

Preventing Coronary Artery Obstruction Using A Designed Device During Transcatheter Aortic Valve Replacement

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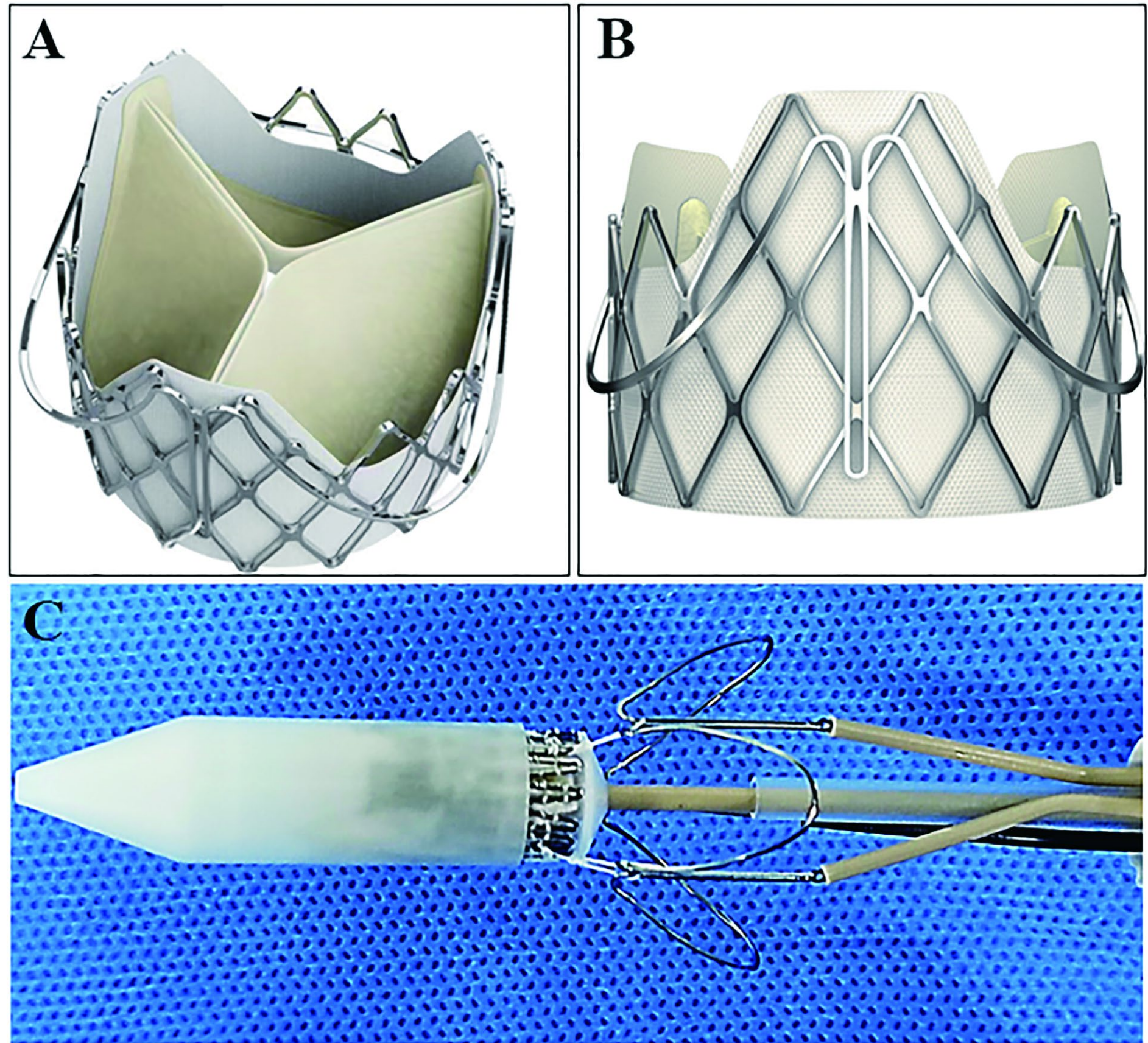
Background

- Transcatheter aortic valve replacement (TAVR) induced coronary artery obstruction (CAO) is a rare but devastating complication.
- Current preventive strategies need additional procedures and may be associated with adverse events.
- This study aimed to evaluate the early safety and efficacy of stand-alone TAVR using the J-Valve (Jianshi JieCheng Medical Technology Co. Ltd, Shanghai, China) in patients at potential high risk for CAO.

