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Přehledový článek | Review article

Aortic valve-in-valve procedures for treatment of failing surgically implanted bioprosthesis

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SOUHRN

Trvanlivost biologických chlopní je omezena na dobu 12–20 let. Degenerativní změny na chlopních vedou buď ke vzniku těžké stenózy (na základě kalcifikace nebo trombózy), nebo regurgitace (na základě strukturálních změn chlopenních cípů, infekční endokarditidy). Protože opakovaná operace je spojena se zvýšeným rizikem, představuje katetrizační implantace aortální chlopně (transcatheter aortic valve implantation, TAVI) rozumné řešení. Při plánování náhrady chlopně metodou „valve-in-valve" (ViV) se nejdříve provede vyšetření zobrazovací metodou „multislice" výpočetní tomografie k určení typu degenerace (kalcifikace nebo destrukce cípu), změření výšky ostia koronární tepny a – hlavně – velikosti chlopně. Dosavadní zkušenosti s náhradou srdeční chlopně metodou ViV se týkají balonkem roztažitelných a samoexpandibilních chlopní. Dlouhodobé výsledky z registrů z reálného světa jsou příznivé. Mezi hlavní problémy patří vysoký reziduální gradient, obstrukce koronární tepny a paravalvulární leak. Výsledky náhrady srdečních chlopní metodou ViV se nejspíše zlepší po zavedení zařízení nové generace.

Keywords:
Biological valve prosthesis failure
Transcatheter aortic valve implantation

ABSTRACT

The durability of bioprosthetic valves is limited to 12–20 years. Valve degeneration results in either severe stenosis (related to calcification and thrombosis) or regurgitation (related to structural leaflet deterioration, infectious endocarditis). The redo surgery is associated with an increased risk, so implantation of transcatheter (TAVI) valve is a reasonable option. Planning of the valve-in-valve procedure consists of imaging using multislice computed tomography which allows the assessment of the type of degeneration (calcification or leaflet destruction), measurement of the height of coronary ostia and most importantly the size of the valve. Current clinical experience with ViV includes balloon-expandable and self-expandable valves. Long-term outcomes in real-life registries are favorable. Key problems are high residual gradient, coronary obstruction and paravalvular leak. Use of new-generation devices will likely improve the outcomes of ViV.

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Degeneration of biological prosthetic valves

Aortic valve stenosis has a major impact on mortality and morbidity of the elderly population, and surgical valve replacement is a standard treatment of severe aortic stenosis (AS). With aging population the number of patients undergoing valve replacement have significantly increased over the course of the past decades [1]. Due to a considerable rise in use of bioprosthetic – as opposed to mechanical – valves implantation related to the concerns of the bleeding risk associated with oral anticoagulation, an increase of patients present with failing bioprosthetic surgical valves facing the prospect of second aortic valve intervention is to be expected [2]. As for the durability of bioprosthetic valves it is limited to 12–20 years, this often inevitable valve malfunction may eventually result in either severe stenosis (related to calcification and thrombosis) or regurgitation (related to structural leaflet deterioration, infectious endocarditis) [1,2].

Treatment options

Reoperation has been the standard treatment for failed tissue heart valves, but this exposes the patient to a significant risk of morbidity and mortality of 3–7%, but in patients with multiple co-morbidities as high as 30% [3]. It has led to an interest in implanting transcatheter aortic valve implantation (TAVI) prostheses within degenerated surgical prostheses to avoid the surgical risk [4]. The emergence of TAVI in recent years, as well as the transcatheter aortic valve-in-valve implantation – the less invasive treatment for failing bioprosthesis – represents a breakthrough in valve therapy across the World. Considered as an alternative to conventional open heart surgery for high surgical risk, it is indications comprise of bio-prosthetic stenosis, regurgitation or both. Valve-in-valve (ViV) implantation provides less surgical trauma, shortens the procedural time and speeds up the post operation recovery.

