

Radiopaque preventive landmarks' placement during stentless bioprosthesis implantation

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Background: In patients with aortic stenosis, bioprosthetic valves are increasingly used. Although their benefits, they are also presenting limitations, as their time-related degeneration. Reoperation which was, until a few years ago, the only treatment for this condition, carries a significant surgical risk, especially in patients with multiple comorbidities, so the benefit of less invasive technique enabling the implantation of aortic valve prosthesis [transcatheter aortic valve-in-surgical aortic valve (TAV-in-SAV)] by a percutaneous access is remarkably important. Eligible patients are judged by a heart team, and imaging plays a key role in this selection, focusing on correct identification of bioprosthetic aortic valves type and size, evaluation of patients at increased anatomical risk for coronary artery occlusion. Radiolucency of stentless bioprosthetic valves, represent a significant challenge.

Methods: Surgical aortic valve replacements (SAVRs) with a bioprosthesis were performed using a stentless valve with no radiopaque components (Solo Smart, Sorin). The chosen method, in order to evaluate the results of the operation, was computed tomography (CT) scanning (64-slice MDCT, Brilliance, Philips). The study consisted of a thin sliced contrast electrocardiograph (ECG) gated chest CT (1 systolic cardiac phase), trying to simulate the required assessment of aortic root and the radiopaque placed markers.

Results: As surgical implant technique varies and may impact the relationship of the prosthetic annulus to the coronary ostia, marking the aortic annulus during the operation in order to have some useful radiopaque landmarks, is a great assistance promoting better orientation and correct identification of the position of the bioprosthetic valve. Although the implantation of metallic vascular clips at the level of aortic annulus (in any commissure or in the middle of any cups) was considered, the decision was to position three metallic clips below the aortic annulus in the three stiches ligated during the solo valve implantation.

Conclusions: We are suggesting the preventive implantation of radiopaque landmarks, during SAVRs using tissue valves which are lacking fixed anatomic markers, as a guide for a presumptive TAV-in-SAV procedure, keeping in mind that appropriate guidance is crucial and can prevent valve misplacement, coronary obstruction and other potentially lethal complications.

Keywords: Landmarks; radiopaque; transcatheter aortic valve-in-surgical aortic valve (TAV-in-SAV)

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Introduction

In patients with aortic stenosis, bioprosthetic valves are increasingly used. Their main advantage is that they do not require constant anticoagulation therapy, due to their lower thrombotic risk compared with mechanical valves, so patients with bioprosthetic valves have a significantly diminished risk of haemorrhage (1,2). Although their benefits, they are also presenting limitations, as their time-related degeneration (3,4). Reoperation which was, until a few years ago, the only treatment for this condition, carries a significant surgical risk, especially in patients with multiple comorbidities (5), so the benefit of less invasive technique enabling the implantation of aortic valve prosthesis [transcatheter aortic valve-in-surgical aortic valve (TAV-in-SAV)] by a percutaneous access is remarkably important (6). Patients eligibility is decided by a heart team, and imaging plays a key role in this selection, focusing on correct identification of bioprosthetic aortic valves type and size, and recognition of patients at increased anatomical risk for coronary artery occlusion (6,7). Radiolucency of stentless bioprosthetic valves, represent a significant challenge.

Methods

We propose a new surgical technique with the addition of landmarks using a knot-tying device which consist of radiopaque Titan clips (Cor-Knot device, LSI Solutions, Inc., Victor, NY, USA) for marking the new annulus. The surgical aortic valve replacement (SAVR) by bioprosthesis was performed using a stentless valve with no radiopaque components (Freedom Solo, Sorin). This valve is created by two bovine pericardial sheets without texture reinforcement. The design pursues the natural shape of native aortic annulus and commissures. This allows a less complicated technique of implantation in a strictly supra-annular position with a single suture line. The implantation starts with three 4-0 polypropylene sutures placed in a supra-annular position at the midpoint of each sinus and then passed through the external pericardial flange of the valve. The bioprosthetic valve is then parachuted into the aortic root and tied. Consequently, these stitches are placed 2 mm above the annulus, in a continuity (8). At the level of the commissures, each suture is passed out of the aorta and tied (with or without pledget) with the suture coming from the adjacent sinus (9-11) (*Figure 1*). The supra-annular implantation provides a greater effective orifice area index

for a given valve size. The strictly supra-annular create a new annulus which is difficult be identified.

