

Transcatheter aortic valve implantation

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INTRODUCTION

Aortic stenosis (AS) is the most common acquired valvular heart disease, occurring in about 5% of patients above 65 years of age [1]. AS is a chronic disease, with the mean survival estimated at two to five years depending on the severity of symptoms [2]. Medical treatment and balloon valvuloplasty do not prolong life in patients with symptomatic AS. In patients with severe AS, the treatment of choice is surgical aortic valve replacement (SAVR) with implantation of a mechanical or biological valve prosthesis.

Long-term outcomes of SAVR are good but depend on the presence of concomitant conditions and patient's age [3], which may increase the surgical risk. Due to perioperative mortality concerns in older patients with multiple comorbidities, often after previous cardiac surgery, and with unfavourable anatomy, about 33% of patients with severe AS are not candidates for surgical treatment [4].

With the novel therapeutic approach of transcatheter aortic valve implantation (TAVI) introduced by a French cardiologist Alain Cribier in 2002, therapeutic options in

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patients with AS who require intervention have been greatly expanded. A series of pivotal, multicentre, randomised clinical trials and registries that evaluated TAVI and compared it with SAVR clearly showed that TAVI reduced mortality in patients who were not candidates for surgical treatment and was at least as effective and safe as SAVR in high and intermediate surgical risk groups [5–8].

Since the first TAVI procedure in 2002, more than 300,000 procedures have been performed worldwide until mid-2016, and TAVI has become the treatment of choice in inoperable AS patients and the preferred treatment method in patients at high risk for SAVR [9].

Due to the high effectiveness of this novel treatment approach, transcatheter valve implantation, mostly of the aortic valve, is currently one of the most important and rapidly developing treatment approaches in interventional cardiology and cardiac surgery [10].

The first procedure in Poland was performed in 2008 in Krakow, followed by Zabrze, Warsaw, and Katowice. The POLTAVI and PICTS registry data indicate that in 2014 TAVI procedures were performed in 21 centres in Poland. By the end of 2016, 3058 procedures had been performed in Poland, including 869 procedures in 2016 [11].

Of note, transcatheter procedures using aortic valve prostheses are increasingly used for the treatment of a degenerated, surgically implanted aortic, mitral, or tricuspid valve bioprosthesis (valve in valve procedures), or dysfunctional native valve following cardiac surgical repair using an annuloplasty rings (valve in ring procedures) [12].

TAVI OUTCOMES IN RELATION TO SURGICAL RISK

The effectiveness and safety of TAVI procedures in comparison to SAVR were evaluated since the very introduction of transcatheter procedures into the clinical practice. Obviously, first experiences and comparisons were in patients at the highest, prohibitive surgical risk. In subsequent years, with technological advances in the valve prostheses themselves, valve stents, and delivery systems, the spectrum of candidates for TAVI has expanded, in clinical trials as well as in common practice. Recently, research projects have been undertaken that include not only intermediate- and high-risk patients but also low-risk patients (PARTNER 3 Trial — The Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low-Risk Patients With Aortic Stenosis (P3), NCT02675114; Medtronic Transcatheter Aortic Valve Replacement in Low-Risk Patients, NCT02701283).

Below, we briefly review the most important clinical studies on the effectiveness and safety of TAVI, starting with the most recent reports on low-surgical-risk patients.

Low-risk patients

In the randomised NOTION study, the efficacy and safety of SAVR and TAVI was compared in unselected patients

(all-comers) at the mean age of 79.1 years. In the study group, 81.8% of patients were low risk (Society of Thoracic Surgeons [STS] score < 4%). Two-year mortality and stroke incidence were similar in both groups (9.8% vs. 8.0%, $p = 0.54$; and 5.4% vs. 3.6%, $p = 0.46$, respectively) [13, 14].

The prospective German GARY registry showed comparable mortality with SAVR and TAVI in higher-risk groups but lower mortality with SAVR in low-risk groups [15].