Preprocedural imaging

In all cases, patients presented with aortic dysfunction referred both for TAVI in the native annulus and transcatheter aortic valve-in-valve implantation are subjected to widely used multislice contrast-enhanced computed tomography (MSCT). In some cases, other imaging techniques such as three-dimensional transesophageal echocardiography (3D TEE) or MRI are preferred, particularly to avoid exposure to contrast media or to evaluate the function of the prosthetic valve. The assessment of anatomy and aortic valve function coupled with the evaluation of transfemoral approach feasibility (iliofemoral arteries measurements, tortuosity, degree of calcification) (Fig.1 A–B) constitute an integral part of the preliminary strategy, which leads to the most appropriate choice of vascular access and – given other patient's clinical data – rational device selection. Considering the significant presence of coronary artery disease (CAD) among patients with severe aortic stenosis, they are routinely subjected to invasive coronary angiography.

The important issue in ViV planning is the detailed knowledge of the type, design, and size of the surgical bioprosthesis, in particular when considering multiple valves on the market. In general, the bioprosthetic valves can be divided into two categories (stented and stentless) based on the presence of rigid stent into which the

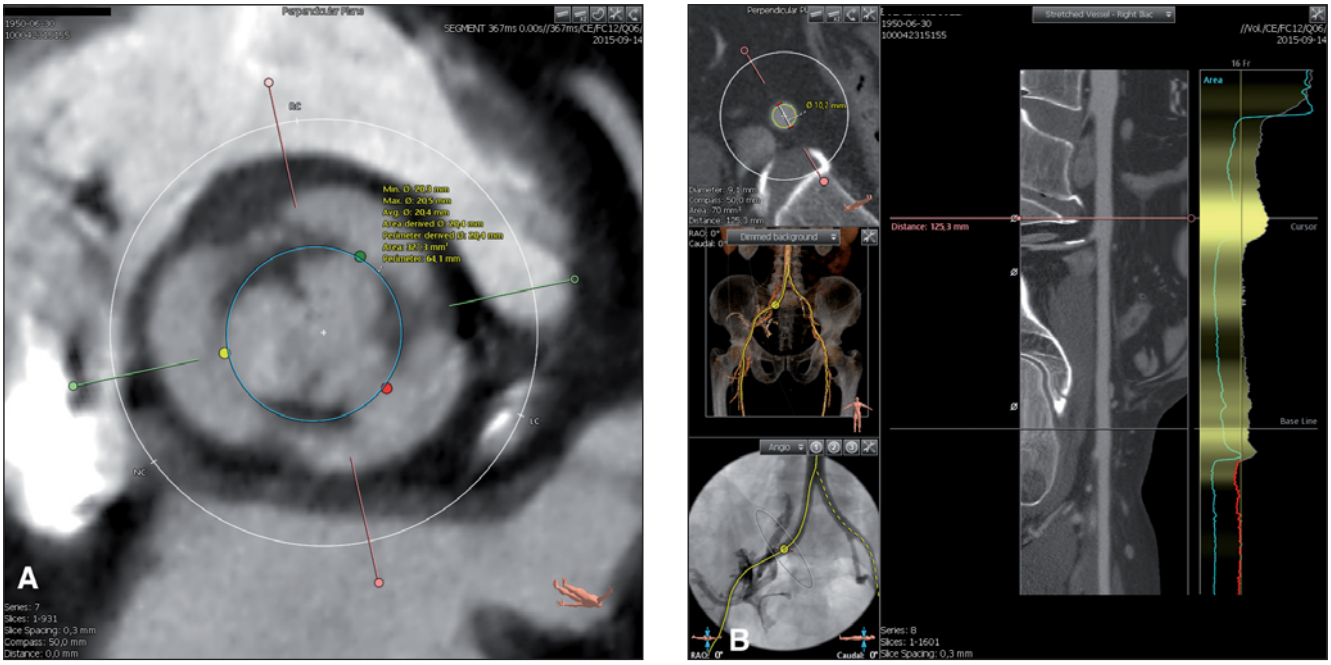


Fig. 1 – (A) Computed tomography three-dimensional multi-slice reconstruction showing aortic root measurements. (B) Computed tomography three-dimensional multi-slice reconstruction showing femoral approach assessment (3Mensio Structural Heart Medical Imaging, Bilthoven, Netherlands).

leaflets are sutured. Also, the radio-opacity of the valves differs about whether the sewing rings or the stent are visible, and some valves are not visible in the X-rays at all. For stentless valves, it is important to know if the valve was replaced subcronary or the full root-replacement surgery was done. In the setting of stentless valve the risk of coronary obstruction increases [3].