The chosen imaging method, in order to evaluate the results of the operation, was computed tomography (CT) scanning (64-slice MDCT, Brilliance, Philips). The study consisted of a thin sliced contrast electrocardiograph (ECG) gated chest CT (1 systolic-1 diastolic cardiac phase), trying to simulate the required assessment of aortic root the evaluation of radiopaque placed markers (6,7,12-17) (*Figures 2-4*).

As there was no randomization, no new treatment being explored and no potential harm to the patients there was no need for ethical approval by the ethics committee of “Evangelismos” General Hospital of Athens, Greece. However, researchers received patient consent after being informed about the type, the purpose of the study and the right to refuse to participate or to withdraw consent to participate any time without reprisal.

Results

SAVR with a bioprosthesis can be performed using either a stented or a stentless or a sutureless valve (3,6,7,13,14).

Stented valves are most of the time constructed using a radiopaque base ring stent frame from which three stent posts arises at a right angle to support the valve leaflets, which serve as perfect markers for positioning of transcatheter valves. There are constructed from porcine or bovine pericardial tissue (*Figure 5*).

Sutureless valves are self-expandable frame valves, maintained *in situ* by the radial force of its stent, no sutures required. Stentless valves are most often constructed from porcine or bovine pericardial tissue or human aortic root tissue, lack a rigid scaffold, and have no radiopaque components (*Figures 5,6*).

In patients with aortic stenosis, bioprosthetic valves are increasingly used while they are often preferred over mechanical valves, as they do not need long-term anticoagulation with associated risks of bleeding and thromboembolism (1,3). Many surgeons are preferring using stentless valves, as they offer an easier and smarter implantable technique, providing superior hemodynamic performance due to the absence of a suture stent-ring and therefore no obstructions to blood flow.

But bioprostheses are also presenting limitations, and the most important one, is their time-related degeneration and structural failure, potentially resulting in either valve stenosis, or regurgitation or combination of both (3,4). This dysfunction can be the result of calcifications

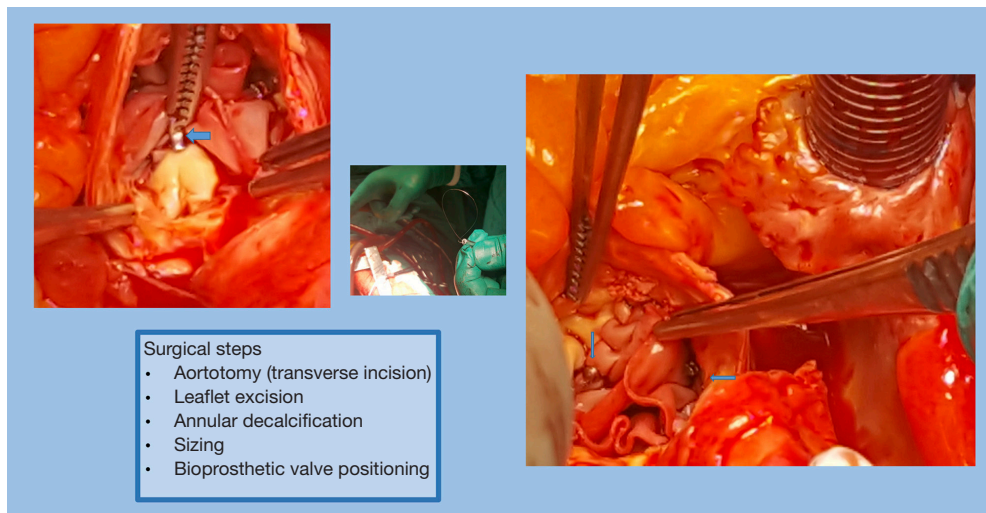


Figure 1 A single suture (blue arrow) was placed at the annulus below the left and right coronary ostia and an additional suture in the nadir of the non-coronary sinus of the new annulus. Placing them at this location can help avoid a potential damage caused to prosthetic leaflet tissue (such as a possible perforation).

Steps in evaluation process for Tav-in-Sav

CT examinations have been performed using a 64-slice MDCT (Brilliance, Philips). Each study consisted of a thin sliced Contrast ECG gated chest CT, from above the clavicles to diaphragm (1 systolic and 1 diastolic cardiac phase) followed by a non- ECG gated CT angiography from diaphragm.