In 2016, three large randomised clinical trials were initiated that compare the efficacy of SAVR and TAVI in low-risk patients, including the PARTNER 3 study with the Edwards Sapien 3 bioprosthesis (STS score < 4%, age ≥ 65 years, NCT02675114), the Medtronic Transcatheter Aortic Valve Replacement in Low-Risk Patients study with the Medtronic Evolute R bioprosthesis (STS score < 3%, no age restrictions, NCT02701283), and the NOTION-2 study using Symetis, Lotus, and Portico bioprostheses (all-comer study, NCT02825134).

Intermediate-risk patients

The randomised PARTNER 2 study compared SAVR and TAVI (using the balloon-expandable Sapien 3 bioprosthesis) in a group of patients with severe AS at intermediate surgical risk (STS score 4–8%). The mean patient age in the TAVI group was 81.5 years, and the STS score was 5.8% in each group. This study showed no differences in the rate of a combined endpoint that included all-cause mortality and stroke [15]. In patients treated using the femoral approach, a statistically significant lower rate of the combined endpoint was shown compared to surgical treatment (HR = 0.79, $p = 0.05$, intention-to-treat) [7].

In the randomised SURTAVI study using self-expandable bioprostheses (CoreValve Evolute R), SAVR was compared with TAVI in a moderate-surgical-risk group. The mean patient age was 79 years, and the STS score was 4.5%. At two years of follow-up, the combined endpoint rate (all-cause mortality and stroke) was 14.0% in the SAVR group and 12.6% in the TAVI group. The rates of periprocedural renal failure, atrial fibrillation, and the need for blood transfusions were higher in the SAVR group, while a residual perivalvular leak and the need for pacemaker implantation were more common in the TAVI group [13]. It should be noted that only 16% of the TAVI patients were treated with second-generation valve (Evolute R), while 84% were treated with the first-generation CoreValve, and that the vast majority of operators who participated in the SURTAVI trial had very limited experience in performing TAVI procedures prior to the study (the pre-requisite for participation was experience of more than 40 cases).

After these studies were reported in 2016, Sapien 3 and CoreValve Evolute R bioprostheses received Conformité Européenne (CE) and Food and Drug Administration (FDA) certificates for transcatheter treatment of severe AS in moderate-surgical-risk patients.

High-risk and prohibitive-risk patients

In an arm of the PARTNER 1 study (cohort A), the efficacy and safety of SAVR and TAVI via the femoral and transapical approach (using the balloon-expandable Edwards Sapien bioprosthesis) was compared in patients with severe AS at a high surgical risk (STS score $\geq 10\%$). The mean patient age was 84 years, the mean STS score was $11.7 \pm 3.5\%$ in the SAVR group vs. $11.8 \pm 3.3\%$ in the TAVI group, and the mean logistic EuroSCORE was $29.2 \pm 15.6\%$ vs. $29.3 \pm 16.5\%$, respectively. At one year and five years, mortality was comparable in the SAVR and TAVI groups (26.8% vs. 24.2% and 62.4% vs. 67.8%, $p < 0.76$, respectively). The stroke rate at five years was also similar (11.3% vs. 10.4%, $p = 0.61$) [8, 16].

A comparison of SAVR and TAVI using self-expandable CoreValve prostheses in patients with severe AS at high surgical risk (30-day mortality risk $\geq 15\%$) was performed in the CoreValve US Pivotal High-Risk Trial. The mean patient age was 83 years, and the STS score was 7.4%. One-year mortality in the SAVR group was significantly higher compared to the TAVI group (19.1% vs. 14.2%, $p < 0.04$). At one year, a non-significant trend for a higher stroke rate was noted in the SAVR group (12.6% vs. 8.8%, $p = 0.1$) [4]. Survival at three years was similar in both groups (39.1% vs. 32.9%, $p = 0.07$) while the stroke rate was significantly higher in the SAVR group (19.0% vs. 12.6%, $p = 0.03$) [17].