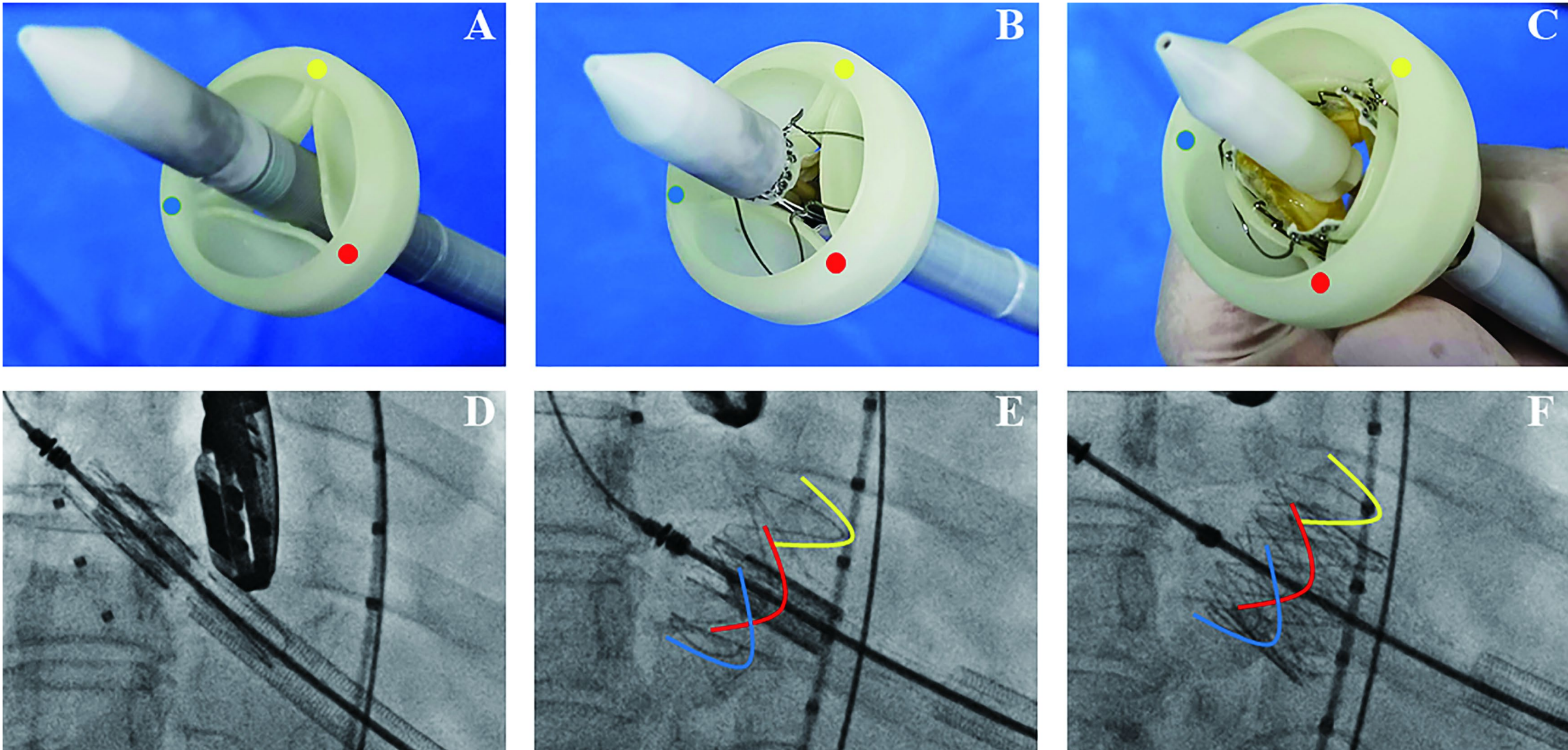
Patients and Methods

Patients:

- A total of 22 consecutive patients (age 72 ± 9 years; 86.4% female; STS 5% (3%-21%)) at potential high risk for CAO were retrospectively identified from January 2015 to July 2022 at Zhongshan Hospital, Fudan university.
- All patients had at least 2 classical risk factors for CAO by pre-procedural CT analysis: coronary height < 10 mm, sinus of Valsalva diameter < 30 mm, and virtual transcatheter heart valve to coronary distance < 4 mm
- 20 patients had native aortic disease, and 2 patients had bioprosthetic degeneration

