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TAVR-in-TAVR and Coronary Access: The Importance of Pre-procedural Planning

Short title: Coronary access after TAVR-in-TAVR

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ABBREVIATIONS

TAVR: transcatheter aortic valve replacement

THV: transcatheter heart valve

RP: risk plane

CA: coronary access

CT: computed tomography

STJ: sino-tubular junction

VTA: valve-to-aorta distance

SE: self-expandable

BE: balloon-expandable

INTRODUCTION

Transcatheter heart valve (THV) degeneration will be increasingly common with the expansion of transcatheter aortic valve replacement (TAVR) indication to low-risk younger subjects with longer life-expectancy[1]. Treatment of structural THV degeneration with the implantation of a second THV is feasible, but data on this subject are scant. In particular, there are concerns about the risk of coronary artery obstruction and the possibility to access the coronary ostia in case percutaneous coronary artery intervention will be needed in the future[2-4].

It is crucial to understand the 3-dimensional interaction among degenerated THV, coronary ostia and aortic root to guide pre-procedural planning of TAVR-in-TAVR with the aim to minimize the risk of acute coronary artery occlusion and preserve future coronary access (CA). In fact, the implantation of a second THV will tilt up the leaflets of the previously implanted device, thereby creating a covered cylindric stent tall as the commissural posts.

METHODS

We defined *risk plane* (RP) the level under which the passage of a coronary catheter will be impossible after the second THV is implanted (Figure 1A). Based on 1) the relationship between the RP and the coronary ostia at computed tomography (CT), and 2) how CA is achieved with the first THV in place, we developed an algorithm to predict the risk of acute coronary occlusion and feasibility of future CA after TAVR-in-TAVR (Figure 1B).

RESULTS

According to aortic root anatomy, three different scenarios can be depicted with Sapien XT/3, Covervalve/Evolut (Figure 2) and other commercially available THVs (Supplementary Figure).

DISCUSSION

1. DEGENERATION OF INTRA-ANNULAR BALLOON-EXPANDABLE SAPIEN XT/3 THV

Balloon-expandable (BE) prostheses Sapien XT and Sapien 3 (Edwards Lifesciences) have an intra-annular design, low frame profile (frame height 14-19 mm for Sapien XT, 15.5-22.5 mm for Sapien 3) and an upper row of open cells (with diameter of 4.4-6.8 mm for Sapien 3, 40% smaller for Sapien XT). Commissural tabs and leaflet attachment are located in 3 of the 12 open cells. Therefore, the RP is approximately 1 mm below the upper margin of the valve frame (Figure 2, upper panel)

1) <u>Coronary ostia *above* the risk plane (Type 1).</u>

When the RP lays below the coronary ostia, either because of high coronary origin or low THV implantation, CA can be gained from above the RP. In this case, TAVR-in-TAVR with a second intra-annular THV (avoiding high implantation) will not impede subsequent coronary cannulation. Implantation of a self-expandable (SE) supra-annular Medtronic Evolut R/Pro inside the first THV is also possible.

2) <u>Coronary ostia *below* the risk plane (Type 2)</u>

When the coronary ostia are low or the first THV is implanted high, the origin of one or both coronaries will be below the RP. In this situation, CT analysis is important to assess the valve-to-aorta distance (VTA), defined as the distance between the prosthesis frame at the level of the RP and the aortic wall. A free space of >2mm is necessary to navigate a 6 French catheter behind the prosthesis struts and engage the coronary ostium[5]. Coronary angiography after index TAVR will single out two different scenarios.

a) <u>Coronary access from *above* the risk plane (Type 2a)</u>

In patients with wide STJ and a CT-assessed VTA >2 mm, CA from above the RP outside the valve frame needs to be confirmed by selective coronary angiography. In this case, TAVR-in-TAVR with a second BE device is feasible, but excessive oversizing and post-dilation should be avoided in order not to flare the superior part of the THV and preserve the VTA. The use of a SE device with taller commissural posts for TAVR-in-TAVR is also possible, but coronary cannulation might be more challenging because of the possibility to place a neo-commissure in front of the coronary.