In cohort B of the PARTNER 1 study, which included patients who were not deemed candidates for SAVR due to extremely (prohibitive) high surgical risk, medical treatment was compared to TAVI using a balloon-expandable Edwards Sapien bioprosthesis implanted by the femoral approach. The mean patient age in the PARTNER 1 study was 83 years, the mean STS score was $12.1 \pm 6.1\%$ in the medical treatment group vs. $11.2 \pm 5.8\%$ in the TAVI group, and the mean logistic EuroSCORE was $30.4 \pm 19.1\%$ vs. $26.4 \pm 17.2\%$, respectively. Surgery was contraindicated if the expected 30-day risk of death and major irreversible surgical complications was above 50%. One-year mortality was 50.7% in the medical treatment group compared to 30.7% in the TAVI group ($p < 0.001$) [6], and five-year mortality was 93.6% vs. 71.8%, respectively ($p < 0.001$). The stroke rate at five years was 18.2% vs. 16.0%, respectively ($p = 0.56$) [18]. The authors concluded that TAVI prolonged life in inoperable patients who were previously only treated medically.

The effectiveness of TAVI in very-high-risk patients was also confirmed using self-expandable bioprostheses in the non-randomised CoreValve US Pivotal Trial Extreme-Risk Iliofemoral Study. The mean patient age was 83.2 years, and the mean STS score was 10.3%. At one year, the combined endpoint rate (all-cause mortality and stroke) was 26%, the mortality rate was 24.3%, and stroke rate was 4.3% [19].

PATIENT SELECTION CRITERIA FOR TAVI PROCEDURES

Treatment decisions in patients with AS require determination of the risk of SAVR and consideration of the clinical status of the patient. According to the European Society of Cardiology (ESC) guidelines, the recommended risk scores in patients with valvular heart disease are the STS score and the EuroSCORE II. Based on the proposed SAVR risk calculators, patients may be divided into four risk groups. Low risk is defined as STS score $< 4\%$ and EuroSCORE II $< 4\%$, moderate risk as STS score 4–8% and EuroSCORE II 4–8%, high risk as STS score $\geq 8\%$ and EuroSCORE II $\geq 8\%$ (or log EuroSCORE $\geq 20\%$), and very high (prohibitive) risk is defined as the expected 30-day risk of death and major irreversible surgical complications above 50% [9, 20, 21].

The proposed risk calculators do not include all factors that are associated with increased surgical risk [22]. When selecting patients for SAVR or TAVI, additional factors that have not been included in the STS score and EuroSCORE II should be taken into account, including severe calcification of the ascending aorta (porcelain aorta), previous chest radiotherapy, chest deformations, osteoporosis, active malignancy, and others. In all cases, the decision regarding the optimal treatment approach in a patient with severe symptomatic AS should be made by a multidisciplinary Heart Team that includes an invasive cardiologist, cardiac surgeon, cardiovascular imaging specialist, and anaesthesiologist experienced in patient selection for, and performance of, TAVI procedures [9, 23]. In some cases, a gerontologist should be part of the Heart Team, in order to evaluate the expected benefit in quality of life in a specific patient.

The recently issued focus-updated AHA/ACC guidelines recommend the following patient selection criteria for TAVI (Fig. 1) [24]:

- For patients in whom TAVI or high-risk SAVR is being considered, a heart valve team consisting of an integrated, multidisciplinary group of healthcare professionals with expertise in valvular heart disease, cardiac imaging, interventional cardiology, cardiac anaesthesia, and cardiac surgery should collaborate to provide optimal patient care (IC);
- SAVR or TAVI is recommended for symptomatic patients with severe AS and high risk for SAVR, depending on patient-specific procedural risks, values, and preferences (IA);
- TAVI is recommended for symptomatic patients with severe AS and a prohibitive risk for SAVR, who have a predicted post-TAVI survival greater than 12 months (IA);
- TAVI is a reasonable alternative to SAVR for symptomatic patients with severe AS and intermediate surgical risk, depending on patient-specific procedural risks, values, and preferences (IIaB);