- A) Confirm the type and size of surgical bioprosthetic aortic valve (it is crucial as stented or stentless valves are requiring a different approach and also will help individualize the size of the prosthesis.)
- B) Determine real internal diameter of surgical aortic valve (SAV)
- C) Measurements
Instead of measuring the native annulus, measure:
 - the inside diameter of stented SAV inflow
 - the inside diameter of stentless SAV outflow
 - the distance between left and right ostia and the valves posts and their difference in height (if it is a stented bioprosthetic valve)
 - height and diameter of Valsalva sinus
 - diameter of sinotubular junction
 - diameter of aorta, subclavian, iliac and femoral arteries and evaluation of severe vessel angulation, severe atheromatosis, aneurysms or dissection (in order to decide the most properly access point)

Figure 2 Steps in CT evaluation process for patient's eligibility assessment for TAV-in-SAV valve-in-valve procedure (6,7,14-16). TAV-in-SAV, transcatheter aortic valve-in-surgical aortic valve.

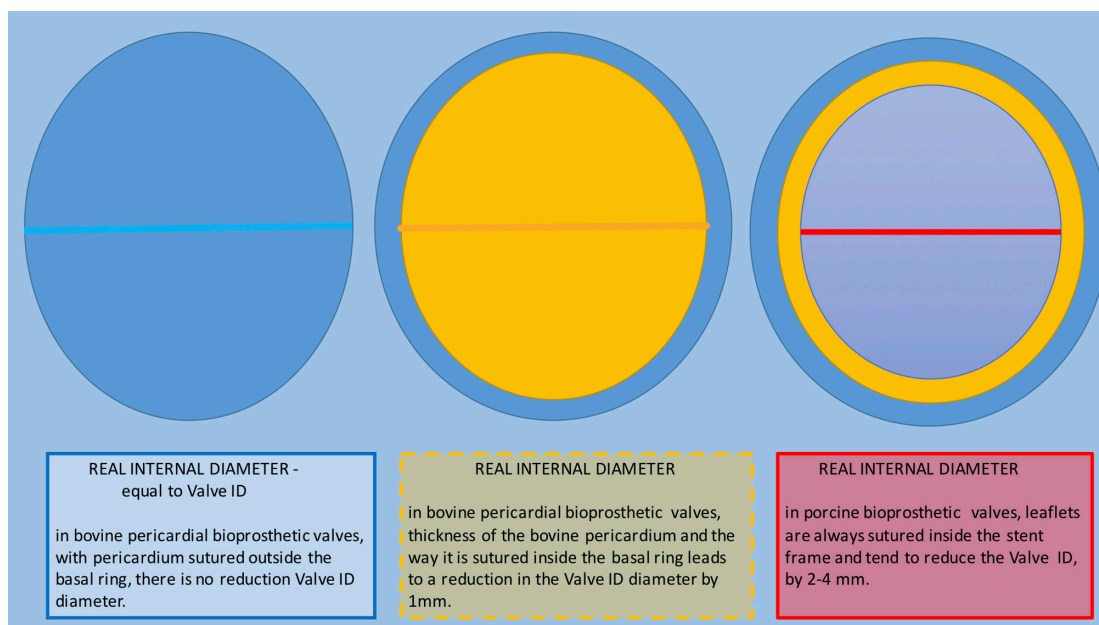


Figure 3 Bioprosthetic aortic valve real internal diameter. Most manufacturer’s label size, corresponds to the outer base ring diameter, which matches the annular measurements made by the implanting surgeon using sizing tools. Although there is variability between various manufacturers, the real internal diameter, which is the most relevant measure during TAV-in-SAV valve-in-valve procedures, is always smaller than the labelled size (6,12-14). TAV-in-SAV, transcatheter aortic valve-in-surgical aortic valve.

TAV - IN - SAV

Contraindications

- Small sized bioprosthetic valves (19mm, 21mm) are presenting treatment limitations, as may yield higher residual gradients and should be avoided. (6,13,17)
- Implanting bioprosthesis in a degenerated SAV should be avoided if there is significant concomitant perivalvular leak (between the prosthesis and the native annulus). (1,12)
- Patients with endocarditis or thrombosis are not candidates for a transcatheter procedure. (17)
- Bulky calcifications and pannus are increasing the risk for coronary occlusion as they may decrease the space between the displaced SAV leaflets and the coronary artery orifices. (4)
- Pre-implant balloon aortic valvuloplasty, within degenerated bioprostheses, is not indicated as may cause friable material, and higher risk for embolization. (4) So use no, or with great cautious, balloon predilation when there is predominant stenosis/ or completely avoid predilation when there is predominant regurgitation. (1)