b) Coronary access from *below* the risk plane (Type 2b)

If the STJ is narrow and VTA is <2 mm, coronary cannulation will be possible only through the upper row cells of the THV frame. Since the leaflets of the first BE THV will form a cylinder when tilted up by the new BE or SE THV, CA after TAVR-in-TAVR will be unfeasible with the risk of coronary occlusion. According to a recent study based on aortic angiogram after TAVR, this unfavorable anatomical scenario could be found in up to 20% of patients treated with a Sapien 3 THV[5]. However, considering that coronary cannulation was not attempted, we cannot exclude over- or underestimation of this situation.

2. DEGENERATION OF SUPRA-ANNULAR SELF-EXPANDABLE COREVALVE/EVOLUT THV

Self-expandable (SE) Corevalve, Evolut R/Pro (Medtronic) have a supra-annular design, a taller frame (45-55 mm) and a commissure height of 26 mm. The risk of coronary obstruction with this type of prosthesis is minimized by their narrow waist and the possibility to be recaptured after partial deployment in case of coronary flow impairment. To cannulate the coronary, a catheter needs to pass through one of the diamond-shaped cells of the stent frame. Given the commissural post height, the RP of supra-annular Evolut R/Pro devices will be considerably higher compared to BE intra-annular THVs (Figure 2, lower panel).

1) Coronary ostia *above* the risk plane (Type 1).

This situation is extremely uncommon with correctly implanted supra-annular devices. In fact, Evolut R/Pro THV have 26 mm high commissures, that invariably expand above the coronary ostia. Accordingly, the RP is almost always above the coronaries, and CA from above the RP is feasible just in anecdotical cases with very high coronary origin or inappropriately low THV implantation. Even though TAVR-in-TAVR with a second Evolut R/Pro device is feasible, selective coronary engagement will be very challenging or impossible. In fact, given the impossibility to precisely orientate the THV during implantation, the two stent layers above the RP might overlap leaving insufficient room to permit the passage of a coronary catheter. An exception to this might be the situation of an extremely large aortic root allowing the passage of the catheter outside the valve frame between the prosthesis and the aortic wall. To note, TAVR-in-TAVR with a low implanted lower-frame intra-annular BE device might not achieve complete vertical displacement of the degenerated leaflets of the first supra-annular SE device.

2) **Coronary ostia *below* the risk plane (Type 2)**

This scenario is by far the most common with supra-annular SE devices.

a) Coronary access from *above* the risk plane (Type 2a)

CA from above the RP, although potentially challenging, is feasible only if the VTA is >2mm. In this situation, TAVR-in-TAVR is possible with the same caveats of the aforementioned Type 1 scenario.

b) Coronary access from *below* the risk plane (Type 2b)

In patients with narrow STJ, the VTA at RP might be <2mm. Accordingly, coronary cannulation is possible just through a cell located below the RP. When the leaflets of the first SE THV are tilted up after the implantation of the second prosthesis, there will be a 26 mm tall barrier in front of the coronary ostia. Subsequent CA will be impossible and TAVR-in-TAVR will likely cause coronary artery obstruction, regardless of the type of prosthesis used.

LIMITATIONS

The main limitation of this short report is the lack of data. Further studies are needed to assess the prevalence of the described scenarios in the contemporary TAVR population and therefore to predict the percentage of patients potentially unsuitable for TAVR-in-TAVR.