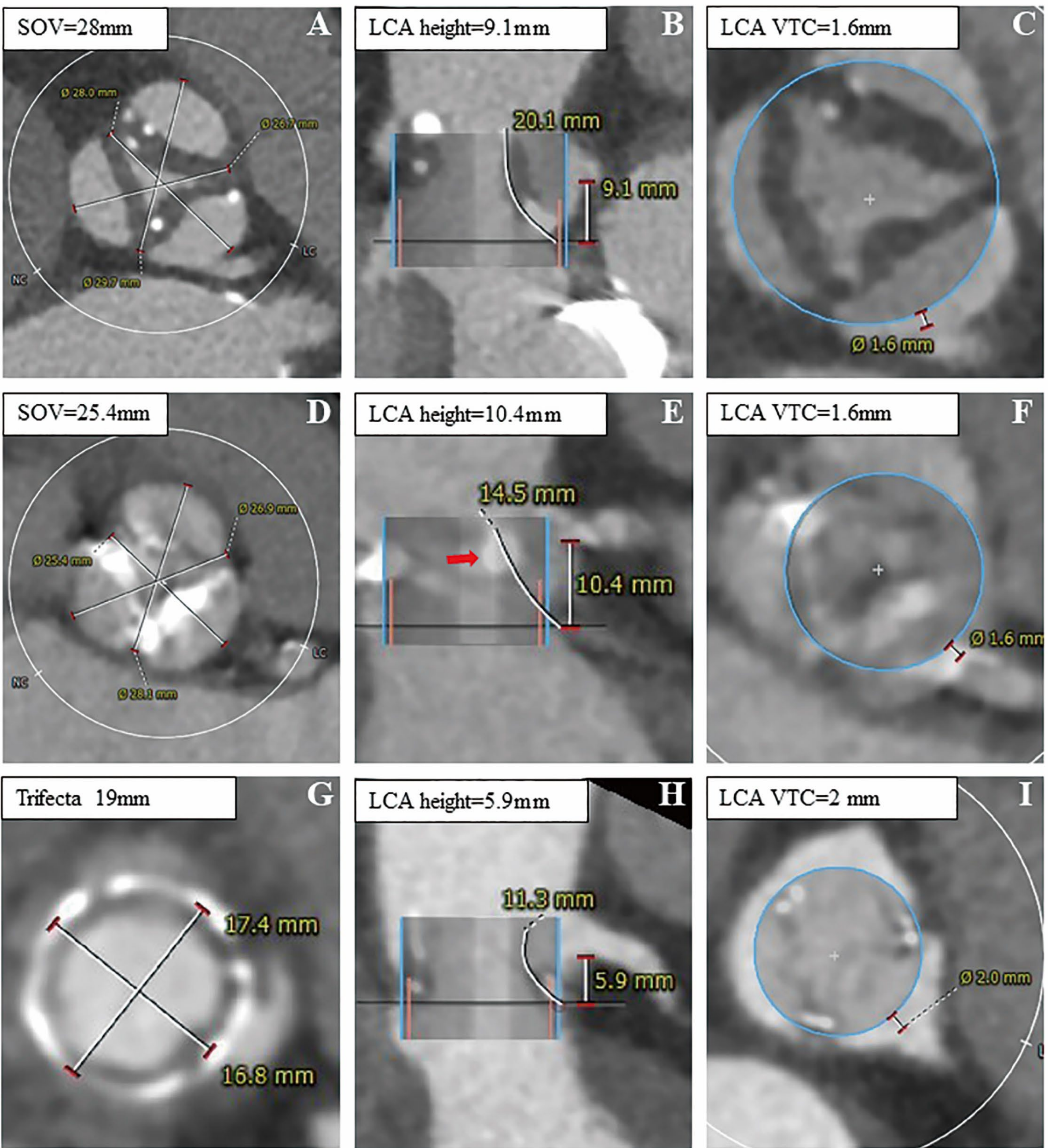


Device:The J-Valve is a self-expanding transapical heart valve with a unique 2-piece structure consisting of 3 “U-shape” claspers and a crown-like frame connected to three stitches