Procedural considerations

Valve sizing

The key step of procedural planning is the sizing of the valve. The sizing of the bioprosthetic valves can be obtained from 1) manufacturers specification; 2) inner diameter measurement using MSCT and 3) smartphone application designed by Vinayak Bapat [5].

If the device specification is known it is important to distinguish between the stent inner diameter (ID) and the true inner diameter (ID) which accounts for the insertion of the leaflets. Use of the sizing charts showing stent ID might lead to overestimation of the true ID so the imaging by MSCT provides the most important information. In general surgical valves with porcine leaflets have true ID approximately 2 mm less than stent ID, valves with pericardial leaflets 1 mm less and pro valves with leaflets sutured outside the stent both ID are equal [4]. Also in cases when the type and size of the bioprosthetic valve are unknown the MSCT can reliably measure the inner diameter (ID), but it shows a trend to overestimate by 1–2 mm the true ID of the prosthetic valve (especially valves with external sewing ring), so the imaging requires a standardized approach. The distinct features of the ViV procedures lead to the need for specific guidelines on the systematic use of MSCT in this setting (standardized way of measurement) and the true ID at the inflow of the prosthetic valve remains the most important parameter [6]. Another way to size the prosthetic valve ID is a balloon-based sizing. However, the safety and precision are not well established in this particular indication. Importantly the transesophageal echocardiography provides an alternative way to obtain the ID with good correlation with true ID [7]. In some instances for given sizes of bioprosthetic valves, two sizes of TAVI devices might be appropriate depending on the type of degeneration. In a severe AS related to severe prosthesis calcification the smaller size of TAVI is more appropriate and in the setting of wear and tear degeneration with leaflet destruction and regurgitation larger size will provide a more complete sealing and anchoring. The use of MSCT and/or TOE is crucial for identification of the type of degeneration.

The true ID values for different prosthetic valves were published. Also, the smartphone application (www.ubqo.com/viv) facilitates the ViV procedural planning and provides reliable information of true ID and radiographic images of TAVI devices implanted into bioprostheses.

Valve positioning

Bioprosthetic valves differ in the design (relation of sewing ring, stent, and leaflets) and radioopacity (stented vs. stentless) [3] and the proper positioning is crucial. An operator should familiarize himself with the fluoroscopic appearance of the surgical valve.

To prevent the PVL and valve migration the optimal depth of implantation has to be identified which is more challenging in ViV procedure. The bench testing demonstrated that the narrowest plane or neo-annulus is located at the level of the sewing ring and this position should be used rather than stent frame as the reference position during implantation [8]. The sewing ring can be either intraannular (above the distal margin of the stent) or supra-annular (sewing ring at the level of the base) [8]. The stentless surgical bioprostheses (e.g., Freestyle) lack the fluoroscopic landmarks. In such cases, the slow staged expansion of the valve with contrast injection through the pigtail can facilitate the identification of the implantation plane. Some authors recommend the use of a coronary guidewire in the left main as a marker as well [9].

TAVI devices for ViV

So far no randomized data allow for comparison of different TAVI devices. The data from case series showed feasibility and safety of both generations of TAVI valves. Currently two first generation TAVI devices (Edwards SAPIEN/SAPIEN XT [Edwards Lifesciences, Irvine, CA, USA] and CoreValve Revalving system [Medtronic, Minneapolis, MN]) are CE-marked for ViV indiction; however growing evidence with repositionable second generation systems shows the safety and feasibility. Also, use of the outer sealing, skirts reduced the risk of PVL.

