Transcatheter Aortic Valve Implantation In Low And Intermediate Risk Septuagenarians With Risk Factors Not Captured By The Traditional Surgical Risk Scores

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Disclosure of Relevant Financial Relationships

I, Andreas Synetos, DO NOT have any financial relationships to disclose.

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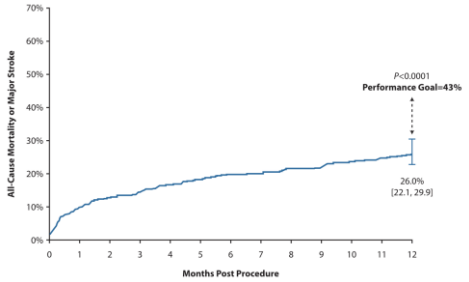
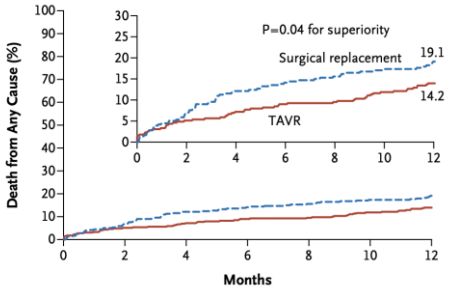
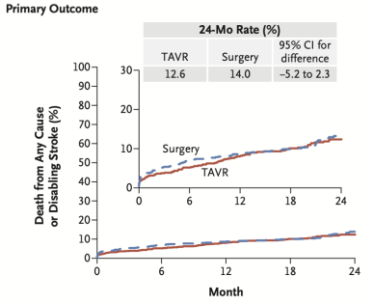
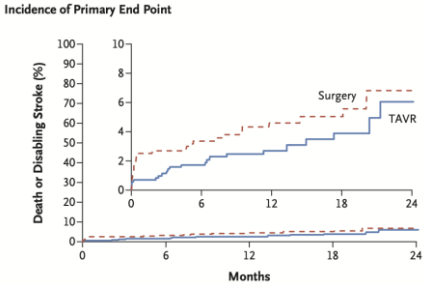
Extreme Surgical Risk	Increased Surgical Risk	Intermediate Surgical Risk	Low Surgical Risk
Corevalve Extreme Surgical Risk Trial	Increased Risk Corevalve Trial	SURTAVI Trial	Evolut Low Risk Trial









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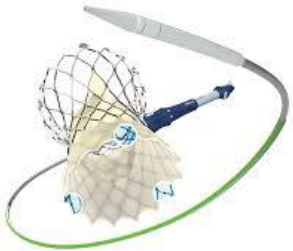
AIM

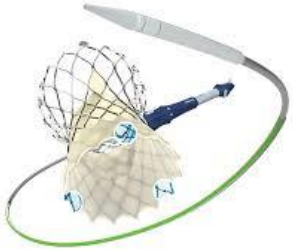
The aim of the present study is to evaluate the safety and the effectiveness of TAVI with the Evolut R and Evolut Pro systems in low and intermediate surgical risk septuagenarians aged 75–79 years old with severe aortic stenosis and specific risk factors that are not included in the traditional risk scores.



Study Design

- ***Single Arm, Multicentre, Observational Trial***
- ***3 Greek Hospitals***
- ***Evolut R and Evolut Pro systems***
- ***Clinical Trials ID: NCT04517955***

- ***This study was initiated in an intermediate income country when the age limit for the TAVI procedure approval was 80 years old.***



Inclusion Criteria

1. Age 75 – 79

2. Patients with Severe Aortic Stenosis with Heart Team decision for TAVI

3. Subject must have STS mortality risk score ≤8%

4. Subject must have at least one from the risk factors presented below:

i. Severely atherosclerotic or porcelain aorta

ii. IMA or other conduit(s) crossing midline and/or adherent to posterior table of sternum

iii. Pre-existing mechanical valve in any other position

iv. Severe right ventricular dysfunction

v. Hostile chest (abnormal chest wall anatomy due to severe kyphoscoliosis or other skeletal abnormalities, evidence of severe radiation damage, history of multiple recurrent pleural effusions causing internal adhesions)

vi. Severe liver disease/ cirrhosis

vii. Frailty

viii. Malignancy with life expectancy that exceeds 24 months

ix. Renal replacement therapy with creatinine levels <200 µmol/L or 2.26 mg/dL

Primary Endpoint

Device success defined as:

1. Absence of procedural mortality and
2. Correct positioning of the prosthetic heart valve into the proper anatomical location and
3. Intended performance of the prosthetic heart valve (mean aortic valve gradient <20 mmHg or peak velocity <3 m/s and no moderate or severe prosthetic valve regurgitation) as assessed within 24h post implantation and pre-discharge echocardiogram

Secondary Endpoints

1. Early safety (at 30 days):

- All-cause mortality
- All stroke (disabling and non-disabling)
- Life-threatening bleeding
- Acute kidney injury—Stage 2 or 3 (including renal replacement therapy)
- Coronary artery obstruction requiring intervention
- Major vascular complication
- Valve-related dysfunction requiring repeat procedure (BAV, TAVI, or SAVR)
- New pacemaker implantation

2. Clinical efficacy (after 30 days and up to two years):

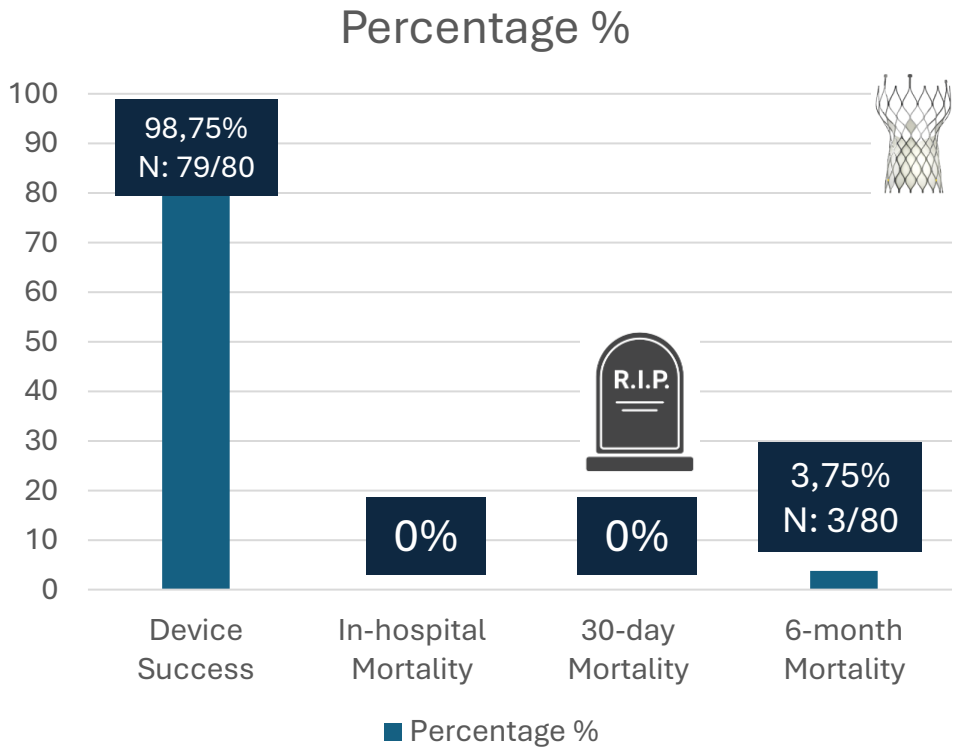
- All-cause mortality
- All stroke (disabling and non-disabling)
- Hospitalizations for valve-related symptoms or worsening congestive heart failure
- NYHA class III or IV
- Valve-related dysfunction (mean aortic valve gradient ≥20 mmHg, EOA ≤0.9–1.1 cm^2 and/or DVI <0.35 m/s, and/or moderate or severe prosthetic valve regurgitation)

Results

- Baseline characteristics

Variable	N: 80
Age	77 ± 1.7 years
BMI	27.8 ± 4.9 kg/m²
STS score	5.0 ± 3.3
Hypertension	93.75%
Dyslipidemia	82.5%
Diabetes	35%
Prior PCM	12.5%

