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Transcatheter Treatment of Chronic Aortic Regurgitation with a Novel Device: 30-day Primary Endpoint Results of J-Valve Transfemoral Early Feasibility Study

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Disclosures
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Medtronic

BSCI

Abbott Vascular

ACC

JC Medical

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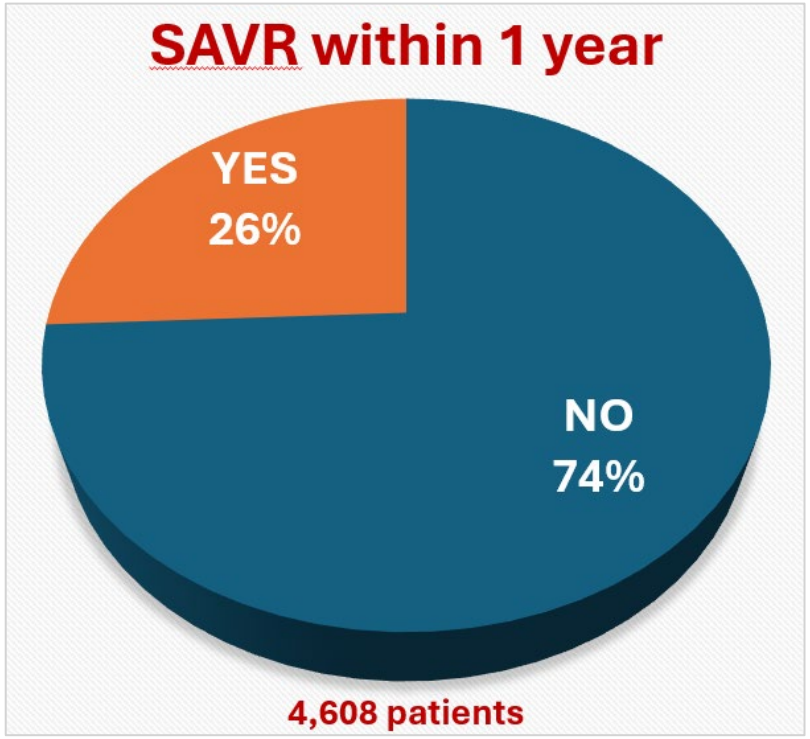
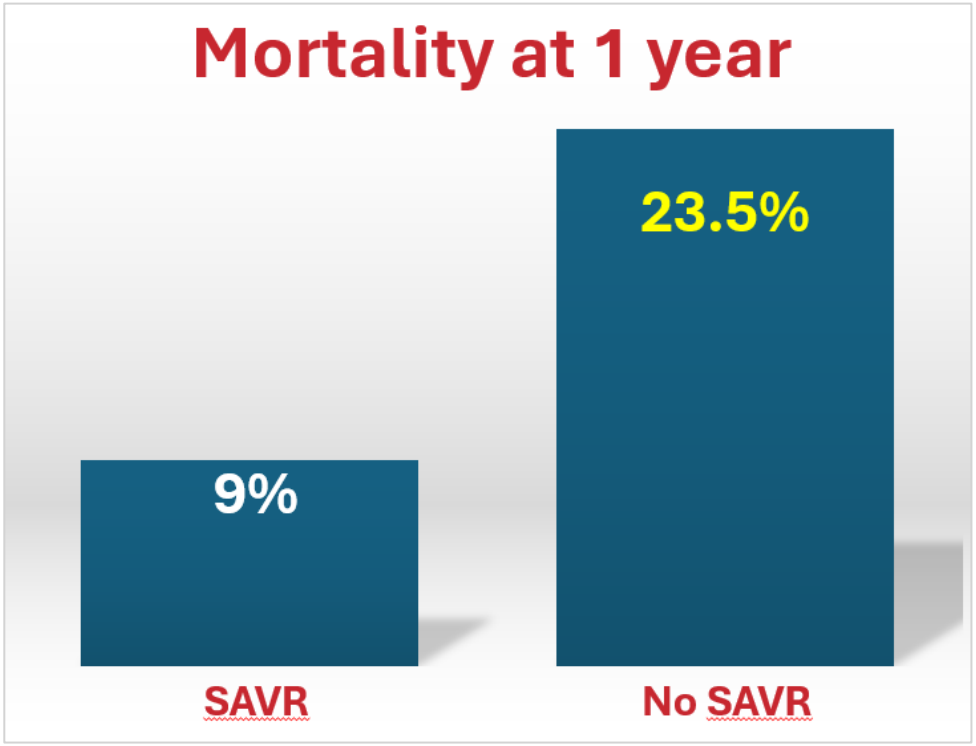
Aortic Regurgitation:

Undertreated & Associated with Increased Mortality

Dramatic undertreatment of symptomatic severe AR



Untreated AR results in a 1-year mortality of 23.5%



Thourani V, et al. Structural Heart. 2021 Nov 2;5(6):608-6018.

Challenges of TAVR to treat AR

- Absence of annular calcium
- Dilated aortic root
- Risk of THV embolization or malposition
- Increased stroke volume
- Unpredictable positioning and deployment
- Large size of aortic annulus

Current Commercial THVs in AR: Not an ideal solution

- Post procedure AR ≥ moderate (15-20%) → higher 1-year mortality
- Lower chance of procedural success (~70%) compared to TAVR for severe AS
- Need for 2nd THV implantation (19%)
- 25% 1-Y mortality when treating AR with non-dedicated devices

Transcatheter treatment of AR requires dedicated devices

Takagi H, et al. Heart Lung Circ 2020;29:729-741. Yoon SH, et al. JACC 2017;70:2752-2763
Otto CM et al. JACC 2021; 77:e25-197. Siddique S, Vora A, Gada H. Structural Heart. 2021 Dec 23;5(1):55-64.

J-Valve® Transfemoral EFS Study

To demonstrate the safety and effectiveness of transfemoral TAVR utilizing the **J-Valve®** transcatheter heart valve system amongst a group of patients with symptomatic ≥3+ aortic regurgitation who are deemed high-risk for surgical aortic valve replacement, as determined by the Heart Team

ClinicalTrials.gov NCT06034028

J-Valve® Transfemoral EFS Study Design

Prospective, single arm, multi-center, interventional study of 15 patients with symptomatic ≥3+ aortic regurgitation deemed high-risk for SAVR by Heart Team

↓

Transfemoral **J-Valve®** Implantation

↓

Follow-up at 30 days, 6 months, 1 year & annually for 5 years including clinical assessment, echocardiography, QoL evaluation, & functional testing

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30-day primary safety endpoint:
All-cause death or disabling stroke at 30 days