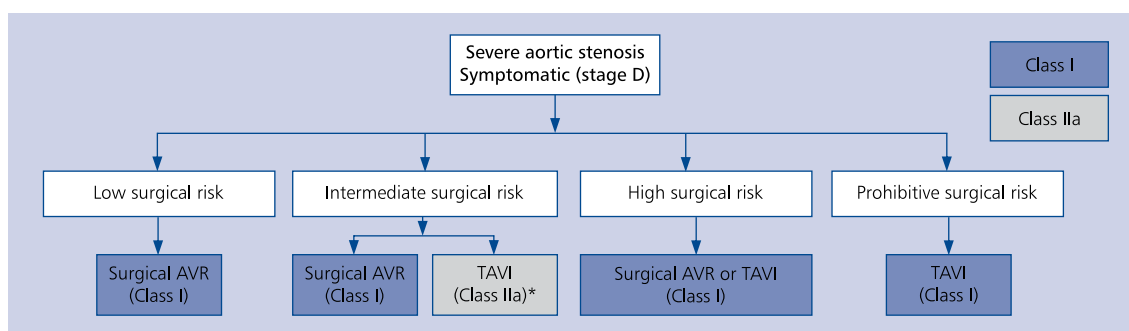


Figure 1. Choice of transcatheter aortic valve implantation (TAVI) versus surgical aortic valve replacement (AVR) in patients with severe, symptomatic aortic stenosis. Modified from: [24]; *TAVI should be considered in patients with severe aortic stenosis with intermediate surgical risk (STS and EuroSCORE II > 4 and < 8) and additional risk factors like porcelain aorta, chest radiotherapy, osteoporosis, frailty, and others

- Percutaneous aortic balloon dilation may be considered as a bridge to SAVR or TAVI for symptomatic patients with severe AS (IIbC);
- TAVI is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS (IIIB).

CONTRAINDICATIONS TO TAVI

According to the 2012 ESC guidelines, absolute contraindications to TAVI procedures include no cardiac surgical unit available in the TAVI centre, life expectancy less than one year, too small (< 18 mm) or too large (> 30 mm) aortic annulus, left ventricular (LV) thrombus, endocarditis, and high risk of coronary artery ostium occlusion.

Relative contraindications include LV ejection fraction (LVEF) below 20%, and haemodynamic instability.

Regardless of these ESC guidelines, the above-mentioned PARTNER studies and FRANCE 2 and TARIS registries identified factors that may adversely affect treatment outcomes in patients selected for TAVI [25, 26]. These include:

- LVEF < 30%, pulmonary hypertension (mean pulmonary artery pressure > 25 mm Hg), low-gradient AS, low stroke volume index (< 35 mL/m²), and significant organic mitral regurgitation in patients with cardiovascular disease;
- oxygen therapy in patients with chronic lung disease;
- atrial fibrillation and dialysis therapy in patients with advanced renal failure.

CHOICE OF VALVE PROSTHESIS

Several types of aortic valve prostheses are currently available for TAVI procedures, including Sapien XT and Sapien 3 (Edwards), CoreValve Evolute R (Medtronic), Lotus (Boston Scientific), Acurate (Symetis), JenaClip (Jena), and Portico (St. Jude/Abbott). All these are bioprostheses made from specially prepared bovine (e.g. Sapien XT, Sapien 3) or porcine pericardium (e.g. CoreValve Evolute R). Bioprosthesis leaflets are sewn in and supported by a metal scaffold: balloon-mounted

cobalt-chromium stent (Sapien XT and Sapien 3) or self-expandable nitinol stent (e.g. CoreValve Evolute R, Acurate, and Portico).

Currently available aortic valve bioprosthesis deployment systems allow valve implantation using a transvascular approach through a femoral artery (used in 80–90% of TAVI procedures), subclavian artery (usually left), right internal carotid, as well as transcaval approach. If no vascular approach is possible, e.g. due to extensive atherosclerotic lesions, some bioprostheses (e.g. Sapien, Symetis, JenaValve) may be implanted using the apical approach. In some cases, vascular access may also be obtained by direct puncture of the ascending aorta following anterior ministernotomy or lateral minithoracotomy.

Currently available prostheses may be implanted in patients with the native aortic annulus size of 18 mm to 30 mm, or perimeter of the aortic annulus in the range 56–94 mm, or area of the aortic annulus between 338 mm² and 683 mm², depending on the manufacturer's specification.