Primary Endpoint



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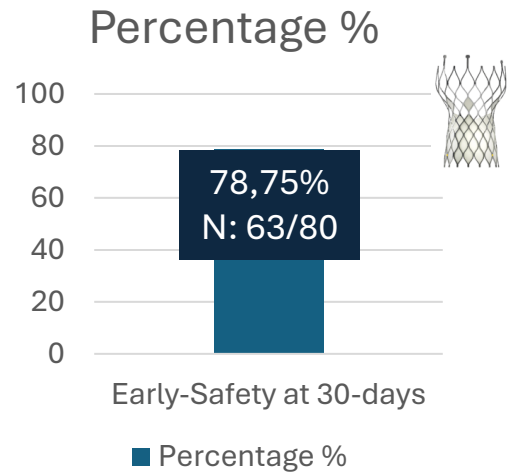

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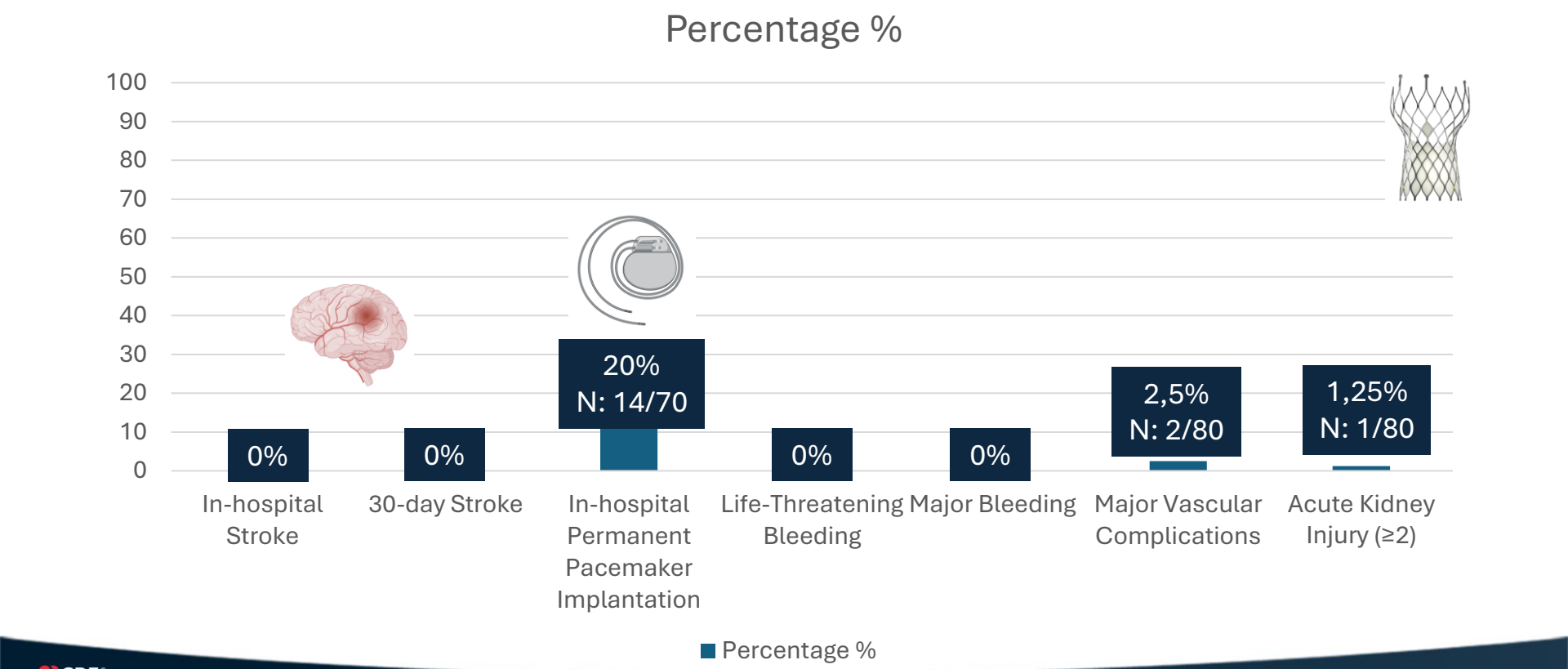
<u>Not yet completed</u>

EARLY SAFETY



Conclusion

- TAVI with the Evolut valve was safe and effective in this population.
- The procedure achieved high device success with no peri-procedural or 30-day mortality.
- Stroke rates were very low, and pacemaker implantation rates were consistent with prior self-expanding valve studies.
- TAVI represents a suitable and less invasive alternative for this population.
- Larger, randomized trials with longer follow-up are needed.