Both bench tests with explanted valves as well as clinical experience showed that implantation of SAPIEN XT within the most frequently used bioprosthetic surgical valves were feasible and safe and provided low risk of migration and excellent hemodynamic profile [10]. Gonska et al. reported the safety and feasibility of second generation SAPIEN 3 (Edwards Lifesciences, Irvine, CA) (S3) device implanted via transfemoral (TF) approach in failing aortic bioprostheses (7 stented and 2 stentless prosthetic valves). Interestingly the authors used balloon predilatation before S3 implantation in all cases without postprocedural stroke/TIA [11]. When S3 device is considered one has to consider the height of the coronary ostia (especially in stentless bioprostheses). Self-expandable CoreValve and more recently Evolut R are used for ViV procedures with low complication rate and excellent hemodynamic results. The advantage of repositionability is that operator can achieve optimal high implantation [12]. Recent publications showed the feasibility of other TAVI devices in the treatment of failing surgical bioprostheses, such as Lotus, JenaValve (JenaValve Technology, Munich, Germany) and Portico (St. Jude Medical, St. Paul, MN, USA) valves [3].

Challenges and complications – data from registries

The largest ongoing Valve-in-Valve International Database (VIVID) Registry enrolling > 1 000 patients treated in 90 centers worldwide reported reassuring data, showing