Practical tips

- Consider rapid pacing to reduce cardiac output and stabilize the positioning of the transcatheter valve, in patients with degenerated aortic valve bioprosthesis and aortic regurgitation. (6)
- Examine where the site of coronary ostia are located. When they are located above the level of tips of the SAV posts, they are not at risk for occlusion. (4)
- There is also reduced risk in the setting of complete surgical coronary revascularization, as coronary flow is not reliant on the patency of the coronary ostia. (4)
- Choose a transcatheter heart valve that is slightly larger than the internal diameter of the bioprosthesis. (1,12)
- There are challenges in correct TAVI deployment in stentless valves, so use careful steps while implanting with contrast injection and slow deployment (some guide wire tricks can be used, such as positioning of a wire in LM) (14)

Risk Factors for Coronary Obstruction

- Low height of coronary ostia/ sinus
- Narrow sinotubular junction / Valsalva sinuses
- Characteristics of previous heart surgery (ex. root reconstruction)
- Bulky leaflets calcifications
- Bioprosthetic valve factors: post height, leaflet height, and position of the valves within the aortic root (supra-annular position, instead of intra-annular position).

Figure 4 Contraindications. Risk factors for coronary obstruction. Practical tips TAV-in-SAV valve-in-valve procedure (1,4,6,12-14,17). TAV-in-SAV, transcatheter aortic valve-in-surgical aortic valve.

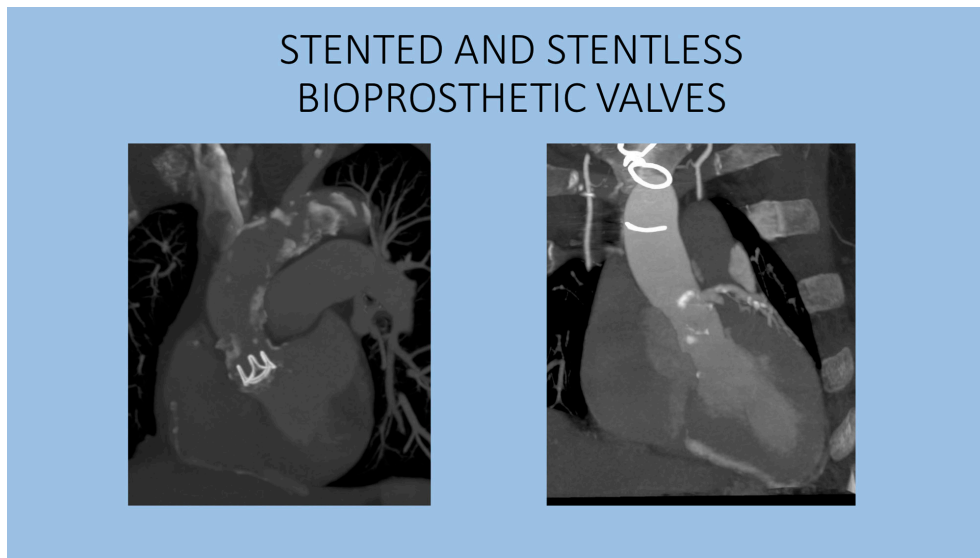


Figure 5 Stented bioprosthetic aortic valve, with radiopaque stent base ring and radiopaque stent posts (white shape outline). Stentless bioprosthetic aortic valve, with no radiopaque markers (black shape outline).

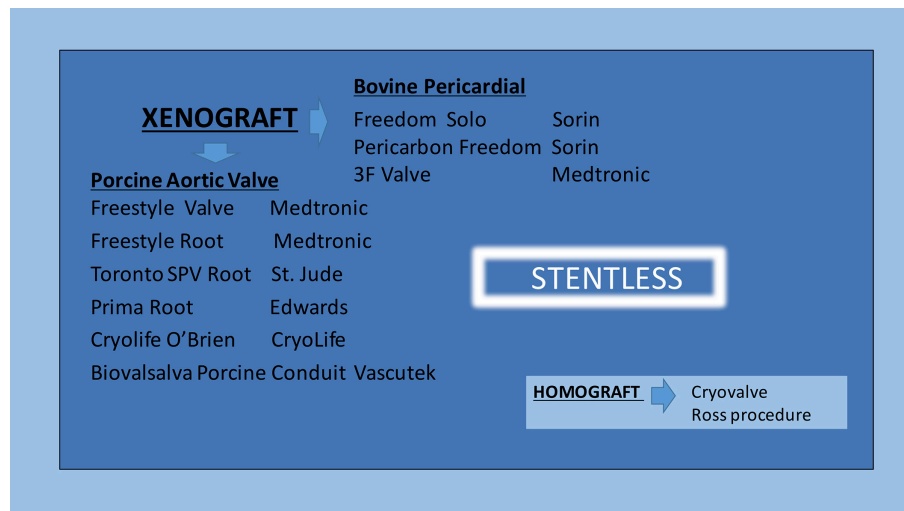


Figure 6 Table of stentless bioprosthetic aortic valves.