CONCLUSION

Percutaneous treatment of a failing THV poses challenges in terms of preventing acute coronary obstruction and preserving future CA. Unlike TAVR in surgical aortic valves, novel leaflet splitting techniques such as BASILICA may be less effective when THV neo-commissures are not aligned to those of the native aortic valve. Computed tomography and coronary angiography are important and complementary for a correct pre-procedural planning of the procedure. CA after TAVR-in-TAVR will be feasible with type 1 (coronary ostia and CA above the RP) and type 2a scenarios (coronary ostia below the RP, VTA >2mm, CA above the RP). On the contrary, in patients with type 2b (coronary ostia and CA below the RP, VTA<2mm) TAVR-in-TAVR will carry high risk of coronary artery obstruction. Given their different design and their higher risk plane, supra-annular devices are more likely to impede CA after TAVR-in-TAVR. Notably, redo-TAVR with the use of partially or fully repositionable devices might reduce the risk of irreversible coronary obstruction in high-risk cases.

IMPACT ON DAILY PRACTICE

Although hypothesis-generating, the aspects described in this short report should be considered when selecting the THV to implant in younger patients with longer life expectancy.

FIGURE LEGEND

Figure 1.

A) Risk plane of Sapien 3, Lotus, Evolut R/Pro, Portico and Acurate Neo THVs.

B) Pre-procedural algorithm for evaluation of feasibility of CA after TAVR-in-TAVR. ** CA challenging if TAVR-in-TAVR with two Evolut R/Pro or Portico THVs.*

Figure 2.

Upper panel. TAVR-in-TAVR for intra-annular BE Sapien XT/3 degeneration.

Type 1. As shown by CT imaging, the RP lays below the coronary ostia. Selective CA is achieved above the RP. After TAVR-in-TAVR, coronary cannulation is feasible above the valve frame.

Type 2a. Coronary ostia are below the RP. The STJ is wide, with a computed tomography measured VTA >2 mm. Coronary cannulation is feasible from above the risk plane, outside the valve frame. In this case, CA after TAVR-in-TAVR should be possible.

Type 2b. Coronary ostia are below the RP. The STJ is narrow, with a VTA <2mm. Coronary cannulation is feasible just through one of the upper row cells. After TAVR-in-TAVR CA will be impossible, with a high risk of acute coronary flow impairment.

Lower panel. TAVR-in-TAVR for supra-annular SE Corevalve/Evolut degeneration.

Given the high position of valve leaflets, coronary ostia will be almost always under the RP (Type 2).

Type 2a. The STJ is wide, with a VTA >2 mm. CA is obtained through a cell above the RP. TAVR-in-

TAVR with a second SE device will not cause coronary flow impairment, but the two layers of overlapping struts will make future CA challenging, if not impossible.

Type 2b. The STJ is narrow, with a VTA <2mm. CA is gained from below the RP. TAVR-in-TAVR carries high risk of acute coronary artery obstruction.