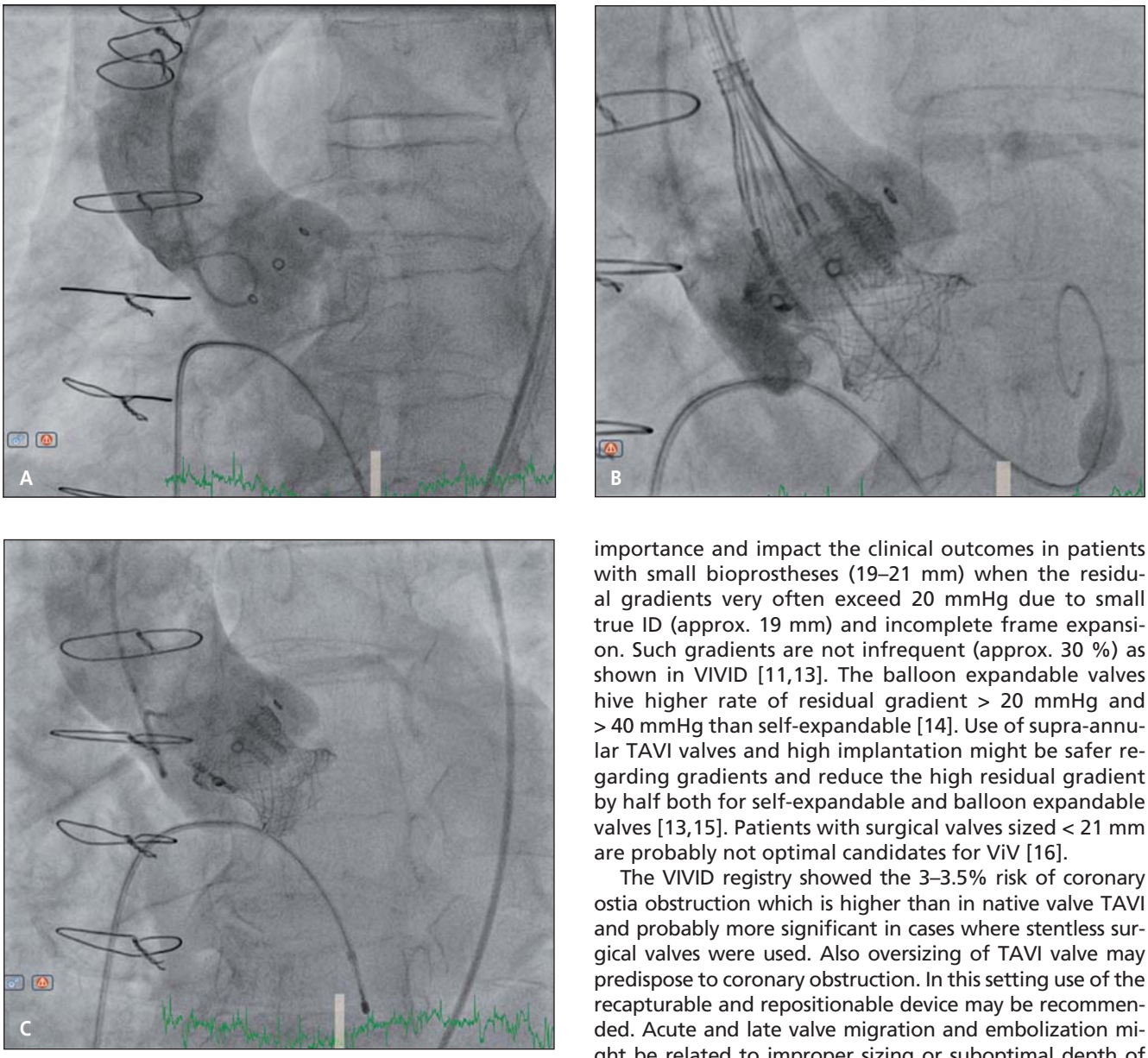


Fig. 2 – Valve-in-valve procedure with Lotus. Fluoroscopic image of aortic root: (A) The image of Mosaic stented bioprosthetic valve. Small fluoroscopic circles are located on the top of the struts. (B) Preimplantation. (C) Fluoroscopic view of deployed 23mm Lotus.

that 459 patients with failing aortic bioprosthesis subjected for ViV, had 30-day and 1-year mortality rates of 7.6% and 16.8%, respectively, with the at least moderate regurgitation in only 5.4% [5].

In addition to well-recognized complications of TAVI in the native aortic valve, ViV has additional challenges: high residual gradient, coronary obstruction, and valve embolization.

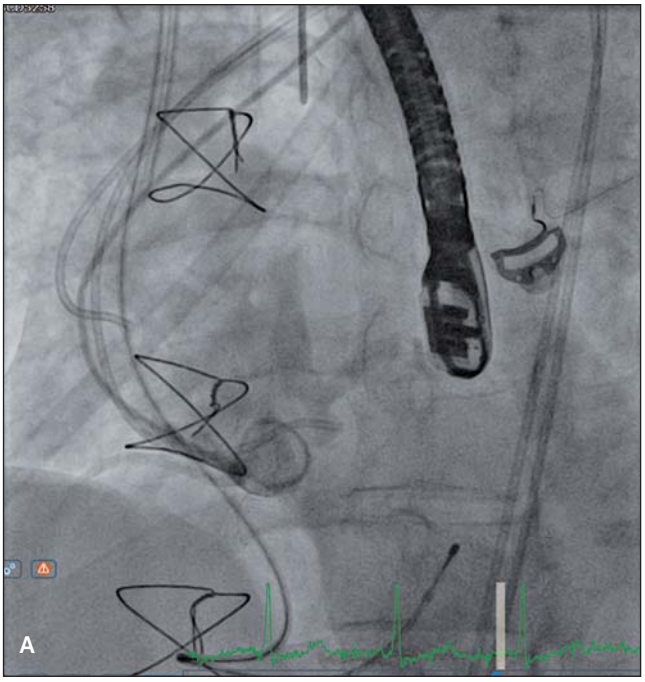
The most significant problem is a high residual gradient. So far most of the ViV procedures lead to a reduction of transvalvular gradient and no significant paravalvular leak (PVL). However in the majority of published cases the residual gradient was higher (10–25 mmHg) than after implantation in the native annulus (5–15 mmHg) even for new-generation devices [11]. I could be of particular importance and impact the clinical outcomes in patients with small bioprostheses (19–21 mm) when the residual gradients very often exceed 20 mmHg due to small true ID (approx. 19 mm) and incomplete frame expansion. Such gradients are not infrequent (approx. 30 %) as shown in VIVID [11,13]. The balloon expandable valves hive higher rate of residual gradient > 20 mmHg and > 40 mmHg than self-expandable [14]. Use of supra-annular TAVI valves and high implantation might be safer regarding gradients and reduce the high residual gradient by half both for self-expandable and balloon expandable valves [13,15]. Patients with surgical valves sized < 21 mm are probably not optimal candidates for ViV [16].