or pannus formation, thrombosis, leaflet wear and tear, and endocarditis (6). However, a “redo” surgery can be associated with substantial mortality and morbidity, particularly in elderly patients and those with significant comorbidities. A transcatheter aortic valve implantation (TAVI) in a SAVR has emerged as a less-invasive alternative (TAV-in-SAV) to conventional redo surgery for bioprosthetic valve dysfunction (3,12).

Although several technical difficulties have been

associated with TAV-in-SAV in a degenerate stentless bioprostheses, notably the absence of radiopaque landmarks from a stent frame or sewing ring and the use of various implantation techniques among surgical operators, presenting the greatest challenge as it may impact the relationship of the prosthetic annulus to the coronary ostia (18), increasing the risk of complications such as coronary obstruction device migration and embolization (13). In order to overcome the challenges in correct TAVI

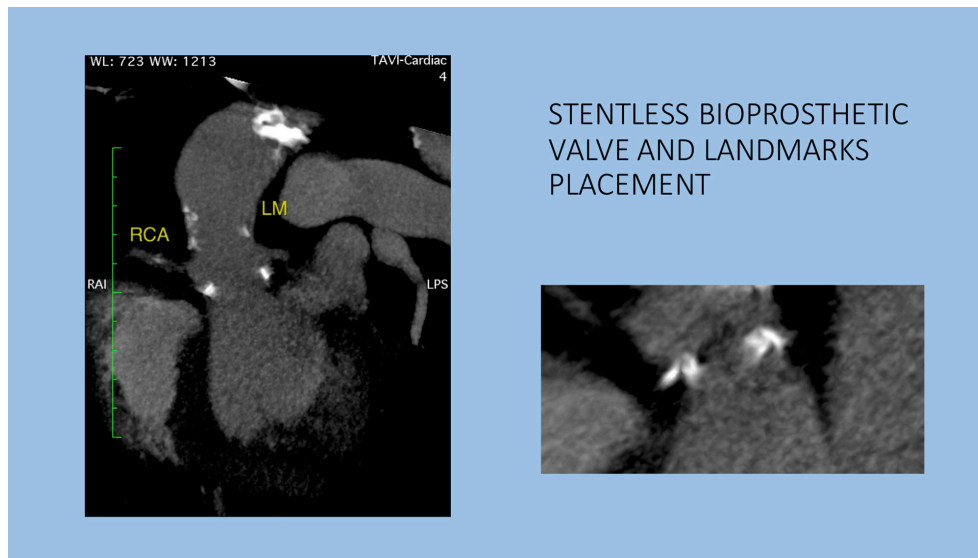


Figure 7 Preventive implantation of three metallic vascular clips marking the aortic annulus. TAVI, transcatheter aortic valve implantation; RAI, right anterior inferior; RCA, right coronary artery; LM, left main (coronary artery); LPS, left posterior superior.

