Transcatheter heart valve implantation for failing surgical bioprostheses: technical considerations and evidence for valve-in-valve procedures

Mylotte D, Lange R, Martucci G, Piazza N.

Transcatheter aortic valve implantation (TAVI) represents a novel technology for treating patients with severe symptomatic calcific aortic stenosis at high or prohibitive surgical risk. In patients at excessive surgical risk, TAVI substantially reduces mortality compared to medical treatment, and in high risk cohorts provides similar safety and efficacy to surgical aortic valve (SAV) replacement.

More recently, the remit of transcatheter heart valve (THV) technology has been expanded beyond that initially conceived: patients at lower surgical risk are being treated despite a lack of evidence in this patient population; and novel implantation techniques, such as the transaortic approach, have been developed. Perhaps the most notable adaptation of this technology is the treatment of patients with failing surgical bioprosthetic valves. In 2007, Wenaweser and colleagues reported the implantation of a Medtronic CoreValve (Medtronic CV, Luxembourg S.a.r.l.) into a degenerated surgical aortic bioprosthesis. Since this first case, numerous transcatheter aortic valve in surgical aortic valve (TAV-in-SAV) procedures have been performed, and experienced physicians are adapting current THVs for treatment of failing surgical atrioventricular and pulmonary bioprostheses.

**DESIGN CHARACTERISTICS OF SURGICAL BIOPROSTHESIS**

Successful valve-in-valve (VIV) procedures are dependent on a thorough understanding of the design characteristics and failure modes of surgical bioprosthetic valves. Surgical bioprostheses are constructed as either stented or stentless valves, while the valve leaflets are of xenograft (porcine aortic valve or bovine pericardium) or homograft origin.

**STENTED VALVES**

Stented valves usually consist of a base ring covered by a fabric sewing cuff from which a stent or frame arises to support the valve leaflets. The base ring may be circular or scalloped and is constructed from a variety of metal alloys or plastics. The stent frame is designed to reduce the loading stress of repeated valve closure on the tissue leaflets, and is composed of metallic or plastic materials. The base ring and/or frame are usually exteriorised by pericardium or another material that acts as an anchoring suture cuff.

Surgical valve sizing is performed intraoperatively using specific sizing tools, and may be affected by several factors including operator experience and the degree of leaflet resection or annular decalcification performed. The inner base ring diameter greatly influences the postoperative transvalvular gradient, while the outer suture ring diameter determines the maximum size of the valve chosen for implantation. Optimisation of these diameters can be achieved by implanting the valve above the native annulus, as the aortic sinuses can...
accommodate the bulky sewing cuff. Therefore, supra-annular implantation affords a larger inner base ring diameter for a given patient. Second and third generation valves, such as the Medtronic Mosaic (Medtronic Inc, Minneapolis, Minnesota, USA), Carpentier-Edwards (CE) Magna (Edwards Lifesciences Inc, Irvine, California, USA), and Sorin Soprano (Sorin Group, Milan, Italy), are designed for supra-annular implantation.

It is of particular importance to note that the manufacturer’s labelled valve size does not correspond to the inner base ring diameter. Manufacturers can provide the inner stent diameter for a given labelled valve size. Of note, pannus and calcification can lead to a discrepancy between observed and expected inner stent diameters obtained by echocardiography/multislice CT and manufacturers, respectively.

**STENTLESS VALVES**

Stentless valves may be of autograft, homograft (a genetically non-identical donor of the same species), or xenograft origin (another species) (figure 1). These valves do not have a base ring or the stent/frame support for the leaflets, but may have a thin basal strip of fabric to cover
the inflow tract and enable suturing of the valve into the site of the excised native valve. These valves are predominately used in the aortic position, as stentless mitral valves have found little clinical utility due to difficulty in insertion and poor durability. Stentless valves were designed to improve important in small aortic roots. To date, clinical postimplantation transvalvular gradients and flow characteristics compared to stented valves. Theoretically, these characteristics are particularly studies have not demonstrated superiority of stentless over stented valves, though they have identified extensive aortic root calcification as a potential drawback to stentless valve reoperation. The labelled size of stentless valves typically

