Valve durability for supra-annular, self-expandable TAV found to be statistically better at five years versus both SAVR and balloon-expandable TAV.

**Structural valve deterioration**†

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Comparison: others versus SAVR (random effects model)</th>
<th>HR</th>
<th>95%-CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE-THV</td>
<td></td>
<td>2.43</td>
<td>[1.39; 4.26]</td>
</tr>
<tr>
<td>SE-THV</td>
<td></td>
<td>0.34</td>
<td>[0.24; 0.47]</td>
</tr>
</tbody>
</table>

Authors noted that additional studies including newer generations of valves are warranted to address known THV-specific risks, such as AR and reintervention.

**SVD was less frequent in SE-THV compared with BE-THV and SAVR (HR 0.14, 95% CI 0.07 to 0.27; HR 0.34, 95% CI 0.24 to 0.47, respectively).**

**Key observations from the five-year meta-analysis:**

At five years, supra-annular, self-expandable (SE) valves demonstrated:

- Lowest risk of structural valve deterioration (SVD) compared with balloon-expandable (BE) valves and SAVR.
- Significantly stronger hemodynamics with larger EOAs and lower mean gradients versus BE valves.

Study design

- Meta-analysis
- 10 randomized controlled trials
- 9,388 patients
- Follow-up 1 to 6 years
- Multiple devices‡

- Based on the longest available follow-up for each of the 10 studies used for this meta-analysis. SVD was defined by the respective authors of each paper.
- ‡CoreValve™, Evolut™ R, Evolut™ PRO, Sapien™*, Sapien 3, Sapien XT, and ACURATE neo™.
INDICATIONS
The Medtronic CoreValve™ Evolut™ R, CoreValve™ Evolut™ PRO, and Evolut™ PRO+ systems are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (e.g., STS predicted operative mortality score ≥ 8% or at ≥ 15% risk of mortality at 30 days).

CONTRAINDICATIONS
The CoreValve Evolut R, CoreValve Evolut PRO, and Evolut PRO+ systems are contraindicated in patients who cannot tolerate RIMA (e.g., patency of RIMA ≤ 30%), an anticoagulation/antiplatelet regimen, or who have active bacterial endocarditis or other active infections.

WARNINGS
General: Implantation of the CoreValve Evolut R, PRO, and PRO+ systems should be performed only by physicians who have received Medtronic CoreValve Evolut R, PRO, or PRO+ training. This procedure should only be performed when emergency aortic valve surgery can be performed promptly. Mechanical failure of the delivery catheter system and/or accessories may result in patient complications. Transcatheter aortic valve (bioprosthesis) Accelerated deterioration due to calcific degeneration of the bioprostheses may occur in: children, adolescents, or young adults; patients with altered calcium metabolism (e.g., chronic renal failure or hyperparathyroidism).

PRECAUTIONS
General: Clinical long-term durability has not been established for the bioprosthesis. Evaluate bioprosthesis performance as needed during patient follow-up. The safety and effectiveness of the CoreValve Evolut R, PRO, and PRO+ systems have not been evaluated in the pediatric population. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in the following patient populations: (1) patients not meeting the criteria for symptomatic native aortic stenosis as defined: (1) symptomatic severe high-gradient aortic stenosis – aortic valve area ≤ 1.0 cm² or aortic valve area index ≤ 0.6 cm²/m², a mean aortic valve gradient ≥ 40 mm Hg, or a peak aortic-jet velocity ≥ 4.0 m/s; (2) symptomatic severe low-flow, low-gradient aortic stenosis – aortic valve area ≤ 1.0 cm² or aortic valve area index ≤ 0.6 cm²/m², a mean aortic valve gradient < 40 mm Hg, and a peak aortic-jet velocity < 4.0 m/s; with untreated, clinically significant coronary artery disease requiring revascularization with a preexisting prosthetic heart valve with a rigid support structure in either the mitral or pulmonic position if either the preexisting prosthetic heart valve could affect the implantation or function of the bioprosthesis or the implantation of the bioprosthetic valve could affect the implantation or function of a preexisting prosthetic heart valve; patients with left heart failure (Child-Pugh Class C); with cardiacogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support; patients who are pregnant or breastfeeding. The safety and effectiveness of a CoreValve Evolut R, PRO, or PRO+ bioprosthesis is not known in the pediatric population. The safety and effectiveness of the bioprosthesis have not been established.

Implantation of the CoreValve Evolut R, Evolut PRO, or Evolut PRO+ bioprosthesis in a degenerated surgical bioprosthetic valve (transcatheter aortic valve in surgical aortic valve [TAV-in-SAV]) should be avoided in the following conditions: The degenerated surgical bioprosthetic valve presents with: a significant concomitant paravalvular leak (between the prosthesis and the native annulus), or is not securely fixed in the native annulus, or is not structurally intact (e.g., wire form frame fracture); partially detached leaflet that in the aortic position may obstruct a coronary ostium; stent frame with a manufacturer-labeled inner diameter < 17 mm. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in patients presenting with the following: (1) patients not meeting the criteria for symptomatic native aortic stenosis as defined as: aortic valve gradient ≥ 40 mm Hg, or peak aortic-jet velocity ≥ 4.0 m/s; (2) symptomatic severe low-flow, low-gradient aortic stenosis – aortic valve area ≤ 1.0 cm² or aortic valve area index ≤ 0.6 cm²/m², a mean aortic valve gradient < 40 mm Hg, and a peak aortic-jet velocity < 4.0 m/s; with untreated, clinically significant coronary artery disease requiring revascularization with a preexisting prosthetic heart valve with a rigid support structure in either the mitral or pulmonic position if either the preexisting prosthetic heart valve could affect the implantation or function of the bioprosthesis or the implantation of the bioprosthetic valve could affect the implantation or function of a preexisting prosthetic heart valve; patients with left heart failure (Child-Pugh Class C); with cardiacogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support; patients who are pregnant or breastfeeding. The safety and effectiveness of a CoreValve Evolut R, PRO, or PRO+ bioprosthesis is not known in the pediatric population. The safety and effectiveness of the bioprosthesis have not been established.

POTENTIAL ADVERSE EVENTS
Potential risks associated with the implantation of the CoreValve Evolut R, CoreValve Evolut PRO, or Evolut PRO+ transcatheter aortic valve may include, but are not limited to: • death • myocardial infarction • cardiovascular injury • cerebrovascular injury • aortic root angulation (angle between plane of aortic valve annulus and horizontal plane) • ascending aortic aneurysm • severe calcification in the aorta and/or vasculature. If a 2 of these factors are present, consider an alternative access route to prevent vascular complications. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve, including patients with aortic valve dysplasia. Preoperative angiographic characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established.

During Use After the procedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. After the procedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment. Excessive contrast media may cause renal failure. Prior to the procedure, measure the patient’s creatinine clearance to determine the proper contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long-term. The safety and efficacy of a CoreValve Evolut R, Evolut PRO, or Evolut PRO+ bioprosthesis implanted within a transcatheter bioprosthesis have not been demonstrated.

REFERENCE:

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