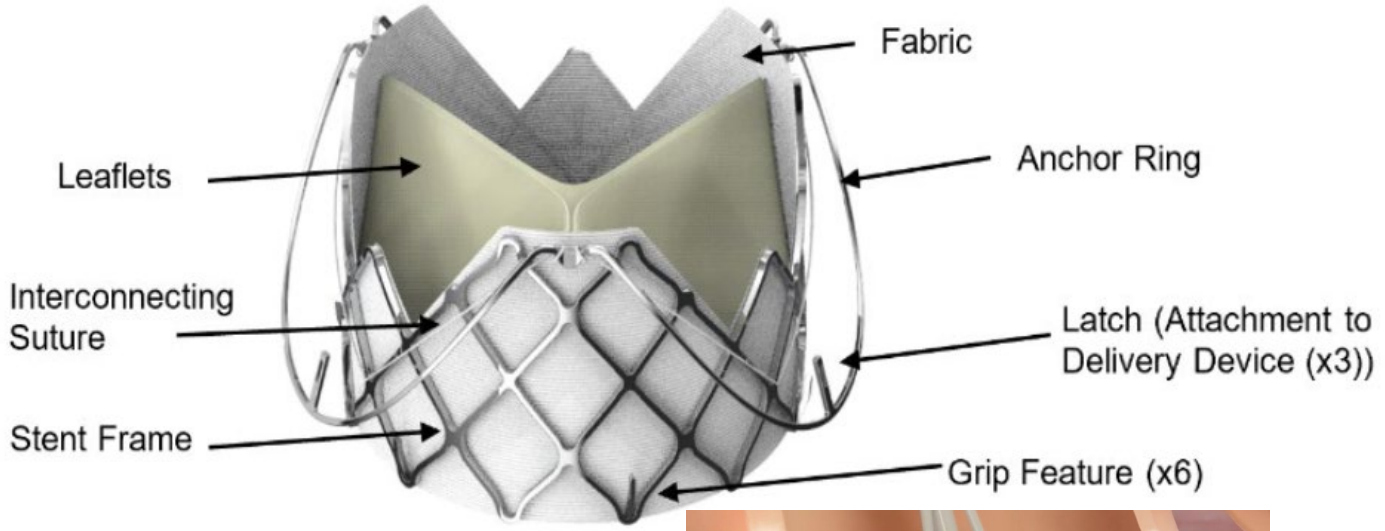
↓

1-year primary efficacy endpoint

J-Valve®

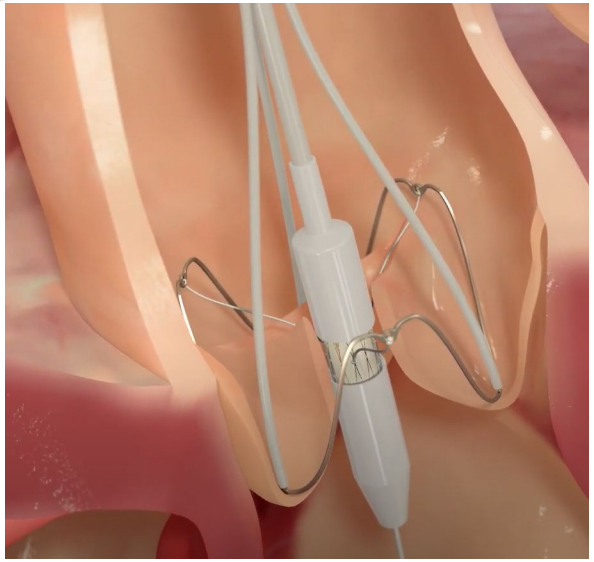
A Novel THV to Treat AR

Comprised of bovine pericardium leaflets, nitinol frame, and a fabric skirt to mitigate PVL



- Unique anchor rings designed to self-center the valve for optimal alignment
- Five valve sizes available intended to treat perimeters 57-104mm
- Rounded, atraumatic rings designed to easily locate and position in the annulus

J-Valve TF Size	Annulus Diameter (mm)	Annulus Perimeter (mm)	Annulus Area (mm^2)
22 mm	18 - 21	57 – 66	254 - 346
25 mm	21 - 24	66 - 75	346 - 452
28 mm	24 - 27	75 - 85	452 - 573
31 mm	27 - 30	85 - 94	573 - 707
34 mm	30 - 33	94 - 104	707 - 855
Valve size recommendations are based on native valve annulus size, as measured by computed tomography (CT). Patient anatomical factors and imaging modality should be considered during valve size selection.			



J-Valve® EFS Study Organization

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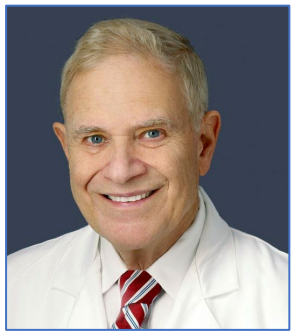

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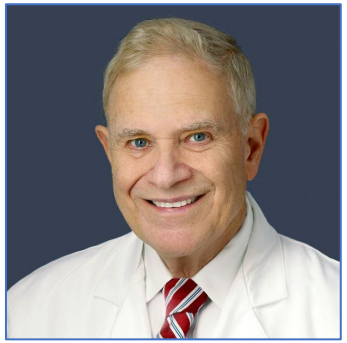

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Only 1 of 5 sites with prior J-Valve® experience

J-Valve® TF EFS Key Inclusion and Exclusion Criteria

- **Inclusion:**
  - Symptomatic (NYHA FC ≥II) severe (≥3+) native AR as diagnosed by echocardiography
    - *Cardiac MR can be utilized in the cases of indeterminate AR*
  - Patient is deemed high-risk for surgery
  - Patient has suitable anatomy for transfemoral **J-Valve®** implantation
- **Exclusion:**
  - Congenital unicuspid or bicuspid aortic valve
  - Mixed aortic valve disease (>moderate AS with severe AR)
  - LVEF <25%
  - Aortic root diameter > 5.0 cm
  - Previous prosthetic aortic valve
  - Mitral regurgitation >moderate
  - CAD requiring revascularization
  - Aortic annulus perimeter <57mm or >104mm