Figure 2 Design characteristics of stented bioprosthetic valves. (A) Carpentier-Edwards Perimount bovine pericardial valve. (B) Medtronic Hancock II porcine aortic valve. (C) Sorin Mitroflow bovine pericardial valve. Understanding the dimensions of surgical bioprostheses is of crucial importance to the success of TAV-in-SAV procedures. The nomenclature of these measurements is based on the anatomical construction of the valve (figure 3). The inner base ring diameter (also known as the inner stent diameter) is the distance between the inner surfaces of the base ring. In the context of TAV-in-SAV procedures, this diameter represents the maximum available diameter for TAVI, as the ring is rigid and relatively non-distensible. The outer base ring diameter (outer stent diameter) is the distance between the outer surfaces of the base ring and does not include the thickness of the covering cloth (sewing cuff). The outer sewing ring diameter (external diameter) is the distance between the outer undisturbed sewing cuff surfaces. 
corresponds to the valve's outer diameter, though the inner diameter and height are usually available. The absence of a rigid base ring with these prostheses suggests that they are more compliant than stented valves when performing VIV procedures.

**MECHANISMS OF BIOPROSTHETIC VALVE FAILURE**

Compared to mechanical surgical valves, bioprosthetic valves are more susceptible to time dependant structural failure. The aetiology of bioprosthetic valve dysfunction has been described in detail elsewhere. Valve failure results from malfunction of the leaflets, the supporting structures (base ring or stent/frame), or both, and can be influenced by the design features of the valve (physical and biochemical), host metabolic pathways, and the mechanical loading stress exerted on the valve. Durability of bioprosthetic valves results from resistance to structural failure in response to repetitive cycling and resistance to calcification over time, particularly in young patients. In most cases, valve failure can be attributed to wear and tear, leaflet calcification, pannus formation, in situ thrombosis, or infective endocarditis.

Leaflet tissue deterioration is the most common aetiology of bioprosthetic valve failure. Leaflet dysfunction is commonly precipitated by calcium deposition, which tends to occur at sites of greatest leaflet flexion and stress: the basal and commissural attachment points. All bioprosthetic valves undergo glutaraldehyde fixation which promotes leaflet durability by enhancing collagen cross-linking and renders the heterograft biologically inert. However, residual glutaraldehyde can promote calcium phosphate deposition and upregulate graft
and host pro-inflammatory pathways. Anticalcification processes (eg, Edwards ThermaFix, Medtronic AOA) reduce calcium binding and improve leaflet longevity.

The development of inflammatory tissue, rich in fibroblasts, at the host–graft interface is known as pannus. Most valves exhibit some evidence of pannus; however, marked pannus formation can induce valve dysfunction if it extends and fixes the leaflet cusps. Valve thrombosis and endocarditis are uncommon causes of valve failure.

**BIOPROSTHESSES FAILURE: AN EMERGING CLINICAL PROBLEM?**

Recent trends suggest that the relative use of surgical bioprosthetic valves has increased substantially in the last decade. The advantage of surgical bioprosthetic valves over mechanical alternatives is the avoidance of long term anticoagulation, and therefore the associated risk of bleeding. In contrast, the requirement for reoperation is greater with bioprosthetic valves. Bioprosthetic valves have therefore traditionally been used in elderly patients, where the risk of bleeding is greatest, and where the life expectancy of the bioprosthesis is expected to exceed that of the patient. However, recent preclinical and clinical studies suggest reducing the age cutoff for bioprosthetic aortic valves from 65 to 60 years. The actuarial freedom from reoperation for a degenerated bioprosthetic valve is approximately 95%, 90%, and 70% at 5, 10, and 15 years, respectively. Therefore, as the population ages and a greater proportion of younger patients are treated with bioprosthetic valves, we can expect to encounter a growing number of patients with degenerated surgical bioprostheses requiring reoperation.

Important comorbid conditions such as diabetes mellitus, renal impairment, congestive heart failure, pulmonary hypertension, and coronary and peripheral vascular disease are more common in redo cohorts. Nevertheless, the mortality risk associated with redo valve surgery has decreased over the last number of decades. Operative mortality for an elective redo aortic valve surgery ranges from 2–7% and can be comparable to the primary valve surgery in low risk cases. In contrast, mortality can be as high as 30% in high risk and non-elective patients. Redo valve surgery can also be associated with significant morbidity including blood transfusion, and delayed wound healing, mobilisation, and hospital discharge.