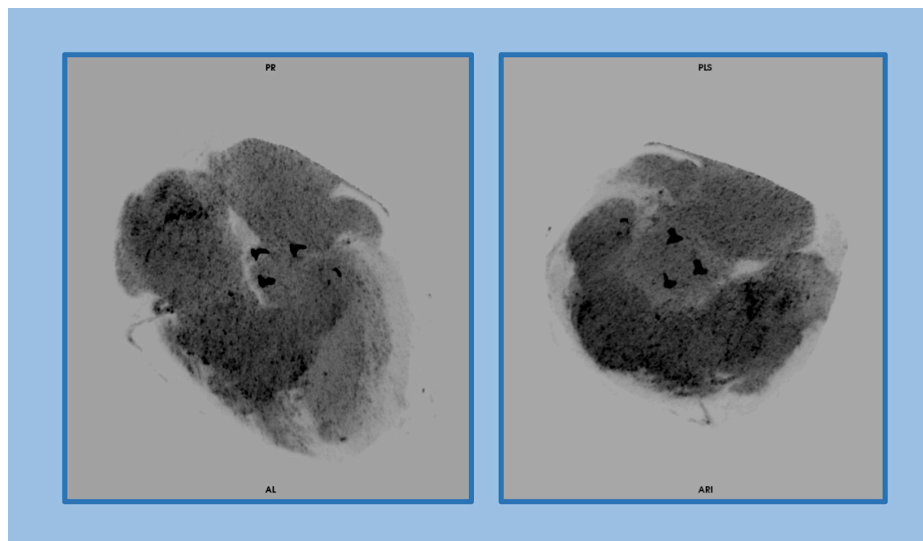


Figure 8 Preventive implantation of three metallic vascular clips marking the aortic annulus. AL, anterior left; ARI, anterior right inferior; PR, posterior right; PLS, posterior left superior.

deployment in stentless valves, careful steps with contrast injection and slow deployment or some guide wire tricks such as positioning of a wire in left main coronary artery (14) or a mainly guided by transoesophageal echocardiography procedure, have been proposed.

The preventive implantation of metallic vascular clips marking the aortic annulus during the operation in order to

have some useful radiopaque landmarks, is a great assistance promoting better orientation and correct identification of the position of the bioprosthetic valve. The postoperative computed tomographic scan depicted the annular plane by the Titan clips. It was sufficient to mark it by placing three clips additional to the running suture at evenly distributed locations (*Figures 7-9*).

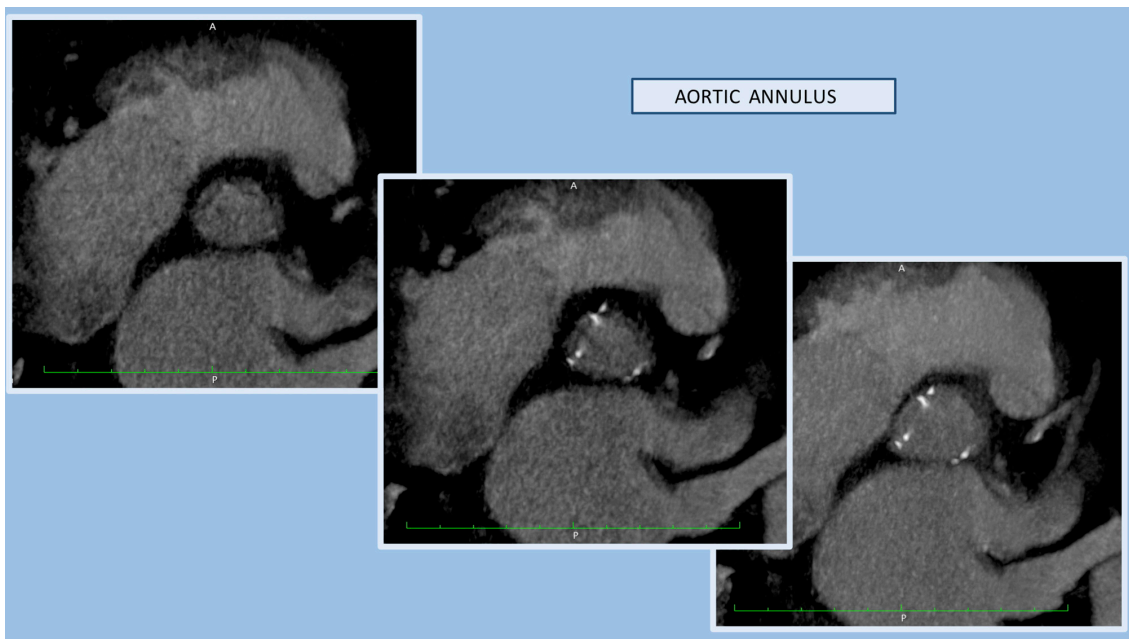


Figure 9 Preventive implantation of three metallic vascular clips marking the aortic annulus.

Conclusions

We are suggesting the preventive implantation of radiopaque landmarks, during SAVRs, using tissue valves which are lacking fixed anatomic markers, as a guide for a presumptive TAV-in-SAV procedure, keeping in mind that appropriate imaging guidance is crucial and can prevent valve misplacement, coronary obstruction and other potentially lethal complications.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: As there was no randomization, no new treatment being explored and no potential harm to the patients there was no need for ethical approval by the ethics committee of “Evangelismos” General Hospital of Athens, Greece. However, researchers received patient consent after being informed about the type, the purpose of the study and the right to refuse to participate or to withdraw consent to

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