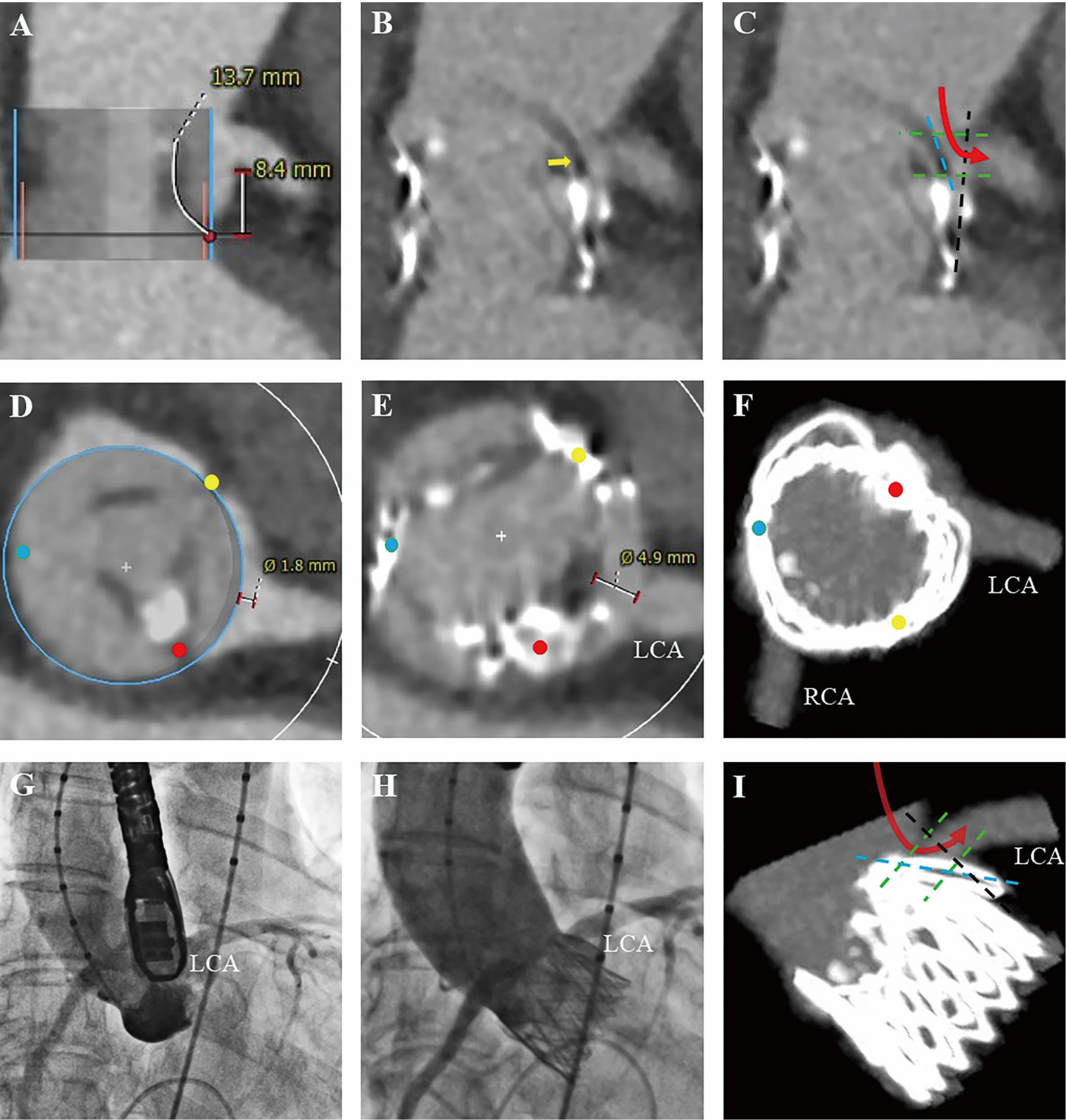


Procedure: The 3 claspers can be individually positioned in 3 aortic sinuses to fix the aortic valve leaflets and align the commissures of the device with commissures of the aortic valve.

Results



Representative cases at potential high risk for transcatheter aortic valve replacement induced coronary artery obstruction



The prosthesis mitigated risk of coronary ostial obstruction in a representative case.