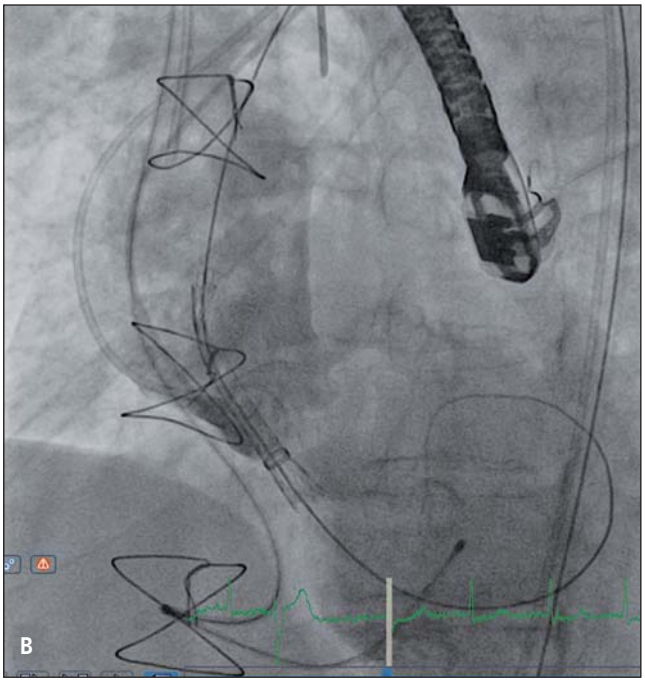
The VIVID registry showed the 3–3.5% risk of coronary ostia obstruction which is higher than in native valve TAVI and probably more significant in cases where stentless surgical valves were used. Also oversizing of TAVI valve may predispose to coronary obstruction. In this setting use of the recapturable and repositionable device may be recommended. Acute and late valve migration and embolization might be related to improper sizing or suboptimal depth of implantation. VIVID registry reported up to 15% of valve malpositioning. Use of new generation devices and advances in procedural planning will probably reduce the risk of valve migration and need of second valve implantation [17].

Examples of different TAVI devices used in treatment of degenerated surgical bioprosthesis

Lotus valve

As one of our patients referred to ViV, a 65-year-old male, previously subjected to coronary artery bypass surgery and aortic valve replacement (Mosaic Medtronic Inc., Minneapolis, Minnesota) was admitted due to dyspnea on slight exertion and mild angina (New York Heart Association grade III, Canadian Cardiovascular Society class II). With suggestive symptoms and transthoracic echocardiography revealing severe aortic valve stenosis (Vmax 4.45m/s; PGmax 79 mmHg; PGmean 58 mmHg), the patient was





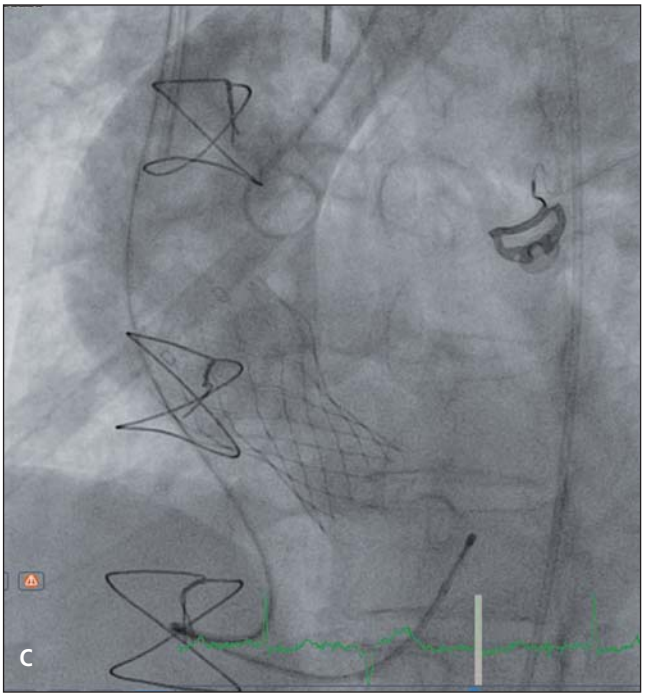


Fig. 3 – Valve-in-valve procedures with Core Valve and Evolut R. Fluoroscopic images of Transcatheter valve-in-valve implantation – CoreValve 23 (Medtronic) in Freestyle aortic root bioprosthesis (Medtronic): (A) Aortic root with transesophageal echocardiography probe. (B) Pre-implantation. (C) Fluoroscopic view of deployed 23 mm CoreValve.