**TAV-IN-SAV PROCEDURES**

In selected cases, where the risk of redo surgery for a failing surgical bioprosthesis is deemed excessive by a dedicated heart team, TAV-in-SAV procedures offer a less invasive and potentially safer alternative to conventional surgery. As with TAVI for native aortic valve stenosis, patient selection is critical to the success of these procedures, and therefore the involvement of a team of interventional cardiologists, cardiac surgeons, cardiac anaesthetists, and imaging
specialists is essential. Currently, three THVs have been successfully implanted into failing bioprostheses: the Edwards Sapien/XT valve, the Medtronic CoreValve, and the Medtronic Melody valve.

**PRECLINICAL STUDIES**

Several important preclinical investigations have been undertaken to test the very concept of TAV-in-SAV procedures. Boudjemline et al reported the first successful VIV experience, having implanted a bovine jugular valve inside a surgically sited Medtronic Mosaic mitral valve in a sheep model. Subsequently, successful transapical implantation of the commercial Edwards Sapien THV inside CE porcine aortic and mitral valves was demonstrated in pigs.

**CLINICAL EXPERIENCE TAV-IN-SAV**

First performed in 2007, TAV-in-SAV procedures represent innovative adaptation of TAVI technology. In the aortic position, TAVI has been performed within both stented and stentless surgical bioprosthetic valves. The Edwards Sapien/XT valve has been implanted using transfemoral, transapical and transaxillary approaches (figure 4). The transapical approach was initially the preferred strategy using the Edwards Sapien/XT valve, as greater stability and coaxial implantation of the THV was achieved, though transfemoral procedures are becoming more common. Medtronic CoreValve TAV-in-SAV procedures are performed via transfemoral, transaxillary, and direct transaortic approaches (figure 5).

Overall, results from small case series of high postprocedural gradients. Intuitively, valve underexpansion should also adversely affect leaflet and stent durability. In contrast, the rigid base ring of a stented valve may provide the necessary platform to produce a nearly circular TAVI that allows for optimal leaflet geometry and durability. The largest TAV-in-SAV series published to date has TAV-in-SAV procedures in high risk patients suggest an acceptable short term safety profile (75–100% 30 day survival). Similar outcomes have been reported following TAV-in-SAV for stented and stentless (homograft and xenograft) valves; however, insufficient data are available to compare outcomes from these different valve designs. Significant paravalvular aortic regurgitation, which is associated with adverse outcomes in TAVI for de novo aortic stenosis, occurs infrequently in TAV-in-SAV procedures. Importantly, the acute haemodynamic results achieved with TAV-in-SAV procedures are suboptimal (approximately 20 mm Hg) compared to TAVI for de novo aortic valve stenosis (usually 10 mm Hg (see online supplementary table S1)). Thus, longer term follow-up is required to confirm the efficacy of these interventions, particularly if these procedures are to be considered in younger patients. An inability to completely expand the THV inside the rigid base ring
of the SAV may be responsible for these reported 100% technical procedural success, one periprocedural death due to low output cardiac failure, and transvalvular mean gradients ≥20 mm Hg in 44% of patients.\textsuperscript{w10} Mortality at 30 days was 17%.

A specific concern relating to TAV-in-SAV procedures is the risk of ostial coronary occlusion with bioprosthetic valves where tissue is mounted external to the valve frame or in prostheses with no stent frame (stentless valves).\textsuperscript{5} In particular, THV deployment within the Mitroflow valve (Sorin Group, Burnaby, BC, Canada), where the leaflet tissue is mounted externally over the stent, has been associated with ostial left main stem occlusion.\textsuperscript{w27} Anecdotal

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**Figure 4** Edwards Sapien TAV-in-SAV procedure. Transapical implantation of a 23 mm Edwards Sapien TAV inside a 21 mm Medtronic Mosaic bioprosthesis. (A) Fluoroscopic identification of the Medtronic Mosaic valve. (B) Positioning of the Edwards Sapien valve. (C) Deployment of the Edwards SAPIEN valve. (D) Final contrast aortography. Images courtesy of German Heart Centre, Munich.
evidence suggests that supravalvular implantation, a short distance between the coronary ostia and the bioprosthesis, and extensive pannus formation are risks for ostial coronary occlusion.