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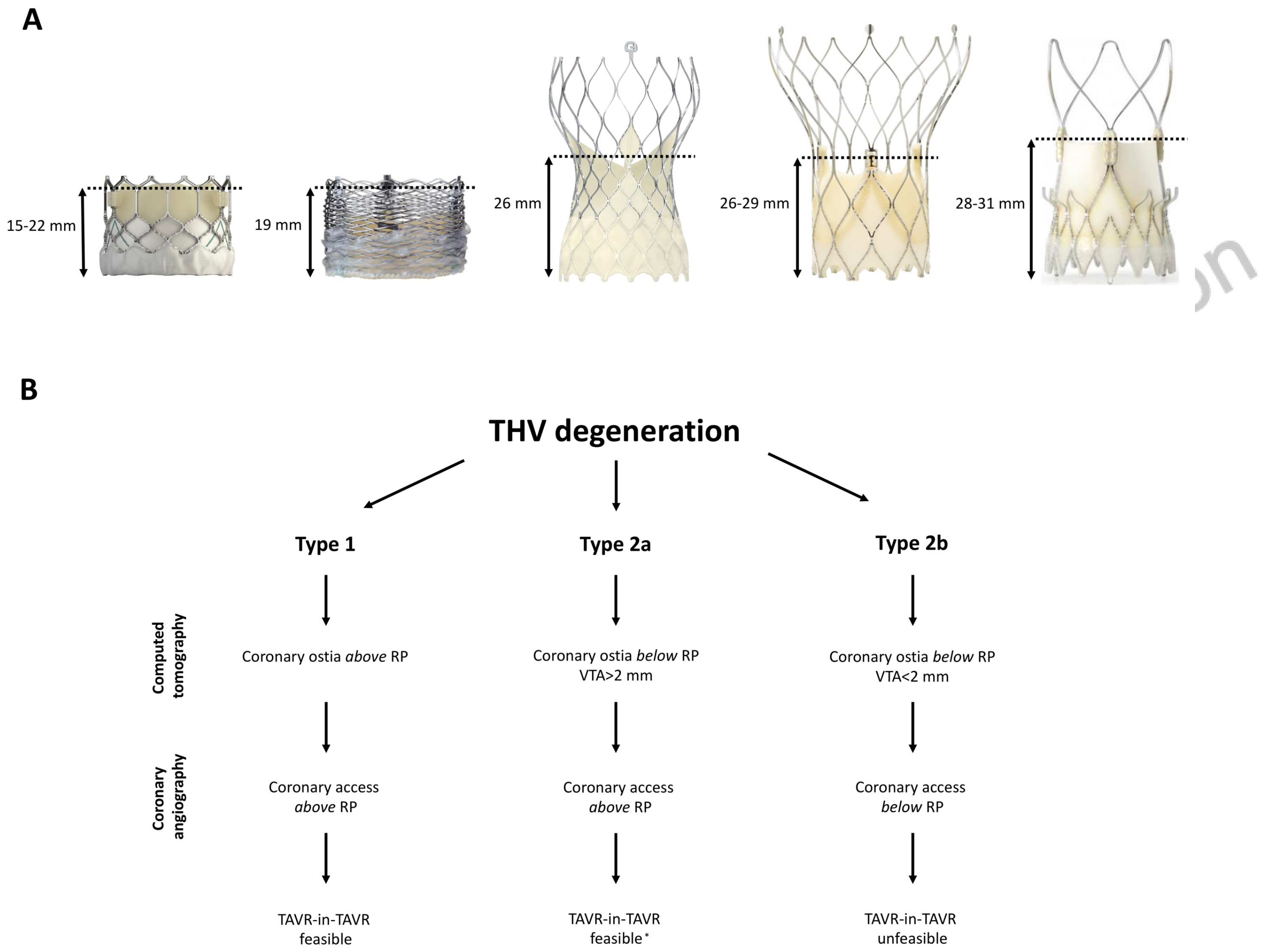
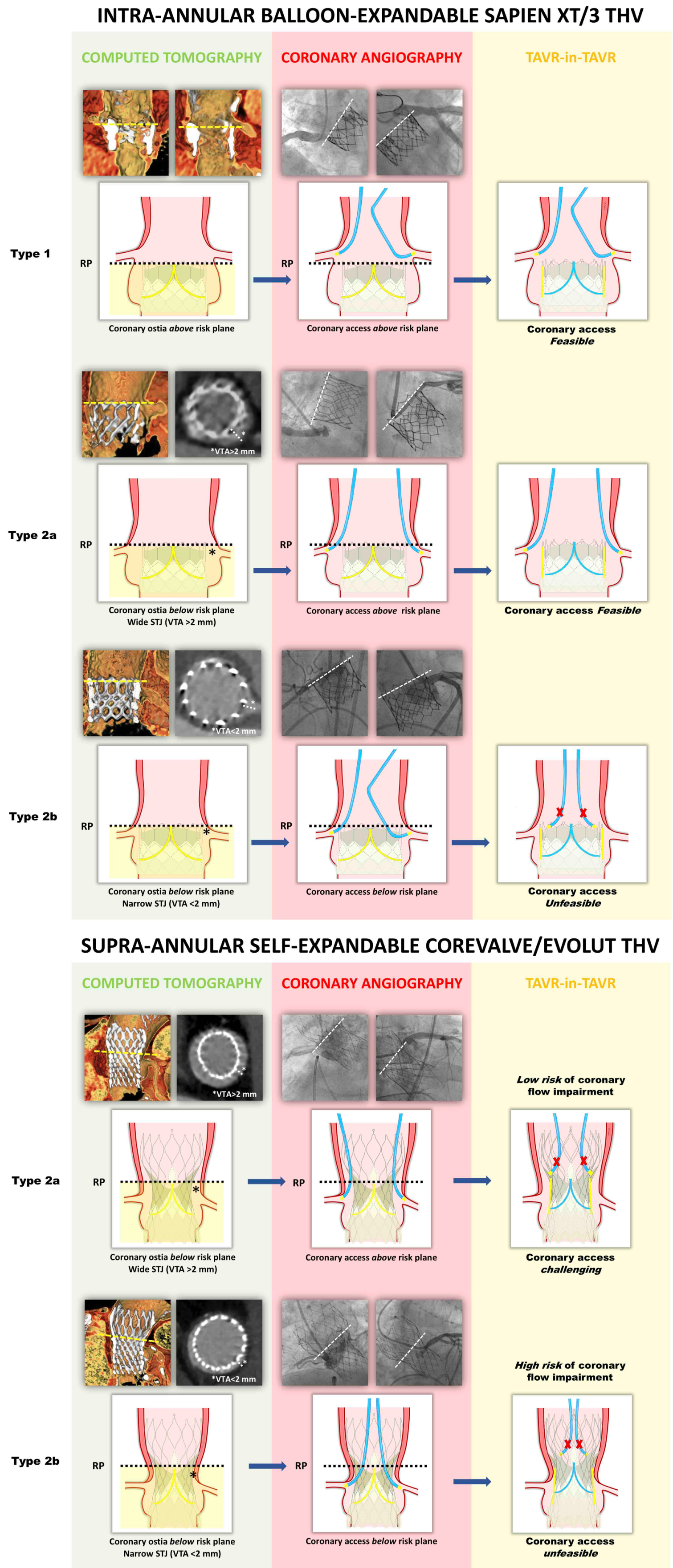