According to some authors, transoesophageal echocardiography is the standard imaging method to measure the aortic annulus diameter, although in clinical practice, measurements of aortic annulus circumference (perimeter) or area by multislice computed tomography (MSCT) are more important for planning TAVI procedures. MSCT also allows precise evaluation of other key anatomic parameters for selecting an appropriate bioprosthesis type, including the width and height of coronary sinuses, the distance between coronary ostia and the level of aortic annulus or aortic cusp attachments, the angle of aortic entry to the left ventricle, the width of the LV outflow tract, presence of ascending aortic calcifications, and others.

Angio-MSCT is also an excellent method to evaluate the course and the diameter of femoral and iliac arteries. These measurements are necessary for the choice of the optimal vascular access site for introduction and passage of the valve deployment system. Vascular sheaths used to introduce the

valve deployment system are sized 14–20 F. The minimum femoral and iliac artery lumen diameter for safe passage of the valve deployment system is 5–6 mm.

PERFORMANCE OF TAVI PROCEDURES — VASCULAR ACCESS

Detailed evaluation and choice of the vascular access site is one of the initial important steps when selecting patients for TAVI. MSCT is the reference imaging method to evaluate femoral, iliac, subclavian, and in some patients also carotid arteries. The extent of imaging should include the whole vascular segment from the vascular access site to the native aortic valve annulus. MSCT allows evaluation of the arterial lumen diameter and course, along with the presence of possible stenoses or calcifications.

Currently, the following access sites are used for TAVI procedures:

1. Transvascular, via:
 - femoral artery;
 - subclavian artery;
 - axillary artery;
 - carotid artery;
 - vena cava inferior and abdominal aorta (transcaval approach).
2. Transthoracic, via:
 - lateral minithoracotomy — transapical approach;
 - ministernotomy or right-sided minithoracotomy — direct aortic approach.

The most commonly used approach for TAVI procedures is via the right or left common femoral artery. The last step of TAVI procedure is to obtain haemostasis at the vascular access site. If the vessel used was not exposed surgically, the femoral artery access site may be closed by percutaneous pre-closing suture technique using the Prostar or Proglide (Abbott) closure devices. Small femoral or iliac artery wall ruptures with extravasation seen on angiography are usually treated with prolonged balloon inflation or stentgraft implantation.

If the femoral access was obtained by surgical vessel exposure, the femoral artery access site is closed surgically.

Subclavian/axillary artery approach requires cooperation with a vascular surgeon. The left subclavian artery is usually used, allowing favourable, more axial alignment of the inserted valve prosthesis in relation to the native aortic valve annulus. Following subclavian artery puncture and insertion of an appropriate vascular sheath, the next steps are similar to those with the femoral artery approach.

The transapical approach is usually used when no access via the femoral or subclavian/axillary artery is possible. The procedure is performed through the fifth or sixth left intercostal space laterally to the sternum, following precise localisation of the LV apex by palpation and echocardiography.

The transapical and direct aortic approaches are cardiac surgical procedures. TAVI procedures, particularly when using surgical access, should be performed in hybrid operation

rooms, combining surgical theatre and cardiac catheterisation laboratory capabilities.

Following TAVI procedure, an immediate drop in aortic valve pressure gradient is observed, usually to several mm Hg. If a more than mild perivalvular regurgitant leak is identified by echocardiography immediately after the procedure, specific measures should be taken in order to minimise the perivalvular leak: if the mechanism is insufficient expansion, a post balloon inflation should be deployed, if the reason is too high or too low implantation, a second valve should be implanted, etc.). This is particularly important as moderate or large perivalvular leaks may be associated with increased long-term mortality. The regurgitant leak does not usually increase by serial echocardiographic evaluation during one year of follow-up. Improvement of LV systolic function, reduction of functional mitral regurgitation, and significant improvement of exercise tolerance as measured by the New York Heart Association class have also been reported.

Transcatheter aortic valve implantation procedures via the femoral artery approach are increasingly commonly performed under conscious sedation with local anaesthesia only, without the use of general anaesthesia, and in some centres, even without the presence of an anaesthesiologist in the room [27]. When combined with percutaneous femoral artery closure, this allows early patient mobilisation (even as early as the next day) and rehabilitation followed by rapid hospital discharge.