**TAV in surgical mitral valve**

To date, only the Edwards Sapien/XT valve has been implanted into failing surgical bioprostheses in the mitral position. The Medtronic CoreValve is not suitable for this purpose due to its height. The majority of cases have been performed via the transapical approach, although transvenous transeptal and open direct visualisation transatrial approaches have been described. In the largest series available (n=11), Cheung and colleagues report 100% 30 day survival in a high risk cohort with a mean age of 81 ±5 years, and a mean Society of Thoracic Surgeons (STS) mortality risk score of 16.1%±5.8%. The median postprocedural transvalvular gradient was 7 mm Hg. The narrow range of currently available THV sizes relative to surgical mitral bioprosthetic valves represents an important limitation for TAV in surgical mitral valve (TAV-in-SMV) procedures. Surgical mitral prostheses range from 25–31 mm; however, given that the 29 mm (internal stent diameter 26–28 mm) and 31 mm (internal stent diameter 28–30 mm) valves are the most commonly implanted, the largest Edwards Sapien valve (29 mm) may be unsuitable for use in a number of patients.

**TAV in surgical annuloplasty ring**

Surgical mitral valve repair using an annuloplasty ring is frequently performed in patients with severe mitral regurgitation (MR). In patients with ischaemic MR, undersizing of the annuloplasty ring can result in recurrent MR in a significant proportion of patients. Animal experiments have demonstrated the feasibility of TAV in surgical annuloplasty ring (TAV-in-SAR) procedures using the Edwards Sapien/XT valve or the Melody valve. Successful transapical TAV-in-SAR procedures have also been performed in high risk patients using the Edwards Sapien/XT valve.
TAV in surgical tricuspid valve

Both the Edwards Sapien/XT \(^{4,8}\) and Medtronic Melody \(^{32}\) THVs have been successfully implanted into failing bioprostheses in the tricuspid position. Percutaneous transvenous access using the femoral, subclavian, and jugular veins, and open direct visualisation transatrial approaches, have been described. The largest reported series (n=15) reported significant reductions in transvalvular gradients (12.9 to 3.9 mm Hg) postimplantation of the Medtronic Melody valve within failing surgical tricuspid bioprostheses, without significant procedural complications.\(^{17}\)

TAV in surgical pulmonary valve

The first VIV procedures related to implantation of the Medtronic Melody valve. This valve was implanted in in the pulmonary position for failing valved conduits that had been used for right ventricular outflow tract reconstruction.\(^{18}\) The first large series using this valve (n=58) demonstrated significant improvement in postoperative transvalvular gradients, right ventricular end-diastolic volume (EDV) and effective stroke volume, and increased left ventricular EDV.\(^{18}\) No significant procedural complications or 30 day mortality was reported. The Edwards Sapien/XT valve has also been used in this position with promising short and medium term (median 22.5 months) results.\(^{15}\)

TAV-IN-SAV: TECHNICAL CONSIDERATIONS

Transcatheter valve sizing

Details of the primary valve surgery, including the type and size of prosthesis used, the site of implantation (annular or supra-annular), and the degree of aortic root calcification are crucial to the success of TAV-in-SAV procedures. Reference tables are available for consultation if the inner base ring diameter of the bioprosthesis is not listed.\(^{10}\) However, the availability of these details does not diminish the key role of multimodal imaging in THV size selection. Multidetector CT and transoesophageal and transthoracic echocardiography should be used to establish the mode of bioprosthesis failure, and to determine the presence of severe calcification or pannus formation that could result in a discrepancy in the manufacturer listed inner base ring diameter. The presence of valve thrombosis or infective endocarditis is a contraindication for VIV procedures.

Much debate surrounds the choice of imaging modality for optimal measurement of the non-circular aortic valve annulus and THV sizing. Transoesophageal echocardiography is the most practical and frequently used modality; however, two dimensional measurements of the three dimensional aortic annulus can lead to underestimation of the true dimensions of the annulus.\(^{33}\) This may result in valve undersizing and increase the risk of paravalvular aortic regurgitation.\(^{34}\) Multidetector CT reconstruction of the annulus orthogonal to the centre
axis of the left ventricular outflow tract allows for the assessment of minimal and maximal
diameter, circumference, and area measurements. As such, multidetector CT is becoming the
default imaging modality to assess aortic annular dimensions.