A
15-22 mm
19 mm
26 mm
26-29 mm
28-31 mm
B
THV degeneration
Type 1
Type 2a
Type 2b
Computed tomography
Coronary ostia *above* RP
Coronary ostia *below* RP
VTA>2 mm
Coronary ostia *below* RP
VTA<2 mm
Coronary angiography
Coronary access *above* RP
Coronary access *above* RP
Coronary access *below* RP
TAVR-in-TAVR feasible
TAVR-in-TAVR feasible*
TAVR-in-TAVR unfeasible



INTRA-ANNULAR BALLOON-EXPANDABLE SAPIEN XT/3 THV
COMPUTED TOMOGRAPHY
CORONARY ANGIOGRAPHY
TAVR-in-TAVR
Type 1
RP
Coronary ostia above risk plane
Coronary access above risk plane
Coronary access Feasible
Type 2a
*VTA>2 mm
Coronary ostia below risk plane Wide STJ (VTA >2 mm)
Coronary access above risk plane
Coronary access Feasible
Type 2b
*VTA<2 mm
Coronary ostia below risk plane Narrow STJ (VTA <2 mm)
Coronary access below risk plane
Coronary access Unfeasible
SUPRA-ANNULAR SELF-EXPANDABLE COREVALVE/EVOLUT THV
COMPUTED TOMOGRAPHY
CORONARY ANGIOGRAPHY
TAVR-in-TAVR
Type 2a
*VTA>2 mm
Low risk of coronary flow impairment
Coronary ostia below risk plane Wide STJ (VTA >2 mm)
Coronary access above risk plane
Coronary access challenging
Type 2b
*VTA<2 mm
High risk of coronary flow impairment
Coronary ostia below risk plane Narrow STJ (VTA <2 mm)
Coronary access below risk plane
Coronary access unfeasible