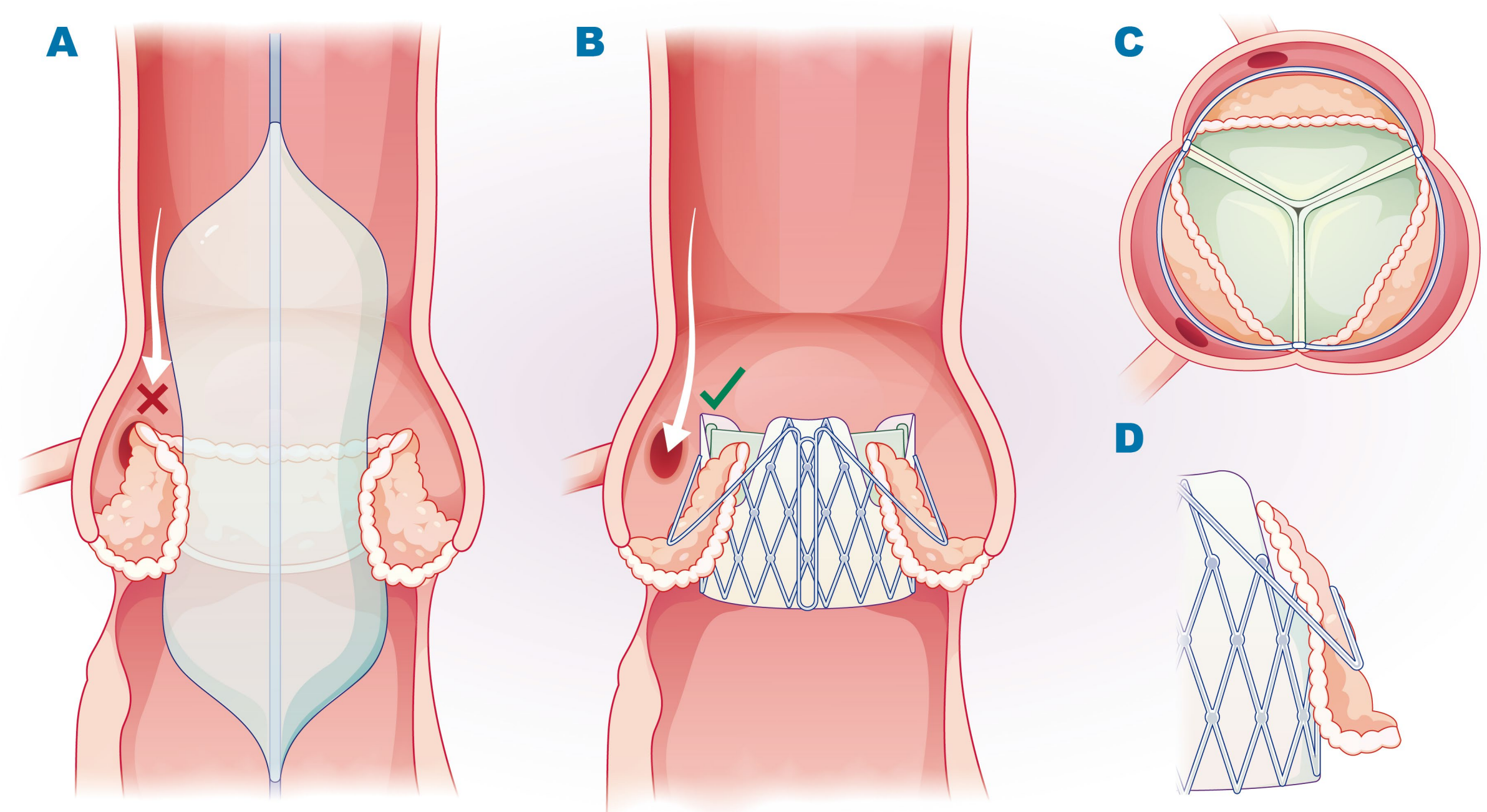
30-day Outcomes:

- 0% Coronary obstruction (defined as required emergency intervention)
- 95.5% Procedural success (one case required ViV implantation)
- 100% Early safety defined by VARC-2

Discussion

Mechanisms:

- Leaflet retraction** (The low-profile and crown-like frame design of the J-Valve facilitates leaflet retraction)
- Clipping leaflet** (The claspers will seize the leaflets of aortic valve and attach them to the frame of the THV)
- Commissure alignment** (The “self-positioning” design of the J-Valve aligns the struts with the commissures of the native aortic valve or bioprosthesis)



Advantages:

- Stand-alone TAVR, avoidance of additional interventions.
- Available for pure aortic regurgitation
- May facilitate future coronary access
- Avoidance of transient hemodynamic compromise
- Available for patients predicted to have a low risk of CAO during TAVR may still develop CAO.

Disadvantages:

- Transapical access is more invasive.
- May not suitable for tediously long leaflets which can hinder the claspers into sinuses.
- Not suitable for eccentricity of coronary ostia
- Not suitable for excessively low coronary ostia
- Not suitable for bulky calcific leaflet nodules which can directly obstruct coronary ostia after device implantation

Conclusions

Stand-alone TAVR using the J-Valve prosthesis prevents unnecessary procedures and is associated with promising early outcomes in treating patients at potential high risk for CAO. The primary mechanisms that underlie the reduction in the risk of CAO include leaflet clipping and retraction, as well as commissure alignment. These mechanisms could also protect future coronary access following TAVR or TAVIV.

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