In the setting of native aortic valve stenosis, TAVIs are oversized relative to the annulus di-
ameter by 10–30%. Oversizing creates enough interference between the bioprosthesis and the
aortic valvar complex to ensure adequate anchoring and sealing. It is not known if sizing rules
should differ for TAV-in-SAV cases, or indeed if they should differ between non-distensible
stented valves and somewhat distensible stentless valves. The authors continue to advocate
manufacturer based sizing principles in the absence of any firm evidence. Other investigators
have suggested that the TAVI external diameter does not necessarily have to be larger than the
bioprosthesis internal diameter and can even match the internal diameter.7

One important preclinical study using a pulse generator evaluated the haemodynamic
consequences of implanting a 23 mm TAVI within degenerated small sized CE Perimount
bioprostheses (19, 12, and 23 mm).w23 In all cases, the rigid base ring and stent posts prevented
complete expansion of the THV. Postimplantation transvalvular gradients were significantly
reduced in the 23 mm and 21 mm bioprostheses; however, there was no improvement within
the 19 mm Perimount bioprosthesis, which also demonstrated considerable central aortic
regurgitation. More recently, preliminary data suggest that the balloon expandable Edwards
Sapien/XT valve may yield greater postoperative transvalvular gradients in small surgical
bioprostheses (<20 mm) than the self-expanding thinner strut Medtronic CoreValve.w35 The
difference in postoperative gradients is probably a reflection of the intra-annular versus supra-
annular leaflet location of the Edwards Sapien/XT versus Medtronic CoreValve prosthesis.

The predilatation conundrum
Balloon aortic valvuloplasty (BAV) is routinely performed before TAVI in native aortic valve
stenosis. The rationale for aortic valve predilatation includes improving the annular seating
space and assisting maximal THV expansion. In TAV-in-SAV procedures, practice patterns
are more heterogeneous. The clinical utility of dilating a non-distensible stented valve can
be debated. Where severe calcification is the mode of failure, there is probably some merit
in performing preimplantation predilatation; however, this may increase the risk of annulus
rupture in stentless valves, or the risk of embolisation of friable material. In light of these
potential risks, most experienced operators avoid preimplantation BAV unless deemed an
absolute necessity (see online supplementary table S1). The American College of Cardiol-
ogy/American Heart Association and European Society of Cardiology valvular heart disease
guidelines contraindicate percutaneous balloon interventions in the treatment of stenotic
aortic bioprostheses, and so routine preimplantation BAV is not recommended for VIV
procedures.
Surgical bioprosthetic valve recognition

Stented surgical bioprostheses can be recognised by identifying the radiopaque components of the base ring and/or stent on fluoroscopy (figure 6). If the base ring is metallic, one should assess its shape (circular, boat, or scallop shaped) and ascertain if it is open or closed. If the stent/frame is radiopaque, assess its design, shape and the angle it arises from the base ring. In some cases, the stent/frame is radiolucent except for circular eyelets near the apices (Medtronic Hancock II or Mosaic prosthesis). Stentless valves are not radiopaque and cannot be identified in the catheterisation laboratory; calcification of the prosthesis, if present, may provide anatomical landmarks for valve positioning.

**Figure 6** Fluoroscopic identification of stented surgical bioprostheses. (A) The Carpentier-Edwards (CE) Porcine Standard valve has a radiopaque wire that outlines the stent posts (U shaped loops) and the base ring. (B) The CE Porcine Supra-Annular Valve is similar to the CE Porcine Standard valve (A) except that it has less defined transition angles between the base ring and stent posts. (C) The CE Pericardial valve has a flattened radiopaque base ring with three holes, and a narrow wire that outlines the three stent posts and the base ring. (D) The Medtronic Mosaic valve has radiopaque metal eyelets only. (E) The Hancock standard valve has a radiopaque Haynes alloy flat base ring. (F) The Ionescu-Shiley low profile valve has three narrow wire arcs separated by radiolucent areas. Figures 6A–E are reprinted, with permission, from Mehlman et al.

