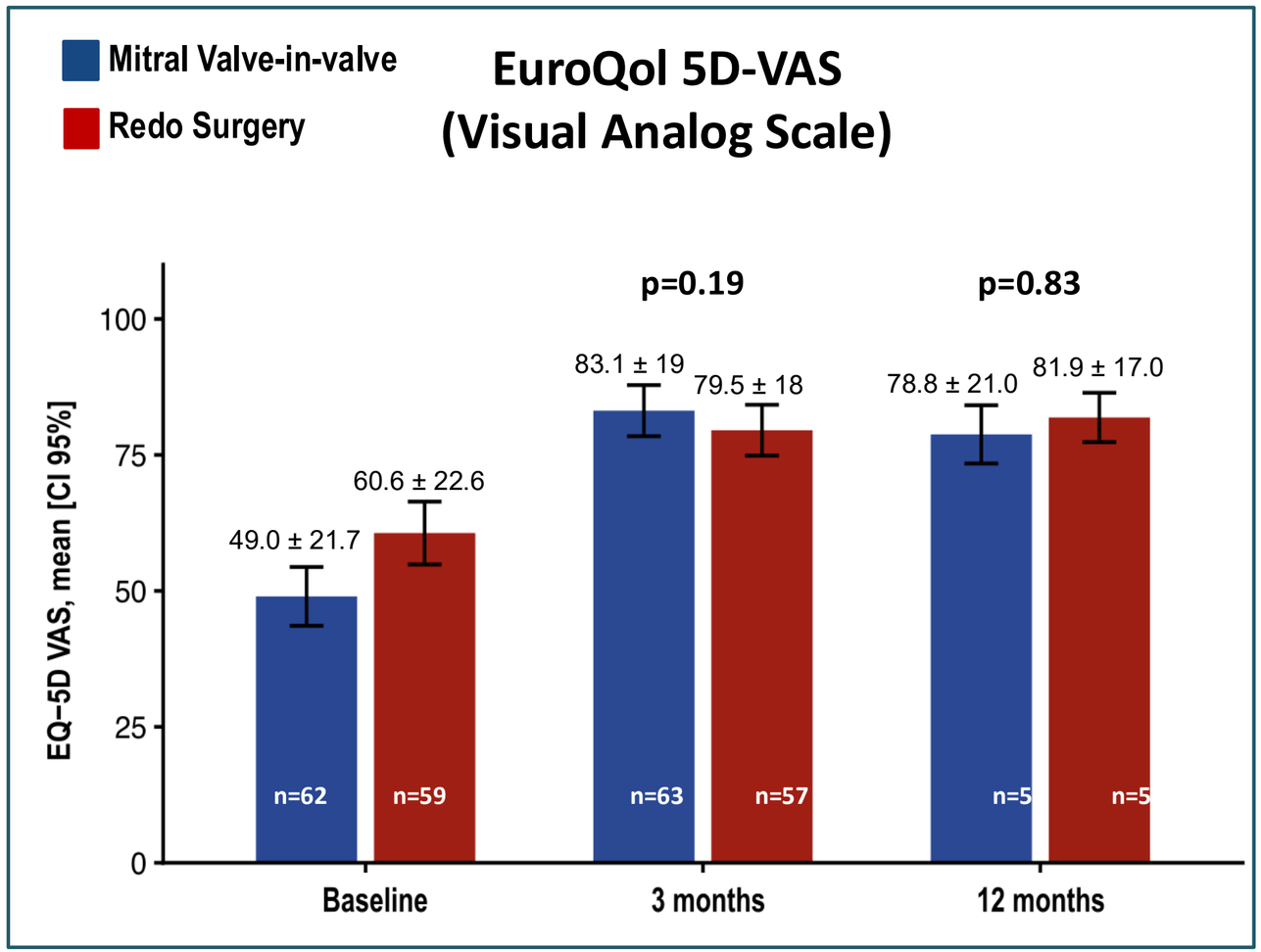

Limitations

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- The present study focuses on 1-year outcomes, and longer-term follow-up is ongoing to assess durability and inform optimal treatment sequencing.
- Outcomes after redo surgery may vary according to institutional volume, although participant centers were high-volume.
- Asymptomatic leaflet thrombosis was not systematically assessed, and a prespecified CT substudy with independent core lab adjudication is planned.
- A proportion of patients were enrolled during the COVID-19 pandemic, which may have affected perioperative care.

Conclusions

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- In this trial involving patients with failed mitral bioprostheses, mitral valve-in-valve implantation was associated with a **significant lower incidence** of all-cause death or disabling stroke at 1 year than redo surgery.

- Mitral valve-in-valve was associated with **fewer early procedural complications**, whereas **both strategies resulted in substantial improvement in symptoms and quality of life**.

- This study provides the **first randomized evidence** to inform treatment selection in this clinical scenario and supports the role of transcatheter valve-in-valve as **a safe therapeutic option** in selected patients undergoing repeat mitral intervention.

Thank you!

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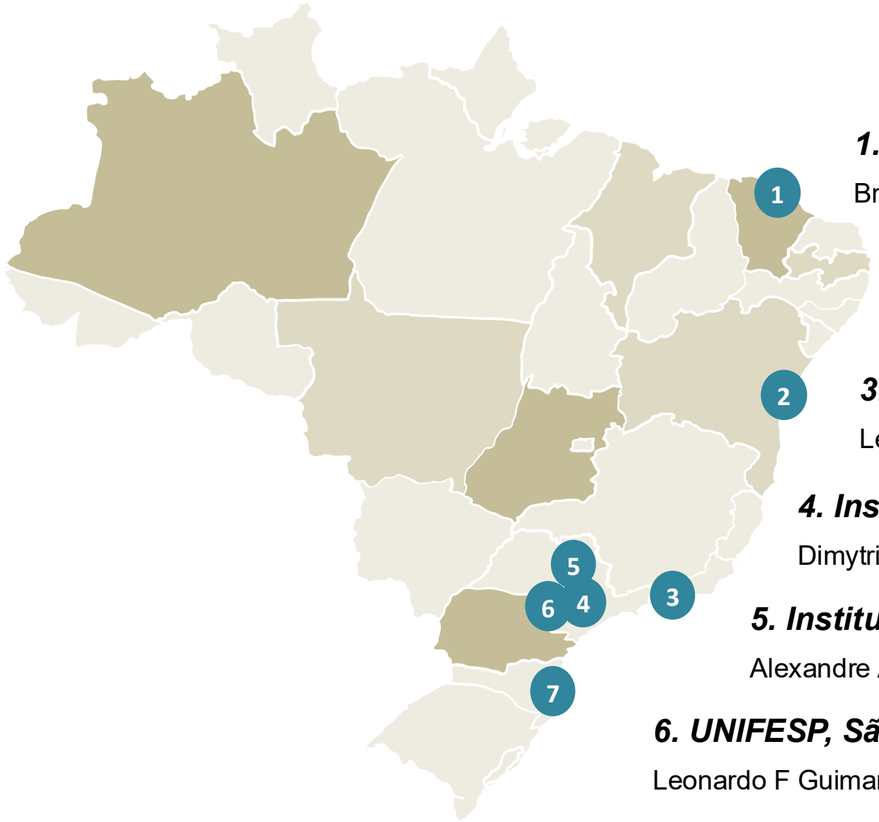
150 patients



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