presented to local interdisciplinary heart team. As considered the too high risk for redo-surgery, after agreement the patient was selected for transcatheter valve-in-valve implantation. Coronary angiography documented non-significant coronary disease. The procedure was performed under general anesthesia from the right femoral access and under fluoroscopic guidance the Lotus 23 Heart Valve (Boston Scientific, Marlborough, Massachusetts) was introduced (Figs. 2A–2C). Since there has not been any residual gradient registered and the following echo documented an improvement of hemodynamic features (Vmax 2.9 m/s; PGmax 35 mm Hg; PGmean 15 mmHg) the procedure led to an optimal implantation. After an uneventful recovery at the Intensive Care Unit, followed by the cardiac rehab, the patient was discharged home with proclaimed improvement of symptoms (NYHA class I).

CoreValve and Evolut R

Patients presented below, both with degenerated aortic stentless bioprostheses underwent transcatheter valve-in-valve implantation involving CoreValve 23 in Freestyle aortic root bioprosthesis (Fig. 3) and Evolut R in Sorin Pericarbon Freedom stentless prosthesis (Fig. 4).

In Figure 3 note that due to the lack of radiographic landmarks AL diagnostic catheter was used to identify the left coronary artery and provide additional guidance.

Edwards SAPIEN 3 valve

Figure 5 shows implantation of SAPIEN 3 TAVI in Perimount 25 mm prosthetic valve with low residual gradient < 10 mm.

Conclusions

Since the numerous studies have shown the feasibility and safety of the valve-in-valve approach, the transcatheter valve interventions emerged as a valid alternative to redo surgery in patients with failing surgical bioprosthesis. The key to the successful ViV procedure is proper procedural planning (sizing and positioning) as well as avoidance of complications (coronary obstruction, embolization). Due to a significant risk of high residual gradient patients wits smaller surgical valves are not optimal candidates for transcatheter valve implantation. Ongoing registries will provide long-term clinical data.