THV positioning

As with TAVI for native aortic valve stenosis, implant positioning is crucial to procedural success. If radiopaque, the surgical bioprosthesis offers stable markers for positioning the TAV (figure 4). If radiolucent, THV positioning is performed in the usual fashion using aortic an-
giography, transoesophageal echocardiography, a pigtail catheter lying in the base of the prosthetic leaflets, and/or identification of calcific spots. The fluoroscopic viewing angle should be perpendicular to the base ring, or selected in the usual fashion using contrast angiography. If possible, the THV should be coaxial within and lie 3–4 mm below the base ring of the surgical prosthesis. Transapical implantation may offer superior coaxial alignment than retrograde access; however, both access routes have been associated with acceptable procedural success rates.4 7

Significant aortic regurgitation, a common occurrence with degenerated bioprosthetic valves, may compromise the stability of the THV during implantation and increase the risk of valve embolisation.4 In such cases, rapid pacing is advised to reduce cardiac output and stabilise the position of the THV. Postimplant dilation may be required in cases of significant paravalvular aortic regurgitation or underexpansion of the prosthesis associated with elevated transvalvular gradients.

FUTURE PERSPECTIVES: CHALLENGES AND OPPORTUNITIES

To date, the published results of VIV procedures have been encouraging, and advocate the continued development of this innovative adaptation of THV technology. However, there remain important knowledge gaps that must be addressed: patient selection criteria; VIV sizing criteria; understanding the clinical impact of elevated transvalvular gradients; potential galvanic (metal-on-metal) corrosion; the potential for THV thrombosis following VIV procedures; and durability issues. Dedicated prospective trials are required to further our understanding of these procedures and are currently being considered by the THV manufacturers in order to secure expanded clinical indications for their products.

Although in their infancy, VIV procedures have the potential to revolutionise the manner in which we treat valvular heart disease. Less invasive and perhaps safer redo procedures may mitigate against the upfront use of metallic surgical valves and their associated requirement for anticoagulation. Indeed, anecdotal evidence suggests that in specific cases, cardiac surgeons are already applying a strategy of implanting a bioprosthetic surgical valve for patients <60 years old, with the intention of performing a subsequent VIV procedure if required. This strategy, although appealing on many fronts, requires further study. Undoubtedly, the future of VIV procedures lies in the development of customised surgical bioprosthesis and/or dedicated VIV transcatheter aortic, mitral, and pulmonary valves. The unrelenting evolution of transcatheter valve technology suggests that this future may soon become a reality.
CONCLUSIONS

An ageing population, longer life expectancy, and increased use of bioprosthetic valves has led to an increase in elderly and high risk patients with degenerated surgical bioprostheses. Transcatheter implantation of commercially available TAVs represents an emerging and potentially advantageous alternative to redo surgery. Indeed, TAV-in-SAV procedures have the potential to become the standard of care for structural valve dysfunction, though large prospective comparisons with long term follow-up are fundamental to the development of the field.

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Transcatheter heart valve implantation for failing surgical prostheses: key points

- A thorough understanding of the design characteristics of bioprosthetic surgical aortic valves is crucial for the success of transcatheter aortic valve in surgical aortic valve (TAV-in-SAV) procedures.
- Stented valves consist of a base ring covered by a fabric sewing cuff from which a stent or frame arises to support the valve leaflets.
- The inner base ring diameter (inner stent diameter) is the distance between the inner surfaces of the base ring, and represents the maximum available diameter for TAV implantation.
- Stentless valves do not have a base ring or the stent/frame support for the leaflets, and may be of heterograft, autograft or homograft origin. TAV-in-SAV procedures
- Both the Edwards Sapien/XT and Medtronic CoreValve have been used successfully for TAV-in-SAV procedures.
- Results from small case series suggest TAV-in-SAV implantation is associated with acceptable medium term results with an acceptable safety profile (75–100% 30 day survival).
- Dedicated prospective trials with longer term follow-up are required to confirm the efficacy of TAV-in-SAV procedures. Other valve-in-valve procedures
- The Edwards Sapien/XT transcatheter heart valve has been implanted into failing surgical bioprostheses in the mitral, tricuspid and pulmonary positions with acceptable medium term outcomes.
- The Edwards valve has also been successfully implanted into failing surgical annuloplasty rings in the mitral and tricuspid positions.
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   • A large case series of TAV-in-SAV procedures and review of available literature.


   • A recently published series of transfemoral Edwards Sapien TAV-in-SAV procedures.


    • A comprehensive review of the design and failure modes of SAVs and the procedural steps involved in TAV-in-SAV procedures.


- An important guide to the fluoroscopic identification of bioprosthetic SAVs.