Supplementary material

DEGENERATION OF OTHER COMMERCIALLY AVAILABLE THVS

1) **Degeneration of intra-annular mechanical-expanding Lotus THV**

The Lotus (Boston Scientifics) is a mechanical-expanding THV with a 19-mm high frame. Being a thick braided nitinol mesh, the latter cannot be crossed by a coronary catheter. Thus, coronary cannulation can be achieved only from above the RP already after the implantation of the first THV (no type 2b scenario can be encountered). When the coronary ostia lay above the RP (type 1) or below the RP with coronary access achieved from above the RP (type 2a), the same considerations previously made for TAVR-in-TAVR with Sapien XT/3 apply (Supplementary Figure, upper panel).

2) **Degeneration of intra-annular SE Portico THV**

The RP of the SE intra-annular THV (Abbott) is located 26 to 29 mm from the lower edge of the frame. Thus, the coronary ostia will be invariably under the RP (type 2a and 2b). TAVR-in-TAVR carries the same caveats of Corevalve/Evolut THVs (Supplementary Figure, central panel).

3) **Degeneration of supra-annular SE Acurate Neo THV**

The Acurate Neo valve (Boston Scientifics) has the tallest RP (28-31 mm depending on valve size), given the height of its commissural posts. Accordingly, the same considerations made for TAVR-in-TAVR with Corevalve/Evolut apply. Nevertheless, its open cell architecture in the upper part of the frame might reduce the risk of struts overlap above the RP in case of redo-TAVR (Supplementary Figure, lower panel).

Supplementary Figure Legend.

Upper panel. TAVR-in-TAVR for a degenerated intra-annular mechanical-expanding Lotus prosthesis.

Type 1. If the RP lays below the coronary ostia, selective coronary access can be achieved above the RP. In this situation, TAVR-in-TAVR is feasible.

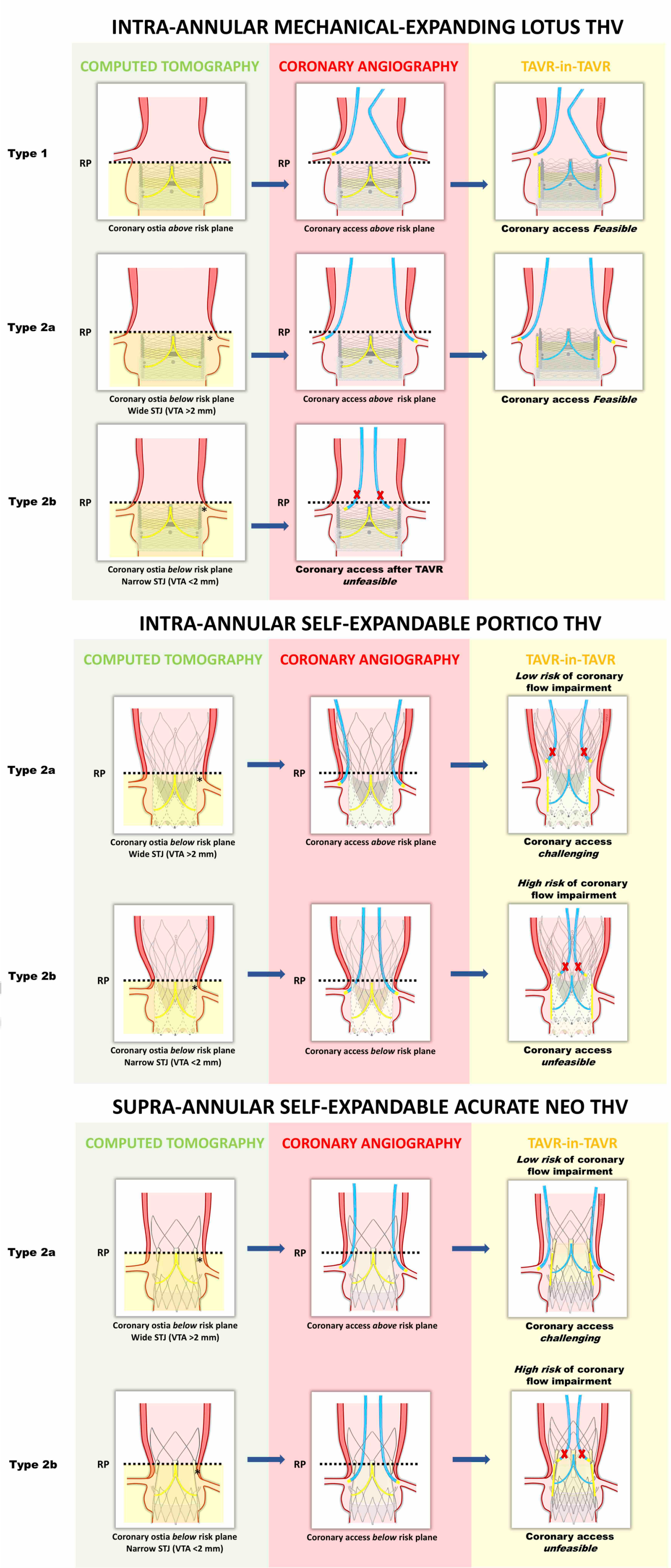
Type 2a. Coronary ostia lay below the RP in the presence of a wide STJ (VTA >2 mm). Coronary cannulation is feasible from above the RP. Thus, coronary access after TAVR-in-TAVR should be possible.