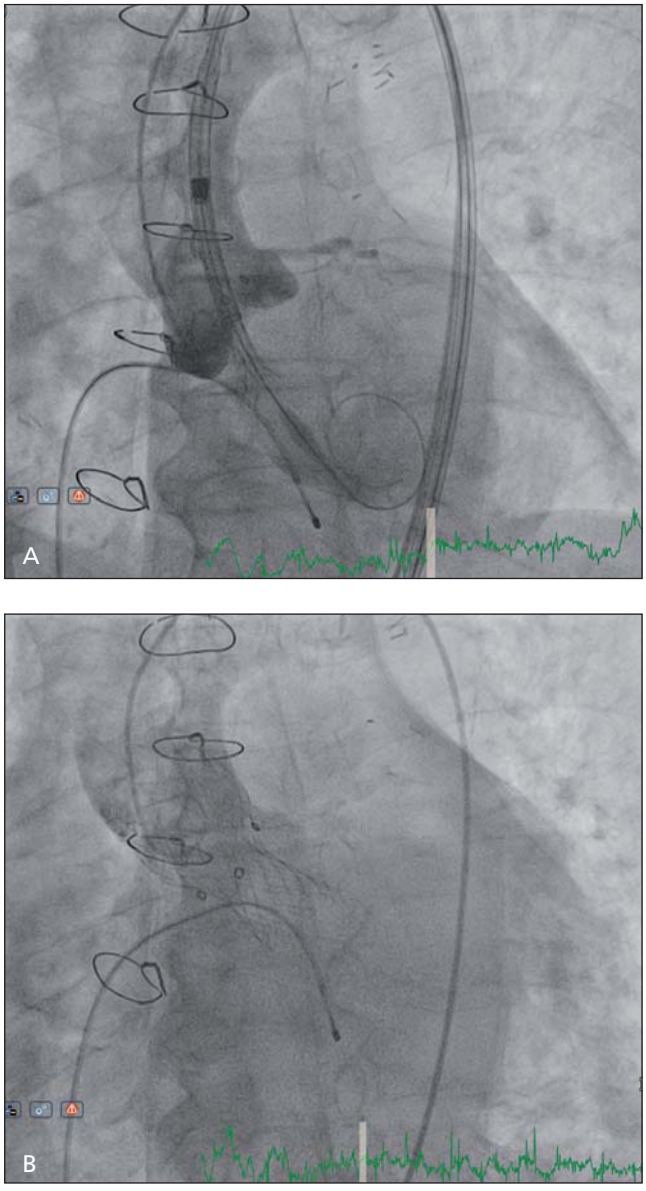


Fig. 4 – Fluoroscopic images of transcatheter valve-in-valve implantation – Evolut R implantation inside Sorin Pericarbon Freedom stentless prosthesis (Sorin Biomedica, Saluggia, Italy): (A) Pre-implantation. (B) Fluoroscopic view of deployed Evolut R.

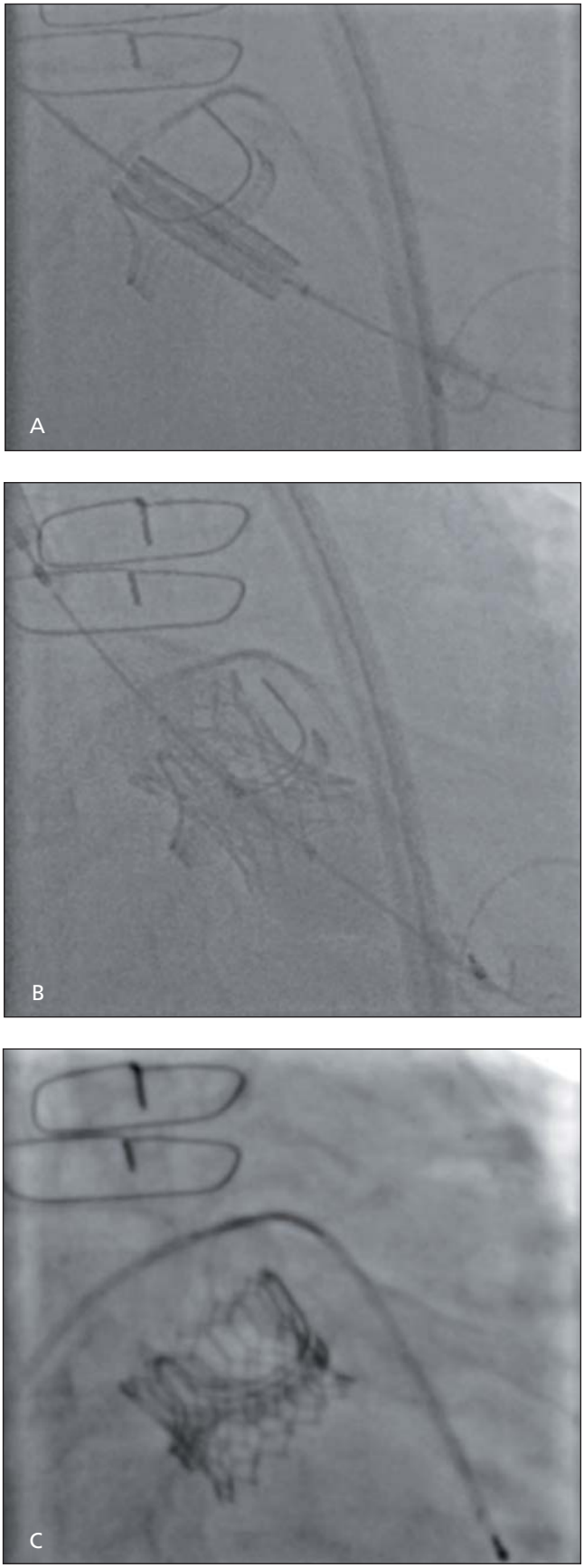


Fig. 5 – Valve-in-valve procedures with Edwards SAPIEN 3 valve. Figure shows implantation of SAPIEN 3 TAVI in Perimount 25 mm prosthetic valve with low residual gradient < 10 mm.

Conflict of interest
W. Wojakowski – lecture honorarium from Edwards Lifesciences.

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Ethical statement
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