J-Valve® TF EFS Baseline Patient Characteristics

Characteristic	% or Mean ± SD
Age	80.5 ± 4.3
Male	11/15 (73.3%)
Female	4/15 (26.7%)
STS Score/PROM	5.5 ± 4.0
NYHA	
I	0/15 (0%)
II	11/15 (73.3%)
III	4/15 (26.7%)
IV	0/15 (0%)

Co-Morbidity	N (%)
HTN	14/15 (93.3%)
Dyslipidemia	12/15 (80%)
Renal insufficiency (GFR<60/min)	6/15 (40%)
Prior PCI	2/15 (13.3%)
Prior CABG	1/15 (6.7%)
Prior valve procedure	2/15 (13.3%)
Prior CVA or TIA	4/15 (26.7%)
COPD	3/15 (20%)
Diabetes	1/15 (6.7%)
RBBB	***3/15 (20%)***
PPM	3/15 (20%)

**all definitions based on VARC-3 criteria*

J-Valve® TF EFS Baseline Imaging Characteristics

All Echo and CT Data CORE LAB adjudicated

Echocardiography	% or Mean ± SD
LVEF (%)	53 ± 7.97
Aortic regurgitation severity Moderate-Severe Severe	 7/15 (46.7%) 8/15 (53.3%)
Aortic valve mean gradient (mmHg)	5.38 ± 2.20
Moderate Mitral regurgitation	5/15 (33.3%)
LVEDD (cm)	5.81 ± 0.86
LVESD (cm)	4.55 ± 1.07
LVEDV (ml)	187.09 ± 62.92
LVESV (ml)	87.66 ± 36.02

Computed Tomography	% or Mean ± SD
Aortic annulus perimeter (mm)	***87.6 ± 8.8***
Aortic annulus area (mm2)	595.7 ± 123.7
AV calcification severity None Mild	 10/15 (66.7%) 5/15 (33.3%)
Aortic root angulation	***53.3 ± 7.5***
Perimeter > 90 mm (%)	***6/15 (40%)***
Root angle ≥ 60 (%)	***3/15 (20%)***

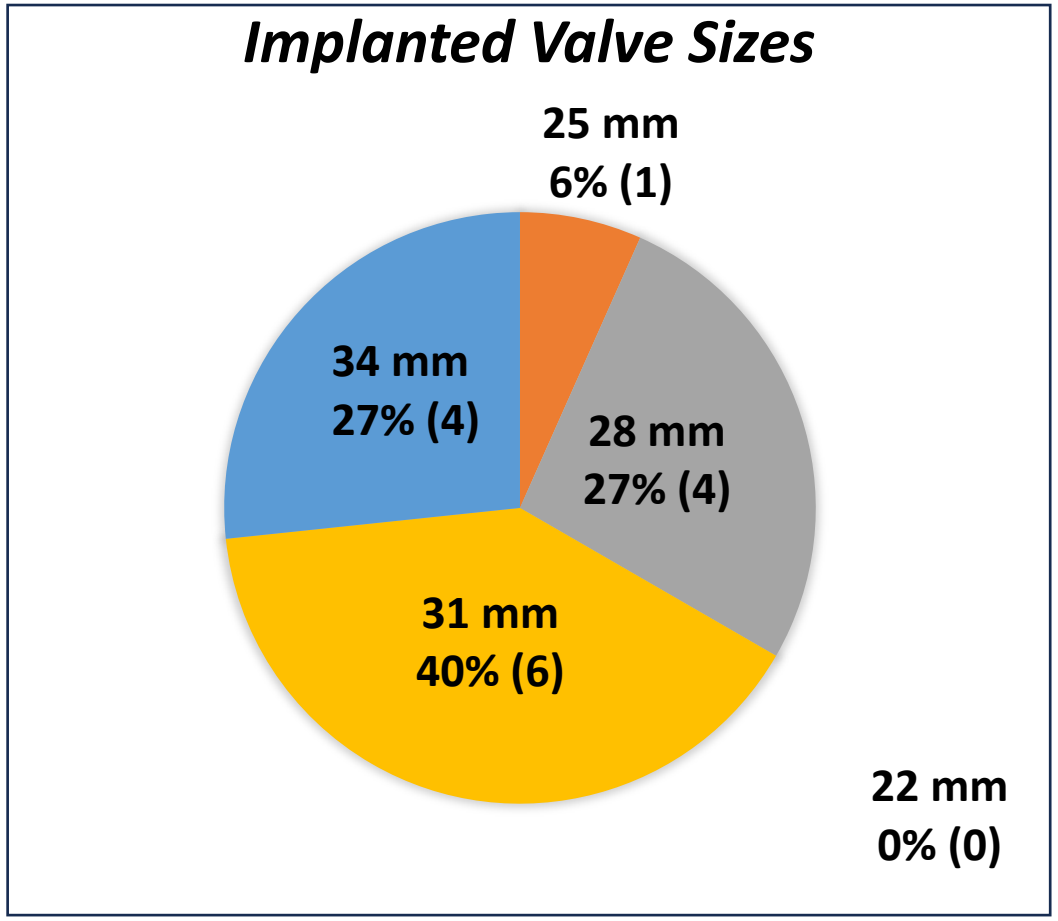
J-Valve® TF EFS Procedural Characteristics