Type 2b. In this situation coronary cannulation is impossible to achieve through the valve frame of the THV already after implantation of the first THV.

Central and Lower panel. TAVR-in-TAVR for intra-annular SE Portico (Central Panel) and supra-annular SE Acurate Neo (Lower panel) degeneration.

As for Corevalve/Evolut valves, coronary ostia will be almost always under the RP (Type 2). TAVR-in-TAVR with these two types of device is feasible with the same caveats. Notably, the open cell design of the Acurate Neo THV might facilitate coronary cannulation from above the RP after TAVR-in-TAVR.

TAVR=transcatheter aortic valve replacement; BE=balloon-expandable; SE=self-expandable; RP=risk plane; VTA=valve-to-aorta distance (asterisk); STJ=sino-tubular junction


INTRA-ANNULAR MECHANICAL-EXPANDING LOTUS THV
COMPUTED TOMOGRAPHY
CORONARY ANGIOGRAPHY
TAVR-in-TAVR
Type 1
RP
Coronary ostia above risk plane
Coronary access above risk plane
Coronary access Feasible
Type 2a
Coronary ostia below risk plane
Wide STJ (VTA >2 mm)
Coronary access above risk plane
Coronary access Feasible
Type 2b
Coronary ostia below risk plane
Narrow STJ (VTA <2 mm)
Coronary access after TAVR unfeasible
INTRA-ANNULAR SELF-EXPANDABLE PORTICO THV
COMPUTED TOMOGRAPHY
CORONARY ANGIOGRAPHY
TAVR-in-TAVR
Low risk of coronary flow impairment
Type 2a
Coronary ostia below risk plane
Wide STJ (VTA >2 mm)
Coronary access above risk plane
Coronary access challenging
High risk of coronary flow impairment
Type 2b
Coronary ostia below risk plane
Narrow STJ (VTA <2 mm)
Coronary access below risk plane
Coronary access unfeasible
SUPRA-ANNULAR SELF-EXPANDABLE ACURATE NEO THV
COMPUTED TOMOGRAPHY
CORONARY ANGIOGRAPHY
TAVR-in-TAVR
Low risk of coronary flow impairment
Type 2a
Coronary ostia below risk plane
Wide STJ (VTA >2 mm)
Coronary access above risk plane
Coronary access challenging
High risk of coronary flow impairment
Type 2b
Coronary ostia below risk plane
Narrow STJ (VTA <2 mm)
Coronary access below risk plane
Coronary access unfeasible