PERIPROCEDURAL DRUG THERAPY

The strategy of periprocedural drug therapy remains to be debated. Most authors agree that patients should receive a loading acetylsalicylic acid (ASA) dose (300 mg), and in most cases also a loading clopidogrel dose (300 mg) before the TAVI procedure. However, this is not a routine approach, particularly in patients with increased bleeding risk (by the HAS-BLED score) or when a surgical (transapical or direct aortic) approach is planned.

Immediately before the procedure, patients receive a single antibiotic dose and unfractionated heparin to increase the activated clotting time above 250 s.

In patients with atrial fibrillation and other indications for oral anticoagulant therapy, the drug should be withdrawn 2–3 days before the procedure and replaced with low-molecular-weight heparin given subcutaneously. Following TAVI, these patients are usually treated with an oral anticoagulant (acenocoumarol or warfarin) combined with a single antiplatelet agent (ASA or clopidogrel) for 1–3 months. Oral anticoagulant monotherapy may also be considered.

No systematic data are available regarding use of novel oral anticoagulants (NOAC) in patients after TAVI. Randomised studies, such as GALILEO, are underway.

In patients without indications for chronic anticoagulation, dual antiplatelet therapy is used to prevent thrombosis of the aortic valve prosthesis for 1–6 months after TAVI, using

daily maintenance doses of 75–100 mg of ASA (continued indefinitely) and 75 mg of clopidogrel (for up to six months) [28–35].

Patients with renal failure require particular attention. Contrast-induced nephropathy should be prevented, primarily by appropriate periprocedural hydration and possibly by administering large N-acetylcysteine doses. Attention should be paid to the amount of contrast agent administered during the procedure — this is usually limited to 60–100 mL.

POST-PROCEDURAL MANAGEMENT

The primary aims of post-procedural management include monitoring and treatment of post-procedural complications, and early patient mobilisation and rehabilitation.

Following the procedure, the patient is usually monitored in an intensive cardiac care unit for 1–2 days or, in the case of transapical or direct aortic approach that required thoracotomy, in a postoperative care unit.

The most common complications during this period include bleeding at the vascular access site, other vascular complications, cardiac arrhythmias, stroke, acute heart failure, or respiratory failure [29].

Regardless of the approach used, a temporary pacing lead is left in the right ventricle for 48 h in all patients without an implanted pacemaker, due to the risk of new heart block.

The need for permanent pacemaker implantation due to a new cardiac conduction block following implantation of an aortic valve prosthesis ranges from a few per cent of patients treated with balloon-expanded Edwards Sapien XT/Sapien 3 prostheses to 30% of patients treated with self-expandable CoreValve Evolute R prostheses [36, 37].

In experienced TAVI centres, the mean duration of hospital stay following TAVI procedures is up to five days for the femoral approach and up to seven days for other approaches [29]. Based on the POLTAVI registry data, the mean duration of hospital stay following TAVI procedures in Polish centres is seven days.

COMPLICATIONS OF TAVI PROCEDURES

In the published registries and observational studies, 30-day mortality following TAVI by a transfemoral/trans-subclavian approach ranges from 0% to 25% [38–41]. In the randomised multicentre PARTNER study that compared outcomes of TAVI using the Edwards Sapien prosthesis and medical treatment in inoperable AS patients (cohort B), one-year mortality was reduced by 20% [6].

Vascular access site complications have been reported in the literature on TAVI. In patients treated with transvascular (transfemoral/trans-subclavian) approach, these included peripheral vessel rupture, acute arterial occlusion or stenosis, and major bleeding requiring surgical intervention. These complications were reported in 9–20% of patients [38–41].

Patients undergoing TAVI by a transapical approach are primarily at risk of chest wall bleeding and, rarely, bleeding

at the LV apex puncture site. The reported rate of surgical interventions due to bleeding following TAVI by a transapical approach is 8–14% [42–44]. Development of LV pseudoaneurysm is another very rare but severe complication in patients treated using a transapical approach [45].