2 out of 3 patients required large valve sizes (31-34 mm)

Characteristic	Minutes
Procedure duration (min) Median- IQR	53 (50-65)
Fluoroscopy time (min) Median- IQR	22 (18-28)

Sheath Size (Fr)	N (%)
20	1/15 (6.7%)
22	12/15 (80%)
Other	2/15 (13.3%)

J-Valve TF Size	Annulus Perimeter (mm)
22 mm	57 – 66
25 mm	66 - 75
28 mm	75 - 85
31 mm	85 - 94
34 mm	94 - 104



J-Valve® TF EFS Procedure Outcomes

Characteristic	N (%)
Intraprocedural Mortality	**0/15 (0%)**
Procedural Success	14/15 (93.3%)
Vascular Complication (Requiring Intervention)	1/15 (6.7%)
Coronary Obstruction	0/15 (0%)
Unplanned PCI	0/15 (0%)
Second THV device	0/15 (0%)

Characteristic	N (%)
Successful Valve Implant (Deliver and Release) Conversion to SAVR	14/15 (93.3%) 1/15 (6.7%)
Device migration or embolization	0/15 (0%)

Unable to release anchor rings from delivery system due to extreme tortuosity of aorta, requiring conversion to SAVR

J-Valve® TF EFS Study 30-day Outcomes

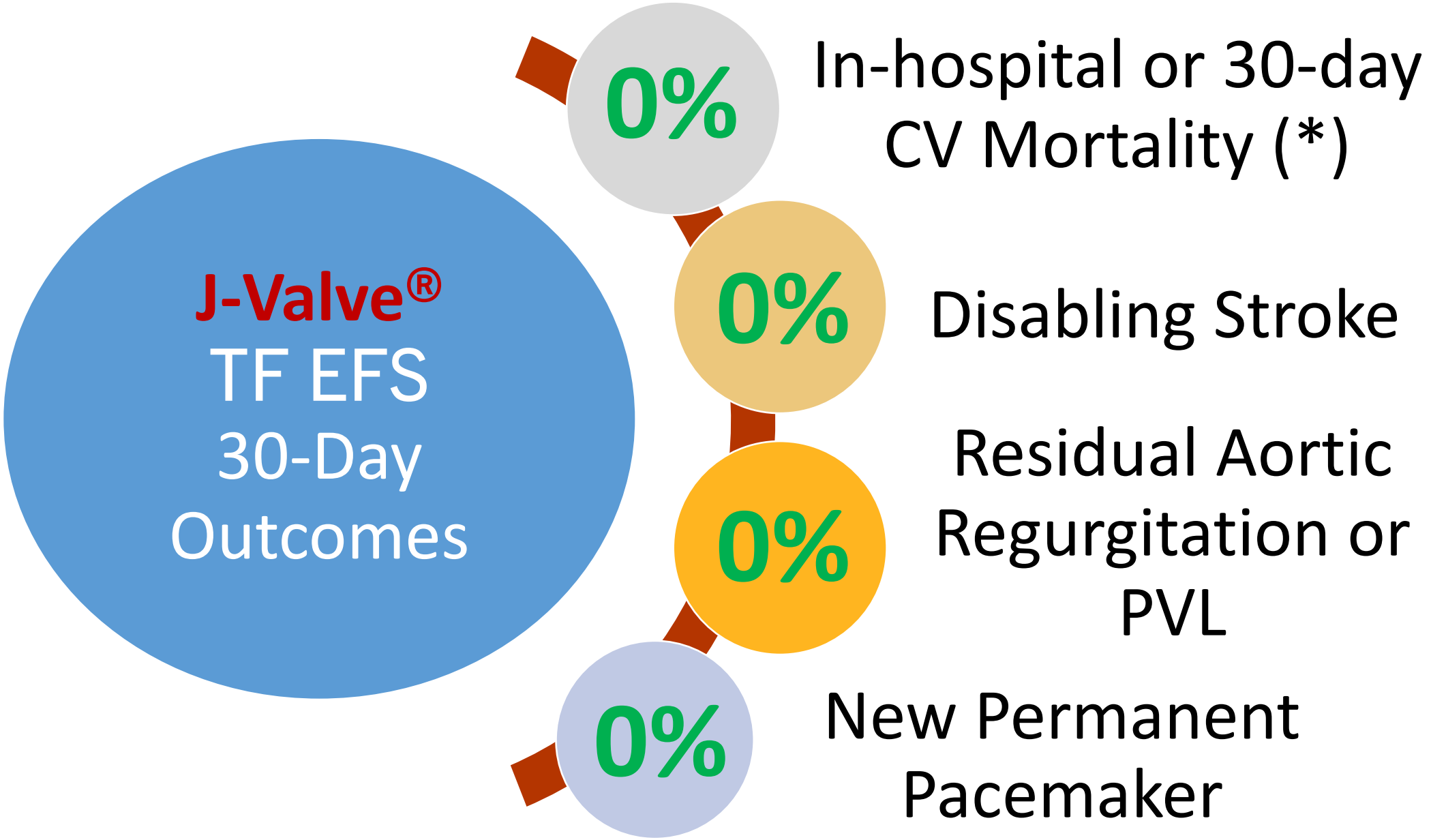
Event	N (%)
Device-related mortality	**0/15 (0%)**
Cardiovascular-related mortality	**0/15 (0%)**
Overall mortality	1/15 (6.7%)
Disabling Stroke	**0/15 (0%)**
Device Related Interventions	**0/15 (0%)**
New Permanent Pacemaker	**0/12 (0%)**

- 1 out-of-hospital mortality at POD #4 due to food asphyxia
- Autopsy revealed **J-Valve®** was in proper position

J-Valve® TF EFS Study: Hemodynamic Assessment

Echo Data CORE LAB adjudicated

Echocardiography Parameter	Baseline %(n) or mean ± SD	Prior to Discharge %(n) or mean ± SD	30-Days %(n) or mean ± SD
LVEF (%)	53 ± 7.97	49 ± 8.38	49 ± 9.31
Aortic valve mean gradient (mmHg)	5.38 ± 2.20	6.36 ± 2.93	**5.57 ± 2.04**
EOA (cm2)	3.02 ± 0.70	3.16 ± 1.08	**2.91 ± 0.67**
Residual AR Severity None/Trace	N/A	**15/15 (100%)**	**15/15 (100%)**
PVL None/Trace	N/A	**15/15 (100%)**	**15/15 (100%)**



* 1 autopsy-confirmed, non-cardiovascular death after discharge due to food aspiration

Conclusions: J-Valve TF System EFS STUDY

- Favorable **J-Valve®** procedural outcomes:
  - 0% CV death
  - 0% disabling stroke
  - 0% residual AR or PVL
  - 0% new permanent pacemaker (3/12 baseline RBBB)
- Excellent hemodynamics at implant and out to 30-days
- Expanded patient population due to the availability of larger valve sizes
- **JOURNEY** Pivotal trial proposed to FDA with anticipated enrollment beginning in Summer 2024

Thank you!

On behalf of the JC Medical Team & J-Valve® TF EFS Steering Committee

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