Implantation of a permanent cardiac pacemaker was required within 30 days of TAVI in 3.4% of patients treated with an Edwards-Sapien valve in the PARTNER study and in 33.3% of patients in the British CoreValve registry [37]. In the latter, independent predictors of permanent cardiac pacemaker implantation included occurrence of a new atrioventricular conduction block during TAVI, balloon angioplasty immediately before valve implantation, use of a larger valve prosthesis, interventricular septal thickness, and increased preprocedural QRS width. In the Dutch registry, preprocedural QRS width and interventricular septal thickness were identified as independent predictors of permanent cardiac pacemaker implantation [36]. A larger rate of pacemaker implantation following treatment with self-expandable valve prostheses has been attributed to compression of the basal segment of the interventricular septum by the distal segment of a metal stent. The underlying conduction disturbance is usually left bundle branch block (LBBB) that develops in the setting of a pre-existing first-degree atrioventricular block. The rate of permanent cardiac pacemaker implantation has been reduced with advances in procedural technique, and a relation between occurrence of a new LBBB and the depth of valve prosthesis implantation and valve stent penetration into the LV outflow tract has been shown for self-expandable valve prostheses [37].

In more recent multicentre registries, a stroke rate of 2–4% at one year after TAVI has been reported. Introduction of dedicated neuroprotection systems offers some hope for a further reduction of periprocedural stroke rate, but the currently available evidence is equivocal.

The learning curve has a major effect on TAVI outcomes. The Vancouver group reported a trend ($p = 0.09$) for lower survival among the first 25 patients who underwent a TAVI procedure compared to the next 25 patients [40]. The experience with the first 30 patients who underwent TAVI at the Institute of Cardiology in Warsaw shows that in-hospital mortality was 6.6% vs. 0%, and 90-day survival was 80% vs. 93%, respectively, when the first 15 patients were compared with the subsequent 15 patients [46].

TAVI IN PERSPECTIVE

Transcatheter aortic valve implantation procedures are currently the only alternative treatment approach in inoperable or surgical high-risk patients with severe, symptomatic AS. All randomised clinical trials showed that in terms of safety, TAVI outcomes were at least comparable to SAVR in patients at high or moderate surgical risk, while the effectiveness of TAVI was also comparable or even better. Also, TAVI outcomes in low-surgical-risk patients were comparable to the surgical

treatment group. Further studies in this patient group are underway. The major problems associated with TAVI include the learning curve, vascular complications, bleeding, strokes, and cardiac conduction blocks requiring implantation of a permanent cardiac pacemaker. With further advances in valve prosthesis design, miniaturisation of deployment systems, introduction of neuroprotection devices, and advances in TAVI procedural technique, the complication rate is likely to decrease. In addition, new types of valve prostheses, currently evaluated in animal and clinical studies, will allow better adjustment of the valve prosthesis and deployment system to the anatomical and clinical characteristics of the patient (tailored therapy), which should result in even better safety and effectiveness of TAVI procedures. This is a main condition to broaden in future transcatheter treatment of AS into the younger patient's cohort with low-risk patients.

In the near future, as TAVI will probably be performed in patients with low risk as well, and patient selection for TAVI will be based more on anatomical suitability regardless of surgical risk or the patient's age. Better cardiac imaging will allow a more precise prediction of the procedure as well as better selection of the specific device to be used. Improved devices that will be dedicated for TAVI procedures in a bicuspid aortic valve stenosis will expand the indication for TAVI to this wide part of the population with aortic valve stenosis, who are not optimal candidates for TAVI today, unless they are at high or prohibitive risk for surgery.

The next step in TAVI is just around the corner. On July 14th, 2017, the first patient was recruited into the EARLY TAVR (Evaluation of Transcatheter Aortic Valve Replacement Compared to Surveillance for Patients with Asymptomatic Severe Aortic Stenosis) randomised (vs. standard of care), multicentre trial [47]. This important trial will evaluate whether there is benefit from replacing the aortic valve via a minimally invasive, catheter-based procedure before patients develop symptoms. The goal of early TAVI is to preserve the heart's function, and prevent further heart deterioration and death.

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